INTRODUCTION

Federal regulations require that Institutional Review Boards (IRBs) have written policies and procedures governing human participant research and that activities at the institution are carried out as described in the written policies and procedures document. These IRB Policies and Standard Operating Procedures (SOPs) are written to enable the IRBs of the University of Oklahoma (University) to maintain a system of human participant research compliance. The SOPs of the IRBs reflect not only the laws and regulations governing human participant research but also the underlying ethical principles that are the basis of the IRBs’ mandate. Finally, these policies also reflect the overarching commitment of the University to provide protection for all human participants involved in research conducted by its faculty, staff, and students or otherwise conducted under its oversight.

The ethically responsible researcher is expected to carry the dual burden to advance knowledge that can improve the human condition or generate new knowledge and, at the same time, to recognize the absolute imperative to treat human research participants with the utmost care and respect.

It is not unreasonable to ask others to share this responsibility. Indeed, the institutions that expect to benefit from the research are expected to share in the responsibility of conducting ethical research.

This responsibility also falls, then, to those who sit on the University IRBs. These individuals are expected to share the responsibility of protecting human participants in research conducted under the auspices of the University of Oklahoma.

The Office of Human Research Participation Protection (HRPP) SOPs are based on current regulations, ethical principles, and guidelines for the protection of human research participants. The policies describe what the University requires for the ethical conduct of research. The procedures detail how these policies are carried out.

The SOPs are not an end unto themselves. They are the framework upon which human participant research activities are conducted. Therefore, all members of the research enterprise who are working within the University or under its oversight are expected to read, understand, and comply with them. This way, the responsibility of conducting sound, effective and ethical research can be shared.

About these SOPs

These SOPs apply to the day-to-day operations of the IRB. The SOPs apply to all persons employed by the IRB, all IRB members who serve, and all research team members and their support staff.

The documents described in the SOPs are referenced in order to assure that the procedures are integrated into the daily activities of not only IRB members and staff, but also the investigative site.

These SOPs are reviewed periodically to ensure that they are up-to-date and that new legislation or regulations or research practices are reflected in the policies.
GLOSSARY

510(K) DEVICE A medical device that is considered substantially equivalent to a device that was or is being legally marketed. A Sponsor planning to market such a device must submit notification to the FDA 90 days in advance of placing the device on the market. If the FDA concurs with the Sponsor, the device may then be marketed. 510(k) is the section of the Food, Drug and Cosmetic Act that describes pre-market notification; hence the designation "510(k) device."

ABUSE-LIABLE Pharmacological substances that have the potential for creating abusive dependency. Abuse-liable substances can include both illicit drugs (e.g., heroin) and licit drugs (e.g., methamphetamines).

ADVERSE EVENT Any untoward or unfavorable occurrence in a human research participant associated with the research project.
Adverse events in medical research projects can include any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not it is considered related to the subject’s participation in the research.

ACTIVE CONSENT Active consent requires parents to sign and return a form if they consent for their child to participate. See also Informed Consent.

AGENTS OF THE ORGANIZATION Agents are defined as individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

ALLEGATION OF NON-COMPLIANCE An unproven assertion of non-compliance. See also Non-Compliance.

ALTERNATE MEMBER HHS regulations at 45 CFR Part 46 do not address the designation of alternate IRB/IEC members. When reviewing rosters that include alternate members OHRP assumes that, in general, with respect to the capacity in which the primary IRB member was intended to serve, each alternate IRB member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary IRB member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol.

AMENDMENT See Modification.
| **ANONYMITY** | The condition that exists when there are no identifiers on research materials that could link or identify the data to an individual subject even to the research investigators. |
| **ASSENT** | Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. |
| **ASSURANCE** | A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. |
| **AUTHORIZED INSTITUTIONAL OFFICIAL** | See Institutional Official. |
| **AUTONOMY** | Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others. |
| **BELMONT REPORT** | A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978. |
| **BENEFICENCE** | An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. |
| **BENEFIT** | A valued or desired outcome; an advantage. |
| **BENIGN BEHAVIORAL INTERVENTIONS** | Behavioral interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Examples would include having participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. Research including benign behavioral interventions may qualify for the Exempt, Category 3 designation. |
| **BIOLOGIC** | Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries. |
| **BLIND STUDY DESIGNS** | See Masked Study Designs, Double-Masked Design and Single-Masked Design. |
| **BOARD** | See Institutional Review Board. |
| **CASE-CONTROL STUDY** | A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (See also Retrospective Studies.) |
| **CDC** | Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services. |
| **CHILD ASSENT** | A child’s affirmative agreement to participate in research. Mere failure to object to research activities should not, absent affirmative agreement, be construed as assent. See also Informed Consent. |
| **CHILDREN** | Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted. |
| **CLASS I, II, III DEVICES** | Classification by the Food and Drug Administration of medical devices according to potential risks or hazards. |
| **CLINICAL INVESTIGATION** | Any experiment in which a drug is administered or dispensed to, or used involving, one or more human research participants. |
| **CLINICAL TRIAL** | A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. |
| **CLINICAL RESEARCH** | Having to do with the examination and treatment of patients. Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science. |
| **CODE OF FEDERAL REGULATIONS (CFR)** | The federal compendium of regulations on numerous topics related to compliance with federal laws. |
| **COGNITIVELY IMPAIRED** | Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., intellectual disability) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. |
| **COHORT** | A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences. |
| **COLD CALLING** | Refers to an Investigator who is conducting VA research and contacts veterans whom they do not know to invite them to participate in a research |
The collection of identifiable information about people who are not participants and have not consented to participate in the research project.

A research team member who is not an employee or agent of any FWA assured institution who is conducting collaborative research activities with a University researcher and is requesting coverage under the University FWA.

A research team member who is not an employee or agent of the assured institution that will be the IRB of record who is conducting collaborative research activities outside the facilities of the assured institution and acting as an employee or agent of another assured institution with respect to his or her involvement in the research being conducted at the assured institution.

See Treatment Use.

(1) A financial or non-financial payment given to research participants for their involvement in a research project. The amount and the method and timing of disbursement must be consistent with the laws, regulations, and guidelines governing human subjects research and must not improperly influence a subject’s decision to participate. See also Remuneration.

(2) Payment or medical care provided to participants who are injured while participating in an IRB approved research project.

Technically, a legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity.)

The withholding of information about the specific purpose or procedures of the research without providing false or misleading information to the research participant. See also Direct Deception.

Pertains to privacy and non-disclosure of personal information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Refers to situations in which financial or other personal considerations may compromise an Employee’s professional judgment in carrying out his/her University responsibilities such as teaching, research, contract administration, or purchasing. The term means (1) an actual conflict of interest exists, or (2) the potential exists for a conflict of interest to occur, or (3) there appears to be a conflict of interest; i.e., if made public, it could discredit the Employee or the University. The term also includes a
Conflict of Commitment.

**CONSENT**

See *Informed Consent*.

**CONSULTANT**

An individual whom the IRB consults because they are knowledgeable about the concerns related to certain vulnerable population and their qualifications that make them able to ascertain the acceptability of proposed research in terms of human research participant protections, institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

**CONTINUING NON-COMPLIANCE**

A pattern or repeated incidents of failure to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB. See also Non-Compliance.

**CONTRACT**

An agreement that a specific research activity will be performed at the request, and under the direction of, the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant.

**CONTRAINDIATED**

Pertains to the use of a treatment that should not be used in certain individuals or conditions due to risks of disadvantageous, perhaps dangerous results (*e.g.*, a drug may be contraindicated for pregnant women and persons with high blood pressure).

**CONTROL (SUBJECTS) OR CONTROLS**

Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

**COOPERATIVE RESEARCH ACTIVITIES**

Research activities in which OU faculty, staff or students participate in human subject research projects through one or more cooperating institutions or when non-OU researchers conduct human subjects research as a member of a research team led by an OU researcher.

**CORRESPONDENSE WITH EXTERNAL AGENCIES**

Any letters, memos, or emails sent to agencies of the federal government, funding agencies whether private or public or their agents.

**CROSS-OVER DESIGN**

A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

**DATA AND SAFETY MONITORING BOARD (DSMB)**

A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial
involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

**DATA MINING, SCRAPING, AND MASHING**

A process of looking for patterns in large batches of data in order to generate new information. Data scraping often involves the use of a computer program that extracts data from large bases of data. Data mashing occurs when mined and scraped data are combined by internet-based applications.

**DEAD FETUS**

An expelled or delivered fetus that exhibits no heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord (if still attached). Generally, some organs, tissues, and cells (referred to collectively as fetal tissue) remain alive for varying periods of time after the total organism is dead.

**DEBRIEFING**

Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

**DECISIONS MADE BY CHAIR**

Any letters, memos, or emails sent representing the decision or opinions of the Chair of the IRB or the respective designee as long as such correspondence does not imply review and approval of research subjects.

**DECLARATION OF HELSINKI**

A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It has been revised several times, most recently in October 2013.

**DEPENDENT VARIABLES**

The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

**DESCRIPTIVE STUDY**

Any study that is not truly experimental (e.g., quasi-experimental studies, correlation studies, record reviews, case histories, and observational studies).

**DESIGNATED STAFF**

Staff designated by the Institutional Official in writing.

**DESIGNEE**

A person selected or designated to carry out a duty or role if the formal responsible party is not available to perform this function. For the HRPP, designees are available for the Institutional Official, Director of Compliance, HRPP Director, and/or IRB Chair.

**DEVICE (MEDICAL)**

See *Medical Device*.

**DHHS**

Abbreviation for U.S. Department of Health and Human Services.

**DIAGNOSTIC (PROCEDURE)**

Test used to identify a disorder or disease in a living person.
<table>
<thead>
<tr>
<th><strong>DIRECT DECEPTION</strong></th>
<th>Providing false or misleading information to the research participant.</th>
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<tbody>
<tr>
<td><strong>DOUBLE-MASKED DESIGN</strong></td>
<td>A study design in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as &quot;double-blind.&quot;</td>
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<tr>
<td><strong>DRUG</strong></td>
<td>Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.</td>
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</table>
| **EMANCIPATED MINOR** | A legal status conferred in some states upon persons who have not yet attained the age of legal competency law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities. *(See also: Mature Minor.)*  
Under Oklahoma law, a minor may self-consent to have health services delivered by a health professional (such services not to include research) if the minor is married, has dependents, or is emancipated; is separated from parents/legal guardians and not supported by them; or meets the other criteria set forth in 63 Okl. Stat. 2602. |
| **EMBRYO** | Early stages of a developing organism. The term embryo is broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy *(i.e., from conception to the eighth week of pregnancy).* *(See also: Fetus)* |
| **EMERGENCY USE** | Use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. FDA regulations consider emergency use of regulated products to be Human Subjects Research. Use of any FDA regulated product is considered Human Subjects Research and requires IRB review. |
| **ENGAGEMENT IN RESEARCH ACTIVITIES** | Any individual who is involved in conducting human participant research. Such involvement would include: 1) obtaining information about living individuals by intervening or interacting with them for research purposes; 2) obtaining identifiable private information about living individuals for research purposes; 3) obtaining the voluntary informed consent of individuals to be subjects in research; and/or 4) studying, interpreting, or analyzing identifiable private information or data for research purposes.  
*See also: Investigator and Key Study Personnel.* |
| **EPIDEMIOLOGY** | A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or given population. |
| **EQUITABLE** | Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed. |
| **ETHICS ADVISORY BOARD** | An interdisciplinary group that advises the Secretary, HHS, on general policy matters and on research proposals (or classes of proposals) that pose ethical problems. |
ETHNOGRAPHIC RESEARCH

Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. See also Fieldwork.

EXCUSPATORY

Pertaining to that which relieves an individual or entity of a responsibility, obligation, or hardship; clearing from accusation or blame.

EXPANDED ACCESS

Policy and procedure that permits individuals who have serious or life-threatening diseases for which there are no alternative therapies to have access to investigational drugs and devices that may be beneficial to them. Examples of expanded availability mechanisms include Treatment INDS, Parallel Track, and open study protocols.

EXPEDITED REVIEW

Review of proposed research by IRB Chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

EXPERIMENTAL STUDY

A study in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. See also Quasi-Experimental Study.

EXPERIMENTAL

Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. See also Research.

EXPERIMENTAL PARTICIPANT or SUBJECT

A Department of Defense research term, see Research Involving a Human Being as an Experimental Subject

EXPIRATION DATE

The last date that the period for which the protocol is approved, typically the last day of the eleventh month from the date of IRB approval of a research project, modification, or continuing review. No research activities are allowed after the IRB expiration date.

EXPORT CONTROLS

Federal laws and regulations that govern the transfer or disclosure of goods, technology, software, services, and funds originating from the United States to persons or entities in foreign countries or TO foreign nationals in any country or location.

FAMILY MEMBER

One who is part of the basic unit in society traditionally consisting of two parents rearing their own or adopted children; also: any of various social units differing from but regarded as equivalent to the traditional family.

FDA REGULATED RESEARCH

Research involving FDA-regulated products (e.g., investigational drugs, biological products, medical devices, and dietary supplements).

FEDERAL POLICY

The federal policy, also known as the "Common Rule," that provides regulations for the involvement of human subjects in research. The policy
applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy.

FETAL MATERIAL
The placenta, amniotic fluid, fetal membranes, and umbilical cord.

FETUS
The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. See also Embryo.

FIELDWORK
Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). See also Ethnographic Research.

FOOD AND DRUG ADMINISTRATION (FDA)
An agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

FULL IRB REVIEW
Review of proposed research at a convened meeting where the majority of the membership of the IRB is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

GENE THERAPY
The treatment of genetic disease accomplished by altering the genetic structure of either somatic (non-reproductive) or germ line (reproductive) cells.

GENERAL CONTROLS
Certain FDA statutory provisions designed to control the safety of marketed drugs and devices. The general controls include provisions on adulteration, misbranding, banned devices, good manufacturing practices, notification and record keeping, and other sections of the Medical Device Amendments to the Food, Drug and Cosmetic Act.

GENERALIZABLE KNOWLEDGE
Knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences. An activity may be thought to develop or contribute to generalizable knowledge if the information collected can be applied beyond a particular program.

GENETIC SCREENING
Tests to identify persons who have an inherited predisposition to a certain phenotype or who are at risk of producing offspring with inherited diseases or disorders.

GENOTYPE
The genetic constitution of an individual.

GRANT
Financial support provided for research study designed and proposed by the Principal Investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.
HELSDINKI DECLARATION
See Declaration of Helsinki.

HHS
See DHHS.

HISTORICAL CONTROLS
Control subjects (followed at some time in the past or for whom data are available through records) who are used for comparison with subjects being treated concurrently. The study is considered historically controlled when the present condition of subjects is compared with their own condition on a prior regimen or treatment.

HUMANITARIAN DEVICE EXEMPTION (HDE)
The approval process provided by the FDA that allows a medical device to be marketed without requiring evidence of effectiveness.
See Humanitarian Use Device.

HUMANITARIAN USE DEVICE (HUD)
A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. An HUD creates an alternative pathway for getting market approval for medical devices that may help people with rare diseases or conditions.

HUMAN PARTICIPANTS
Under the DHHS regulations, human subjects are defined as: living individual(s) about whom an Investigator conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Under the FDA regulations, human subjects are defined as individuals who are or become participants in research, either as recipients of the test article or as controls. A subject may be either a healthy individual or a patient. For research involving medical devices, a human subject is either: (1) an individual on whose specimen an investigational device is used; or (2) unidentified tissue specimens when the device involves in vitro diagnostics.

Under the VA regulations, human subjects are living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individuals or through identifiable private information. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.

HUMAN SUBJECTS RESEARCH
See Research Study.

IDE
See Investigational Device Exemptions.

IDENTIFIABLE PRIVATE
Private information for which the identity of the subject is or may readily be
INFORMATION
ascertained by the investigator or associated with the information.

IDENTIFIABLE BIOSPECIMEN
A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

IMPLIED CONSENT
See Informed Consent.

IN VITRO
Literally, "in glass" or "test tube"; used to refer to processes that are carried out outside the living body, usually in the laboratory, as distinguished from in vivo.

IN VIVO
Literally, "in the living body"; processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (in vitro).

INCAPACITY
Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. See also Incompetence.

INCOMPETENCE
Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. See also Incapacity.

IND
See Investigational New Drug.

INFORMATION, PRIVATE
Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

INFORMED CONSENT
A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

See also Child Assent, Implied Consent, Parental Permission. Passive Consent, Surrogate Consent.

INSTITUTION
(1): Any public or private entity, department, or agency (including federal, state, and local agencies).

(2): A residential facility that provides food, shelter, and professional services (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include general, mental, or chronic disease hospitals; inpatient community mental health centers; halfway houses and nursing homes; alcohol and drug addiction treatment centers; homes for the aged or dependent, residential schools for the mentally or physically handicapped; and homes for dependent and
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>INSTITUTIONAL OFFICIAL (IO)</td>
<td>An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.</td>
</tr>
<tr>
<td>INSTITUTIONAL REVIEW BOARD</td>
<td>A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.</td>
</tr>
<tr>
<td>INSTITUTIONALIZED COGNITIVELY IMPAIRED</td>
<td>Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital, home, or school for the intellectually disabled).</td>
</tr>
<tr>
<td>INSTITUTIONALIZED</td>
<td>Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).</td>
</tr>
<tr>
<td>INTERACTION</td>
<td>In the context of research, interaction includes communication (including conversations, monitoring, gathering, or recording of data, which occurs via telephone, e-mail, or other electronic device) or interpersonal contact between the investigator, and/or member of the research staff, or other individual who is gathering and recording data for a research study.</td>
</tr>
<tr>
<td>INTERNATIONAL RESEARCH</td>
<td>Research carried out in one or more country settings.</td>
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<tr>
<td>INTERNET / SOCIAL MEDIA SERVICES</td>
<td>Internet and mobile device-based services that provide a collection of ways for users to interact, such as social networking sites, blogs, discussion groups or other information sharing or communication services that support messaging, email, video, posting comments.</td>
</tr>
<tr>
<td>INTERVENTION</td>
<td>In research, intervention includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.</td>
</tr>
<tr>
<td>INVESTIGATOR</td>
<td>An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. More than one investigator may conduct some research studies, and usually one investigator is designated the “principal investigator” with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects. See also Engagement in Research Activities and Key Study Personnel.</td>
</tr>
<tr>
<td>INVESTIGATIONAL DEVICE EXEMPTIONS</td>
<td>Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations.</td>
</tr>
</tbody>
</table>
INVESTIGATIONAL NEW DRUG (IND) OR DEVICE (IDE)

A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

INVESTIGATOR

In clinical trials, an individual who actually conducts an investigation. Carries out a formal inquiry or investigation. The Principal Investigator (PI) is the individual who conducts the study and is ultimately responsible for assuring compliance with applicable University IRB policies and procedures, DHHS Federal Policy Regulations, and FDA regulations and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study.

See also Principal Investigator.

IRB

See Institutional Review Board.

JUSTICE

An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

KEY STUDY PERSONNEL (KSP)

Individuals who provide research project-related services or assistance and who have knowledge of the research protocol and the identity of research participants or their protected health information. Key study personnel include principal investigators, co-principal investigators, sub-investigators, and research coordinators, and individuals from an affiliated institution.

See also Engagement in Research Activities and Investigator.

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

LEGALLY EFFECTIVE CONSENT

See Informed Consent.

LIMITED IRB REVIEW

A type of expedited review process to be conducted by the IRB Chair/Designee for certain categories of exempt research.

Note: Because the IRB's current exempt review process exceeds the requirements set forth under limited IRB review, limited IRB review will not be implemented by the OU-NC or OU-HSC IRBs.

LONGITUDINAL STUDY

A study designed to follow subjects forward through time.

MASKED STUDY

Study designs comparing two or more interventions in which either the Investigators, the subjects, or some combination thereof do not know the
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESIGNS</td>
<td>treatment group assignments of individual subjects. Sometimes called &quot;blind&quot; study designs. See also Double-Masked Design; Single-Masked Design.</td>
</tr>
<tr>
<td>MATURE MINOR</td>
<td>Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care in certain circumstances). Note that a mature minor is not necessarily an emancipated minor. See also Emancipated Minor.</td>
</tr>
<tr>
<td>MEDICAL RESEARCH</td>
<td>Relating to medicine or the practice of medicine. This includes studies in which the focused population has a specific medical diagnosis.</td>
</tr>
<tr>
<td>MEDICAL DEVICE</td>
<td>A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.</td>
</tr>
<tr>
<td>MENTALLY DISABLED</td>
<td>See Cognitively Impaired.</td>
</tr>
<tr>
<td>MINIMAL RISK</td>
<td>A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.</td>
</tr>
<tr>
<td>MINOR PROTOCOL DEVIATION</td>
<td>A minor protocol deviation is any change, divergence, or departure from the research protocol that has not been approved by the IRB and that DOES NOT have a major impact on the participant’s rights, safety, or well-being or on the completeness, accuracy, and reliability of the research project data.</td>
</tr>
<tr>
<td>MODIFICATION</td>
<td>A change or revision, to any item that was previously approved by the IRB (e.g., protocol, informed consent document, advertisement). Also referred to as Revision, Amendment.</td>
</tr>
<tr>
<td>MONITORING</td>
<td>The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections.</td>
</tr>
<tr>
<td>MULTI-SITE MANAGEMENT PLAN</td>
<td>A document submitted to the IRB when a research project involves multiple data collection sites and researchers containing information regarding the communication process between sites and the management of information obtained during the course of the research project.</td>
</tr>
<tr>
<td>NATIONAL COMMISSION</td>
<td>National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations.</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>NDA</td>
<td>See <em>New Drug Application</em>.</td>
</tr>
<tr>
<td>NEONATE</td>
<td>Newborn.</td>
</tr>
<tr>
<td>NEW DRUG APPLICATION</td>
<td>Request for FDA approval to market a new drug.</td>
</tr>
<tr>
<td>NIAAA</td>
<td>National Institute on Alcohol Abuse and Alcoholism; an institute in NIH.</td>
</tr>
<tr>
<td>NIDA</td>
<td>National Institute on Drug Abuse; an institute in NIH.</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.</td>
</tr>
<tr>
<td>NIJ</td>
<td>National Institute of Justice: NIJ is the research, development, and evaluation agency of the U.S. Department of Justice and is dedicated to researching crime control and justice issues.</td>
</tr>
<tr>
<td>NIMH</td>
<td>National Institute of Mental Health; an institute in NIH.</td>
</tr>
<tr>
<td>NONAFFILIATED MEMBER</td>
<td>Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community <em>(e.g., minister, business person, attorney, teacher, homemaker)</em>.</td>
</tr>
<tr>
<td>NON-COMPLIANCE</td>
<td>A proven failure to follow the regulations or the requirements and determinations of the IRB.</td>
</tr>
<tr>
<td>NON-SCIENTIFIC MEMBER</td>
<td>IRB members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline. They are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.</td>
</tr>
<tr>
<td>NONSIGNIFICANT RISK DEVICE</td>
<td>An investigational medical device that does not present significant risk to the patient. See also <em>Significant Risk Device</em>.</td>
</tr>
<tr>
<td>NONTHERAPEUTIC RESEARCH</td>
<td>Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future.</td>
</tr>
<tr>
<td>NONVIALE NEONATE</td>
<td>An expelled or delivered neonate which, although it is living, cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy. Although it may be presumed that an expelled or delivered neonate is nonviable at a gestational age less than 20 weeks and weight less than 500 grams, a specific determination as to viability must be made by a physician in each instance. See also <em>Viable Infant</em>.</td>
</tr>
<tr>
<td>NORMAL</td>
<td>Volunteer subjects used to study normal physiology and behavior or who...</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<td>-------------------------------</td>
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<tr>
<td>VOLUNTEERS</td>
<td>Volunteers do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. &quot;Normal&quot; may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the &quot;normals&quot; in a study of diabetes complicated by heart disease.</td>
</tr>
<tr>
<td>NULL HYPOTHESIS</td>
<td>The proposition, to be tested statistically, that the experimental intervention has &quot;no effect,&quot; meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the Investigator to reject the null hypothesis.</td>
</tr>
<tr>
<td>NUREMBERG CODE</td>
<td>A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.</td>
</tr>
<tr>
<td>OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)</td>
<td>The office within the Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.</td>
</tr>
<tr>
<td>ONLINE IDENTITIES</td>
<td>In some online contexts, the persona or avatar used by the participant to represent his or her identity.</td>
</tr>
<tr>
<td>OPEN DESIGN</td>
<td>An experimental design in which both the Investigator(s) and the subjects know the treatment group(s) to which subjects are assigned.</td>
</tr>
<tr>
<td>PARENTAL PERMISSION</td>
<td>The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.&quot; The term &quot;parent&quot; means a &quot;child's biological or adoptive parent.&quot; The term “guardian” means “an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. See also Guardian, Legally Authorized Representative.</td>
</tr>
<tr>
<td>PASSIVE CONSENT</td>
<td>Passive consent, which is ethically questionable, requires parents or guardians to sign and return a form if they refuse to allow their child to participate in research. Active consent, on the other hand, requires parents or guardians to sign and return a form if they consent for their child to participate. The OU IRB does not allow passive consent. See also Informed Consent.</td>
</tr>
<tr>
<td>PASSIVE DATA COLLECTION</td>
<td>This type of research involves no interaction or intervention with the individual about whom data are being collected (examples: public twitter feeds; public Facebook profiles or wall postings; information from public/open chat rooms, whether the data is collected through silent observation or from archives; etc.).</td>
</tr>
<tr>
<td>PATERNALISM</td>
<td>Making decisions for others against or apart from their wishes with the intent of doing them good.</td>
</tr>
<tr>
<td>PERMISSION</td>
<td>The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.</td>
</tr>
</tbody>
</table>
PERSONAL HEALTH INFORMATION

See Protected Health Information.

PERSONAL IDENTIFYING INFORMATION

Defined by the Office of Management & Budget as “Information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother’s maiden name, etc.”

PHARMACOLOGY

The scientific discipline that studies the action of drugs on living systems (animals or human beings).

PHASE 1, 2, 3, 4 DRUG TRIALS

Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phases 2 and 3), to post-marketing studies (Phase 4).

PHASE 1 TRIALS

Clinical studies that include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects involved in Phase 1 investigations is generally in the range of 20-80.

PHASE 2 TRIALS

Controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects.

PHASE 3 TRIALS

Clinical studies that involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide an adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for
approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.

**PHASE 4 TRIALS**

Studies conducted after a drug has been approved by the FDA to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.

**PHENOTYPE**

The physical manifestation of a gene function.

**PHS**

Public Health Service. Part of the U.S. Department of Health and Human Services, it includes FDA, NIH, CDC, SAMHSA, and HRSA.

**PHYSICAL**

Concerning the corporeal body.

**PLACEBO**

An inert substance or sham activity used in the guise of treatment; used in controlled clinical trials as a comparator to determine if an investigational therapy is more effective than no treatment.

**PLANNED EMERGENCY RESEARCH**

Planned research in a life-threatening emergency where the requirement to obtain prospective informed consent has been waived and is covered by 21 CFR 50.24. The research plan must be approved in advance by the IRB and either the FDA or DHHS, as appropriate, and the project, as well as its results, must be publicly disclosed to the community in which the research is conducted.

**PRECLINICAL INVESTIGATIONS**

Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans.

**PREGNANCY**

The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test. This "confirmation" may be in error, but, for research purposes, investigators would presume that a living fetus was present until evidence to the contrary was clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

**PREMARKET APPROVAL**

Process of scientific and regulatory review by the FDA to ensure the safety and effectiveness of Class III devices.

**PRESIDENT'S COMMISSION**

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. An interdisciplinary advisory group, established by congressional legislation in 1978, which was in existence until 1983, and which issued reports on ethical problems in health care and in research involving human subjects.

**PRINCIPAL INVESTIGATOR**

The scientist or scholar with primary responsibility for the design and conduct of a research project, more fully defined in *Investigator* above.
PRISONER

An individual involuntarily confined in a penal institution, including persons:
(1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.

The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

PRISONER OF WAR

Department of the Navy regulations at SECNAVINST 3900.39D, define a Prisoner of War (POW) as a detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his government is captured by the armed forces of the enemy.

Department of the Army regulations at 70-25, define a Prisoner of War, under Prisoner, as any person (adult or minor) involuntarily confined or detained in a penal or correctional institution (for example, jail, workhouse, house of detention, prison, military stockade, or brig). The term is intended to encompass individuals detained pending arraignment, trial, or sentencing; and prisoners of war including detained personnel).

For other DoD Components, the definition of Prisoner of War will be specific to the DoD component regulation.

Under VA regulations, a former prisoner of war (POW) is defined in Title 38 U.S.C. 101(32) as a person who, while serving in the active military, naval, or air service, was forcibly detained or interned in the line of duty by:
- an enemy government or its agents, or a hostile force, during a period of war, or
- a foreign government or its agents, or a hostile force, under circumstances which the Secretary finds to have been comparable to the circumstances under which persons have generally been forcibly detained or interned by enemy governments during periods of war.

PRIVACY

A person’s right to control the extent, timing, and circumstances of sharing access to oneself (physically, behaviorally, or intellectually) and one’s information with others.

PROTECTED HEALTH INFORMATION (PHI)

Individually identifiable health information that:
1. Is created or received by a health care provider, health plan, employer or clearinghouse; can be linked to a particular person and
2. Relates to the individual's past, present, or future physical or mental health, treatment, or condition; the provision of health care to the individual; or the payment for the provision of health care, and
3. Is maintained or transmitted electronically in any form or medium.
Common identifiers of health information include names, Social Security numbers, addresses, and birth dates, all of which are considered PHI as
A complete list of identifiers is available in the HIPAA Definitions policy, available on the HIPAA webpage.

PPRA is a law intended to protect the rights of pupils and the parents or guardians of pupils in programs funded by the US Department of Education (ED). The PPRA was written to protect the rights of parents/guardians and students in two specific ways: 1) any material used by students in ED funded surveys, analyses, or evaluations will be made available to parents/guardians to inspect prior to use with their child, and 2) it ensures that schools and contractors acquire written parental/guardian consent before a minor student is required to participate in ED funded surveys, analyses, or evaluations which may reveal personal information.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

This information may be clearly private by law or expectation (e.g., a medical record or personal diary), but it may also include information protected by the individual, such as a person’s Facebook profile that is set so only friends can see messages or photographs.

The person whose case serves as the stimulus for the study of other members of the family to identify the possible genetic factors involved in a given disease, condition, or characteristic.

Preventive or protective; a drug, vaccine, regimen, or device designed to prevent, or provide protection against, a given disease or disorder.

Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Events that are departures from the specific protocol procedures approved by the IRB.

The act of developing a protocol. For instance, some external research projects provide funding for the design of the protocol and the development of the data collection instruments. During the period of time between when study funding is available to the investigator and the human subjects research project is approved by the IRB, investigators may get permission for protocol development activities in order to release funding.
for study personnel. No human research activities, including recruitment or advertising, can occur during protocol development. When the investigator is ready to commence research activities, a new study application and related supporting materials must be submitted to the IRB using the standard review procedures.

**QUASI-EXPERIMENTAL STUDY**

A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups. See also *Experimental Study*.

**QUORUM**

A quorum is achieved if more than one half of the members for the IRB are present, meeting the criteria for the IRB.

A quorum may be met by members or their alternates and must include at least one member whose expertise is in a scientific area, one member whose expertise is in a nonscientific area, and one member who is not otherwise affiliated with the University.

**RADIOACTIVE DRUG**

Any substance defined as a drug in the Federal Food, Drug and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. Included are any non-radioactive reagent kit or nuclide generator to be used in the preparation of a radioactive drug and "radioactive biological products." Drugs such as carbon-containing compounds or potassium-containing salts containing trace quantities of naturally occurring radio-nuclides are not considered radioactive drugs.

**RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)**

An institutional committee responsible for the use of radioactive drugs in human subjects for research purposes. Research involving human subjects that proposes to use radioactive drugs must meet various FDA requirements, including limitations on the pharmacological dose and the radiation dose. Furthermore, the exposure to radiation must be justified by the quality of the study and the importance of the information it seeks to obtain. The committee is also responsible for continuing review of the drug use to ensure that the research continues to comply with FDA requirements, including reporting obligations. The committee must include experts in nuclear medicine and the use of radioactive drugs, as well as other medical and scientific members.

**RADIO-PHARMACEUTICAL**

Drug (compound or material) that may be labeled or tagged with a radioisotope. These materials are largely physiological or sub-pharmacological in action, and, in many cases, function much like materials found in the body. The principal risk associated with these materials is the consequent radiation exposure to the body or to specific organ systems when they are injected into the body.

**RANDOM. RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED**

Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.
RECOMBINANT DNA TECHNOLOGY
DNA resulting from the insertion into the chain, by chemical or biological means, of a sequence (a whole or partial chain of DNA) not originally (biologically) present in that chain. Recombinant DNA technology is also used to develop diagnostic screens and tests, as well as drugs and biologics for treating diseases with genetic components.

RECUSE
To disqualify (oneself) as a reviewer for a research project based on a real or perceived conflict of interest.

REMUNERATION
A financial or non-financial payment given to research participants for the involvement in a research projects. The amount and the method and timing of disbursement must be consistent with the laws, regulations, and guidelines governing human subjects research and must not improperly influence a subject’s decision to participate. See also Compensation.

RESEARCH
Research as defined by DHHS regulations is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives.

Research as defined by FDA regulations is any experiment that involves a test article and one or more human subjects, and is subject to requirements for prior submission to the FDA that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug, and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspections by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The terms research, clinical research, clinical study, study and clinical investigation are synonymous.

Research as defined by VA regulations is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.

RESEARCH PARTICIPANT
See Human Participants.

RESEARCH PROJECT
A term used as a standardized term in reference to human subjects research, human research, etc. of only those projects that are under the purview of the IRB.

RESEARCH INVOLVING A HUMAN BEING AS AN EXPERIMENTAL SUBJECT
An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving experimental subjects as defined in DODI 3216.02 is a subset of research involving human participants. Examples include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject’s
environment, or the withholding of an intervention that would have been undertaken if not for the research purpose.

**RESEARCH PARTICIPANT**

See Human Participants.

**RESEARCH PROCEDURE THAT MAY RESULT IN GREATER THAN A MINIMAL LEVEL OF PHYSICAL RISK**

Any research procedure that, when utilized as a component of an intervention or measurement procedure, elevates physical risks by increasing the probability of development of a negative physical outcome (i.e., elevated blood pressure, arrhythmia).

**RESPECT FOR PERSONS**

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and those persons with diminished autonomy is protected.

**RETROSPECTIVE STUDIES**

Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

**REVIEW AND APPROVAL OF RESEARCH PROJECTS**

Any action or decision taken by the IRB through full or expedited review mechanisms, which grants or may appear to grant Investigators with initial or continuing approval or research, training or educational projects involving human subjects.

**RESEARCH PROCEDURE THAT MAY RESULT IN GREATER THAN A MINIMAL LEVEL OF PHYSICAL RISK**

Any research procedure that, when utilized as a component of an intervention or measurement procedure, elevates physical risks by increasing the probability of development of a negative physical outcome (i.e., elevated blood pressure, arrhythmia).

**REVIEW (OF RESEARCH)**

The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

**REVISION**

See Modification.

**RISK**

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: Minimal Risk.)

**ROUTINE INTERNAL CORRESPONDENCE**

Any action, letters, memos, or emails between the IRB and staff and members of the faculty or staff of the institution/organization that provide information concerning the review of research protocols by the IRB or staff that do not imply or appear to imply approval of this activity.
SECONDARY RESEARCH USE

Re-using identifiable and non-identifiable information and biospecimens for research purposes that are collected for some other “primary” or “initial” activity, such as clinical care or research studies other than the proposed research study.

SCHOLARLY MISCONDUCT

See also Scientific Misconduct.

SCIENTIFIC MEMBER

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline. Scientific members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.

SCIENTIFIC MISCONDUCT

Scientific misconduct is the violation of the standard codes of scholarly conduct and ethical behavior in professional scientific research. Refer to the appropriate campus Ethics in Research policy for the University’s policy on Scientific Misconduct.

SCIENTIFIC REVIEW GROUP

A group of highly regarded experts in a given field, convened by NIH to advise NIH on the scientific merit of applications for research grants and contracts. Scientific review groups are also required to review the ethical aspects of proposed involvement of human subjects. Various kinds of scientific review groups exist, and are known by different names in different institutes of the NIH (e.g., Study Sections, Initial Review Groups, Contract Review Committees, or Technical Evaluation Committees).

SERIOUS NON-COMPLIANCE

Disregarding or failing to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB. See also Non-Compliance.

SERIOUS ADVERSE EVENT

For FDA safety reporting purposes, any adverse drug experience occurring at any dose that results in any of the following outcomes: (1) Death, (2) a life-threatening adverse drug experience, (3) inpatient hospitalization or prolongation of existing hospitalization, (4) a persistent or significant disability/incapacity, or (5) a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

SIGNIFICANT RISK DEVICE

An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject.
**SINGLE-MASTRED DESIGN**

Typically, a study design in which the Investigator, but not the subject, knows the identity of the treatment assignment. Occasionally the subject, but not the Investigator, knows the assignment. Sometimes called "single-blind design."

**SINGLE IRB (sIRB)**

Defined by NIH as the selected IRB of record that conducts the ethical review for participating sites of a NIH multi-site study.

**SITE VISIT**

A visit by agency officials, sponsor representatives, consultants, or the like to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

**SOCIAL EXPERIMENTATION**

Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

**SPECIAL POPULATION**

Individuals whose willingness to volunteer in a research project may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

**SPONSOR (OF A DRUG TRIAL)**

A person or entity that initiates a clinical investigation of a drug — usually the drug manufacturer or research institution that developed the drug. The Sponsor does not actually conduct the investigation, but rather distributes the new drug to Investigators and physicians for clinical trials. The drug is administered to subjects under the immediate direction of an investigator who is not also a Sponsor. An Investigator may, however, serve as a Sponsor-Investigator. The Sponsor assumes responsibility for investigating the new drug, including responsibility for compliance with applicable laws and regulations. The Sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

**SPONSOR-INVESTIGATOR**

An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as Sponsor-Investigators.

**STATISTICAL SIGNIFICANCE**

A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. More simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).
<table>
<thead>
<tr>
<th>STUDY SECTION</th>
<th>See Scientific Review Group.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUB-FORM</td>
<td>A form within the IRB’s application that appears in the electronic information system based on the answer an investigator provides to an application question. Sub-forms gather additional details about what is being proposed by the investigator in order for the IRB reviewer to make a determination.</td>
</tr>
<tr>
<td>SUBJECTS (HUMAN)</td>
<td>See Human Participants.</td>
</tr>
<tr>
<td>SURROGATE CONSENT</td>
<td>The act of an individual giving consent for another person who has limited capacity to make voluntary and informed decisions about participation in a research project. Federal regulations and state laws provide additional guidance and restrictions governing surrogate consent and who is eligible to sign as a legally authorized representative. See also Informed Consent.</td>
</tr>
<tr>
<td>SURVEYS</td>
<td>Studies designed to obtain information from a large number of respondents through online or paper questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.</td>
</tr>
<tr>
<td>SYSTEMATIC INVESTIGATION</td>
<td>Generally refers to a predetermined method for answering certain questions or studying a specific program or topic.</td>
</tr>
<tr>
<td>TECHNICAL NON-COMPLIANCE</td>
<td>Non-compliance that is neither serious nor continuing non-compliance.</td>
</tr>
<tr>
<td>TEST ARTICLE</td>
<td>Any drug (including a biological product for human use), medical device for human use, or any other article subject to regulation by the Food and Drug Administration.</td>
</tr>
<tr>
<td>THERAPEUTIC INTENT</td>
<td>The research physician's intent to provide some benefit to improving a subject's condition (e.g., prolongation of life, shrinkage of tumor, or improved quality of life, even though cure or dramatic improvement cannot necessarily be affected.) This term is sometimes associated with Phase 1 drug studies in which potentially toxic drugs are given to an individual with the hope of inducing some improvement in the patient's condition as well as assessing the safety and pharmacology of a drug.</td>
</tr>
<tr>
<td>THERAPY</td>
<td>Treatment intended and expected to alleviate a disease or disorder.</td>
</tr>
<tr>
<td>THIRD-PARTY WITNESS</td>
<td>An individual not involved in the study or related to the study who observes the consent process attesting that the participant was provided the study information.</td>
</tr>
<tr>
<td>TRANSNATIONAL RESEARCH</td>
<td>Research that is conducted with the purpose of comparing across the countries.</td>
</tr>
<tr>
<td>TREATMENT USE</td>
<td>The use of an investigational drug or device when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than obtain the kind of information about the drug that is generally derived from</td>
</tr>
</tbody>
</table>
clinical trials. Treatment use protocols are not primarily intended to obtain information about the safety or effectiveness of a drug.

**UNANTICIPATED / UNEXPECTED – VA RESEARCH**

Generally, refers to something that is not planned for or considered.

For purpose of VA research projects, the terms “unanticipated” and “unexpected” refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

**UNANTICIPATED PROBLEM INVOLVING RISKS TO PARTICIPANTS OR OTHERS**

Any incident, experience, or outcome that meets **all** of the following criteria:

a.) Is unanticipated or unexpected.

b.) Is related or possibly related to the research

c.) Places participants or others at greater risk of harm than previously known or recognized.

**UNIFORM ANATOMICAL GIFT ACT**

Legislation adopted by all 50 States and the District of Columbia that indicates procedures for donation of all or part of a decedent's body for such activities as medical education, scientific research, and organ transplantation.

**VACCINE**

A biologic product generally made from an infectious agent or its components — a virus, bacterium, or other microorganism — that is killed (inactive) or live-attenuated (active, although weakened). Vaccines may also be biochemically synthesized or made through recombinant DNA techniques.

**VARIABLE (NOUN)**

An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

**VIABLE INFANT**

When referring to a delivered or expelled fetus, the term "viable infant" means likely to survive to the point of sustaining life independently, given the benefit of available medical therapy. A physician makes this judgment. In accordance with DHHS regulations, the Secretary, HHS, may publish guidelines to assist in the determination of viability. Such guidelines were published in 1975, and specify an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more as indices of fetal viability. These indices depend on the state of present technology and may be revised periodically. See also Nonviable Fetus.

**VOLUNTARY**

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

**VULNERABLE SUBJECTS**

Groups of potential research participants who are entitled to additional protections according to federal regulations including Prisoners, Children, Pregnant Women and Fetuses. See also Special Populations.
STATEMENT OF AUTHORITY AND PURPOSE

1. Mission Statement

The mission of the University of Oklahoma’s (University) Office of Human Research Participant Protection (HRPP) is to protect the rights, privacy, and welfare of all human participants in research projects conducted by University faculty, staff, students and those who conduct human research projects under the auspices of the University or otherwise under its oversight.

2. Human Research Participant Protection Plan

2.1 Governance and Leadership

2.1.1 Uphold the University’s Federalwide Assurance for the Protection of Human Subjects (FWA) with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP).

2.1.2 Improve the research infrastructure by providing a human research participant protection program through strong and effective leadership.

2.1.3 Ensure an effective regulatory review system by providing excellent support services to the IRB members who review research.

2.1.4 Ensure SOPs are maintained for the University’s adherence to established policies, ethical guidelines, and compliance with regulatory requirements.

2.2 Research Infrastructure

2.2.1 Provide effective support to University faculty, staff, students, and other individuals under University oversight involved in human research.

2.2.2 Promote open communication and foster an atmosphere of compliance with all of the University’s components.

2.3 Education and Quality Improvement

Maintain rigorous education and quality improvement programs in order to ensure all of the human research participant protection components are in compliance with the applicable regulations, University policies, and SOPs.

2.4 Risk Assessment

Evaluate and assess risks for strengthening the human research participant protection program and initiate improvements.

3. The HRPP

The HRPP is the University’s established program designed to support the University’s commitment to the protection of human participants in research. The goals of this program are to provide for the safety of human participants in research, to educate the University’s investigators, and to provide continuous quality improvement of the University’s research activities.

4. Governing Principles

All of the University’s Institutional Review Boards (IRBs) are guided by the ethical principles applied to all research involving humans as participants, as set forth in the report of the National
Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").

These principles are defined in the Belmont Report as follows:

**Respect for Persons** -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

**Beneficence** -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

**Justice** -- The selection of participants is equitable and is representative of the group that will benefit from the research. Justice requires that the benefits and burdens of research be distributed fairly.

5. Applicable Laws

Each IRB's purpose and responsibility are to protect the rights and welfare of human participants. The IRBs review and oversee such research to ensure that the research complies with federal regulations at 45 CFR 46, and its subparts A, B, C, D and E; the U.S. Food and Drug Administration 21 CFR 50, 56, 312, 314, 601, 812, and 814; Oklahoma law; and all other pertinent regulations and applicable guidelines.

The University will apply the Federal Policy for the Protection of Human Subjects (the Common Rule) to all human subject research, regardless of the source of funding, except where specified otherwise in the HRPP SOPs policies.

The University agrees to apply additional regulations such as the Health Insurance and Portability and Accountability Act of 1996 (HIPAA) at 45 CFR 160 and 164, and the U.S. Department of Veterans Affairs regulations, 38 CFR 16, to research involving human participants under review when applicable.

The University agrees to apply the Department of Defense (DOD) Directive 3216.02 as additional requirements when human participant research is conducted or supported by the DOD.

6. Organizational Components, Structure, Roles, and Responsibilities

6.1 Institutional Officials

6.1.1 The Senior Vice President and Provosts of the Norman Campus and Health Sciences Center Campus or their designees are the Institutional Officials. They report to the University President.

6.1.2 The Senior Vice President and Provosts or their designees have signatory authority for the OHRP FWAs and FWA addenda when human participant research is conducted or supported by the DoD on their respective campuses.
6.1.3 The Senior Vice President and Provosts or their designees are responsible for the conduct of human research of their respective campuses. The Senior Vice President and Provosts or their designees have been granted authority to provide for the appropriate allocation of funds, facilities, and employees necessary to operate the HRPP programs and to maintain and enforce the independent nature of the relationship of the IRB within the University.

6.1.4 For more information about the organizational structure, see the HRPP/IRB organizational chart located on the University Office of Compliance website.

6.2 Organizational Official

6.2.1 The Vice President of the University and General Counsel is the Organizational Official responsible for the Office of Human Research Participant Protection (HRPP), through the Director of Compliance, and is obligated to promote and foster ethical integrity involving research and other activities. The Organizational Official reports to the President.

6.2.2 The Vice President of the University and General Counsel has the authority to oversee the HRPP and ensure its effectiveness in protecting research participants. The HRPP operates under the auspices of the Vice President of the University and General Counsel, but signatory authority for signing the OHRP FWAs lies with the Senior Vice President and Provost or designee for each campus.

6.2.3 For more information about the Organizational Official, see the HRPP/IRB organizational chart and the Presidential Policy-Organizational Official for Human Research Protection Program, located on the University Office of Compliance website.

6.3 Director of Compliance

6.3.1 The Board of Regents of the University of Oklahoma created the Office of Compliance to address adherence to federal, state, and institutional regulations regarding standards of conduct in research and other areas. The Office of Compliance promotes and fosters ethical integrity involving research and other activities. Through the Office of Compliance, the University coordinates resources to train HRPP staff, IRB members, investigators, and research staff in human participant protection, care, and safety.

6.3.2 The Director of Compliance has direct oversight of the Norman Campus Office of HRPP and reports to the Vice President of the University and General Counsel. The Director of Compliance is responsible for oversight of the operation of the Office of HRPP for Norman Campus including staffing, budget, and performance of the HRPP.

6.3.3 The Director of Compliance maintains a Hot Line where individuals can anonymously report compliance-related concerns or violations. The Director of Compliance can direct audits of areas of potential concern and reports the findings to the Senior Vice President and Provost or designees for the respective campuses and to the Vice President and General Counsel.

6.3.4 The University established the Compliance Advisory Committee (CAC) composed of senior University administrators who meet regularly to review the status of the Compliance Program, including the Office of HRPP.

6.3.5 The Director of Compliance reports the status of the HRPP to the CAC.

6.4 Health Sciences Center Vice President of Research

6.4.1 Through the Vice President for Research, the University coordinates resources to train
HSC HRPP staff, IRB members, investigators, and research staff in human participant protection, care, and safety.

6.4.2 The Vice President for Research has direct oversight of the HSC Office of HRPP and reports to the Senior Vice President and Provost. The Vice President for Research is responsible for oversight of the operation of the HSC HRPP including staffing, budget, and performance of the HSC HRPP.

6.5 Offices of Human Research Participant Protection

6.5.1 The Directors of the Offices of HRPP manage the Norman and Health Sciences Center Campus Offices of HRPP.

6.5.2 The Norman Campus HRPP Director reports to the Director of Compliance, and the HSC HRPP Director reports to the HSC Vice President for Research. The Directors of the Offices of HRPP are responsible for the day-to-day management and operations of the respective program. This responsibility includes managing the IRBs; upholding and maintaining of the FWA; and managing the Education Program, Quality Improvement Program, and Participant Outreach Program. The Education Program is designed to ensure that Investigators, key personnel, IRB members, and HRPP staff are knowledgeable in the applicable elements of the Human Research Participant Protection Program. The Quality Improvement Program is designed to continually evaluate, provide education, and improve the research process, ultimately providing a higher degree of safety to human research participants. The Participant Outreach Program is designed to enhance the understanding of human research by participants or prospective participants, respond to concerns and questions about research from participants and the community, and conduct outreach and education activities with participants and the community.

6.6 Institutional Review Boards

6.6.1 The Directors of the Offices of HRPP manage the Norman and Health Sciences Center Campus IRBs, respectively. The IRBs, units within the HRPP, are established and empowered under the auspices of this University’s executive authorities to review biomedical and behavioral research submissions involving human participants and make a determination to approve, contingently approve, defer, or deny research submissions, as well as to suspend or terminate any approved research. Although the IRBs function independently, their review can be coordinated with the requirements of other University offices and committees, such as those mentioned in section 602 of the SOPs. There are two IRBs on the Norman Campus and five on the Health Sciences Center Campus.

6.6.2 The Directors of the Offices of HRPP are responsible for the day-to-day management and operations of their respective IRBs, including management of IRB staff, IRB membership, and IRB membership rosters; maintenance of policies and SOPs; and prompt reporting of 1) unanticipated problems involving risks to participants or others, 2) serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s), and 3) suspension or termination of IRB approval.

6.6.3 The IRBs have the responsibility to provide oversight for the research conducted under the University’s FWA. The University requires that all research projects involving humans as participants or human material that are conducted by University faculty, staff, and students, as well as those conducted under its authority as described in Section 9.1.2 below be reviewed and approved by an IRB prior to initiation of any research-
related activities, including recruitment and screening activities. This responsibility includes training key personnel, processing submissions to the IRBs, coordinating IRB meetings, and acting as a liaison between the Investigators and the IRBs. The IRBs are responsible for documenting their findings regarding ethical considerations, scientific and scholarly merit, and adherence to applicable regulations and policies of research projects reviewed.

6.7 Offices of Research Services/Administration

6.7.1 The Office of Research Services (Norman Campus) and the Office of Research Administration (Health Sciences Center Campus) serve as central resources to faculty for all pre- and post-award administrative aspects for sponsored research, training, and service activities.

6.7.2 The Office of Research Services (Norman Campus) and the Office of Research Administration (Health Sciences Center Campus) are responsible for negotiating sponsored and non-sponsored agreements, including but not limited to clinical trial, confidentiality, material transfer, professional service agreements, and subcontracts. These offices serve as the University’s liaisons with external funding agencies for all pre- and post-award administrative matters.

6.8 Investigators

6.8.1 Investigators perform their work under the direct supervision of the department chairs, who report to the Senior Vice President and Provost or designee for the respective campuses.

6.8.2 Investigators are responsible for conducting research in such a manner as to guard the safety of participants and to be compliant with all applicable laws, regulations, ethical principles and guidelines.

6.8.3 Investigators shall ensure that key study personnel are adequately trained and for complying with all applicable regulations and human research participant protection policies.

6.8.4 It is the Investigator’s responsibility to keep the IRB informed of all problems for which the IRB requires prompt reporting.

7. Interactions of Organizational Components

7.1 The successful fulfillment of the University’s organizational components to protect participants requires open communication among the components. As such, meetings and other forms of communication are used both horizontally and vertically within the groups and individuals participating in the HRPP.

7.2 The University’s organizational policies relating to the conduct of human research are coordinated through the Office of Compliance. The Office of Research Administration (Health Sciences Center Campus) and the Office of Research Services (Norman Campus) coordinate and administer the University’s policies and SOPs with sponsors. The Office of HRPP coordinates and administers the University’s standards for research participants.

7.3 The University is comprised of multiple review committees for proposed research, depending upon the type of research. As such, there are multiple lines of communication between the IRB and the other review committees, as well as between the Norman and HSC Offices of HRPP and representatives of the IRBs.

7.4 The University does not allow any organizational components to approve human participant
research or authorize the initiation of human research activities unless the activities have already been approved by the IRB.

7.5 The University maintains the authority, through its administration, to disallow the conduct of IRB-approved research activities at the University or by University employees.

8. Commencement of Research

The University components work together to ensure that research does not commence until all required approvals are obtained. All research activities involving human participants must be reviewed and approved by one of the appropriate IRBs. Research may not commence until all committees and offices have completed their review and provided documentation to the IRB.

9. Conditions Under Which Activities Become Subject to HRPP

9.1 When an Activity is Research

9.1.1 The University becomes engaged in human participant research when its employees or agents\(^1\) (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(e), (l)]. The University is automatically considered to be "engaged" in human participant research whenever it receives a direct HHS award to support such research.

9.1.2 Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46 Section 104, all research involving human participants and all other activities that involve such research, even in part, regardless of sponsorship, are subject to IRB review if one or more of the following apply:

A. The research is sponsored by the University; or

B. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University in connection with his or her University responsibilities; or

C. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University using any of the University’s properties or facilities; or

D. The research involves the use of the University’s non-public information to identify or contact human research participants or prospective participants; or

E. The research is conducted by or under the direction of an individual employed by any affiliated site who is performing the research at that site.

9.2 When Research is Subject to HRPP

9.2.1 University policy states that all research involving human participants, as defined in 45 CFR 46 Section 102 (e) and the glossary term, even if it may be exempt from IRB review per 45 CFR 46 Section 104, must be reviewed by an IRB or IRB designee before research activities commence, to ensure that participants and/or participant interests are appropriately protected.

9.2.2 The definition of research with human participants includes: "A systematic investigation,

\(^1\) Agents are defined by the University as individuals performing institutionally-designated activities or exercising institutionally-delegated authority or responsibility.
including research development, testing and evaluation designed to develop or contribute to generalizable knowledge that involves a living individual about whom an investigator, (whether professional or student) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. The intention to contribute to such knowledge is key to the definition, whether or not the completed research does make such a contribution or is accepted for publication.

9.2.3 According to federal regulations, the activities that require IRB review include any activities involving research with human participants (as defined in 9.2.2).

9.2.4 Examples of activities that are considered human participant research and require IRB review are described on the HRPP website.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 101: STANDARD OPERATING POLICIES AND PROCEDURES MAINTENANCE

1. POLICY

The IRB shall follow regulations and guidance of DHHS, FDA, and Institutional policies to facilitate the protection of the rights and welfare of human participants. The IRB shall oversee, review human research, and maintain it in a uniform manner regardless of changes in personnel. Written Standard Operating Policies and Procedures (SOPs) foster the highest quality and integrity of the review and oversight of research involving human participants and for the adequate documentation of such oversight.

SOPs provide the framework for the ethical and scientifically sound conduct of human participant research. The policies are general statements of principles within the SOPs and provide overall ethical guidance that includes specific detailed directives for their implementation.

Specific Policies

1.1 Review, Revision, and Approval of SOPs

1.1.1 Changes to regulations, federal guidelines, research practice, and University policies may require a new SOP or a revision to an existing SOP.

1.1.2 The HRPP Director of the applicable campus shall review all SOPs.

1.1.3 Appropriate Institutional Officials or their designees shall review SOPs at intervals established by the Director of Compliance.

1.1.4 The Director of Compliance or designee must approve new or revised SOPs.

1.1.5 Documentation of approval shall be by signature of the responsible and authorized individuals.

1.2 SOP Dissemination and Training

1.2.1 When new or revised SOPs are approved, the IRB office shall disseminate them to the Institution via campus-wide email distributions, if possible; IRB website postings; and educational sessions.

1.2.2 All IRB members, IRB staff, and HRPP staff shall receive training on any new or revised SOPs. The Education Coordinator and/or HRPP Director shall document and keep on file.

1.2.3 Each new IRB member shall be advised by the Education Coordinator and the HRPP Director of all SOPs prior to undertaking any responsibilities at the IRB. Each new IRB member shall sign a form acknowledging receipt of the SOPs.

1.2.4 Each new IRB staff member shall be advised by the Education Coordinator and the HRPP Director of all SOPs prior to undertaking any responsibilities at the IRB. Each IRB staff member shall sign a form acknowledging receipt of the SOPs.

1.2.5 The HRPP office shall maintain all documentation of IRB member and staff training.

1.3 Revision Logs

The IRB shall use the SOP Revision Log to document the review, track the date, and describe the purpose for the revision or new SOP.
2. SCOPE
   This SOP applies to all HRPP staff, IRB staff, and IRB members.

3. RESPONSIBILITY
   3.1 The Director of Compliance is responsible for granting final approval of new and revised SOPs for both campuses and maintaining standardized policies across campuses, to the extent appropriate.
   3.2 The HRPP Director is responsible for establishing and periodically reviewing and modifying SOPs, subject to approval of the Director of Compliance.
   3.3 The IRB Chair or IRB designee is responsible for periodically reviewing and suggesting modifications to the SOPs, to the HRPP Director.

4. APPLICABLE REGULATIONS AND GUIDELINES
   21 CFR 56.108, 56.109, 56.113
   45 CFR 46.108

5. REFERENCES TO OTHER APPLICABLE SOPS
   None.

6. ATTACHMENTS
   101-A SOP Revision Log
   101-B Forms Revision Log
   101-C SOP Template
   101-D HRPP SOP Acknowledgment Form

7. PROCESS OVERVIEW
   7.1 The IRB shall maintain written procedures for quality of review and integrity of research.
      7.1.1 Revisions to an existing SOP or a new SOP may be required when changes to regulations, federal guidelines, University policies, or research practices occur.
      7.1.2 SOPs are reviewed by the HRPP Director and IRB Chair at intervals established by the Director of Compliance.
      7.1.3 Proposals for SOP changes are reviewed by the IRB Executive Committee for each campus. If lack of consensus regarding an issue or SOP change occurs, the issue or change is brought to the Joint IRB Executive Committee meeting for further discussion and resolution.
      7.1.4 Final approval is granted by the Director of Compliance or designee.
   7.2 The HRPP Director monitors and notes the need for revisions or new SOPs as needed.
7.2.1 The HRPP Director and IRB Chairs meet regarding changes.

7.2.2 The HRPP staff and IRB staff discuss changes and determine if additional procedures are required.

7.2.3 The HRPP Director revises or creates new SOPs along with any forms that need to be created or revised.

7.2.4 The Director of Compliance or designee reviews and signs new or revised SOPs that are approved.

7.2.5 The HRPP Director updates SOPs, archives copies of the previous SOPs, and delegates that these changes be made to the electronic information system.

7.2.6 The new or revised SOPs will include an effective date. Old versions of the SOPs will be archived.

7.2.7 SOPs are integrated into the daily operations of the IRB.

7.2.8 The HRPP Director notifies the research community of revised SOPs via campus-wide email distributions, if possible; IRB website postings; and educational sessions.

7.3 Approved revised or new SOPs are distributed to appropriate individuals.

7.3.1 Training is provided to all IRB members and staff for revised or new SOPs.

7.3.2 New IRB staff receives training by the Education Coordinator or HRPP Director on SOPs prior to undertaking IRB responsibilities.

7.3.3 New IRB members receive training by the Education Coordinator or HRPP Director on SOPs prior to beginning their work as IRB members.

7.3.4 A member of the Office of HRPP documents evidence of training.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 102A: IRB MEMBER EDUCATION

1. POLICY

Education of IRB members in human research participant protection is critical if the IRB is to protect the rights and welfare of research participants in a consistent manner throughout the University research community.

IRB members charged with responsibility for reviewing, approving, and overseeing human participant research shall receive education in the regulations, guidelines, ethics, and policies applicable to human participant research.

All IRB members shall be apprised of University organizational structure with emphasis on the independent nature of the relationship of the IRB within the University. The actions of the Board members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of institutional or financial goals.

Specific Policies

1.1 Training

1.1.1 IRB members who are overseeing research on human participants, as defined in the Glossary, that is managed by, funded by, or taking place in an entity under the jurisdiction of the Board of Regents of the University of Oklahoma shall receive initial and ongoing education by the HRPP Director or designee regarding the responsible review and oversight of human participant research and these SOPs.

1.1.2 The NC HRPP Director, under the direction of the Director of Compliance and the HSC HRPP Director, under the direction of the HSC Vice President for Research, shall establish the educational requirements for IRB members who review biomedical and behavioral research involving human participants. The HRPP Education Coordinator shall provide and document initial and continuing education.

1.1.3 Members of the IRB shall participate in initial and continuing education in areas germane to their responsibilities.

1.1.4 IRB Chairs and Vice-Chairs shall receive additional education in areas germane to their additional responsibilities.

1.1.5 IRB members shall attend workshops and other educational opportunities focused on IRB functions. The University shall support such activities to the extent possible based on budget considerations and as appropriate to the responsibilities of IRB members and staff.

1.2 Documentation

The HRPP Education Coordinator shall document such training and continuing education and include the document in the records of the IRB as described in this SOP.

2. SCOPE

This SOP applies to all IRB members.
3. RESPONSIBILITY

The HRPP Education Coordinator, under the direction of the HRPP Director, is responsible for establishing, conducting, and/or supervising all relevant education programs for all campuses.

The HRPP Education Coordinator is responsible for guiding the development of IRB member education programs, in collaboration with the HRPP Director.

The HRPP Education Coordinator documents new IRB member training.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107
45 CFR 46.107
OHRP IRB Guidebook
NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

5. REFERENCES TO OTHER APPLICABLE SOPS

None.

6. ATTACHMENTS

102A-A Bibliography & Resource List
102A-A-1 Bibliography & Resource List-NC
102A-B Training Checklist and Documentation – IRB members
603B-A Federalwide Assurance- HSC Campus
603B-C Federalwide Assurance-Norman Campus

7. PROCESS OVERVIEW

7.1 Initial Education Requirements

7.1.1 Attendance of the New IRB Member Orientation Session

The HRPP Director and/or HRPP Education Coordinator will conduct this education session, which provides new IRB members with a general overview for applying the regulatory and ethical principles to IRB review, an overview of the SOPs pertinent to IRB meeting functions, and Board member expectations. The timeframe for completion is prior to appointment to the IRB.

The HRPP Education Coordinator will provide IRB members with a new IRB Member Packet that includes the reference materials listed below. Training on the IRB electronic information system will also be conducted to familiarize the new member with the IRB electronic review process and the reviewer checklist. IRB members are expected to read and become familiar with the information included in the following reference materials:

- OHRP IRB Guidebook containing federal regulations, Belmont Report, and OHRP and FDA guidance documents
- Orientation PowerPoint Handout
7.1.2 **Successful Completion of the CITI Basic Web-based Course**

A. **HSC Campus**: the timeframe for completion is within three months of attending the first IRB meeting as an appointed member.

B. **Norman Campus**: new members shall complete the CITI Basic Social/Behavioral training within the first three months of their employment or assignment to a research project.

7.2 **Continuing Education Requirements**

7.2.1 **Successful Completion of the (CITI) Refresher Web-based Course**
Timeframe for completion: Required every three years for both HSC and Norman campus IRB members.

7.2.2 **Board Member Education Series**
The HRPP Director periodically distributes updated information regarding new or revised IRB policies and federal regulations/guidance as well as informative articles on current events in human research participant protection.

7.2.3 **Attendance of the PRIM&R Annual Conference**
IRB Chairs, Vice-Chairs, and members are encouraged to attend as funds allow.

7.2.4 **Attendance of Regional or National Conferences**
As conferences on current regulatory issues or issues pertaining to human participant research protection become available, IRB members (including Chairs and Vice-Chairs) are encouraged to attend based on their role and area of expertise in relation to topics covered at available conferences. Frequency of conference attendance is based on availability of funding.

7.3 **Documentation of Training & Education**

The HRPP Education Coordinator documents the completion of the education requirements.

- New IRB Member Orientation Session: Sign-in sheet documenting attendance.
- CITI Web-based Courses: Completion reports are generated by the CITI program and are automatically forwarded to the HRPP Education Coordinator at HSC and to the HRPP Director at OU-NC.
- Norman Campus: Sign-in sheet documenting receipt of educational materials.
- PRIM&R Annual Conference: Recorded in the file of each attending IRB member on both campuses.
- Attendance of additional regional or national conferences: Attendance recorded in the file of each attending IRB member on both campuses.

Documentation of training requirements and completion will be kept on file for each IRB member. IRB tracks completion of IRB member education requirements electronically.

If the IRB education requirements are not fulfilled by an IRB member, an email reminder will be forwarded to the IRB member by the IRB Education Coordinator or designee. If the IRB member does not comply, the HRPP Director will send a reminder to the member regarding
their noncompliance with the education requirements. Any IRB member who fails to comply with the education requirements shall not be allowed to serve as a reviewer or vote on any submissions reviewed by the IRB; ultimately such member may be removed from the board.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 102B: KEY STUDY PERSONNEL EDUCATION

1. POLICY

Education of Key Study Personnel (KSP) involved in human research is critical for the University to protect the rights and welfare of research participants in a consistent manner throughout the University research community.

KSP are individuals who provide research-related services or assistance and who have knowledge of the research protocol and the identity of research participants or their protected health information. KSP include Principal Investigators, Co-Principal Investigators, Sub-Investigators, Research Coordinators, Faculty Sponsors, collaborators, and individuals from an affiliated institution.

HSC Campus: The Senior Vice President and Provost requires education for all HSC KSP engaged in human research. This requirement includes residents, fellows, and graduate students.

Norman Campus: The Office of Compliance mandates education for all Norman KSP faculty, staff, and students.

The IRB will not approve new project submissions that include KSP who have not completed the required IRB education.

The IRB shall provide KSP who are engaged in research involving human participants with education regarding the regulations, guidelines, ethics, and policies applicable to human participant research. The Office of Compliance provides Standards of Conduct training, which all faculty and staff are required to complete.

IRB Standard Operating Procedures and the Investigator's Manual are available to KSP involved in human research.

Specific Policies

1.1 Education

1.1.1 KSP who are engaged in research involving human participants, as defined in 45 CFR 46.102 (f) and/or 21 CFR 56.102(e), that is managed by, funded by, or taking place in an entity under the jurisdiction of the Board of Regents of the University of Oklahoma shall receive initial and continuing education by the HRPP Director or designee regarding the responsible review and oversight of human research.

1.1.2 The HRPP Education Coordinator, under the direction of the HRPP Director, shall establish the education requirements for KSP involved in biomedical and social behavioral research involving human participants and provide and document both initial and ongoing education for them as required.

1.1.3 KSP shall participate in initial and continuing education in areas germane to their responsibilities.

1.2 Documentation

The HRPP Education Coordinator shall document KSP education and add it to the records of the HRPP office as described in this SOP.
2. SCOPE

This SOP applies to all KSP engaged in human participant research.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for establishing, conducting, and/or supervising all relevant education programs for KSP at each campus. Based on requirements and budget, the HRPP Director will determine the training and education schedule and notify KSP as to available program schedules.

3.2 The HRPP Education Coordinator is responsible for guiding the development of KSP education programs, in collaboration with the HRPP Director. The HRPP Education Coordinator prepares materials, schedules speakers, and organizes and conducts additional education modules and continuing education seminars as appropriate for each campus.

3.3 The HRPP Director or HRPP Education Coordinator maintains and updates the Collaborative IRB Training Initiative (CITI) Institutional Module as needed, submitting changes to the University of Miami.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Guidance Document, IRB Guidebook

NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

102B-A Written Attestation
603B-A Federalwide Assurance-HSC Campus
603B-C Federalwide Assurance-Norman Campus

7. PROCESS OVERVIEW

The education status of all KSP designated on the research project is verified by the HRPP Director or designee. The IRB does not accept or approve new research submissions that include as KSP any individuals who have not completed the required IRB education.

Non-OU Collaborators: Individuals from non-affiliated institutions (those not designated under the University FWAs) must provide documentation of current training in human research participant protection as required by their institution. In lieu of such a course or training requirements at their institution, these individuals must fulfill the requirement as stated under either 7.1.1 or 7.1.5 of this SOP.

The HRPP Education Coordinator will discuss with the HRPP Director and the Quality Improvement (QI) Coordinator implementation of improvements to the Education Program identified through the QI Program.

7.1 Initial Education Requirements

The IRB will not accept new research project submissions that include KSP who have not completed the required IRB education.
Health Sciences Center Campus

7.1.1 Completion of the web-based CITI Human Research Basic Course. The CITI Basic Course consists of modules covering the protection of human participants in both biomedical and social/behavioral research.

7.1.3 Written Attestation signed by KSP to follow applicable federal regulations governing research involving human participants. As of May 1, 2018, the Written Attestation is captured in CITI as a module and completion of the quiz serves as documentation of a signed attestation.

7.1.4 Timeframe for Completion of Initial Requirements:
KSP must complete the CITI Basic Course prior to submission of a new research project to the IRB.

Norman Campus

7.1.5 KSP must complete the CITI Basic Social Behavioral Course before their IRB research project can be approved. For Graduate Student research, this includes the Faculty Sponsor.

7.2 Continuing Education Requirements

Health Sciences Center Campus

7.2.1 KSP are required to successfully complete the web-based CITI Refresher Course every three years in areas germane to their responsibilities.

7.2.2 IRB workshops are available throughout the year covering a variety of topics such as the consenting process, documentation, and record-keeping procedures. KSP are encouraged to attend.

7.2.3 The HRPP Director and Education Coordinator routinely educate graduate students, and investigators upon request.

Norman Campus

7.2.4 KSP are required to successfully complete the web-based CITI Refresher Social Behavioral Course every three years subsequent to the completion of the Basic Social Behavioral course.

7.2.5 The HRPP Director and Education Coordinator routinely educate students and KSP in classroom settings.

7.3 Documentation of Education

The HRPP Director or HRPP Education Coordinator will maintain documentation regarding KSP education status. The education status of all KSP is also tracked electronically. Human participant research project submissions will not be accepted or approved by the IRB without confirmation that all KSP have completed the required education.

Health Sciences Center Campus

7.3.1 Education Requirements
CITI Basic Course:
A completion report is generated by the program and automatically forwarded to the IRB. Once the user completes the course, the program allows the user to print a copy of the completion report.

Written Attestation:
KSP will review the elements of the Attestation within a CITI course module. Completion of the module quiz will serve as documentation of a signed Written Attestation.

7.3.2 Continuing Education Requirements
CITI Refresher Course:
A completion report is generated by the program and automatically forwarded to the IRB. Once the user completes the course, the program allows the user to print a copy of the completion report.

IRB Workshops:
Attendance is documented with a sign-in sheet. A copy is retained by the HRPP Education Coordinator.

Norman Campus
7.3.3 Education Requirements
CITI Basic Course:
A completion report is generated by the program and automatically forwarded to the IRB and to the faculty, staff, or students.

Student as Principal investigator: Graduate Students must complete a Student as Principal investigator form. This assurance confirms that the Graduate Student is qualified by their Faculty Sponsor to conduct independent research.

Staff as Principal investigator: Staff must complete a Staff as Principal investigator form. This assurance confirms that the Staff member is qualified by their Supervisor to conduct independent research.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 102C: IRB & HRPP STAFF EDUCATION/TRAINING

1. POLICY

Training of IRB and Human Research Participant Protection (HRPP) staff involved in the review of research projects is critical if the IRB is to protect the rights and welfare of research participants in a consistent manner throughout the University research community.

IRB and HRPP staff charged with responsibility for reviewing and overseeing human participant research shall receive training by the HRPP Director or designee in the regulations, guidelines, ethics, and policies applicable to human participant research.

Specific Policies

1.1 Education and Training

1.1 HRPP and IRB staff who oversee review of research on human participants, as defined in 45 CFR 46.102 (f) and/or 21 CFR 56.102(e), that is managed by, funded by, or taking place in an entity under the jurisdiction of the Board of Regents of the University of Oklahoma shall receive initial and ongoing training by the HRPP Director or designee regarding the responsible review and oversight of research and these SOPs.

1.2 The NC HRPP Director, in consultation with the Director of Compliance, and the HSC HRPP Director, in consultation with the HSC Vice President for Research shall establish the educational and training requirements for IRB and HRPP staff who review Biomedical and Social Behavioral research involving human participants and who perform related administrative duties. Initial and ongoing training shall be provided and documented by the University through the HRPP Education Coordinator.

1.3 HRPP and IRB staff shall receive initial and continuing training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOPs).

1.4 HRPP and IRB staff shall attend workshops and other educational opportunities focused on IRB functions. The University shall support such activities to the extent possible and as appropriate to the responsibilities of staff.

1.5 The Quality Improvement (QI) Coordinator shall discuss with the HRPP Director and HRPP Education Coordinator implementation of improvements to the HRPP Education Program identified through the QI Program.

1.2 Documentation

The HRPP Education Coordinator shall document such training and continuing education and add it to the records of the IRB as described in these SOPs.

2. SCOPE

This SOP applies to all HRPP and IRB staff.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for guiding the development and curriculum of IRB and HRPP staff training programs.
3.2 The HRPP Education Coordinator is responsible for conducting and/or supervising all relevant training programs.

3.3 The HRPP Education Coordinator orders and distributes all reference materials, guidebooks, and regulatory texts necessary for new staff training and education.

3.4 The HRPP Director or designee prepares and gathers materials for the orientation session. The HRPP Education Coordinator notifies staff of the next scheduled In-House Education Program (HSC only).

4. APPLICABLE REGULATIONS AND GUIDELINES
   OHRP Guidance Document, IRB Guidebook
   NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

5. REFERENCES TO OTHER APPLICABLE SOPS
   None

6. ATTACHMENTS
   102C-A Training Checklist and Documentation – IRB Staff
   603B-A Federalwide Assurance- HSC Campus
   603B-C Federalwide Assurance-Norman Campus

7. PROCESS OVERVIEW
   7.1 Initial Education & Training Requirements
      7.1.1 Attendance of the IRB and HRPP Staff Orientation Session
      The HRPP Director or designee conducts this session promptly, which provides new staff with a general overview of the HRPP program, the organizational structure of the individual units, and their relationship within the University.

      Staff are expected to read and become familiar with the information included in the following reference materials:
      - OHRP Guidance Document, IRB Guidebook
      - *Institutional Review Board Management and Function*, by Robert J. Amdur, MD, and Elizabeth A. Bankert, MA
      - OU IRB Standard Operating Procedures (SOP)
      - IRB/Clinical Investigator Reference Guide (HSC only)
      - CFR & ICH Guidelines Reference Guide (HSC only)
      - CFR Medical Device Reference Guide (HSC only)

      7.1.2 Successful Completion of the Web-Based Collaborative IRB Training Initiative (CITI) Human Research Basic Course.
      All modules included in the program are required and shall be completed within the first week of employment.
7.1.3 Completion of Individual Instruction Provided by the HRPP Staff
Using the University SOP as a guide, instruction entails day-to-day IRB functions and utilization of the IRB electronic information system and shall be completed within the first month of employment.

7.2 Continuing Education Requirements


7.2.2 Attendance of PRIM&R Annual Conferences
Eligibility: After 2 years of service.

7.2.3 Attendance of IRB Continuing Education Sessions
These sessions will consist of IRB regulatory, University, and/or operational policies and procedures.

7.3 Documentation of Training & Education
The HRPP Education Coordinator or designee documents completion of all education and training requirements by the following:

- IRB & HRPP Staff Orientation: Document attendance with training checklist.
- CITI Web-based Course: A completion report is generated by the program and automatically forwarded to the HRPP Education Coordinator.
- Individual and group training instruction: Progress report of topics covered recorded by the HRPP Education Coordinator.
- Annual Conference Attendance: Recorded in the personnel file of each attending individual IRB staff member.

APPROVED BY: ____________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 103: MANAGEMENT OF HRPP AND IRB PERSONNEL

1. POLICY

The staff of the HRPP and IRB shall provide consistency, expertise, and administrative support to the IRB and shall serve as a daily link between the IRB and the research community. HRPP and IRB staff are vital components in the effective operations of the University human participants protection program. Therefore, the highest level of professionalism and integrity on the part of HRPP and IRB staff is expected.

The HRPP Director of each campus shall review the HRPP budget with the Director of Compliance for the NC and the HSC VPR for HSC on an annual basis and, in accordance with the current needs of the program, allocate resources for prioritized needs.

Specific Policies

1.1 Job Descriptions and Performance Evaluations

The HRPP Director shall provide members of the HRPP and IRB staff a description of the responsibilities expected of their positions and shall review the performance of the staff annually and provide feedback.

1.2 Hiring and Terminating IRB Staff

The Department of Human Resources policies of the University govern the recruiting, hiring, and termination of IRB and HRPP staff.

1.3 Delegation of Authority or Responsibility

The HRPP Director documents in writing delegation of specific functions, authorities, or responsibilities by the IRB Chair to the HRPP Director or HRPP Assistant Director.

1.4 Documentation

The policies of the University’s Department of Human Resources govern the means of identifying, documenting, and retaining formal staff interactions such as performance reviews and termination procedures.

1.5 Periodic Evaluation of Staff and Resources

The University shall provide staff, office space, meeting space, educational training, and equipment sufficient to support the HRPP’s responsibilities.

Staffing levels and function allocation shall be determined by the HRPP Director according to University policy, management assessment of support requirements, and budget constraints.

The HRPP Director or designee shall conduct a periodic evaluation of the resources and staff in order to assess whether the HRPP is able to carry out its functions. The HRPP Director or designee shall conduct the periodic evaluation at least annually.

2. SCOPE

This SOP applies to all HRPP and IRB staff.
3. RESPONSIBILITY

3.1 Norman Campus: The Director of Compliance or designee is responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of the HRPP Director.

3.2 HSC Campus: The HSC Vice President for Research is responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of the HSC HRPP Director.

3.3 The HRPP Director for each campus is responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of IRB and HRPP staff.

3.4 The IRB Chairs are responsible for providing input on the ongoing performance of the HRPP Directors to the Director of Compliance for the Norman campus and the HSC Vice President for Research for HSC.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Guidance on Written IRB Procedures

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

103-A HRPP/IRB Job Descriptions
103-B HRPP/IRB Performance Standards
103-C Performance Evaluation Form
103-D Description of Delegation of Authority
603B-A Federalwide Assurance – Oklahoma City Campus
603B-C Federalwide Assurance – Norman Campus

7. PROCESS OVERVIEW

The HRPP Director of each campus provides management policies and procedures to HRPP and IRB Staff to promote the professional development and the long-term commitment of employees. The SOPs are developed to promote the efficient and effective administration and enforcement of IRB decisions.

7.1 The HRPP Director is responsible for composing job descriptions and for establishing the requirements for the HRPP and IRB Staff. The HRPP Director is responsible for conducting performance evaluations annually and providing feedback. The HRPP Director develops performance standards and job expectations and makes modifications as necessary.

7.2 The HRPP Director provides staff a copy of their job description, performance standards, job expectations, and the web location for the University Staff Handbook.

7.3 The HRPP Director is responsible for the recruitment, hiring, and termination of HRPP and IRB Staff, following the University’s Human Resources Department policies and procedures.
7.4 Delegation of specific functions, authorities, or responsibilities by the IRB Chair to the HRPP Director or Assistant Director will be documented by the HRPP Director in writing and maintained in the individual's IRB member file.

7.5 In the absence of the IRB Chair or Vice-Chair, the HRPP Director or HRPP Assistant Director has the authority to sign correspondence reflecting IRB actions to the Investigator.

7.6 The periodic evaluation of resources and staff conducted by the HRPP Director takes into consideration the volume of items administered by the staff; complexity and types of human research activities administered by the staff; the time staff has to devote to the activities and quality of the activity outcome; and whether the entire administrative process is accomplished in a timely manner. The evaluation assesses whether additional staff, equipment, finances, education, and space are needed to protect the rights and welfare of human research participants. The HRPP Director reports the results of the evaluation to the Director of Compliance or the HSC Vice President for Research. The Director of Compliance reports the results of the evaluation to the Compliance Advisory Committee for consideration.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 104A: CONFLICTS OF INTEREST IN HUMAN PARTICIPANT RESEARCH

1. POLICY

The purpose of this policy is to provide an overview for identifying, disclosing, and managing conflicts of interest so that the rights and welfare of human participants in research, the integrity of human participant research, and the credibility of the Office of Human Research Participant Protection (HRPP) is not compromised by outside institutional interests or obligations or by individual conflicts of interest. The policy describes the process used by the IRB to identify and manage financial and non-financial relationships and possible conflicts of interest that might arise in studies proposed to the IRB. The IRB is concerned with the processing of disclosures of conflicts of interest involving human participant research and how they are managed in order to ensure there are adequate protections in place for human participants. Researchers and key study personnel working with human participants shall follow policies and procedures for reporting and managing potential conflicts of interest.

Specific Policies

1.1 Institutional Conflict of Interest Policy

Institutional conflicts of interest can occur whenever the external financial interests or business relationships of the University or one of its officials are such that their actions could affect, or could reasonably appear to affect, the conduct review or oversight of the University’s research. It is the policy of the University that all institutional conflicts of interest, whether real or perceived, must be fully disclosed. The reported conflict must be properly identified and either managed or eliminated prior to initiating any contract, sponsored project, dedicated gift, or transaction that might appear to be influenced by the conflict. The institutional policy is implemented using a three-step approach: 1) disclose always, 2) assess the potential for institutional conflicts of interest, and 3) manage the conflict in most cases, and prohibit the activity when necessary to preserve the University’s mission or protect the public’s interest.

The University maintains an Institutional Conflict of Interest Policy that covers departments most likely to be involved in an institutional conflict of interest (Research, Technology Development, Development) and individuals who are authorized to act on behalf of the University (Board of Regents members, Executive Officers). A link to the policy is available on the IRB website, which provides a detailed description of the process to disclose and identify conflicts of interest including what information to disclose, who must disclose, and how to disclose.

1.2 Individual Investigator Conflict of Interest Policy

1.2.1. The protection of human participants in research requires a process to handle conflicts of interest involving investigators so that the results of the research are free from bias or the appearance of bias. All investigators (defined as those responsible for the design, conduct, or reporting of research) shall disclose in writing to the IRB all conflicts of interest (COI) that will provide the opportunity for economic gain and external commitments that relate to, or could be reasonably affected by, the outcome of the human participants research. Disclosures shall be made of all COI for Investigators, their staff, spouses / domestic partners, and dependent children. A list of examples of required disclosures may include but are not limited to:

- anything of monetary value, received or held by an investigator or their family member, whether or not the potential value that can be readily determined, including but not
limited to salary or payment for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works);

- equity interests (e.g., stocks, stock options, or other ownership interests);
- intellectual property rights and interest (e.g., patents, trademarks, service marks, and copyrights);
- positions such as Director, Trustee, Scientific Officer, or member of the Board of Directors, and other related interests or activities of the investigator that could possibly affect or perceive to affect the results of the research;
- any other financial interest or relationship with an entity related to the research that involves the sponsor, product, or service being tested.

1.2.2. Significant financial interest consisting of one or more of the following interests of the investigator or research staff (and their spouse, domestic partner and dependent children) that reasonably appears to be related to the investigator’s institutional responsibilities must be reported to the IRB, and the VPR for HSC, or the University official for Norman, in accordance with the applicable affiliated campus COI policy:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $10,000, unless the sponsoring agency has identified more stringent/restrictive financial requirement or thresholds, in which case those requirements will prevail (For purposes of this definition, remuneration includes salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value);

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $10,000 or when the investigator (or the investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interests;

- Interests that exceed $1,000 in dividends or similar interests derived during the preceding calendar year;

- Interests that involve the ownership or promise of stock or stock options or similar interests of any amount in a privately-held or Spin-Off Company;

- Annual income for professional or consulting activity from a Company in excess of 25% of the Employee’s Institutional Base Salary;

- Certain reimbursed or sponsored travel disclosures required by the sponsoring agency.

For examples of strategies to manage financial conflicts of interest, refer to the applicable Faculty Handbook, Conflicts of Interest policy.

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1 If the sponsoring agency has identified more stringent/financial requirements or thresholds, in which case those requirements will prevail.
In the absence of compelling rebuttal, an investigator with a conflict of interest in a research project involving human participants may not conduct that research. However, an investigator will have the opportunity to present compelling reasons and circumstances to justify exceptions to this general rule. Although the Vice President for Research (VPR) for HSC, or the University official for Norman has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately, the IRB may elect not to approve a human research project where it believes a COI is not eliminated or managed.

Investigators shall cooperate fully with the IRB and any other individuals or groups involved in the review of the pertinent facts and circumstances regarding any conflict of interest disclosed.

This policy is not intended to prohibit investigators’ relationships with companies that have no influence on the design, conduct, or publication of a human research project and that occur prior to the initiation of a sponsored human research project or after publication of its results. However, that notwithstanding, compensation in the form of an economic interest which may be affected by the outcome of the human research project shall be avoided. (Examples of conflicts of interest due to compensation that require disclosure pursuant to this Policy include, but are not limited to, consulting agreements; speaking or other fees; honoraria; gifts; licensing revenues; equity interests; loans or notes, including stock options, regardless of value; expectations of receiving equity interests; and/or other fees or compensation received from sponsors.)

1.2.3. Public Health Services (PHS)-Sponsored Research: For investigators with PHS funding or those applying for PHS funding, significant financial interest includes, but is not limited to:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000 or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

In addition to the above requirements, for Public Health Services (PHS) sponsored studies, investigators must also disclose to the IRB the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value might not be readily available) related to the institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

For a complete definition of significant financial interest, refer to the Board of Regent’s Conflict of Interest Policy, applicable Faculty Handbook, and the appropriate campus Conflict of Interest website.

1.2.4. For VA research projects, in addition to adhering to the above, investigators who are VA employees or hold a VA appointment shall adhere to the requirements of the VA Office of
General Counsel, Office of Government Ethics and comply with all applicable VA and other federal requirements regarding conflict of interest.

2. SCOPE

This SOP applies to all University investigators who submit human research projects to the University IRBs.

3. RESPONSIBILITY

3.1 Senior Vice President & Provost

For Institutional conflict of interest, the Senior Vice President & Provost for each University campus is responsible for collecting and maintaining the applicable information on an annual basis in accordance with the University Institutional Conflict of Interest in Research Activities Policy. The monitoring and enforcement of institutional conflicts of interest are detailed in that policy.

All records related to disclosures and management of COI are maintained according to COI policies: Policy Regarding Conflict of Interest – Health Sciences Center or the Faculty Handbook – Norman Campus, and SOP 304: Documentation, Documents, and Data Management.

3.2. Individual Investigator

3.2.1 Investigators shall disclose to the IRB conflicts of the investigator, investigator’s spouse / domestic partner, and dependent children with regard to a research project involving human participants on an annual basis.

The investigator shall evaluate whether a conflict of interest exists or may exist. If a potential conflict of interest exists, the investigator shall complete the HRPP Conflict of Interest sub form within the IRB application. The investigator shall disclose any such conflicts to the IRB at the following times:

a. Concurrent with the IRB submission;
b. At each continuing review of the project;
c. When a conflict of interest arises, as described herein;
d. Within 30 days of acquisition or discovery of financial interests

3.2.2 Additionally, the Principal Investigator shall verify whether other key study personnel may have a conflict of interest as described in this SOP and, if so, shall disclose those interests, by completing the HRPP Conflict of Interest sub-form.

3.2.4 If an investigator discovers that any member of the research team has a conflict of interest during the conduct of a research project involving human participants, the investigator shall report the conflict to the IRB in writing within 30 calendar days of the investigator becoming aware of the conflict. The investigator shall submit a Modification/Notification request to the IRB and complete the HRPP Conflict of Interest sub-form describing proposed or anticipated changes to the human research procedures or informed consent documents to address the conflict of interest.

3.2.5 Each investigator and/or research staff member is responsible for completing the education requirements related to conflicts of interest. Initial training for all investigators will include completing the CITI Basic education course – “Conflicts of Interest in
Research Involving Human Subjects” module for each of the Norman and HSC Campuses. The HSC CITI training also includes Conflict of Interest in its local context module.

Education pertaining to financial conflict of interest is required, as set forth in SOP 102B: Key Study Personnel Education. Investigators shall follow University policy for University-required COI training at the designated intervals per campus policy.

3.2.6 Investigators and/or research staff are responsible for complying with all COI policies and their implications. Sanctions for failure to comply with COI policies may include, without restriction, reprimand, restitution, loss of pay, suspension, or dismissal.

3.2.7 If the investigator is a VA employee, the investigator shall adhere to the VA Office of General Counsel Office of Government Ethics, as well.

3.3 Institutional Review Board

3.3.1 It is not the purview of the IRB to reinterpret institutional conflict of interest policies or their implementation. Rather, the IRB’s function is to ensure that participant protection, the integrity of IRB review, and the conduct of a research project are not jeopardized by an undisclosed, unidentified or unmanaged conflict of interest.

3.3.2 The IRB, IRB Chair or IRB designee will review each IRB submission for disclosure of a potential COI which includes a completed HRPP Conflict of Interest Disclosure sub-form and may also include the conflict of interest management plan that has been approved by the VPR for HSC or the University official for Norman.

When reviewing human research projects that include an approved COI management plan, in determining the appropriateness of the management plan for research participant protection, the IRB shall take into consideration any compelling justification presented by the investigator, including, but not limited to:

a. The nature of the research;
b. The magnitude of the interest or the degree to which the conflict is related to the research;
c. The extent to which the interest could affect the research;
d. The fact that a specific individual is unique in his/her clinical or scientific qualifications to conduct the research;
e. The degree of risk to the human participants involved that is inherent in the research protocol; and/or

3.3.3 The IRB may require additional participant protections in the management plan such as, but not limited to:

a. Requiring divestiture or termination of relevant economic interest;
b. Requiring investigator recusal from a human research project;
c. Altering participation of the investigator in all, or a portion, of the research;
d. In case of equity, imposing a bar on insider trading, or requiring the transfer of securities to an independent financial manager or blind trust, or limiting the timing of sales or distributions;
e. Monitoring research; i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data);
f. Requiring independent clinical review of appropriateness of clinical care given to research participants, if applicable;
g. Monitoring the consent process; and/or
h. Requiring disclosure of the conflict to institutional committees, research participants, journals, and data safety monitoring boards.
i. After a review of the COI determination by the appropriate VPR, the IRB may elect to disapprove research that the IRB believes involves a conflict of interest that cannot be managed. In this situation, the IRB may consult with the VPR and the investigator on how to revise the COI management plan to address the human participants research concerns.

3.3.4. For VA research projects, the IRB shall advise the VA facility of any conflict of interest issues that occur related to a VA investigator and of any management plans implemented.

4. APPlicable REGULATIONS AND GUIDELINES

None

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

6. ATTACHMENTS

University Institutional Conflict of Interest in Research Activities Policy
Health Sciences Center Faculty Handbook – Appendix E
Norman Campus Faculty Handbook – section 5.10
Norman Campus PHS Funding-Specific Conflict of Interest Policy

7. PROCESS OVERVIEW

7.1 Investigators who have a potential conflict of interest shall indicate the conflict on the initial application for research involving human participants. Investigators will complete the HRPP Conflict of Interest Disclosure sub-form as part of the initial application and submit it to the IRB for review. If the conflict has been disclosed to the VPR or University and a management plan is available, the investigator shall also include these documents with the IRB submission. If the management plan is not yet available, the investigator may notify the IRB that it is in process at the time of submission and shall provide it to the IRB as soon as it is received. The IRB shall not act on the submission until it has received and reviewed the management plan.

7.2 IRB Staff conducts a pre-review of all documents for submission per SOP 301: Research Submission Requirements. If the IRB application indicates there is a potential COI, IRB staff confirms that the HRPP Conflict of Interest Disclosure sub-form is included with the submission materials.

7.3. During pre-review of a research submission, if the investigator indicates a potential conflict of interest, the IRB staff shall forward a copy of the HRPP Conflict of Interest Disclosure sub-form to the VPR or University’s designee to be addressed under either the Policy regarding Conflict
of Interest - Health Sciences Center or the Faculty Handbook, Conflicts of Interest section–Norman Campus, as appropriate.

7.4 The VPR or University designee shall communicate to the IRB staff its findings and whether a management plan is required. If a management plan is required but not yet submitted, IRB staff will notify the investigator to submit as required.

7.5 Upon receipt of the management plan, the IRB staff will forward the submission for IRB review. The IRB, IRB Chair or designee will review the conflict of interest disclosure sub-form for completeness. The sub-form and management plan will then be distributed to the IRB for determination. The IRB will review the sub-form and all study documents to determine whether the disclosed interest is likely to affect or appear to affect the design, conduct, or reporting of the study.

7.6 The IRB may request modifications or additional restrictions to the approved conflict of interest management plan. The revisions must be reviewed and approved by the VPR or VPR designee or the University designee, as applicable.

7.7 IRB final approval of a research submission involving a conflict or potential conflict of interest is contingent upon the VPR or VPR designee and the University designee, if applicable approving the management plan.

7.8 The IRB may elect to disapprove the research submission if conflict of interest issues cannot be resolved to its satisfaction.

7.9 The COI management plan and all communication will be maintained in the IRB electronic information system.

APPROVED BY: _______________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 104B: CONFLICT OF INTEREST – IRB MEMBERS

1. POLICY

All Institutional Review Board (IRB) members and IRB consultants shall disclose in writing to the IRB all conflicts of interest (COI) for themselves and their spouses/domestic partners, parents, siblings and their spouses, and dependent children. For purposes of this policy, a conflict of interest may be identified as either financial in nature (such as when an IRB member or consultant holds an economic interest in the research) or non-financial in nature (such as when an IRB member or consultant participates in the research or will be included as a co-author on a publication from the research), either of which could affect or appear to affect the design, conduct, oversight, or reporting of the research project. An IRB member or consultant shall be considered to have a financial COI with anything of monetary value when the member/consultant or the member’s spouse/domestic partner, parents, sibling and their spouses, and dependent children has any of the following, but not limited to:

a. Ownership interest, stock options, or other economic interest related to the research, which involves the sponsor, product, or service being tested;
b. Compensation related to the research;
c. Proprietary interest related to the research including, but not limited to, patent, trademark, copyright, or licensing agreement;
d. Interests in dividends or similar interests derived during the preceding calendar year;
e. Any other reason that the member/consultant believes that they cannot provide an independent review.

Non-financial COIs that require disclosure include but are not limited to:

a. Participation in the human research project as key study personnel;
b. Co-Author on a publication of the human research project’s results;
c. Other relationships which may influence judgment of the IRB member in reviewing the human research project:
   i. is a direct supervisor or trainee of the investigator(s)
   ii. is related to an investigator whose protocol is under consideration
   iii. has a prominent role in a directly competing research team or product
   iv. has a close personal relationship with an investigator or for other reasons feels unable to render a fair and unbiased review.

An IRB member or consultant with either a financial or non-financial conflict of interest in a research project involving human participants may not participate in the IRB review of that research. The IRB shall not approve a human research protocol where a conflict of interest is not managed or eliminated, and the IRB has the final authority to determine whether a conflict of interest has been managed or eliminated appropriately for research participant protection.

IRB members and consultants shall cooperate fully with the IRB and any other individuals or groups involved in the review of the pertinent facts and circumstances regarding any conflict of interest disclosed.

This policy is not intended to prohibit IRB members’ relationships with companies that have no influence on the design, conduct, or reporting of a human research project and that occur prior to the initiation of a sponsored research project or after publication of its results. However, that
notwithstanding, compensation in the form of an economic interest that may be affected by the outcome
of the research project shall be avoided. Examples of conflicts of interest due to compensation that
require disclosure pursuant to this Policy include, but are not limited to, consulting agreements;
speaking or other fees; honoraria; gifts; licensing revenues; equity interests; loans or notes, including
stock options, regardless of value; expectations of receiving equity interests; and/or other fees or
compensation received from sponsors.

2. SCOPE

This SOP applies to all University IRB members and consultants to the IRBs.

3. RESPONSIBILITY

3.1 IRB Member/Consultant Responsibilities

3.1.1 The IRB member/consultant shall evaluate whether a conflict of interest exists, and
he/she shall disclose any identified conflicts to the IRB at the next IRB meeting. IRB
members and consultants shall disclose to the IRB all conflicts of the IRB
member/consultant, their spouse/domestic partner, and their dependent children with
regard to a research project involving human participants. Such disclosure shall be
sufficiently detailed and timely to allow the IRB Administrator to transfer the project to
another IRB or allow time for an alternate member or consultant to attend the IRB
meeting.

3.1.2 If an IRB member/consultant discovers that he/she has a conflict of interest during the
conduct of a research project over which the IRB provides oversight, the IRB
member/consultant shall report the conflict to the IRB at the next IRB meeting.

3.1.3 IRB members/consultants shall cooperate with the IRB and other officials in their review
of the conflicts of interest issues and shall comply with all University requirements to
eliminate or manage the conflict before the IRB will approve the project or continue the
project.

3.2 IRB Responsibilities

3.2.1 After the IRB member/consultant discloses to the IRB a potential conflict of interest, the
IRB shall require the member/consultant to recuse him/herself from review of the
research project.

3.2.2 Upon the member’s/consultant’s recusal, the IRB shall review the research project
pursuant to HRPP policy (SOP 403: Initial Review – Criteria for IRB Approval, SOP 404:
Continuing Review, SOP 405: Modifications, and SOP 407: Unanticipated Problems
Involving Risks to Participation or Others and Protocol Deviations, SOP 903: Non-
Compliance/Scholarly Misconduct.)

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107 (e)
45 CFR 46.107 (e)
42 CFR Part 50 Subpart F
Oklahoma Statutes Citationized, Title 74. State Government
Chapter 62 Appendix – Title 257. Ethics Commission, Article Chapter 20
5. REFERENCES TO OTHER APPLICABLE SOPS AND POLICY

303B: IRB Meeting Administration
403: Initial Review – Criteria for IRB Approval
404: Continuing Review
405: Modification/Notification
407: Protocol Deviations and Unanticipated Problems
Institutional Conflict of Interest Policies maintained by the respective Vice Presidents

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 Disclosures

7.1.1 IRB members will disclose to the IRB in writing, financial and non-financial conflicts of interests when they are appointed to the IRB. The IRB Chair will remind IRB members to report disclosures to the IRB on at least an annual basis and as needed to reflect changes that add or delete conflicts of interest.

7.1.2 The HRPP Director and IRB Chair shall review disclosures to determine whether a conflict of interest exists and to determine appropriate management of the conflict of interest.

7.2 Prior to a Convened IRB Meeting

7.2.1 The IRB Administrator will include the definitions and examples of potential financial and non-financial conflicts of interest with each IRB meeting agenda. IRB members will be asked to disclose any potential conflicts of interest relating to any review item to the IRB Administrator, IRB Chair or IRB designee prior to each IRB meeting. Once the IRB office receives notice of a recusal, the IRB Administrator will seek an alternate IRB member to join the meeting for the review of that project, if necessary to meet quorum Primary and secondary reviewers will be reassigned as necessary to manage conflicts of interests.

7.2.2 The IRB Administrator will check the IRB agenda prior to the meeting to identify IRB members who may have a conflict of interest due to their participation as key study personnel on agenda items. If a conflict of interest is identified, the research project is assigned to another member who does not have a conflict of interest.

7.2.3 An IRB member who has a conflict of interest with regard to a research project that will be reviewed at a convened IRB meeting must notify the IRB office of the conflict prior to the meeting and will recuse him/herself from discussion and voting on that research project.

7.3 At the Convened IRB Meeting

7.3.1 At the beginning of each convened IRB meeting, the IRB Chair or IRB designee will ask the members if anyone has a financial or non-financial conflict of interest with regard to any of the research projects that will be reviewed at the meeting. The HRPP Director or IRB Chair or IRB designee will announce that members with a conflict of interest must recuse themselves from deliberation and voting on that research protocol.
7.3.2 Any IRB member who has a conflict of interest with regard to a research project that will be reviewed at the convened IRB meeting will recuse him/herself from the convened IRB meeting for the discussion and voting on that research project. The recused member can answer questions from the IRB but cannot be present for IRB deliberations and voting. If the conflict affects quorum, see SOP 303B: IRB Meeting Administration.

7.3.3 The recusal of the IRB member for conflict of interest is recorded in the IRB meeting minutes.

7.4 Expedited Review

7.4.1 IRB members who are conducting expedited review must disclose to the IRB Chair or IRB designee or HRPP Director any conflicts of interest they have related to the research project under review, and they must not review those items.

7.4.2 The IRB Administrator identifies IRB members who are conducting expedited review and who have a conflict of interest with a research project. Items identified to have a conflict of interest by the IRB Administrator are presented to an IRB Chair or IRB designee who does not have a conflict with the research project.

APPROVED BY: _______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 105: SIGNATORY AUTHORITY

1. POLICY

The IRB Chair or IRB designee is authorized to sign any and all documents in connection with the approval of human research projects that involve the use of humans as participants that have been reviewed and approved pursuant to the University policies and procedures.

Specific Policies

1.1 Authorization for Signatory Authority

Requests from the HRPP and IRB staff for authorization to sign documents not described in this policy shall be made in writing to the HRPP Director for each campus.

1.2 Results of Reviews, Actions, and Decisions

The results of reviews and actions taken by the convened IRB and described in a letter that grants or may appear to grant investigators with initial or continuing approval of research, training, or educational projects involving human research participants shall be signed by IRB Chairs or IRB designees only.

The results of reviews for expedited items that require changes from the investigator will be sent via the IRB’s electronic information system.

1.3 Routine Internal Correspondence

Any routine internal letters, memos, or other communication/correspondence between the IRB and/or members of the faculty or staff of the University that provide information concerning the review of human research protocols by the IRB or staff that do not imply or appear to imply approval of the activity shall be signed only by designated IRB staff members.

1.4 Correspondence with External Agencies

Any letters, memos, or other communication/correspondence regarding IRB actions sent to agencies of the federal government, funding agencies (whether private or public), or their agents shall be signed only by the HRPP Director, HRPP Assistant Director or designee.

1.5 Decisions Made by IRB Chair

The IRB Chair or IRB designee shall sign letters, memos or other communication/correspondence representing the decision or opinions of the IRB Chair or IRB designee as long as such correspondence does not imply review and approval of human research projects.

2. SCOPE

This SOP applies to all IRB staff, HRPP staff, and IRB Chairs.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for establishing the overall procedure for delegating signatory authority.

3.2 The HRPP Director is responsible for implementing and controlling signatory authority delegations.

3.3 The IRB Chair, HRPP staff, and IRB staff are responsible for adhering to applicable institutional signatory authority policies.
4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109
21 CFR 56.109

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

The circumstances under which signatory authority may be delegated and to whom such delegation may be granted are described below.

7.1 All requests from HRPP and IRB staff to obtain authorization to sign documents are submitted to the HRPP Director. The NC HRPP Director consults with the Director of Compliance and the HSC HRPP Director consults with the HSC VPR as well as the IRB Chairs, as appropriate, when considering such requests.

7.2 All correspondence on IRB submissions must be signed by the IRB Chair or IRB designee and communicated to the investigator via the IRB’s electronic information system.

7.3 The HRPP Director makes the designations of signatory authority as follows:

- Any letters, memos, or other communication/correspondence between the IRB and the Investigator or the research staff that provide information concerning the review of human research protocols by the IRB or staff that do not imply or appear to imply approval of the activity shall be signed only by designated IRB staff members. Examples include Continuing Review reminder notices, Exempt status letters, Pending letters, Pre-review letters, and Administrative Withdrawal due to lack of education requirements.

7.4 The HRPP Director or the HRPP Assistant Director signs all correspondence to agencies of the federal government (OHRP, FDA, VA) and funding agencies.

7.5 Any correspondences representing the decisions or opinions of the IRB Chair are signed only by the IRB Chair or IRB designee. This includes advice on how to write a protocol, how to conduct recruitment, and research practices. The IRB Chair or IRB designee drafts all disapproval and deferral letters.

7.6 When authorized by the IRB Chair or IRB designee, the IRB staff may use the signature stamp of the IRB Chair or IRB designee for correspondence generated within the IRB’s electronic information system.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

Each IRB shall be composed of members who are able to ascertain the acceptability of proposed human participant research in terms of University commitments (including policies and resources), regulations, applicable law, and standards of professional conduct and practice. Each IRB shall also be composed of members able to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

Each IRB shall consist of at least five regular voting members. Qualified persons from multiple professions shall be considered for membership. IRB membership shall not consist entirely of members of one profession. Each IRB has at least one member who represents the perspective of research participants.

The University shall make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct IRB functions.

Individuals who are responsible for University business development or raising funds or garnering support for research are prohibited from serving as IRB members and/or carrying out the day-to-day operations of the review process.

Specific Policies

1.1 Membership Selection Criteria

1.1.1 The members of the IRB shall be sufficiently qualified, through experience and expertise (professional competence), to review human research proposals in terms of regulations, applicable law, standards of professional conduct and practice, and University commitments. The IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes to assess the human research submitted for review.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with the University, either self or family member. For research involving an FDA-regulated article, at least one member who is a licensed physician must be included in the quorum.

1.1.2 VA Research

The HSC IRBs 1, 2, 3, and 4 have been designated as the IRBs of record for the Oklahoma City Veterans Affairs Medical Center. The HSC IRB 4 has been designated as the IRB of record for the Eastern Oklahoma VA Healthcare System (EOVAHCS), Muskogee, Oklahoma. The HSC IRB membership for IRBs 1, 2, 3, and 4 shall include two or more VA employees as voting members.

The Norman Campus IRB shall not review VA research.

The VA members shall serve as full members of the IRB and review both VA and non-VA research matters presented to the IRB. The members must hold a minimum of 1/8th VA-compensated appointment unless a waiver is obtained from the VA’s chief research and
development officer. Consideration will be given to including a veteran or veteran's representative as an IRB member. At least one of the VA members of the IRB must have scientific expertise. Examples include, but not limited to: physicians, dentists, nurses, pharmacists, social workers, other clinicians, statisticians, and allied health professionals. At least one VA voting member of the IRB must be in attendance when VA research is discussed at a convened meeting. Alternate members must have qualifications similar to the member they replace. Alternate members may not serve for a class of members (for example, a physician may not serve for all physician regular members, but must be designated to serve for a specific physician member). The individual the alternate is serving for must be referenced specifically by name, in the minutes and in the IRB roster.

VA Research and Development administration officials, including but not limited to the Associated Chief of Staff for Research and Development and the Administrative Officer for Research and Development, are prohibited from serving as voting members of the IRB.

The facility director, administrative staff, chief of staff, other senior administrators such as associate or assistant directors, and the chief nurse may observe meetings but may not serve as voting or non-voting members of the facility's IRB. VA Research and Development office staff, including but not limited to the associate chief of staff for Research and Development, the administrative officer for Research and Development, and IRB administrative staff, may not serve as voting members of the IRB.

The VA facility director appoints the VA privacy officer and information security officer as non-voting members or consultants of the IRB or Research and Development committee.

The VA's research compliance officer may serve as a non-voting consultant, as needed, to the VA facility's IRB. The VA research compliance officer may not serve as a voting or non-voting member of the IRB. The VA research compliance officer may attend meetings of the IRB when requested by the IRB or as specified by local procedure.

Individuals working without compensation (WOC) appointments from the VA facility and those with intergovernmental personnel act (IPA) appointments cannot be VA representatives.

Veterans whose only relationship with the VA facility is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are not considered to be affiliated for the purpose of being an IRB member. Individuals who perform occasional volunteer activities without compensation are not considered affiliated. However, those who hold a WOC appointment for volunteer activities other than IRB service are considered to be affiliated. Individuals who have retired from the VA and who are receiving VA retirement benefits are considered affiliated.

The non-affiliated voting member must be given a VA WOC appointment if the non-affiliated voting member is performing the duties and responsibilities of an IRB voting member.

Officials in Research and Development administration, including but not limited to the Associate Chief of Staff for Research and Development, the Administrative Officer for Research and Development, and IRB administrative staff, do not serve as voting members of the IRB.
1.2 Composition of the IRB

IRB members: The backgrounds of the IRB members shall be varied in order to promote complete and adequate reviews of the types of human participant research activities commonly reviewed by the IRB. Regular members shall include:

1.2.1 Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, shall be knowledgeable about the local community and be willing to discuss issues and research from that perspective. The HRPP Director shall give consideration to recruiting individuals who speak for the communities from which the University will draw its human research participants. The nonaffiliated member(s) shall not be vulnerable to intimidation by the professionals on the IRB, and their services shall be fully utilized by the IRB.

1.2.2 Scientific members: Most IRBs include physicians and Ph.D. level physical, social, or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 45 CFR 46.107(f) and 21 CFR 56.107(f). When research involving an FDA-regulated article is reviewed, at least one member who is a licensed physician must be included in the quorum; therefore, at least one (1) member of each IRB shall be a physician licensed in the State of Oklahoma.

1.2.3 Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, at least one nonscientific member whose education, work, and interests are not solely in medical or scientific areas shall be on each IRB.

1.2.4 Representatives of special groups of research participants: The IRB may require members or consultants who are knowledgeable about the concerns of certain groups, especially those who are vulnerable to coercion or undue influence. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.

1.2.5 IRB Chairs: The individual IRB Chairs shall be highly respected individuals from within or outside the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

1.2.6 Special Consultants: The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB, including review of the scientific merit of a study. The IRB Chair may invite consultants to either attend the IRB meeting or provide a written report so that IRB members are made aware of and provided with information concerning the consultants’ review. Special consultants shall not vote with the regular and alternate members of the IRB, and their presence or absence shall not be used in establishing a quorum for an IRB meeting. Special consultants shall be used at the IRB Chair’s discretion or if requested by the convened IRB. All special consultants shall be asked to sign an IRB Guest Confidentiality Agreement. The consultant may be asked to participate via a teleconference or attend the IRB meeting to lend his/her expertise to the discussions. Special consultants shall not vote.

Documentation of key information provided by special consultants shall be summarized in the IRB minutes and, if available, the special consultant’s written report shall be stored in the IRB file.
1.2.7 **Alternate members:** The IRB shall appoint an alternate member for each primary member. The IRB roster shall identify the primary member(s) for whom each alternate member may substitute. To ensure an appropriate quorum is maintained, the alternate’s qualifications shall be comparable to the primary member to be replaced. The IRB minutes shall document when an alternate member replaces a primary member. When an alternate serves for a primary member, the alternate member shall have received and reviewed the same material that the primary member received or would have received. If both the primary and alternate members attend the meeting, only one may vote. The non-voting member is specified in the minutes.

1.3 **Conflict of Interest**

See SOP 104B: Conflicts of Interest for IRB Members, for information regarding an IRB member’s participation in the IRB’s review of any project in which the IRB member has a conflicting interest.

2. **SCOPE**

This SOP applies to the primary and alternate membership of the IRB.

3. **RESPONSIBILITY**

The HRPP Directors and IRB Chairs are responsible for the composition of the IRB.

4. **APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.107  
21 CFR 56.107  
VHA Handbook 1200.05

5. **REFERENCES TO OTHER APPLICABLE SOPS**

SOP 104B Conflict of Interest for Board Members.

6. **ATTACHMENTS**

201-A IRB Roster Template  
201-B HSC Campus IRB Membership Rosters  
201-C Norman Campus IRB Membership Rosters  
201-D HSC Campus IRB Meeting Schedules  
201-E Norman Campus IRB Meeting Schedules

7. **PROCESS OVERVIEW**

7.1 The HRPP Director identifies IRB members with varied backgrounds and experiences to provide optimal review of human participant research, giving consideration to gender, race, ethnicity, community affiliation, and professional experience. The HRPP Director consults with IRB Chairs as needed for selection of IRB members.
7.2 The HSC HRPP Director consults with the VA Medical Center Director as needed for selection of IRB member representation from the VA.

7.3 The HRPP Director considers a number of factors in developing IRB membership. These factors include, but are not limited to: the specialty of the IRB (i.e., Oncology, Pediatrics, and Behavioral), number of members required to fill the IRB and allow for a thorough review of all human participant research, and consideration of the requirements of an IRB as described above in Section 1.2.

7.4 The HRPP Director recommends IRB membership to the Senior Vice President and Provost, in accordance with SOP 202: Management of IRB.
1. **POLICY**

The HRPP Director shall manage the membership of the IRB(s) and oversight of member appointments, IRB membership rosters, IRB related activities, IRB communications, and other IRB administrative details.

The Senior Vice President and Provost or designee, in consultation with the HRPP Director, shall appoint IRB Chairs, Vice-Chairs, and IRB members. The HRPP Director shall solicit members from the University of Oklahoma and surrounding communities.

**Specific Policies**

1.1 **Duty to the University of Oklahoma**

The IRBs are appointed as University committees. As such, IRB members serve the University as a whole, rather than a particular department. Members shall not allow their own interests or those of their departments to supersede their duty to protect the rights and welfare of human research participants.

1.2 **Term of Duty**

IRB members, including IRB Chairs and Vice-Chairs, shall commit to a four-year renewable term to fulfill certain duties. These duties shall be described prior to appointment, and each IRB member is expected to fully understand the duties of IRB members prior to accepting such an appointment.

1.3 **Appointments**

The Senior Vice President and Provost or designee of each campus has the authority to appoint IRB Chairs, Vice-Chairs, and IRB Members for the respective campus. The HRPP Director shall solicit the University and surrounding communities for selection of potential IRB Chairs, Vice-Chairs, and IRB members. (See SOP 201: Composition of IRB, for membership selection criteria.) In consultation with the HRPP Director, the Senior Vice President and Provost or designee of each campus shall appoint IRB Chairs, Vice-Chairs, and IRB members to serve on the IRB.

1.3.1 **Appointments of IRB Chair and Vice-Chair**

The Senior Vice President and Provost or designee of each campus shall appoint IRB Chairs. The IRB Chair shall have served as a member of the IRB and understand all functions, policies, and procedures of the IRB.

The Senior Vice President and Provost or designee of each campus shall appoint IRB Vice-Chairs. The IRB Vice-Chair shall have served as a member of the IRB and understand all functions, policies, and procedures of the IRB.

1.3.2 **Appointment of VA Members**

The VA Medical Center Director shall approve VA members appointed to the IRB every three years.

1.3.3 **Appointment of Unaffiliated Members**

On selection of unaffiliated IRB members for appointment to the IRB, the HRPP Director shall determine whether any of their immediate family members are affiliated with the University. If so, they are changed to affiliated members.
The HRPP Director polls each unaffiliated IRB member annually to determine whether any of his or her immediate family members are affiliated with the University. If so, that member is changed to an affiliated member. IRB members who are affiliated with the VA or whose immediate family members are affiliated with the VA shall be considered affiliated with the University.

1.3.4 Appointment of Alternate Members

The HRPP Director shall solicit current IRB members, the University, and surrounding communities for selection of potential alternate members. In consultation with the HRPP Director, the Senior Vice President and Provost or designee of each campus shall appoint alternate members to serve on the IRB.

1.4 IRB Membership

1.4.1 Roster

The IRB membership rosters shall be maintained by the HRPP Director or designee.

Rosters of IRB members shall identify the members by name, earned degrees, representative capacity, scientific/nonscientific status, affiliation status (whether the member or an immediate family member of the member is affiliated with the University), employment or other relationship between each IRB member and the University (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant), and indications of experience sufficient to describe each member's chief anticipated contribution to the IRB deliberations. The rosters shall be maintained by the IRB office.

Alternate members shall be included on the IRB membership rosters. In addition to the above information, the rosters shall indicate the member for whom the alternate substitutes.

The IRB Office shall maintain current and obsolete membership rosters.

1.4.2 Curricula Vitae or Resumes

Curricula vitae or resumes shall be maintained with the IRB office for each current member of the IRB.

1.4.3 Periodic Review of IRB Membership

The HRPP Director or designee shall conduct a periodic review of the IRB membership and the composition of the IRB in order to maintain a diverse spectrum of qualified individuals. The HRPP Director or designee shall conduct the periodic review at least annually and adjust the IRB membership and composition of the IRB to meet the regulatory and University requirements of the IRB.

1.4.4 Periodic Review of IRB Members

The performance of the IRB Chairs, Vice-Chairs, and IRB Members shall be evaluated and provided feedback on an annual basis. The periodic evaluation is conducted to assess performance, taking into consideration completion of education requirements, attendance, preparedness, knowledge and abilities in applying the ethical principles and regulations governing human research, and knowledge of IRB policies and procedures.
1.4.5 Resignations and Removals

An IRB member may resign but shall first give a one-month notice to the HRPP Director. An IRB member may be removed with or without cause by the Senior Vice President and Provost or designee, after consultation with the NC HRPP Director and Director of Compliance for the NC, and the HSC HRPP Director and HSC VPR for HSC, and with input from the IRB Chair and Vice-Chair, if applicable.

1.5 Compensation

Service on the IRB by the University faculty, staff, or students shall be considered a component of the individual’s job responsibilities as established by their supervisors. IRB members who are not affiliated with the University shall receive reimbursement for parking and miscellaneous expenses upon request.

1.6 Coverage

IRB members and alternate IRB members acting within the course and scope of their duties are covered by the Oklahoma Governmental Tort Claims Act.

1.7 Periodic Evaluation of IRBs

The NC HRPP Director, in consultation with the Director of Compliance, and the HSC HRPP Director in consultation with the HSC VPR, shall evaluate each IRB annually to assess whether an additional IRB should be created to handle an increase in volume and to ensure compliance with policies and other applicable requirements and regulations.

2. SCOPE

This SOP applies to management of the IRB.

3. RESPONSIBILITY

3.1 The Senior Vice President and Provosts or designee of each campus are responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members.

3.2 The HRPP Director is responsible for management of the IRB and IRB membership.

3.3 The HRPP Director is responsible for recommendation and recruitment of new IRB members and the Senior Vice President and Provost makes the final decision.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107
38 CFR 16.107
45 CFR 46.107

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 201: Composition of IRB

6. ATTACHMENTS

201-A, IRB Roster Template
201-B, HSC Campus IRB Membership Rosters
201-C, Norman Campus IRB Membership Rosters
202-A, HSC New Member Information Packet Checklist
202-A-1, Norman Campus New Member Information Packet Checklist
7. PROCESS OVERVIEW

7.1 Terms

IRB members, including the IRB Chairs and Vice-Chairs, serve on the IRB for four-year renewable terms. Shorter terms and reappointments are made by mutual agreement between the HRPP Director and the IRB Chair, Vice-Chair, or IRB member.

7.2 Appointments

7.2.1 The HRPP Director discusses with IRB candidates the general responsibilities and time commitment involved with IRB membership and confirms the candidates’ interest in serving on the IRB.

7.2.2 The HRPP Director requests each candidate’s curriculum vitae (CV) or resume and presents it to the IRB Chair for discussion and review. The HRPP Director provides a schedule of IRB meeting dates to the candidate for consideration, and the HRPP Director invites the candidate to attend and observe an IRB meeting.

7.2.3 The HRPP Director notifies the HRPP Education Coordinator of the candidate. The HRPP Education Coordinator schedules a New Member Orientation with the candidate and prepares a New Member Information Packet and Checklist. An IRB Guest Confidentiality Agreement is prepared for the candidate to sign prior to the IRB meeting.

7.2.4 The HRPP Director or designee and HRPP Education Coordinator conduct the New Member Orientation.

7.2.5 If the candidate agrees to serve and the IRB Chair concurs with the recommendation of the HRPP Director, the Senior Vice President and Provost or designee will send an appointment letter to the IRB Member. Copies of the appointment letter and curriculum vitae or resume of the IRB member are maintained in the IRB office.

7.2.6 The HRPP Director or designee notifies the new member of the next scheduled IRB meeting, sends a packet of agenda materials, and informs the new member that he/she will not be assigned specific research protocols for review until after his/her first meeting.
7.3 Rosters
The HRPP Director or designee updates the IRB roster on the IRB website.

7.4 Resignations
When IRB members resign from the IRB prior to the conclusion of their term, the HRPP fills vacancies as soon as possible via the appointment process outlined in Section 1.3 above.

7.5 Reimbursement
7.5.1 On the HSC Campus, the IRB Administrative staff prepares an Agreement for non-affiliated IRB members for reimbursement of travel expenses. The IRB Administrative staff prepares an invoice for each meeting attended by the non-affiliated member. Attendance is monitored by the meeting sign-in-sheet.

7.5.2 On the Norman Campus, the HRPP Director prepares travel expense reimbursements for non-affiliated members upon request.

7.6 Periodic Evaluation of IRBs
The periodic evaluation of IRBs conducted by the HRPP Director takes into consideration the volume of items for review, complexity and types of human research reviewed, time IRB members devote to the activity, quality of the review, and whether the entire review process is accomplished in a timely manner. This analysis is used to assess whether an additional IRB should be created to handle an increase in volume and to ensure compliance with policies and other applicable requirements and regulations. The HRPP Director presents the results of the evaluation to the IRB Executive Committee for consideration.

7.7 Periodic Review of IRB Members
IRB Chairs, Vice-Chairs, and relevant HRPP staff members shall evaluate the IRB members from their respective Boards. IRB members and relevant HRPP staff members shall evaluate the IRB Chair and Vice-Chair from their respective Board. The evaluations will be conducted using the IRB Chair/Vice-Chair Evaluation Form and the IRB Board Member Evaluation Form.

The HRPP Director or designee shall review the evaluations and provide a summary of results to the individual IRB Chair, Vice-Chair, and IRB Member evaluated. Based upon the results of the evaluations, the HRPP Director may elect to take no additional actions or to consult with the Director of Compliance for the NC or the HSC VPR for HSC concerning the performance of an IRB Chair or Vice-Chair; consult with the IRB Chair or Vice-Chair concerning the performance of an IRB member; meet with the IRB Chair, Vice-Chair, or IRB member concerning responsibilities and expectations; provide additional training to improve performance; or remove the IRB Chair, Vice-Chair, or IRB member from the IRB.
1. POLICY

Each IRB member’s primary duty shall be the protection of the rights and welfare of the individual human beings who are serving as the participants in research. The IRB member shall understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the investigator and the human research participants. In order to fulfill their duties, IRB members shall be versed in regulations governing human participants’ protection, biomedical and social behavioral research ethics, and the policies of the University germane to human research participant protection.

Specific Policies

1.1 Attendance

Members of the IRB shall attend IRB meetings on a regular basis. Failure to attend regularly could result in the member’s removal from the IRB.

1.2 Expectations

1.2.1 Member Expectations

Nonaffiliated member(s): Nonaffiliated members shall provide input based on their knowledge about the local community and be willing to discuss issues and human participant research from their perspective.

Non-scientific members: Nonscientific members shall provide input on areas within their knowledge, expertise, and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants.

Scientific members: Scientific members shall contribute to the evaluation of a human research project on its scientific and statistical merits and standards of practice. These members shall also be able to advise the IRB if additional expertise in a scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants.

IRB Chair: In addition to the above responsibilities, the IRB Chair shall chair meetings of the IRB. IRB Chairs shall perform or delegate to an appropriate voting IRB member expedited review when appropriate and suspend the conduct of a research project deemed to place individuals at unacceptable risk, pending IRB review. The IRB Chair shall be empowered, pending IRB review, to suspend the conduct of a human research project if he/she determines that an investigator is not following IRB requirements.

The IRB Chair, in consultation with the Director of Compliance for the NC or the HSC VPR for HSC, and the respective HRPP Director, may appoint an IRB Vice-Chair to assist or act on behalf of the IRB Chair in particular IRB matters and at IRB meetings, either as a general procedure or on a case-by-case basis. The IRB Chair also may delegate any of his/her responsibilities as appropriate to other qualified individuals. Such documentation shall be in writing and maintained by the respective HRPP Director.
1.2.2 IRB Expectations

The IRB shall operate as a fair and impartial Board, immune from pressure by the University’s administration, the Investigators whose protocols are reviewed, or other sources.

1.3 Primary and Secondary Reviewer Model

1.3.1 Convened IRB Review

The IRB utilizes the primary and secondary reviewer model to review human research projects reviewed by the convened IRB. The primary and secondary reviewer model is used for initial review, continuing review, and review of modifications to currently approved human research projects. The IRB Chair is authorized to delegate the review to one primary and one secondary reviewer based upon their expertise and experience. The criteria used to determine whether IRB members are considered experienced to conduct reviews are in the general opinion of the IRB Chair or IRB designee. However, at least one of the reviewers shall have the appropriate scientific or scholarly expertise to conduct an in-depth review of the research project.

A. Primary Reviewer

The primary reviewer shall conduct an in-depth review of all materials. The primary reviewer (one member) shall present his/her findings and provide an assessment of the soundness and safety of the protocol to the IRB. He/she shall make specific recommendations or clarifications required for approval and lead the IRB discussion of the human participant research project.

B. Secondary Reviewer

The secondary reviewer shall conduct an in-depth review of all materials. The secondary reviewer (one member) shall add to the discussion, as necessary.

C. Other IRB Members

Other IRB members are expected to review all provided materials in enough depth to discuss the information at the convened meeting.

1.3.2 Expedited Review

The IRB Chair reviews or delegates review to an appropriate Vice-Chair for protocols that qualify for expedited review. In the event both the IRB Chair and Vice-Chair are unavailable, the IRB Chair, HRPP Director, or IRB staff shall select a reviewer from the IRB members to conduct expedited review.

1.4 Review Requirements

1.4.1 VA Research

The IRB shall regularly review VA research that involves mentally disabled persons or persons with impaired decision-making capacity; the IRB membership shall include at least one member who is an expert in the area of the research. The IRB Administrator shall make certain that one or more individuals who are knowledgeable about or experienced in working with such participants will be present at the meeting.

1.4.2 Special Populations

When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Administrator shall make certain that one or more
individuals who are knowledgeable about or experienced in working with such participants will be present at the meeting.

**A. Prisoners**

When the IRB reviews research that involves prisoners, the IRB Administrator shall make certain that one or more individuals who are prisoner representatives or prisoners will be present at the meeting. The prisoner representative may be a prisoner, an employee of the prison, or an individual not affiliated with the prison.

When the IRB reviews research that involves prisoners, a majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

2. **SCOPE**

This SOP applies to all IRB members and staff.

3. **RESPONSIBILITY**

3.1 The HRPP Director is responsible for clearly articulating IRB member duties to potential and current IRB members.

3.2 IRB members are responsible for fulfilling their duties as specified in this SOP.

3.3 IRB members are responsible for utilizing appropriate checklists for verifying and documenting the review determinations.

4. **APPLICABLE REGULATIONS AND GUIDELINES**

- OHRP Guidance Document, IRB Guidebook, VA Handbook 1200.05

5. **REFERENCES TO OTHER APPLICABLE SOPS**

SOP 202: Management of IRB

6. **ATTACHMENTS**

- 203-A HSC Reviewer Checklist
- 203-A-1 Norman Campus Reviewer Checklist
- 203-L Member Responsibilities - Member
- 203-M Member Responsibilities - Chairperson
- 203-N Member Responsibilities - Alternate Member
- 203-O Member Responsibilities - Reviewer Duties

7. **PROCESS OVERVIEW**

7.1 IRB(s) are appointed as committees to serve the University. Each IRB member serves the University as a whole. IRB members act as gatekeepers between the investigator and the research participants by protecting the rights and welfare of human research participants.

7.2 Certain duties are expected of each member during the term served. The HRPP Director explains the duties to potential members before a member is appointed to the IRB.
7.3 The HRPP Director documents the expectations for members of the IRB. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human research participant protection, biomedical and social behavioral research ethics, and the University policies concerning human research protection.

7.3.1 The HRPP Director documents the duties and expectations of IRB members and periodically reviews members’ duties.

7.3.2 The HRPP Director or designee maintains current descriptions of IRB member responsibilities and answers questions from IRB members as needed.

7.3.3 The HRPP Director meets with prospective members to discuss the expectations of IRB members.

7.3.4 The HRPP Director notifies the HRPP Education Coordinator of a new member appointment. The HRPP Education Coordinator schedules a New Member Orientation with the new IRB member and prepares a New Member packet. The HRPP Director or designee and HRPP Education Coordinator conduct a New Member Orientation for each new member appointed to the IRB.

7.3.5 The HRPP Director or designee attends the IRB meetings and monitors IRB member performance to make certain that members are carrying out their expected duties.

7.3.6 The HRPP Director monitors the membership of the IRB, per SOP 202: Management of IRB.

7.3.7 The HRPP Director makes recommendations to the IRB Chair as needed regarding changes to description of member responsibilities, staffing, meeting scheduling, and other factors that affect members’ ability to perform their duties.

7.4 At the convened IRB meetings, IRB members’ responsibilities include acting as Primary and Secondary Reviewers.

7.4.1 The HRPP Director documents the duties and expectations of IRB members acting as Primary and Secondary Reviewers.

7.4.2 The HRPP Director or designee maintains current descriptions of Primary and Secondary Reviewers’ responsibilities and answers questions from IRB members as needed.

7.4.3 The IRB Administrator requests the IRB Chair to assign Primary and Secondary Reviewers for the meeting before the agenda is completed.

7.4.4 The IRB Administrator includes the names of the Primary and Secondary Reviewers on the agenda for each convened Board meeting item. IRB members are responsible for acting as the Primary or Secondary Reviewers at the convened meeting.

7.5 IRB Chairs, Vice-Chairs, and IRB members’ responsibilities include utilizing reviewer checklists.

7.5.1 IRB Chairs, Vice-Chairs, and IRB members review initial research projects, continuing reviews, and modifications to previously approved research utilizing the appropriate reviewer checklists.

7.5.2 IRB Chairs, Vice-Chairs, and IRB members document and verify their review determinations utilizing the appropriate reviewer checklists.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 301: RESEARCH SUBMISSION REQUIREMENTS

1. POLICY

IRB members rely on the documentation submitted by investigators to review all submissions. Therefore, this material must provide IRB reviewers with enough information about a research project for them to assess whether it adequately meets the IRB's criteria for approval. All IRB submissions must include the appropriate documentation and information to be forwarded to the appropriate Board for review.

Specific Policies

1.1 Each IRB submission will include a combination of IRB forms generated by the electronic information system and uploaded documents the research team has created using IRB-provided templates. There are other documents that the research team may create, or that the research team must secure from another person or organization, that are required for the IRB review of the submission. These may include the following, as applicable:

- Investigator’s Brochure or device specifications (if research project involves an investigational drug or device)
- Data collection instruments (for example: questionnaires, surveys, assessments, field observation forms, chart/records abstracting forms)
- Recruitment and/or advertising materials
- Copy of the grant application (required for projects with external funding)
- Participant Study Instructions or Participant Diary
- Documentation that the research project has been or will be reviewed by other committees charged with oversight of research at the University or at outside sites, such as Radiation Safety or Institutional Biosafety Committee
- Documentation that the research project has been approved by the Cancer Center Protocol Review and Monitoring Committee
- Appropriate HIPAA Authorization or Waiver of Authorization form
- The DHHS-approved sample consent document
- The complete DHHS-approved protocol
- Letters of Support from external research project sites
- Documentation of approval from external IRBs
- Curriculum vitae of Non-OU investigators (NC only)

1.2 Submission Requirements for Review of a New Research Project

1.2.1 Investigators applying for approval of a new research project must complete and submit the Study Application and IRB submission materials through the IRB’s electronic information system and upload all related research project documents. At a minimum, the following documents must be included with the IRB submission:

- Protocol- Investigators submitting to HSC are encouraged to use the Research Protocol Outline available from the IRB website for investigator-initiated studies.
- Informed consent documents or information supporting a request for waiver of informed consent.
• Norman Campus – Student as Principal Investigator form approved by the designated Faculty Sponsor for the graduate student who wishes to serve as Principal Investigator.

• Norman Campus – Staff as Principal Investigator form approved by the designated Supervisor for the staff member who wishes to serve as Principal Investigator.

1.3 Submission Requirements for Continuing Review
Investigators requesting renewal of an approved research project must complete and submit the Continuing Review/Final Report form in the IRB’s electronic information system. Investigators must upload all related research project documents specified in the document upload section of the Continuing Review/Final Report form.

Investigators will be notified electronically that a Continuing Review/Final Report must be received by the specified date to allow sufficient time for IRB review.

For specific details, see SOP 404: Continuing Review.

1.4 Submission Requirements for Modifications to Currently Approved Research Projects
Investigators requesting modifications to previously-approved research projects must: 1) complete and submit the Modification/Notification form in the electronic information system, 2) upload the additional documents specified on the Modification/Notification form, and 3) upload all related research project documents. When uploading these documents, the Investigator shall provide updated versions with the modifications noted using the track changes function to highlight the investigator-requested changes (i.e., protocol, informed consent documents, recruitment flyers, data collection instruments).

For specific policy details, see SOP 405: Modifications

1.5 Submission Requirements for Continuing Review with Modifications
Investigators requesting modifications at the time of renewal of an approved research project must complete and submit the Continuing Review form in the IRB’s electronic information system. In addition, investigators must upload the additional documents specified on the Continuing Review form and all related research project documents. When uploading these documents, the investigator shall provide updated versions with the modifications noted using the track changes function to highlight the investigator requested changes (i.e., protocol, informed consent documents, recruitment flyers, data collection instruments).

For specific policy details, see SOP 404: Continuing Review, and SOP 405: Modifications

1.6 Submission Requirements for Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations
Investigators informing the IRB of unanticipated problems involving risks to participants or others and/or protocol deviations must complete and submit the appropriate report form for their reviewing campus IRB.

Investigators reporting to the Health Sciences Center IRB must use the HSC Incident Report Form for both unanticipated problems and protocol deviations.

Investigators reporting to the Norman Campus IRB must use the NC Unanticipated Problem Report and/or NC Protocol Deviation/Violation Report forms in the electronic information system.

In addition, investigators must upload relevant supporting documents.

For specific policy details, see SOP 407: Protocol Deviations and Unanticipated Problems.
1.7 Submission Requirements for Requesting Inactivation

Investigators requesting inactivation of an approved research project that is not exempt must complete and submit the Continuing Review/Final Report form in the IRB’s electronic information system. For exempt research, investigators must submit the Exempt Study Closure Report. Investigators must upload all related research project documents specified in the document upload section of the submission form.

For specific details, see SOP 408: Study Completion.

1.8 Submission Requirements for Human Research Determinations

Investigators requesting an IRB review to determine if proposed research does constitute human participant research must complete and submit the Determination of Human Research Worksheet in the IRB’s electronic information system. In addition, investigators must upload relevant supporting documents.

For specific policy details, see SOP 406: Determination of Human Research and Protocol Development.

1.9 Submission Requirements for Protocol Development (Norman Campus only)

Norman Campus Investigators who will need evidence of IRB review of research protocols in order to have external funding released from ORS for research activities must complete and submit the Norman Campus Protocol Development form in the IRB’s electronic information system. In addition, investigators must upload relevant supporting documents.

For specific policy details, see SOP 406: Determination of Human Research and Protocol Development.

1.10 Action Taken If Documentation is Not Adequate or Additional Information is Required

If the IRB, IRB reviewer, or IRB staff determines that the submitted documents are not adequate, investigators may be required to submit additional documents or may be required to answer questions or explain the details of the research project to the IRB. The IRB will not review incomplete submissions.

All IRB forms can be accessed in the IRB’s electronic information system. Templates for many of the supporting documents are available on the respective campus IRB websites. The Investigator or members of the research team shall not alter the IRB forms.

2. SCOPE

This SOP applies to all research projects submitted to the IRB.

3. RESPONSIBILITY

The HRPP Director or designee is responsible for maintaining research project submission requirements.

The IRB Administrator is responsible for conducting the pre-review and assigning the submission to the IRB reviewer for evaluation.

The IRB Administrator is responsible for documenting in the IRB’s electronic information system any investigator communication that occurs outside of the electronic information system.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115
5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 102b: Key Personnel Education
SOP 404: Continuing Review
SOP 405: Modifications
SOP 406: Determination of Human Research and Protocol Development
SOP 407: Protocol Deviations and Unanticipated Problems
SOP 408: Study Completion

6. ATTACHMENTS

301-A-1 Research Protocol Outline (HSC)
301-A-2 Protocol Description Form (NC)
301-B Continuing Review/Final Report
301-C Modification/Notification
407-A NC Unanticipated Problem Report
407-B NC Protocol Deviation/Violation Report
407-C HSC Incident Report Form
408-A Exempt Study Closure Report

7. PROCESS OVERVIEW

7.1 Submission of a New Research Project

7.1.1 Upon receipt of a new submission, IRB Staff review the submission to make sure required documents have been submitted and to confirm that key personnel have met all education requirements.

7.1.2 The IRB Staff will notify the Investigator if additional documents are required or education requirements are incomplete for any key personnel. See SOP 102B: Key Personnel Education, for specific education requirements.

The IRB will not accept a new research project submission until required documents are submitted and all key personnel have completed the HRPP education.

7.1.3 Once the education requirements are met, the IRB Staff assigns the new research project submission to an appropriate IRB and forwards to the IRB Administrator for pre-review to determine whether the information and materials submitted by the Investigator contain an adequate description of the proposed research. The IRB Administrator reviews the consent documents for inclusion of required elements. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.

7.1.4 The IRB Administrator evaluates the research project to determine if it will require IRB review, and, when appropriate, posts the research project to the next appropriate IRB meeting agenda.
7.15 The IRB Administrator assigns all other new submissions to the IRB Chair or IRB designee for review.

7.1.6 If the documents submitted for IRB review are not adequate, stipulations will be sent to the Investigator describing required changes or requesting additional information. The IRB reviewer may also request that the Investigator attend the IRB meeting to answer questions or to explain the details of the research project.

7.2 Submission of a Continuing Review, Modification, Protocol Deviations, Unanticipated Problems

7.2.1 Submission materials for Continuing Review, Modification, Reporting Unanticipated Problems Involving Risks to Participants or Others, and Protocol Deviations must provide the IRB with enough information for the IRB to approve continuation of the research project.

IRB Staff will review submissions for Continuing Review and Modification to confirm the education requirement for key personnel has been met.

7.2.2 The IRB Staff will notify the Investigator if additional documents are required or education requirements are incomplete for any key personnel. See SOP 102B: Key Personnel Education, for specific education requirements.

7.2.3 Once the education requirements are met, the IRB Staff assigns the submission to the appropriate IRB Administrator for processing.

7.2.4 The IRB Administrator conducts a pre-review to determine whether the information and materials submitted by the Investigator provide adequate information and documentation for IRB review. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.

7.2.5 The IRB Administrator evaluates the research project to determine if it will require convened IRB review, and, when appropriate, posts the research project to the next appropriate IRB meeting agenda.

7.2.6 The IRB Administrator assigns all other submissions to the IRB Chair or IRB designee for review.

7.2.7 If the documents submitted for IRB review are not adequate, stipulations will be sent to the Investigator describing required changes or requesting additional information. The IRB reviewer may also request that the Investigator attend the IRB meeting to answer questions or to explain the details of the research project.

7.3 Human Research Determination

7.3.1 Upon receipt of a Human Research Determination request, IRB Staff review the submission and assign to an IRB Chair or IRB designee to make a determination.

7.3.2 If the documents submitted for IRB review are not adequate, stipulations will be sent to the Investigator describing required changes or requesting additional information.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 302: ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS

1. POLICY

The efficiency and effectiveness of the IRB is supported by administrative procedures that allow IRB members to have adequate time for a thorough assessment of each proposed human research project.

Specific Policies

1.1 Submissions

Upon receipt of a new submission to the IRB, the IRB staff assesses the documents for assignment to the appropriate IRB by determining the campus affiliation of the investigator, research project site, type of research, scope of the research, date received, deadline submission, and volume of research assigned to each IRB. The IRB staff may seek guidance from the HRPP Director or HRPP Assistant Director as necessary.

1.1.1 Human research submitted to the HSC IRB office will be assigned to one of the five HSC IRBs. Typically, HSC IRBs review the following:

- IRB 1 reviews Medical/Behavioral research projects
- IRB 2 reviews Medical/Oncology/Surgical/Radiotherapy research projects
- IRB 3 reviews Medical/Pediatric research projects
- IRB 4 reviews Medical/Behavioral/Pediatric research projects
- IRB 5 reviews Medical research projects on an as-needed basis, except for VA studies

1.1.2 Typically, OU Norman IRBs review social behavioral research. The two OU Norman IRBs are equivalent in the scope of research reviewed. For OU Norman studies with biomedical interventions, see SOP 602G: Determination of Reviewing OU Campus IRB

- Board 1 reviews Social Behavioral research projects
- Board 2 reviews Social Behavioral research projects

1.1.3 Submissions of ongoing research: Upon receipt of any submission of ongoing research to the IRB, the IRB staff assesses the documents for assignment to the appropriate IRB for the project.

1.1.4 The IRB responsible for the initial project review will generally be the IRB responsible for subsequent reviews (e.g., continuing reviews, protocol modifications, unanticipated problems involving risks to participants or others, deviations, and miscellaneous items).

1.2 Administrative Assessment

The IRB staff shall conduct an administrative assessment of all research project submissions received from investigators to verify the submission of required documentation is complete. This is not an official determination of the IRB. The IRB Administrator shall conduct this assessment of submissions and may seek guidance from the HRPP Director or HRPP Assistant Director as necessary.

1.2.1 As part of the administrative assessment, the IRB Administrator makes a determination as to the type of review (Full Board or Expedited) required for the particular submission.
Assignments are determined according to the scope of research, with consideration given to date received and deadline for submission.

1.3 Incomplete Submissions
Incomplete submissions are not presented for review. The investigator must provide all necessary materials, as determined by the IRB Administrator. The IRB Administrator shall return incomplete submissions to the investigator for outstanding documentation or additional information before the submission is scheduled for review.

1.4 Review Assignment
Complete submissions that appear to meet the requirements for review by the convened IRB are added to the agenda for the next appropriate meeting, as described in SOP 303B: IRB Meeting Administration.

Complete submissions that appear to meet the requirements for Expedited or Exempt review are presented to the IRB Chair or IRB Chair designee. If a submission meets the Exempt or Expedited review requirements, the review is conducted as described in SOP 401: Research Exempt from IRB Review, and SOP 402: Expedited Review.

1.5 Materials Provided to Members Prior to IRB Meetings
Submission materials described in SOP 301: Research Submission Requirements, are provided to all IRB members the week prior to the regularly scheduled IRB meeting. Each member of the IRB, and any alternate member, if applicable, is provided the initial submission materials via the IRB’s electronic information system. Consultants are provided access only to material that pertains to their requested review assignment.

The original paper submission materials are retained in the IRB Office and are available at the IRB meeting. The original electronic submission materials are retained in the IRB’s electronic information system.

1.6 Confidentiality
All material provided by the IRB is considered confidential and is made accessible via the IRB’s password-protected electronic information system only to IRB staff and meeting participants (members, alternate members and consultants) for the purpose of review. Consultants and guests who have access to confidential IRB material are expected to sign IRB Guest Confidentiality Agreements prior to receiving any material.

2. SCOPE
This SOP applies to all human research submitted to the IRB.

3. RESPONSIBILITY
3.1 The IRB Administrator is responsible for conducting appropriate assessment of submissions for review purposes.

3.2 The IRB office is responsible for providing complete review material to IRB members and other relevant parties, via the IRB’s electronic information system.

3.3 The HRPP Director or designee is responsible for IRB assignment of new human research projects, based on the scope of the research, applicable meeting submission deadline dates, and current IRB agenda volume.
4. APPLICABLE REGULATIONS AND GUIDELINES
   21 CFR 56.109
   45 CFR 46.109
   OHRP Guidance on Written IRB Procedures, July 1, 2011

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 301: Research Submission Requirements
   SOP 303B: IRB Meeting Administration
   SOP 401: Research Exempt from Federal Regulations
   SOP 402: Expedited Review
   SOP 602G: Determination of Reviewing OU Campus IRB

6. ATTACHMENTS
   202-E  IRB Guest Confidentiality Agreement

7. PROCESS OVERVIEW
   The following overview describes the process for receiving and routing the materials submitted by
   investigators. This overview includes the requirements for pre-review and routing of documents
   before IRB review can occur.

   7.1 The IRB staff assesses submissions submitted to the IRB per Section 1.1 above. The HRPP
   Director or designee provides guidance and oversight for the routing of submissions when
   needed.

   7.1.1 The IRB Administrator reviews the submissions for New Studies, Continuing Review,
   Modification Forms, NC Unanticipated Problem Report Forms, NC Protocol Deviation
   Report Forms, HSC Incident Report Forms, and Miscellaneous items.

   7.1.2 The IRB Administrator conducts an initial assessment of all research project
   submissions received from investigators to ascertain completeness and make a
   preliminary determination as to the type of review.

   7.1.3 The IRB Chair or IRB designee makes the final determination as to the type of review.

   7.1.4 Incomplete submissions are not presented for review to the convened IRB. The IRB
   Administrator may seek guidance regarding incomplete submissions that require
   substantial revisions. If deficiencies are noted, the IRB Administrator contacts the
   investigator for resolution.

   7.2 Complete submissions that appear to meet the qualifications for review by the convened IRB
   are added to the agenda for the next appropriate meeting, as described in SOP 303B: IRB
   Meeting Administration.

   Complete submissions that appear to meet the requirements for Expedited or Exempt review
   are presented to the IRB Chair or IRB Chair’s designee. If a submission meets the Exempt or
   Expedited review requirements, the review is conducted as described in SOP 401: Research
   Exempt from IRB Review; and SOP 402: Expedited Review.

   7.3 Submission materials described in SOP 301: Research Submission Requirements, are
provided to all IRB members and alternate members if applicable, before the meeting. The IRB staff is responsible for verifying that all meeting materials are available to the IRB members.

7.4 Submission materials are provided to each member of the IRB and any alternate members attending the meeting. Consultants are provided access only to material that pertains to their requested assignment of review.

The original electronic submission materials are retained in the IRB’s electronic information system. The original paper submission materials, where applicable, are retained in the IRB Office and are available in the IRB meeting.

7.5 All materials received by the IRB are considered confidential and are provided to IRB staff and meeting participants (regular members, alternate members, and consultants) only for the purpose of review. The IRB Administrator is responsible for providing IRB Guest Confidentiality Agreements for signature to guests and consultants prior to giving them access to confidential IRB materials or information.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB meeting agenda provides the framework for the IRB meeting. It is used as a critical tool to facilitate management of the IRB meeting as it provides the meeting content and establishes a sequence of review. It also provides, in advance of the IRB meeting, an overview for each IRB member of all items that have been previously reviewed and approved by the IRB Chairs as well as a list of items that are pending review by the convened IRB and assigned reviewers.

Information documented in the meeting agenda provides the foundation for the IRB meeting minutes.

Specific Policies

1.1 Agenda Development

Each item submitted to the IRB for review is posted to the agenda of the appropriate Board. All items that receive approval by either the convened IRB or the IRB Chair are posted to the agenda reflecting the appropriate status (i.e., Approved by Board or Approved by Chair).

1.2 Information Documented

The agenda format is as follows:

1.2.1 Document Header: includes specific IRB Board (1-5) for HSC; IRB Board (1-2) for NC and meeting date
1.2.2 Board Members: names of IRB members listed on the meeting roster
1.2.3 Old & New Business: presentation of the previous meeting’s minutes
1.2.4 Protocol Items: miscellaneous items such as discussion items, investigator correspondence, or investigator question
1.2.5 Pending Board Review Items (items for discussion): new human participant research projects, continuing reviews (both active and closed to enrollment), modifications, protocol deviations, and unanticipated problems
1.2.6 Approved Items (items approved and listed for presentation to the IRB): includes Board requested revisions for new research submissions, modifications, continuing reviews, and protocol deviations and unanticipated problems, and items approved by expedited procedures.
1.2.7 Other Items: includes inactivations and withdrawals of protocols or modifications
1.2.8 Other Information: items that involve the Veterans Affairs Medical Center and names of IRB members assigned to review.

1.3 Primary and Secondary Reviewer Model

The IRB utilizes the Primary Reviewer model for research proposals reviewed by the convened IRB. The IRB Chair is authorized to delegate the review to one Primary and one Secondary Reviewer with appropriate backgrounds and expertise. For protocols that are granted Expedited Review, the IRB Chair reviews or delegates review to an appropriate Vice Chair or IRB designee.
2. SCOPE
   This SOP applies to all policies and procedures.

3. RESPONSIBILITY
   It is the responsibility of the IRB Administrator to consistently update the agenda applicable to her/his assigned Board.

4. APPLICABLE REGULATIONS AND GUIDELINES
   45 CFR 46
   21 CFR 56
   OHRP Guidance on Written IRB Procedures (July 1, 2011)

5. REFERENCES TO OTHER APPLICABLE SOPS
   None

6. ATTACHMENTS
   303A-A Agenda Template

7. PROCESS OVERVIEW
   All of the following processes involve the IRB electronic information system. For specific instructions, refer to the Operating Procedures of the electronic information system.

7.1 Items Requiring Convened IRB Review
   7.1.1 The IRB Administrator posts all items that require convened Board review (new research projects, continuing reviews, modifications, protocol deviations, and unanticipated problems and miscellaneous items) to the appropriate meeting agenda.
   7.1.2 Once an item has been reviewed by the convened Board, the IRB Administrator updates the review outcome and research project status in the IRB’s electronic information system.

7.2 Items Reviewed by the IRB Chair or IRB Designee
   7.2.1 The IRB Administrator posts all items that are reviewed by the IRB Chair or IRB designee to the meeting agenda and assigns the review outcome and research project status as described in 7.1.2 above.

7.3 Agenda Preparation for IRB Meeting
   7.3.1 Following consultation with the IRB Chair or IRB designee, the IRB Administrator assigns the appropriate reviewers to each item pending Board review.
   7.3.2 The agenda should generally be finalized 7-10 calendar days prior to the IRB meeting date.
   7.3.3 If additional items need to be added to the meeting agenda after the agenda has been finalized, the IRB Administrator will update the agenda.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020

Version No. 9.1
Effective Date: 09/03/2019
SOP 303A
SOP 303B: IRB MEETING ADMINISTRATION

1. POLICY

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present. Each IRB will meet monthly, or at some other frequency determined by the IRB Chair and the HRPP Director for each campus.

Specific Policies

1.1 Quorum

The IRB meeting cannot begin until quorum exists. Should the quorum fail during the meeting, the IRB may not take further actions or votes until the quorum is restored.

1.1.1 A quorum is defined as more than one half of the number of IRB members.

1.1.2 A quorum consists of members, or their alternates, and includes at least one member whose expertise is in a scientific area, one member whose expertise is in a non-scientific area and one member who is not otherwise affiliated with the University.

1.1.3 For research involving an FDA-regulated article, a licensed physician must be included in the quorum.

1.1.4 An alternate member may attend in the place of an absent member in order to meet the quorum requirements outlined above.

1.1.5 A special consultant(s) may not be used to establish a quorum.

1.1.6 Even if a member abstains from voting, the member may be used to establish a quorum.

1.2 Conflict of Interest for IRB members

IRB members shall not review their own studies. See SOP 104B: Conflict of Interest-IRB Members, for information concerning conflicts of interest for IRB members.

1.3 Meeting Materials Sent Prior to IRB Meetings

The meeting agenda and submission materials described in SOP 301: Research Submission Requirements, are provided to all IRB members the week prior to the regularly scheduled IRB meeting. The process for compiling meeting materials for review by IRB members is described in Section 7.3 below.

1.4 IRB Research Project Files

The IRB research project files are available to IRB members for their review in the IRB’s electronic information system. IRB members may request the IRB Administrator to obtain additional information. IRB members may request the IRB Administrator for assistance in obtaining the protocol file and relevant IRB minutes before or during the convened IRB meeting.

1.5 Minutes

Minutes shall be recorded at each meeting, as described in SOP 303C: Meeting Minutes.

1.6 Meeting Materials and Equipment

1.6.1 All IRB members shall have access to a laptop computer in order to participate in the review during the meeting. The University provides support for this technology.
1.6.2 IRB meetings are conducted electronically. The IRB has access to a monitor that displays the agenda items via the IRB electronic information system.

1.6.3 Circumstances sometimes warrant conducting IRB meetings via telephone conference call and/or video-conference call, provided that each participating IRB member (i) has received all pertinent material prior to the meeting, and (ii) can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied.

1.6.3.1 Convened Meeting Using Speakerphone:

Should one or more members not be able to be physically present during a convened meeting, but be available by telephone, the meeting may be convened using a speakerphone or similar device. The members who are not physically present are connected with the meeting via speakerphone or similar device. In this manner, all members are able to discuss all protocols, even though one or more members are not physically present.

1.6.3.2 Meetings Conducted Via Teleconference Calls:

On occasion, meetings may be convened via a telephone conference call where all or most members will participate via teleconference call. A quorum (as defined in 1.1 above) must be on line or present for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

1.6.3.3 Meetings conducted via Videoconferencing Calls:

IRB members from remote areas may choose to attend the IRB meeting via videoconference or similar method. These members have the same responsibilities and voting privileges as the rest of the IRB.

1.7 Unscheduled Meetings

It may be necessary to hold unscheduled IRB meetings in order to review studies. Typically, these meetings are held to review studies to provide treatment for participants more quickly than scheduled meetings; for example, HUD protocols, Treatment IND protocols, or studies that have a limited time for enrollment.

1.8 Voting

1.8.1 Members of the IRB vote according to the criteria for approval (SOP 403: Initial Review-Criteria for IRB Approval, and SOP 404: Continuing Review). Members also determine level of risk, the frequency of review for each protocol, monitoring requirements of the investigative site, and whether third party assessment and follow-up will be needed.

1.8.2 In order for a human research project to be approved, it must receive approval from the majority of the members present at the meeting. If an approval majority does not exist, the human research project is NOT approved.

1.8.3 Should an IRB member recuse him/herself during a meeting, that member is not counted toward the quorum. If quorum is lost due to the recusal, any further discussion/deliberation regarding the project must cease until quorum can be re-established. This may result in a deferral.

1.8.4 Following discussion of the research project, the IRB Chair/Vice-Chair shall call for a vote on one of the following motions: approve, contingently-approve, defer, disapprove, or abstain. An IRB member can abstain from voting if he/she is undecided as to how to
vote. That individual is still counted toward the quorum count; however, the abstention is not counted as an approval. For example: If a protocol is being voted on by seven Board members and one abstains, a majority of those present must vote “for” the protocol in order to receive approval; i.e., at least four must vote in favor of approval. In addition, if the community member abstains from voting, that person is still counted toward the quorum and also fulfills the regulatory requirements as having a community member present, but the abstention does not count in favor of approval; a majority of the members present must still vote in favor before approval can be granted.

1.8.5 Description of the Options for Motions:

A. **Approved** – The research project has been approved by the convened IRB as submitted and the investigator is not requested to revise any aspect of the project. The approval date is the date of the IRB meeting.

B. **Contingently Approved** – The convened IRB imposes specific revisions that require simple concurrence requests from the investigator or requires modifications that are minor as defined in SOP 405: Modifications. Research cannot be contingently approved if the IRB requests clarifications, additional information, or changes that are more than minor. Examples of revisions that cannot be contingently approved are:
   - Indicate the number of participants to be enrolled
   - Change the drug dosage to be consistent
   - Indicate why children cannot be participants
   - Provide additional details about the data monitoring plan.

All minor revisions must be submitted and reviewed by the IRB Chair or IRB reviewer for final approval of the project before the research project begins. The approval date will be the date that the IRB Chair or IRB Chair’s designee reviews and approves the requested revisions. If there are revisions that require judgment(s) not allowable under expedited review procedures, these revisions must be presented to the IRB at the next convened meeting.

C. **Deferred** – The convened Board requires significant additional information and/or a risk/benefit assessment could not be made with the information provided to make a determination regarding the human research project. The investigator may submit the requested information to be reviewed at the next scheduled IRB meeting.

D. **Disapproved** – The magnitude and/or number of concerns, questions, or problems relating to the human research project are such that a ‘contingently approved’ or a “deferred” determination cannot be made. The investigator has an opportunity to respond in writing or in person regarding the determination. The investigator can resubmit the research project; it undergoes review again by the convened IRB. Disapproved protocols cannot be approved by University administration.

2. **SCOPE**

This SOP applies to all human research submitted to the IRB.

3. **RESPONSIBILITY**

3.1 The HRPP Director or designee will attend all IRB meetings to provide consistency in applying the federal regulations, state law, and University and HRPP policies.
3.2 The HRPP and IRB staff are responsible for ensuring that the IRB meets procedural conduct and documentation requirements.

3.3 The HRPP and IRB staff are responsible to monitor the members present at the convened meeting and determine that meetings are appropriately convened and held, such as ensuring quorum is maintained and that there are no IRB members with a conflict of interest present at the meeting.

3.4 Primary and Secondary Reviewers are responsible to conduct an in-depth review of all materials.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

3.6 The IRB Chair or IRB Chair’s designee is responsible for the IRB meeting reviewer conduct and leading discussion for all business that is addressed. The IRB Chair or IRB Chair’s designee directs the proceedings of the meeting and requires that any member who has a conflict of interest does not vote or participate in the IRB’s consideration of the research project for determination, except as requested by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.108
21 CFR 56.108
FDA Information Sheet, Guidance for IRB’s and Clinical Investigators, 1998 Update
OHRP Guidance on Written IRB Procedures, July 1, 2011
OHRP Guidance on IRB Meetings Convened via Telephone Conference Call, March 28, 2000
Department of Veterans Affairs, VHA Handbook 1200.5, October 15, 2010

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 104B: Conflict of Interest – IRB Members
SOP 203: Duties of IRB Members
SOP 301: Research Submission Requirements
SOP 303C: IRB Meeting Minutes
SOP 403: Initial Review-Criteria for IRB Approval
SOP 404: Continuing Review
SOP 405: Modifications

6. ATTACHMENTS

203-A   HSC Reviewer Checklist
203-A-1 Norman Campus Reviewer Checklist
303B-A   Board Meeting Checklist
303B-B   Sign-In Sheets-OKC
303B-B-1 Sign-In Sheets-Norman
7. PROCESS OVERVIEW

7.1 Meeting Attendance
IRB staff contacts IRB members to verify intended meeting attendance to ensure presence of a quorum at the IRB meeting.

7.2 Primary Reviewers
The IRB Chair or IRB Chair’s designee assigns primary reviewers for each research proposal. The primary and secondary reviewers’ duties are described in SOP 203: Duties of IRB Members.

7.3 Meeting Materials Sent Prior to IRB Meetings

7.3.1 The IRB Administrator provides all IRB members with research project documentation required for review the week prior to the regularly scheduled IRB meeting. These documents include:

- Agenda
- Minutes from the previous IRB meeting
- Reviewer materials

The IRB Administrator finalizes the meeting agenda and provides it and all meeting materials to IRB members prior to each meeting. A copy of the agenda and meeting minutes are maintained electronically. IRB members review the agenda and meeting materials for any potential conflict of interest they may have so that they may recuse themselves from the discussion and vote of an item. The IRB minutes also specifically reflect such recusals as they occur during meetings.

7.3.2 For initial review by a convened IRB, all IRB members have access to:

- Research project submission
- Proposed consent documents and verbal consent scripts
- Full investigator or sponsor protocol
- HIPAA Research Privacy Form
- Recruitment materials
- Any relevant grant applications, if required
- The investigator’s brochure (when one exists)
- Copies of letters of assurance or Memoranda of Understanding with human research sites
- IRB Review of NIH-Approved Informed Consent Documents for NIH-Supported Multi-center Clinical Trials: If available, for NIH-supported multi-center clinical trials, the IRB receives and reviews an electronic copy of the NIH-approved sample informed consent document and the full NIH-approved investigator’s protocol as a condition for approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the investigator, approved by the IRB, and reflected in the IRB minutes.

In addition, primary members receive a reviewer checklist.
7.3.3 For continuing review by a convened IRB, all IRB members have access to:
   • Continuing Review/Final Report form
   • The complete protocol incorporating protocol modifications previously approved by
     the IRB
   • Full investigator or sponsor protocol updated with any changes
   • Current and proposed consent documents and scripts
   In addition, primary members receive a reviewer checklist.

7.3.4 For review of modifications to previously approved research, all IRB members receive:
   • Modification/Notification Form
   • Modified documents
   In addition, primary members receive a reviewer checklist.

7.3.5 For expedited review of new research submissions, continuing review, or review of
   modifications, the IRB reviewer will receive and review all information that the convened
   IRB would have received.

7.4 Minutes
   For specific information regarding meeting minutes, refer to SOP 303C: Meeting Minutes.

7.5 Voting
   Following discussion of each agenda item, the IRB Chair or IRB member makes a motion,
   another IRB member seconds the motion, the IRB members vote on the item, and the IRB staff
   counts and records all votes for, against, or abstaining from the motion.

   7.5.1 A vote is official only when it takes place with a quorum present.

   7.5.2 A member who is determined to have a conflict of interest on a research project is
   recused from IRB deliberations and must not vote on that research project.

   7.5.3 A member who is recused from IRB deliberations cannot be counted towards the
   quorum.

   7.5.4 No proxy votes are permitted.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. **POLICY**

The IRB meeting minutes document all actions that occur during an IRB meeting. The minutes are the critical document that demonstrates appropriate review of human participant research. The IRB minutes are required to document the following information by the IRB:

- Actions taken by the IRB
- Separate deliberations for each action
- Votes for each research project as numbers for, against, or abstaining
- Attendance at the meeting for each action
- When an alternate member replaces a primary member
- The basis for requiring changes in research
- The basis for disapproving research
- A written summary of the discussion of controverted issues and their resolution
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent documents
- For initial and continuing review, the approval period
- The names of IRB members who recuse themselves from the meeting due to a conflict of interest along with the fact that a conflict of interest was the reason for the recusal
- Determinations required by the regulations and research project-specific findings justifying those determinations for:
  - waiver or alteration of the consent process
  - research involving pregnant women, human fetuses, and neonates
  - research involving prisoners
  - research involving children
  - research involving participants with diminished capacity to consent
- The rationale for significant risk/non-significant risk device determinations
- The determination of the level of risk
- Attendance of members or alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions
- The approval of research contingent on specific minor conditions by the IRB Chair or IRB Chair’s designee (to be documented in the minutes of the first IRB meeting that takes place after the date of the approval)
- Whether reports of protocol deviations and unanticipated problems involving risk to participants or others (1) are or are not determined to be unanticipated problems involving risk to participants or others and (2) are or are not due to serious or continuing
noncompliance

- Information that pertains to action that must be taken by the investigator

For VA research:

- The IRB will provide the un-redacted minutes for IRBs reviewing VA protocols to the VA Research and Development Committee in a timely manner.

- IRB determinations and expedited review categories must be communicated in the minutes of the next available meeting.

The minutes are prohibited from being altered by anyone, including a higher authority, once they are finalized and accepted by the IRB.

Specific Policies

1.1 Meeting Minutes Preparation

The preparation of the meeting minutes begins with the preparation of the meeting agenda. Each item submitted to the IRB for review, either by the convened committee or the IRB Chair is posted to the agenda. Refer to SOP 303A: Meeting Agenda, for information pertaining to the IRB Agenda.

1.2 Information Documented

The minutes document:

1.2.1 Meeting Attendance: Individuals (member, alternate member, consultant, guest, etc.) attending, each individual’s representative capacity (scientist, non-scientist, community member), and the status of each attendee (i.e., COI/recused, voting, non-voting).

1.2.2 Board Discussion and Action: Separate deliberations for each action and the basis for requiring changes in human research, the basis for disapproving research, a justification of any changes to the DHHS-approved sample consent documents, the approval period for initial and continuing review, justification for a waiver of alteration of the consent process, research involving pregnant women, human fetuses and neonates, prisoners and children, and the rationale for significant risk or non-significant risk device determinations.

1.2.3 Review Items: Individual items of a new research project. These items may include the research protocol, investigator brochure, informed consent documents, HIPAA privacy document(s), surveys, questionnaires, and advertisements.

1.2.4 Controverted Issues: A written summary of the discussion of the controverted issues and their resolution.

1.2.5 Voting for Each Action: Including the number of members counting toward the vote; those members who recused themselves from voting; and the number voting for, against, and abstaining from the vote. When appropriate, the minutes will indicate why a member abstained from voting.

1.2.6 The determination of the level of risk and the rationale for the IRB’s determinations of the level of risk.

1.3 Information Documented As Applicable

The minutes document the following as applicable:
1.3.1 **Device Studies:** Determination of whether the device is a significant risk or non-significant risk. This determination is included in the letter to the investigator.

1.3.2 **Inclusion of Children:** The risk for children as stated in 45 CFR 46.404 - 46.407 and 21 CFR 50.51 - 54.

1.3.3 **Inclusion of Prisoners:** Seven additional findings under 45 CFR 46.305(a), as noted in SOP 501: Special Populations.

1.3.4 **IND/IDE:** Determination of whether an IND or IDE is required.

1.3.5 **Certificate of Confidentiality:** Determination of the need for an NIH Certificate of Confidentiality or an NIH Privacy Certificate.

1.3.6 **Conflict of Interest:** Methods recommended by the IRB to address situations that involve a conflict of interest. (i.e., asking the investigator to identify someone other than the investigator to consent participants or including a statement within the consent documents that the investigator is a paid consultant of the sponsor).

1.3.7 **Continuing Review:** Those research projects that require continuing review more often than annually, due to the degree of risk to the participants. The minutes of the IRB meetings reflect these determinations regarding risk and approval period.

1.3.8 **Informed Consent:** A consent procedure that does not include or that alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. These findings are documented in the minutes of the IRB meeting, including research project-specific information justifying each IRB finding. This procedure also applies when the convened IRB reviews research (a) involving pregnant women, human fetuses, or neonates, (b) approving research involving prisoners, and (c) approving research involving children.

1.3.9 **Protocol Deviation:** Whether the deviation is or is not an unanticipated problem involving risks to participants or others or is due to continued or serious non-compliance.

1.3.10 **Unanticipated Problems:** Whether the unanticipated problem involving risks to participants or others is or is not an unanticipated problem involving risks to participants or others or is due to continued or serious non-compliance.

1.3.11 **For VA Research: Non-Veteran Participants:** a summary of the justification for including non-veterans as participants.

1.3.12 A summary of the discussion when real social security numbers (SSNs), scrambled SSNs, or the last four digits of SSNs will be used in the study. The summary needs to include the security measures that are in place to protect the SSN instances embedded in the study.

1.3.12 If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant’s expertise, and documentation that the consultant did not vote with the IRB or EC on the study.

### 1.4 Other Information

The following information originally documented on the meeting agenda is reflected in the meeting minutes:

1.4.1 **Old Business**

1.4.2 **New Business Items – Review of previous meeting’s minutes and miscellaneous items**

1.4.3 **Items Reviewed By the Convened IRB: Submissions – New, Continuing Reviews, Modifications, Protocol Deviations, Unanticipated Problems**
1.4.4 Board-Requested Revisions reviewed by expedited procedures

1.4.5 Items Reviewed by Expedited Procedures: Submissions - New, Continuing Reviews, Modifications, Protocol Deviations, and/or Unanticipated Problems

2. SCOPE
   This SOP applies to all other SOPs.

3. RESPONSIBILITY
   3.1 The IRB Administrator must attend the IRB meetings and record the meeting minutes and actions of the IRB.
   3.2 The IRB Administrator shall complete, review, and present the meeting minutes to the HRPP Director or Assistant Director within 2 weeks of the meeting.
   3.3 The IRB Administrator shall present the meeting minutes to the IRB at the next scheduled meeting.
   3.4 The IRB members shall review, recommend changes, and accept the meeting minutes.
   3.5 The IRB Chair shall provide guidance and assistance to the IRB staff in the development of the minutes as needed and provide electronic signature on the finalized meeting minutes.

4. APPLICABLE REGULATIONS AND GUIDELINES
   45 CFR 46
   21 CFR 56
   38 CFR 16
   OHRP Guidance on Written IRB Procedures, July 1, 2011
   VHA Directive 1200.05

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 303A: IRB Meeting Agenda
   SOP 501: Special Populations

6. ATTACHMENTS
   303C-A Minutes Review Checklist
   303C-B Meeting Minutes Template

7. PROCESS OVERVIEW
   7.1 During the Meeting – Meeting Minutes Documentation
      7.1.1 The IRB Administrator begins the documentation process by bringing items as needed to the meeting in order to record meeting discussion.
      7.1.2 When possible, two IRB Administrators attend each IRB meeting. One IRB Administrator shall record electronic notes during the meeting; the second IRB Administrator shall serve as technographer.
7.2 Post Meeting – Meeting Minutes Development

7.2.1 The IRB Administrator gathers all notes from the meeting and utilizes these notes to prepare the Board minutes.

7.2.2 Phase One – Correspondence: The first phase of IRB meeting minutes begins with the IRB Administrator writing all outcome letters and stipulations regarding new research projects, continuing reviews, modifications, protocol deviations, and unanticipated problems submissions. All IRB-requested changes are addressed in this letter and stipulations, which are forwarded to the investigator. All information documented in the letter and stipulations are also included in the meeting minutes.

7.2.3 IRB outcome letters are expected to be completed on or before the third University business day following the meeting. The IRB Administrator notifies the HRPP Director or designee to review the letters and stipulations. Following this review, the IRB Administrator notifies the IRB Chair for review and electronic signature of the outcome letter.

7.2.4 Phase Two – Meeting Minutes: The second phase of IRB meeting minutes involves completing the minutes by recording all deliberations, decisions, IRB actions, controverted issues, and votes. This information is not included in the communication to the investigator.

7.2.5 The minutes are expected to be completed within 10 University business days from the meeting date. The IRB Administrator proofreads the draft version for accuracy using the Minutes Review Checklist. Items in the minutes must correspond with items reflected on the meeting agenda. The minutes are presented to the HRPP Director or designee for review.

7.2.6 The IRB Administrator prepares the final version of the minutes for review at the next appropriate IRB meeting and adds the item for review to the next meeting agenda.

7.2.7 Once the minutes are approved, all notes from the meeting that are used to develop the minutes are retained for a period of one year. Following that time period, they are destroyed. Any recordings are destroyed after minutes are finalized.

7.3 Meeting Minutes Approval

7.3.1 The minutes are presented at the next appropriate convened IRB meeting for review/approval. The IRB Staff electronically distributes the minutes to the IRB members.

7.3.2 Following approval by the convened IRB, the IRB Administrator obtains an electronic signature on the minutes from the IRB Chair or designee in the electronic information system. A signed copy of the minutes is printed from the electronic information system and filed in the IRB meeting minutes notebook.

7.3.3 When the minutes are contingently approved because of revisions noted by the IRB members, the IRB Administrator makes the revisions, presents the revised minutes to the IRB Chair for electronic signature, and records the approval of the minutes by the IRB Chair on the next appropriate agenda.

7.3.4 Completed and signed IRB meeting minutes are made available to the Institutional Official at the HSC campus and the Norman campus.

7.3.5 At HSC, completed and signed IRB meeting minutes are made available to the VA Research and Development Committee.

7.4 Summary of Expectations
7.4.1 Meeting Week – The expectation is that all Board action letters and stipulations are to be completed 3 business days after the meeting.

7.4.2 Meeting Week – The expectation is that all Board action letters and stipulations will be reviewed by the HRPP Director or designee and, once all requested revisions have been completed, the IRB action letters and stipulations are forwarded by the IRB Administrator to the IRB Chair for review and electronic signature of the outcome letter.

7.4.3 Following electronic signature by the IRB Chair or IRB designee, the Board action letters are forwarded by the IRB Administrator to each investigator.

7.4.4 Week following meeting – The expectation is that a completed version of the minutes is forwarded by the IRB Administrator to the HRPP Director or designee for review 10 University business days after the meeting.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 304: DOCUMENTATION, DOCUMENTS, AND DATA MANAGEMENT

1. POLICY

The IRB shall document determinations required by applicable laws, regulations, codes, and guidance. The IRB office shall maintain IRB files in a manner that contains a complete history of all IRB actions and determinations related to review and approval of New Studies, Continuing Reviews, Modification, Unanticipated Problems involving risks to participants or others, Protocol Deviations, Human Research Determinations, Protocol Developments, and miscellaneous items.

The IRB Office shall maintain and retain study documents related to research project submissions pursuant to applicable federal, state, and local regulations, collaborating institution requirements, and University policies and procedures. IRB research project documents will be provided to sponsors, collaborating institutions, or funding entities according to the terms of the study-specific research agreement. IRB research project documents may be made available for inspection and copying by authorized representatives of regulatory agency and University auditors at reasonable times and in a reasonable manner.

The IRB Office shall maintain IRB records related to IRB and Privacy Board proceedings and determinations pursuant to applicable federal, state, and local regulations and University policies and procedures. These records may be made available for inspection and copying by authorized representatives of the sponsor, collaborating institutions, funding department or agency, regulatory agency, and institutional auditors at reasonable times and in a reasonable manner. Requests for documents or IRB records by other individuals will be processed according to SOP 307: Copy and Record Requests.

Specific Policies

1.1 Document Retention

The IRB office shall retain all records on site regarding a research project (regardless of whether it is not approved, active, or inactive) for as long as possible or as space allows on site. All IRB paper records are permanently stored in an off-site location approved by the University for storage of PHI when space is no longer available in the IRB office. All electronic records are maintained in the IRB’s electronic information system.

The IRB office shall retain on site or electronically, all records regarding research projects that are submitted for at least three (3) years after completion of the research or after the non-approval.

The HSC HRPP office shall retain on behalf of the Privacy Board all records related to the HSC Privacy Board, in the same manner as described above.

A. Study-related Documents

Adequate study-related documentation of each IRB activity is prepared and maintained in a secure location. These documents may include paper or electronic copies of:

- Research project proposals (including grant applications as applicable)
- Investigator brochures (if applicable)
- Scientific evaluations (if applicable)
- Participant recruitment materials and data collection instruments
- Consent documents
- Progress reports submitted by investigators
- Research Privacy forms
- DHHS-approved sample consent documents
- Continuing review reports and records of continuing review activities
- Reports of any complaints or injuries received from participants
- Reports of unanticipated problems involving risks to participants or others, reports of injuries to participants, and/or protocol deviations
- Monitoring reports and site visit reports
- Modifications to previously approved research
- Documentation of non-compliance with applicable regulations
- Statements of any significant new findings provided to participants
- Correspondence between the IRB and the investigators
- Documentation of determinations required by the regulations and protocol-specific findings supporting those determinations

For VA research:
- All correspondence between the IRB and the VA Research and Development Committee
- Correspondence between the IRB and Researchers
- Serious and unexpected adverse events submitted to the IRB reported on the Unanticipated Problem report form, including internal serious adverse events
- Protocol violations/deviations submitted to the IRB
- A resume for each IRB member
- All previous membership rosters
- Copies of regulatory audits and any correspondence related to the audit.

B. VA Research Records Access

Records for VA Research, including the investigator’s research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are according to the VHA Records Control Schedule (RCS 10.1). The VA Research and Development Committee shall have access to all VA-related IRB records. All IRB records will be accessible to appropriate VA personnel for inspection as requested. (A confidentiality agreement must be signed by the VA prior to the latter.) See SOP 603A: Veterans Health Care System for additional information.

C. Privacy Board Documentation

The IRB staff maintains a restricted location for adequate documentation of the Privacy Board activities. These documents include copies of all original Research Privacy Forms submitted for review.

D. Department of Defense

Department of Defense-sponsored research may require the IRB to submit records to the Department of Defense for archiving.
1.2 IRB Administration Documents

The IRB office shall maintain on site or electronically all records regarding IRB administrative activities that affect research project review for at least three (3) years or as space allows.

1.2.1 All IRB paper records are stored in a warehouse when space is no longer available in the IRB office. On site, electronic or archived documents may include:

A. Rosters of IRB members identified by name, earned degrees, representative capacity, scientific/nonscientific status, affiliation status (whether the member or an immediate family member of the member is affiliated with the organization), employment or other relationship between each IRB member and the organization, and indications of experience sufficient to describe each member’s chief anticipated contribution to the IRB deliberations.

B. Alternate members including the member for whom the alternate substitutes.

C. Records of any employment or other relationship between each IRB member and IRB and/or the University (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

Current and obsolete membership rosters remain in the IRB Office and are archived according to University policy in an approved University storage location for permanent storage. The roster of IRB members is submitted to OHRP. Any changes in IRB membership are reported to OHRP in accordance with OHRP requirements. Reports submitted to OHRP are maintained on site. See SOP 202: Management of IRB, for detailed information pertaining to IRB Rosters.

On appointment of unaffiliated IRB members, it is determined whether any of the members’ immediate family members are affiliated with the University. If so, they are changed to affiliated members. Each unaffiliated IRB member is polled annually to determine whether any of their immediate family members are affiliated with the University and if so they are changed to affiliated member. Documentation of the initial and annual poll is retained in the member’s file.

1.2.2 The HRPP Director or designee maintains copies of current and obsolete SOPs, Investigator Manuals and the “OUHSC Human Subject Protection in Research” and Investigator Education Manual.

1.2.3 The HRPP Director or designee is responsible for maintaining written records of delegation of specific functions, authorities, or responsibilities of the IRB Chair.

1.3 IRB Records for Initial Review, Continuing Review and Modifications by the Expedited Procedure shall include:

- The specific permissible category.
- Description of actions taken by the IRB reviewer.
- Any determinations required under the regulations, along with protocol-specific findings supporting those determinations.
- Note regarding the frequency for the next continuing review.

1.4 IRB Records for Exempt Determinations shall include:

- The specific category of exemption.
- Description of actions taken by the IRB reviewer.
• Any determinations required under the regulations, along with protocol-specific findings supporting those determinations.

1.5 Destruction of Copies
All paper materials received by the IRB that are considered confidential and are not original documents that need to be retained in the study-records, as well as confidential materials distributed to the IRB members, shall be collected by the IRB staff at the end of each IRB meeting and destroyed by an authorized records destruction agent.

1.6 Archiving
All documents and materials related to IRB activities shall be retained on site or electronically for three (3) years or as space allows and archived according to University policy. University policy is governed by a state statute that requires files containing applications submitted by faculty, students and staff to conduct research projects involving human subjects, correspondence relating to review of applications, and federal guidelines regarding the uses of human subjects in research projects to be retained permanently in an office maintained by the University. Any IRB files that contain PHI will be stored at a location approved by the University for storage of PHI.

1.7 Data Management
The IRB’s electronic information system shall be managed to contain records of all IRB activities, facilitate correspondence with investigators, and provide access to reports and data needed for internal and external business functions.

2. SCOPE
This SOP applies to all documents submitted to the IRB.

3. RESPONSIBILITY
The HRPP Director is responsible for maintaining complete files on all research projects submitted to the IRB and for all applicable regulatory compliance requirements.

The HRPP, IRB staff, and IRB members are responsible for the maintenance and confidentiality of the IRB files.

The Compliance Applications and Technology Office is responsible to maintain, archive, and support the electronic information system.

4. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46.103, 115
21 CFR 56.115
Veteran’s Health Administration Handbook 1200.05 § 26 - 29
VHA RCS 10.1

5. REFERENCES TO OTHER APPLICABLE SOPS
SOP 202: Management of IRB
SOP 307 Copy and Data Request
6. ATTACHMENTS

304-A State Universities and Colleges General Records Disposition Schedule
VHA RCS

7. PROCESS OVERVIEW

The following process overview describes the requirements for document management.

7.1 Document Retention

The IRB office shall retain on site or electronically all records regarding a research project (regardless of whether it is not approved, approved or inactivated) for at least three (3) years after completion of the research or after non-approval. All IRB paper-based records are stored in a warehouse when space is no longer available in the IRB office. The HRPP Office retains on behalf of the Privacy Board all records related to the Privacy Board, in the same manner as described above.

Study-related documents: The HRPP Director oversees the maintenance of adequate documentation of IRB activities in a secure location. These documents include those described in Section 1.1 of this policy.

7.2 IRB Administration Documents

The HRPP Director oversees the retention of all records regarding protocols that are approved and the research initiated for at least three (3) years after completion of the research. All IRB paper records are stored in a warehouse when space is no longer available in the IRB office.

The HRPP Director oversees the maintenance of adequate documentation of IRB Administrative activities in a secure location. These documents include those described in Section 1.2.

7.3 Destruction of Confidential Materials

The IRB staff is responsible for collecting at the end of each IRB meeting all confidential materials that were used by the IRB members. These materials will be destroyed by an authorized records destruction agent.

7.4 Archiving

The HRPP Director or designee oversees the archiving of inactive study files, retained on site for three (3) years according to University policy. The paper IRB records are moved and stored in an off-site location approved by the University for storage of PHI. The HRPP Director maintains records of study files permanently as required by state statute.

7.5 Data Management

All HRPP staff members shall be trained on the proper use of the IRB electronic information system used to document study review and compliance activities. The HRPP Director or designee maintains appropriate security methods, such as reviewing and processing requests to access the IRB’s electronic information system by researchers at affiliated institutions and to limit access to secure areas. The IRB’s electronic information system shall be backed up daily.

APPROVED BY: _____________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

Following a system of file organization is critical in the daily activities of the HRPP office. An organized system facilitates adherence to the regulations of DHHS and FDA and the maintenance of the rights and welfare of the human participants of such research. Standardized procedures for maintaining appropriate documentation of IRB activities must be in place to facilitate the highest quality of review and oversight of research involving human participants.

Specific Policies

1.1 Filing

The IRB Staff maintains all files onsite or electronically in the IRB’s electronic information system. All files are filed in the IRB’s electronic information system in numeric order according to the assigned IRB Number.

Access to the IRB file room shall be limited to authorized IRB Staff, HRPP Staff, IRB Chairs and Vice Chairs, IRB members, Institutional Officials, authorized federal agency employees, and University officials from the offices of Legal Counsel, Internal Audit, and Compliance. Archived files are stored in an appropriate facility.

1.2 File System

The IRB Staff uses the IRB’s electronic information system as its filing system for IRB records. The IRB maintains paper files for archival purposes.

2. SCOPE

This SOP applies to the file system in the Office of Human Research Participant Protection for each campus.

3. RESPONSIBILITY

3.1 The IRB staff is responsible for maintaining the electronic information system and the archival files in an organized and functional manner.

3.2 IRB staff is responsible for verifying that all human research project documents are in the IRB’s electronic information system.

3.3 The investigator is responsible for uploading all necessary human research project documents into the IRB’s electronic information system.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 56
OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

None

7. PROCESS OVERVIEW
The following overview describes the systematic approach used to maintain an organized filing system for documentation of IRB activities.

7.1 A research project is received in the IRB’s electronic information system, assigned a unique IRB number, and is assigned to an appropriate IRB. The IRB staff reviews the submission for completeness and assigns it to an IRB reviewer.

7.2 The Research project summary in the IRB’s electronic information system is comprised of the following:
   a. Online Application
   b. Informed Consent documents
   c. Other research project documents, which may include the research project protocol, the grant application, investigator’s brochures, recruitment advertisements, surveys, questionnaires, HIPAA form(s), and other research project-related documents.
   d. Submission history, which may include modifications, continuing reviews/final reports, initial submission packets, unanticipated problem reports, and deviation reports.
   e. Official correspondence among or between the investigator, Sponsor, regulatory bodies, and/or the IRB Office. A letter from the FDA is an example of official correspondence.

7.4 The IRB Administrator manages and maintains the assigned individual files in the IRB’s electronic information system.

7.5 The IRB files are available for use only by IRB Staff, HRPP Staff, IRB Chairs and Vice Chairs, IRB members, Institutional Officials, authorized federal agency employees, and University officials from the offices of Legal Counsel, Internal Audit, may use certain IRB records. The IRB files are not accessible to other individuals without approval from the HRPP Directors, the Director of Compliance for the NC, or the HSC VPR for HSC, or their designee.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 306: IRB FEES

1. POLICY

The IRB at the Health Sciences Center (HSC) charges an IRB research review fee to industry-sponsored human research projects. The Norman Campus does not charge an IRB research review fee.

Specific Policies

1.1 Fee Structure

The HSC IRB shall charge a one-time, non-refundable IRB research review fee of $2,500 to all industry-sponsored human participant research projects. This fee does not apply to federally-funded research, investigator-initiated research, or research supported by grants from non-profit foundations or organizations.

The HSC IRB shall charge a non-refundable continuing IRB research review fee of $750 to all industry-sponsored human research projects. This fee does not apply to federally-funded research, investigator-initiated research, or research supported by grants from non-profit foundations or organizations.

The HSC HRPP shall charge a one-time, non-refundable HRPP administrative fee of $2,000 to all industry-sponsored human research projects that rely on a non-OU IRB.

1.2 Budget Preparation

The investigator or Office of Research Administration (ORA), as appropriate, shall include the IRB research review fees as a separate line item in all industry-sponsored budgets or payment schedules. Also, the investigator may negotiate a separate budget line item for IRB preparation and submission.

1.3 Invoicing and Collection

1.3.1 Upon receipt of an IRB submission, the HSC IRB shall generate and send an invoice to the investigator or his/her designee for each initial and continuing review of the industry-sponsored human research project. Payment is due within 30 days of receipt of invoice.

1.3.2 The IRB shall send past due notices to the investigator or designee for payments not received within 45 days of the invoice, followed by a letter of collection for payments not received within 60 days. In the event the IRB does not receive payment within 90 days, the IRB may send a demand letter to the sponsor.

1.3.3 The IRB reserves the right to administratively withdraw IRB approval for any IRB research review study that is over 90 days past due and to take any legal action against the sponsor to recover payment.

1.4 Deposits and Accounting

1.4.1 The IRB staff shall maintain a current accounting of IRB research project review fees invoiced and fees collected.

1.4.2 The IRB makes deposits with the HSC Bursar’s Office according to HSC policy. The IRB staff shall maintain deposit records.

1.4.3 Alternatively, the investigator or designee shall submit a cost transfer from the appropriate study account to the HRPP. The University’s account system shall maintain accounting records of the transactions.
2. SCOPE
   This SOP applies to all Investigators who utilize an HSC IRB as the IRB of record or the HSC HRPP.

3. RESPONSIBILITY
   3.1 The HRPP Director is responsible for the management and conduct of the IRB research review fee policy and procedures assuring compliance with University policy.
   3.2 The IRB staff is responsible for the appropriate invoicing, collection, and accounting of IRB research review fees charged to industry sponsors. The IRB staff is responsible for making deposits of these payments within 24 hours of receipt with the HSC Bursar’s Office.

4. APPLICABLE REGULATIONS AND GUIDELINES
   The University of Oklahoma Health Sciences Center Administrative Policies, Financial Services, Section 510.

5. REFERENCES TO OTHER APPLICABLE SOPS
   None

6. ATTACHMENTS
   306-A  HSC IRB Sample Invoice
   306-C  HSC Cash Receipts Policy, Section 510

7. PROCESS OVERVIEW
   7.1 The HSC VPR, in collaboration with the HSC Senior Vice President and Provost, will determine the fee structure for the IRB research review fee.
   7.2 The investigator or ORA, as appropriate, is responsible for including the IRB research review fees as a separate line item in all industry-sponsored budgets and payment schedules. Also, the investigator may negotiate a separate budget line item for IRB preparation and submission.
   7.3 The IRB staff is responsible for generating a weekly report listing research studies submitted to the IRB for the previous week. The HRPP Director is responsible for reviewing the report to verify that the appropriate industry sponsors are invoiced.
   7.4 The IRB staff will use the IRB Report to generate an invoice for each initial and continuing review industry-sponsored project received by the IRB. The IRB research review fee is due upon receipt of the invoice by the sponsor. The IRB staff will generate an aging report to monitor accounts receivable. If payment is not received within 45 days following invoicing, the IRB shall send a past due letter, followed by a letter of collection for payments not received within 60 days. In the event the IRB does not receive payment within 90 days, the IRB shall send the sponsor a demand letter.
   7.5 The HRPP Director, in collaboration with the Director of Compliance, may decide to administratively withdraw IRB approval for any research study fees that are over 90 days past due and will consult with Legal Counsel regarding the appropriate legal action against the sponsor afforded to it by applicable law to recover payment.
   7.6 The IRB staff processes payments received, endorses the checks, verifies amounts collected, and delivers deposits to the Bursar’s Office within 24 hours of receipt of the payment.
   7.7 The IRB staff will verify the amount deposited against the Deposit Voucher to confirm that the amount received was appropriately deposited with the Bursar’s Office.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 307: COPY AND RECORD REQUESTS

1. POLICY

The IRB shall prepare and maintain adequate documentation of IRB activities as described in SOP 304, Documentation, Document and Data Management. IRB records are defined as all documents that describe IRB activities.

Specific Policies

1.1 Access to IRB Records.

The IRB staff shall maintain all IRB records in locked filing cabinets or a locked storage room and in the IRB’s electronic information system.

Access to IRB records shall be limited to authorized IRB Staff, HRPP Staff, IRB Chairs and Vice Chairs, IRB members, Institutional Officials, authorized federal agency employees, and University officials from the offices of Legal Counsel, Internal Audit, and Compliance. Upon request and signature of a confidentiality agreement, VA R&DC employees may also access certain IRB records.

Investigators and research project coordinators are provided reasonable access to IRB files related to their research upon advance notice to the IRB.

All other access to IRB records is limited to those who have legitimate business need for them, as determined by the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee.

1.2 Copying IRB Records

Requested copies of IRB records are given only to the principal investigator (PI), co-principal investigator (co-PI), the research coordinator/project contact listed on the particular research project, and members of the IRB.

Copies are not given to anyone else unless authorized by the HRPP Director, for NC the Director of Compliance and for HSC the HSC VPR, or their designee or as required by applicable law.

All IRB records maintained in the IRB’s electronic information system are available to those who have authorization to access the system, according to their role.

1.3 Requests for IRB Records from Non-Authorized Individuals

All requests for IRB records from non-authorized individuals (i.e., sponsor, research project monitor, or an individual not listed as PI, co-PI, or research project coordinator in the protocol) shall be made in writing to the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee.

2. SCOPE

This SOP applies to all requests for IRB Records.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for providing copies of requested paper materials to authorized persons and for directing inquiries from non-authorized individuals to the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee for consideration.
3.2 The HRPP Director or designee is responsible for approving the distribution of IRB records to non-authorized individuals on a case-by-case basis.

3.3 The Director of Compliance is responsible for providing guidance to the NC HRPP Director and the HSC VPR is responsible for providing guidance to the HSC HRPP Director in the determination of approving distribution of IRB records to non-authorized individuals.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115
45 CFR 46.115

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 304, Documentation, Document and Data Management.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The IRB Administrator or designee processes requests for IRB records from the principal investigator, co-investigator, or research project coordinator in a timely fashion.

7.2 The IRB Administrator notifies the HRPP Director if a request involves copying that will require a significant amount of time to complete (pull file, get document, copy document, re-file, provide to requester) or access the IRB record in the IRB’s electronic information system and print. If copying or printing requires a significant amount of time, the HRPP Director will assign the task to an available IRB staff member.

7.3 The IRB Administrator notifies the HRPP Director if multiple requests are made by the investigator, co-investigator, or research project coordinator for any particular research project.

7.4 No request for IRB records by a non-authorized individual shall be fulfilled until approval for the access has been granted by the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee.

7.5 The HRPP Director reviews, on a case-by-case basis, all requests for IRB records from any non-authorized individual and either approves or denies the distribution of IRB records.

7.6 The NC HRPP Director shall consult with the Director of Compliance and the HSC HRPP Director shall consult with the HSC VPR, and/or Office of Legal Counsel or the Open Records Office for guidance as necessary.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

This SOP addresses the reporting requirements of the IRB to regulatory agencies when serious or continuing non-compliance, unanticipated problems involving risks to participants or others, or suspension/termination of IRB approval occurs. Noncompliance, unanticipated problems, and suspension/termination are described in detail in SOP 903: Non-compliance/Scholarly Misconduct; SOP 407: Protocol Deviations and Unanticipated Problems; and SOP 411: Suspension or Termination of IRB Approval.

Specific Policies

1.1 Notification

1.1.1 The HRPP Director shall be notified by IRB staff when serious or continuing non-compliance, unanticipated problems involving risks to participants or others, or suspension/termination of IRB approval occurs.

The HRPP Director shall notify, at a minimum, the Director of Compliance, the Senior Vice President and Provost or designee of the applicable campus, the Health Sciences Center (HSC) Vice President for Research (for events involving HSC), the University Controller, ORA/ORS and Legal Counsel. The HRPP Director shall also notify OHRP, FDA and/or sponsors/, each as applicable. The HRPP Director is responsible for distributing the written communication to the appropriate Senior Vice President and Provost or designee prior to distribution to any outside agency.

Maximum time from the recognition of a reportable event and reporting the event to the appropriate external authorities is generally thirty (30) University business days.

When research is not covered by DHHS regulations, reports of unanticipated problems involving risks to participants or others are not reported to OHRP.

When research is not covered by FDA regulations, reports of unanticipated problems involving risks to participants or others are not to be reported to FDA.

1.1.2 For reporting requirements of non-compliance, unanticipated problems involving risks to participants or others, unanticipated serious adverse events, and suspension/termination of IRB approval in VA research projects, see 603A: Veterans Affairs Medical Center.

1.1.3 Any determinations of unanticipated problems involving risk to participants or others, serious or continuing noncompliance, or suspension or termination of Department of Defense(DoD)-supported research must be promptly (within 30 University business days) reported to the DoD human research protection officer.

1.2 Contents of the Letter/Report

The HRPP Director shall include in the written communication details regarding how the event was discovered, the IRB or IRB Chair or IRB designee response to the event, the investigator response to the event, and the IRB plan for monitoring the outcome of the event.
1.3 Approval of the Letter/Report

The HRPP Director or designee shall draft the letter/report regarding serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and suspension/termination of IRB approval. The HRPP Director may consult with the Director of Compliance, appropriate VPR, Office of Legal Counsel and the appropriate IRB chair for guidance in preparing the letter/report.

2. SCOPE

This SOP refers to reporting to outside agencies/entities only. For internal communication procedures, consult SOP 903: Non-Compliance/Scholarly Misconduct; SOP 407: Protocol Deviations and Unanticipated Problems; and SOP 411: Suspension or Termination of IRB Approval.

3. RESPONSIBILITY

3.1 The HRPP Director or designee is responsible for drafting letters to external agencies as described in Section 1.1 above in instances involving serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and suspension/termination of IRB approval.

3.2 The Director of Compliance for NC issues and the HSC VPR for HSC issues, and IRB staff are responsible for notifying the IRB Chair or IRB designee regarding alleged serious or continuing non-compliance and/or unanticipated problems involving risks to participants or others that involve human participant research.

3.3 The IRB Chair or IRB designee is responsible for reporting to the convened IRB any suspension/termination of IRB approval.

3.4 The Investigator is responsible for notifying the IRB of unanticipated problems involving risks to participants or others, maintaining accurate documentation, and investigating and following up all possibly related serious and unexpected harm to participants, per SOP 407: Protocol Deviations and Unanticipated Problems.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103
21 CFR 56.108

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 407: Protocol Deviations and Unanticipated Problems
SOP 411: Suspension or Termination of IRB Approval
SOP 603A: Veterans Affairs Health Care System
SOP 903: Non-compliance/Scholarly Misconduct

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 When the IRB makes a determination of serious or continuing non-compliance, unanticipated problem involving risks to participants or others, and/or when the IRB suspends or terminates IRB approval, IRB staff immediately notify the HRPP Director.
7.2 The HRPP Director is responsible for distributing the written communication to the Senior Vice President and Provost or designee, prior to distribution to any outside agency. The HRPP Director is responsible for drafting and distributing follow-up communication with applicable federal agencies and the Institutional Official, as needed.

7.3 The HRPP Director drafts written communication within 30 University business days to be distributed to applicable federal and institutional officials, including, but not limited to:

- Senior Vice President and Provost
- Organizational Official
- Director of Compliance
- HSC Vice President for Research
- IRB Chair
- OU Legal Counsel
- University Privacy Official
- OHRP, when the research is covered by DHHS regulations
- FDA, when research is FDA-regulated
- Other federal agencies when the research is subject to the authority of those agencies and those agencies require reporting separate from that to OHRP.
- Office of Research Administration/Office of Research Services
- Controller

7.4 The letter shall include the following:

- Investigator name
- IRB number and project title
- Applicable grant number(s)
- Applicable IND/IDE number
- Nature of the event
- IRB or QI Audit findings
- IRB actions and rationale
- Investigator actions and preventative measures
- Plan for continued evaluation

APPROVED BY: _________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 401: RESEARCH EXEMPT FROM FEDERAL REGULATIONS

1. POLICY

All research involving the collection of data about living individuals through intervention or interaction with those living individuals or by collection of those individuals’ private identifiable information during or after their lifetimes shall be reviewed by the IRB. **An investigator may not make the determination of whether a research project is exempt from federal regulations (and therefore from IRB review).** The investigator shall forward all human participant research projects to the IRB and the IRB shall determine if the research project is exempt from the regulations. The IRB Chair or Vice-Chair makes the determination of exemption based on regulatory and University criteria, except as specifically noted below.

When a research project is reviewed under exempt criteria, the IRB reviewer shall take into consideration the level of risk involved as well as ethical concerns that may pose potential harm to a participant. If the IRB reviewer finds that the ethical issues pose more than a minimal risk to the participant but the type of research falls within the exempt criteria, the IRB reviewer shall determine whether the project will be reviewed either as expedited or by the convened IRB.

Research projects cannot be exempt from federal regulations (and therefore IRB review) if:

- The research is FDA-regulated
- The research involves prisoners as participants.

Specific Policies

1.1 Classroom-Based Research Projects Conducted by OU Students

In addition to the federal regulations, the University considers research projects in which the involvement of human participants fall into the following category are exempt from IRB review:

1.1.1 Many OU courses include instruction on research design and methods and feature an experiential learning component requiring data collection from humans. The majority of these projects do not require IRB review because they are limited in scope and sample size, do not collect sensitive information, and are not intended to be publically disseminated as generalizable knowledge.

1.1.2 There are three types of classroom-based research projects that have an elevated level of risk and require IRB review to determine they if are human research. These include:

1. Projects that include deception or that may elicit a strong emotional response from the participant and require referrals to a mental health professional.
2. Projects that include a physical testing procedure, such as large volume blood draws or exposure to radiation.
3. Projects that gather data from protected or special populations such as children, cognitively impaired persons, prisoners, or the elderly.

1.2 Exempt Research Project Criteria

**NOTE: Research projects that the IRB determined to be exempt prior to January 21, 2019, under the pre-2018 Common Rule will continue to be subject to the pre-2018 regulations until closure. Please refer to the pre-2018 Common Rule for the applicable federal regulations.**
exemption categories. New research projects reviewed for an exemption determination on or after January 21, 2019, are subject to the 2018 Common Rule exemption categories listed below.

Projects subject to the 2018 Common Rule in which the involvement of human participants will be in one or more of the following categories may be exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings and that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes:
   a. Research on regular and special education instructional strategies.
   b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:
   a. Information obtained is recorded in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
   b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation. (NOTE: The Department of Veterans Affairs (VA) also includes loss of insurability in this category); OR
   c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by 45 CFR46.111(a)(7).

Additionally, the research must meet the following:

- If the research involves children as participants, the procedures do not involve survey procedures, interview procedures, or observation of public behavior where the investigators participate in the activities being observed.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   a. The information is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; OR
   b. Any disclosure of the human participants’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to
the participants’ financial standing, employability, educational advancement, or reputation; OR

c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR§46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the participants, and give investigator no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having participants plan an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;

b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human participants cannot be readily ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;

c. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA, 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); OR

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
5. Research and demonstration projects that are conducted by or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   a. Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

   a. If wholesome foods without additives are consumed, or

   b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1.2 Exempt Research Project Review

Protection of participants in exempt research includes determining that:

- the research involves no more than minimal risk to participants
- selection of participants is equitable
- if there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
- if there are interactions with participants, there will be a consent process that will disclose such information as:
  - that the activity involves research
  - a description of the procedures
  - that participation is voluntary
  - name and contact information for the investigator
- there are adequate provisions to maintain the privacy interests of participants
The IRB Chair, Vice-Chair, or IRB designee shall review research projects meeting exempt criteria; these projects do not require convened IRB review. The IRB Chair or Vice-Chair shall document the appropriate exempt criteria in the research project file. The IRB staff will send written documentation to the investigator indicating the project meets exempt criteria and no additional action is required by the IRB.

The investigator is responsible for notifying the IRB of any proposed changes to the research. Investigators requesting approval of revisions to previously approved research projects must submit a protocol modification for approval prior to implementation. For specific details, see SOP 405: Modifications.

The investigator is responsible for notifying the IRB of the completion of the research project. For specific details, see SOP 408: Research Project Completion.

2. SCOPE
This SOP applies to investigator requests to the IRB for exemption determinations.

3. RESPONSIBILITY
The IRB Chair or IRB designee is responsible for the review of exemption requests and making exempt determinations.

4. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46.101, 104
21 CFR 56.104, 105
Pre-2018 Common Rule 45 CFR 46.101

5. REFERENCES TO OTHER APPLICABLE SOPS
SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 405: Modifications
SOP 408: Research Project Completion
SOP 501: Special Populations

6. ATTACHMENTS
Reviewer Checklist (HSC)
Reviewer Checklist (NC)

7. PROCESS OVERVIEW
7.1 Exempt Review / Determination Procedure
7.1.1 IRB Staff makes sure all documents are reviewed for submission, per SOP 301: Research Submission Requirements.
7.1.2 The IRB Administrator assigns to the IRB Chair or IRB designee the item to be reviewed. The IRB Chair is provided a Reviewer Checklist in the IRB's electronic information system to conduct the review.

7.1.3 Upon initial review of the research project, the IRB Chair may request verification and/or additional Information from the investigator in order to determine whether exemption is appropriate. The IRB will communicate this request to the investigator.

7.1.4 If the research project meets exempt criteria as described in Section 1.1 above, the IRB Chair will approve, indicate the exempt criteria number, and forward the research project to the IRB Administrator.

7.1.5 If the research project fails to meet the criteria for exemption, the IRB Chair will determine whether the project requires approval under expedited criteria as referenced in SOP 402: Expedited Review, or by convened IRB review.

7.1.6 The IRB Administrator will record the date of the exempt determination and category of exemption in the IRB’s electronic information system, generate the approval letter, and forward the approval letter to the investigator.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 402: EXPEDITED REVIEW

1. POLICY

The categories of human research that may be reviewed by the IRB Chair or IRB designee through an expedited review process include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures in one or more of the specific categories listed in the regulations at 45 CFR 46.110 and 21 CFR 56.110.

The criteria for approval using the expedited procedure are the same as those for review by a convened IRB found in SOP 403; Initial Review-Criteria for IRB Approval. The IRB Chair or IRB designee cannot disapprove an item submitted for expedited review. The item must be presented to the convened IRB for a determination.

Specific Policies

1.1 Research Categories Eligible for Expedited Review

The following human research categories are eligible for expedited review:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period, and collection may not occur more frequently than 2 times per week; or
   b) From other adults and children, considering the age, weight, and health of the subjects; the collection procedure; the amount of blood to be collected; and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.

3) Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples include:
   a) hair and nail clippings in a non-disfiguring manner
   b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c) permanent teeth if routine patient care indicates a need for extraction
   d) excreta and external secretions (including sweat)
e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
f) placenta removed at delivery
g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
j) sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples include:
   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy
   b) weighing or testing sensory acuity
   c) magnetic resonance imaging (MRI)
   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate, given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

   NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

   NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.
8) Continuing review of research previously approved by the convened IRB as follows:
   a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b) where no subjects have been enrolled and no additional risks have been identified; or
   c) where the remaining research activities are limited to data analysis.

9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories of research two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1.2 Definition of Minimal Risk

Minimal risk is defined as when “…the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests…” 45 CFR 46.102 (i) and 21 CFR 56.102 (i).

1.3 Expedited Review of Human Research Involving Prisoners

Expedited review procedures are not recommended for research involving prisoners. However, if the IRB chooses to use the expedited review procedure for research involving prisoners, the prisoner representative of the IRB shall be one of the designated IRB reviewers.

For studies supported by Department of Defense, expedited review procedures are prohibited for research involving prisoners.

SOP 501-Special Populations, includes additional guidance for these kinds of research projects.

1.4 Cautions

A. Activities listed in Section 1.1 are not deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review process when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

B. The expedited review process may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to the participants’ financial standing, employability, insurability, reputation; or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Furthermore, the expedited review process may not be used for classified research involving human participants.

1.5 Authority of the IRB Chair or IRB Designee

When a submission is reviewed via expedited procedures, generally only the IRB Chair or IRB designee reviews the submission. In such cases, the submission is not reviewed by the
convened IRB. However, a submission reviewed via expedited procedures may be reviewed by one or more consultants (in addition to the IRB Chair or IRB designee) on a case-by-case basis.

The IRB Chair or IRB designee may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. Only the convened IRB can disapprove a research project. In the event the IRB Chair or IRB designee believes an expedited review submission may need to be disapproved, he/she shall forward the submission to the convened board for consideration.

### 1.6 Notification of the IRB

When the expedited review process is used, the IRB office shall inform the investigator of the expedited review decision, including the qualifying category for expedited review.

All IRB members are informed of the actions taken by the IRB Chair or IRB designee at the next convened meeting. The meeting agenda reflects those items approved under an expedited review. IRB discussion of the expedited items is generally limited unless there are questions.

### 1.7 Documentation

If the research qualifies for expedited review, the IRB Chair or IRB designee shall document the justification for using the expedited procedure, his/her determination of risk, and actions taken by the reviewer on the reviewer checklist, along with any other findings required by applicable laws, regulations, codes, and guidance to be documented. If research appearing on the list of eligible expedited review categories is greater than minimal risk or if a continuing review of research is conducted for research that otherwise would not require a continuing review, rationale must be documented in the Reviewer Checklist.

The IRB minutes shall include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members raised concerning the research reviewed.

### 1.8 Additional Items That May be Reviewed by the IRB Chair or IRB Designee

Modifications of the human research project that do not materially affect an assessment of the risks and benefits of the research project or substantially change the specific aims/design of the research project are considered minor (or non-substantive) changes and qualify for expedited review. Examples of additional items appropriate for expedited review:

- Board requested changes that require simple concurrence.
- Minor modifications as described in SOP 405: Modifications.
- Events reported on the Unanticipated Problem Form that the IRB Chair or IRB designee determines are not unanticipated problems involving risks to participants or others.
- Miscellaneous items such as correspondence from the sponsor or investigator.
- IRB minutes contingently approved by the convened IRB.
- Changes in Key Study Personnel.

### 2. SCOPE

This SOP applies to all human participant research submitted to the IRB that qualifies for expedited review.
3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for the initial identification of submissions that qualify for expedited review and for forwarding all such submissions to the IRB Chair or IRB designee. Submissions forwarded to the IRB Chair or IRB designee include the same materials that would be reviewed by the convened IRB. The IRB Chair or IRB designee is responsible for making the final determination of eligibility for expedited review and for documenting the expedited category.

3.2 The IRB Chair or IRB designee is responsible for conducting the expedited review.

3.3 The convened IRB is responsible for reviewing research projects initially reviewed under the expedited categories that the IRB Chair or IRB designee recommends for review by the convened IRB in accordance with the non-expedited review process.

3.4 The IRB Administrator is responsible for posting the expedited reviews to the agenda/minutes for presentation and review by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102
21 CFR 56.102
45 CFR 46.110
21 CFR 56.110

OHRP Guidance Document, IRB Guidebook
OHRP Guidance on the Use of Expedited Review Procedures, August 11, 2003

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 405: Modifications
SOP 407: Protocol Deviations and Unanticipated Problems
SOP 501: Special Populations

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 The IRB Staff confirms all documents are reviewed for submission per SOP 301: Research Submission Requirements.

7.2 The IRB Administrator assigns to the IRB Chair or IRB designee the submission to be reviewed.

7.3 The IRB Chair or IRB designee determines the eligibility for expedited review according to the Research Categories listed in Section 1.1 above. The IRB Chair or IRB designee considers the methods used to conduct the research, recruitment practices, participant population,
confidentiality of data, involvement and training of the research staff, and feasibility of the research project when considering whether a research project is minimal risk.

7.4 The IRB Chair or IRB designee documents in the IRB’s electronic information system minor revisions or requests for additional information. The IRB Administrator communicates the requests for information or revisions to the investigator. When received, the IRB Administrator forwards the revisions to the IRB Chair or IRB designee for approval.

7.5 When approval is granted, the IRB Chair or IRB designee documents in the IRB’s electronic information system the determination of risk, expedited category, and if applicable, rationale for a determination that research appearing on the list of eligible expedited review categories is greater than minimal risk. The IRB Administrator posts the expedited review approval to the next appropriate IRB agenda and generates an approval letter for the investigator.

7.6 For other submissions that qualify for expedited review (continuing reviews as described in 1.1(8), final closure reports, modifications, miscellaneous items), the IRB Chair or IRB designee documents in the IRB’s electronic information system minor revisions or requests for information, or if approved, indicates approval. If applicable, the IRB Chair or IRB designee also documents the rationale for conducting a continuing review of research that would otherwise not require continuing review. The IRB Administrator then posts the expedited review approval to the next IRB agenda and generates an approval letter for the investigator.

7.7 If the submission entails more than minimal risk, the IRB Chair or IRB designee documents in the IRB’s electronic information system that the submission should be reviewed by the convened IRB review. The IRB Administrator posts the item to the next appropriate IRB agenda.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

All research projects that include human participants must meet the criteria specified in Section 1.1 below. These criteria are based on the principles of respect for persons, beneficence, and justice, as discussed in the Belmont Report. In addition, certain other criteria that are unique to the University of Oklahoma may apply and must be met when applicable.

No investigator has a right to conduct research within the University. Rather, it is a privilege granted by society as a whole and the Board of Regents of the University of Oklahoma in particular.

The IRB shall evaluate each project on an individual basis in order to assess whether the investigator is providing adequate resources to protect the participant. Such resources may include research staff, social support services, counseling, ancillary care, equipment, and training provided by the investigator to external or internal entities involved in the research project.

This evaluation shall be based on the investigator’s initial IRB submission, which includes the protocol, outside IRB approval letters, letters of support, advertisements, and all other supporting documents. The IRB shall consult the investigator for additional information regarding necessary services.

The IRB will systematically review the IRB submission, research protocol, consent document, and the HIPAA documents that address the proposed arrangement for protecting privacy and confidentiality of research participants and their information during and after the conduct of the research.

The IRB will also systematically review the IRB submission, research protocol, consent documents, and the HIPAA documents that address the proposed arrangement for storage of identifiable data during and after the conclusion of the research project.

Specific Policies

1.1 Minimal Criteria for Approval of Research

In order for a human research project to be approved, the IRB must find that:

A. Risks to participants are minimized:
   - By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
   - Whenever appropriate, by using procedures already being performed by or on the participants for diagnostic or treatment purposes.

B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may be expected to result.

   In evaluating risks and benefits, the IRB shall consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research).

C. Selection of participants is equitable:
The IRB shall take into account the purpose(s) of the research, the setting in which the research will be conducted, and the inclusion/exclusion criteria so that fair and equitable burdens and benefits are maximized. The IRB shall evaluate the recruitment and enrollment practices and the amount and timing of any payments to participants. The IRB should also be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

D. The investigator will obtain informed consent/assent from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, state, and federal laws and regulations.

E. Informed consent/assent will be appropriately documented or appropriately waived as required by local, state, and federal laws and regulations.

F. If the protocol is more than minimal risk, the research plan includes adequate provisions for monitoring the data collected to protect participants.

G. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of identifiable data.

H. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, or participants enrolled at international sites, additional safeguards have been included in the research project and in the IRB review process to protect the rights and welfare of these participants.

1.2 Other Criteria

The IRB will review the plan for data and safety monitoring when the protocol is submitted for initial review. The investigator is required to provide a Data and Safety Monitoring Board (DSMB) report at the time of continuing review or as available for studies that are overseen by a DSMB. The IRB may suggest a data safety monitoring plan (DSMP) to the investigator, if applicable, to protect participants.

The IRB shall determine the time period for continuing review of research projects at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. Additional guidelines for Continuing Review can be found in SOP 404: Continuing Review.

For VA Research:

The IRB has the option to require the medical record be flagged to protect the participant's safety by indicating participation in the research project and the source of more information on the research project. Additional guidelines for initial review of research projects involving the VA can be found in SOP 603A: Veterans Affairs Health Care System.

1.3 Reliance on Other IRBs for Review and Approval of Research Conducted at the University of Oklahoma.

For collaborative research projects that involve investigators who are not affiliated with the University of Oklahoma, the IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-wide Assurance agreements (FWAs).
Guidelines for determining the IRB of record can be found in SOP 602J: Use of Single IRB (sIRB) in Multicenter Research.

1.4 Reciprocal Review and Approval of Research Conducted at One of the University of Oklahoma Campuses.

When a human research project involves both University campuses, a reviewing campus shall be designated in accordance with SOP 602G: Determination of Reviewing OU Campus IRB.

1.5 Review of Research Conducted by Persons with University of Oklahoma Appointments at Non-University Facilities.

Human research carried out by persons with University of Oklahoma affiliations impacts the University, even if the research is not conducted at University facilities. Any individual who has a University appointment, whether full- or part-time, salaried or voluntary, staff or faculty, is required to notify the appropriate IRB of his/her plans to conduct human participant research, regardless of location of the research. The IRB Chair or IRB designee shall review such proposed activities and determine whether the rights and safety of the participants have been adequately considered by another IRB. If no IRB review has taken place, or if the IRB Chair or IRB designee has sufficient concerns about the research project, the research shall not proceed until those concerns have been adequately addressed by the IRB Chair or the convened IRB (per SOP 801: Investigator Qualifications and Responsibilities) or review by another IRB has occurred.

1.6 Length of Approval Period

The approval period for research is based on the date of the convened meeting at which the IRB approved the protocol or approved the research with modifications. When continuing review is required by law or regulations, length of IRB approval period is typically one year. However, the IRB may require more frequent reviews.

A. If any of the following are true, the IRB will require review more often than annually:
   - There is a high degree of risk to the participant.
   - The stage of the research is such that many of the risks are unknown.
   - Any other reason an IRB member believes that warrants more frequent review.

B. The IRB will consider review of research more often than annually when any of the following are true:
   - Proposed procedures have not been used in humans.
   - The nature of and any risks posed by the clinical investigation.
   - The degree of uncertainty regarding the risks involved.
   - More than minimal risk to special populations exists, with no prospect of direct benefit.
   - A high likelihood exists that participants will die due to the research procedures.
   - The vulnerability of the participants.
   - The experience of the clinical investigator in conducting clinical research.
• The IRB’s previous experience with the researcher or sponsor (e.g. compliance history, previous problems with the researcher obtaining informed consent, prior complaints from participants about the researcher).
• The projected rate of enrollment.
• Whether the study involves novel therapies.
• Any other reason for which the IRB requests closer monitoring.

1.7 Scientific Review
   The IRB shall evaluate proposed research for scientific and scholarly validity. The scientific/scholarly review is documented on the Reviewer Checklist. The IRB shall evaluate the following:
   • Whether the research uses procedures consistent with sound research design and that do not unnecessarily expose participants to risk.
   • Whether the research is designed to answer the proposed question.
   • The importance of the knowledge reasonably expected to result from the research.

1.8 Multi-Site Management of Research
   Refer to SOP 801: Investigator Qualifications and Responsibilities, Section 1.5, for information regarding multi-site management of research projects.

1.9 Pre-review of Research
   The IRB may elect to conduct a pre-review of research prior to review at the convened meeting. All changes resulting from this pre-review may be reviewed and approved by the convened IRB.

1.10 Transfer of Research
   The investigator must submit human participant research for IRB review and approval when transferring research from another institution to the University. The research submission shall include all the documents reviewed by the original IRB. Note: The research is considered ongoing if the investigator is in the process of data analysis, and this activity requires IRB approval.
   The investigator is responsible for obtaining a memorandum of understanding or other similar agreement from the transferring institution allowing the investigator to remove the data and any source documents from the previous institution and continue the research at OU.

2. SCOPE
   This SOP applies to all IRB staff and IRB members and to researchers submitting protocols to the IRB.

3. RESPONSIBILITY
   3.1 The IRB Administrator is responsible for initial identification of submissions that may qualify for review by the convened IRB. The Administrator will coordinate with the IRB Chair or IRB designee to assign Primary and Secondary reviewers and forward these assignments to those reviewers to complete their reviews.
   3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary
reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer the review to another IRB with Primary and Secondary reviewers with the relevant expertise, or obtain that expertise through a special consultant.

3.3 The IRB Chair or IRB designee and the IRB Administrator are responsible to check each item on the agenda to determine whether a special consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context, or knowledge or experience in working with special populations.

3.4 Primary and Secondary reviewers are responsible to conduct an in-depth review of all materials and present their findings at the convened IRB.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

3.6 The HRPP Education Coordinator is responsible for the initial and continuing education of the IRB members.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111
21 CFR 56.108, 56.111
VHA Directive 1200.05

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 404: Continuing Review
SOP 602G: Determination of Reviewing OU Campus IRB
SOP 602J: Use of Single IRB (sIRB) in Multicenter Research
SOP 603A: Veterans Affairs Health Care System
SOP 801: Investigator Qualifications and Responsibilities

6. ATTACHMENTS

203-A   HSC Reviewer Checklist
203-A-1  NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 The IRB Staff will verify that all necessary documents are received per SOP 301: Research Submission Requirements.

7.2 The IRB staff will conduct pre-review of the submission, assign the appropriate Board, and forward the item to the IRB Administrator for processing. The IRB Administrator will check the new research project submission for accuracy of information and to verify that all required documents are submitted. The staff will conduct an initial assessment of the research project to determine if the project requires review by expedited procedures or a convened IRB and will
either assign the project to the next appropriate agenda or to the IRB Chair or IRB designee for review.

7.3 The IRB Chair or IRB designee will review the content with respect to the risk/benefit analysis, research project design, selection of participants, and the inclusion of required elements in the informed consent according to applicable federal law and regulations, the Belmont Report, and applicable local and state requirements. If the research project requires convened IRB review, the IRB Chair or IRB designee will forward the submission to the IRB Administrator, who will assign the research project to the next appropriate IRB agenda.

7.4 The IRB Chair may require verification of information submitted by an investigator. This information may be obtained from third parties such as the sponsor, other institutions participating in the research, and other IRBs reviewing the research. The IRB Chair or IRB designee will document this verification in the IRB’s electronic information system.

7.5 Prior to the meeting, the IRB Chair will designate the Primary and Secondary reviewers for each submission on the agenda. The IRB Administrator will assign the Primary and Secondary reviewers which is reflected in the agenda.

7.6 The IRB Administrator will provide to IRB members the agenda and previous IRB meeting minutes prior to each convened IRB meeting.

7.7 The IRB Primary and Secondary reviewers will summarize their findings on the reviewer checklists provided in the electronic information system. All IRB members are encouraged to use the IRB’s electronic information system to provide information arising from their review of agenda items. The IRB reviewers will determine whether special considerations exist that may influence the review of a submission and whether evidence exists for third party verification of submitted information or is needed. The IRB reviewers will present a summary of findings and recommendations at the convened IRB meeting. The IRB Administrator will record the conclusions in the IRB meeting minutes.

7.8 All submissions eligible for expedited review shall follow the expedited review process outlined in SOP 402: Expedited Review.

7.9 For DOE research projects, the IRB Chair shall send a letter to the investigator indicating that the research has been approved in accordance with DOE expectations and will be monitored and tracked by the IRB.

APPROVED BY: _______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall conduct continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk to participants. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research requiring continuing review must be reviewed no less than once per year.

For research subject to the 2018 Common Rule:

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances for research not regulated by the FDA:

(1) Research is eligible for expedited review;

(2) Research has progressed to the point that it involves either or both of the following:
   
   (i) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or;
   
   (ii) Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

All research falling into the categories noted above requires submission of an “Administrative Check-In Form” annually.

The IRB systematically reviews the Continuing Review/Final Report submission form, research protocol, consent documents, and the HIPAA forms that address the arrangement for protecting privacy and confidentiality of research participants and their information during the conduct of the research and for storage of identifiable data during and after the conclusion of the research project.

IRB approval may be withdrawn at any time if warranted by the conduct of the research.

Federal regulations authorize the IRB to establish procedures for the concurrent monitoring of research activities involving human participants.

The IRB may revoke approval for the conduct of a research project if it determines that the risks to the participants are unreasonably high; for example, in cases in which there is more than an expected number of adverse events or unexpected serious adverse events; if the investigator and/or research staff have not completed the education requirements; or if there is evidence that the investigator is not conducting the research in compliance with IRB SOPs or University policy.

Such findings may result in more frequent IRB review of the research project to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or in the termination of the research project.

The expiration date of IRB approval is defined as the last date that the research project is approved.

Specific Policies

1.1 Determining Appropriate Interval for Continuing Review

For studies subject to continuing review, the IRB shall conduct continuing review of research projects at intervals appropriate to the degree of risk to participants, which is determined at the initial review. Continuing review shall occur not less than once per year. The review and approval must occur on or before the one-year anniversary of the previous IRB review date,
even though the research activity may not have begun until sometime after IRB granted approval.

Investigators shall submit a Continuing Review/Final Report submission form prior to the expiration of the research project or as specified by the IRB, but at least once per year.

The IRB must receive the Continuing Review/Final Report by the appropriate board-meeting deadline, prior to expiration of the research project. Prior to the expiration date, the IRB’s electronic information system generally provides a 60-day notice of expiration to the investigator; however, it is the investigator’s responsibility to ensure the Continuing Review/Final Report is submitted by the deadline.

1.2 Extensions of Approval Period

There shall be no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date are not granted. If the Continuing Review/Final Report and other supporting documents are not received when required and the Continuing Review/Final Report has not been approved by the IRB, or IRB-requested conditions have not been reviewed and approved by the expiration date, the investigator must stop enrollment and all other research project activities, including but not limited to recruitment, interventions, interactions, and collection of private identifiable data until the Continuing Review/Final Report is reviewed and approved. The IRB shall notify the investigator to stop research project activities and to submit to the IRB Chair a list of participants who could experience harm if research procedures are stopped, along with the investigator’s reasons for that assessment.

If the investigator submits such a list to the IRB Chair and if in the opinion of the IRB Chair (or in the case of VA research, the opinion of the IRB Chair and VA Medical Center Chief of Staff), participants in the research project could suffer a hardship if medical care is discontinued, appropriate medical care may continue beyond the expiration date of the IRB approval for a reasonable period of time as determined by the IRB Chair or IRB designee. For VA research, the IRBs shall report expiration (suspension) of research to the appropriate University administrators, the sponsor, and other agencies as described in SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

The investigator must seek continuing review as long as the research remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions.

The investigator must seek continuing review when the remaining research activities are limited to collection of private identifiable information.

The IRB addresses, on a case-by-case basis, instances where failure to enroll new participants could seriously jeopardize the safety or well-being of an individual.

Prospective research data cannot be collected nor can research-related procedures be performed until the IRB reviews and approves a Continuing Review/Final Report.

1.3 Continuing Review Criteria

1.3.1 When conducting continuing review, the IRB reviewer should start with the working presumption that the research, as previously approved, does satisfy all of the initial review criteria (SOP 403: Initial Review - Criteria for IRB Approval). The IRB reviewer should focus on whether there is any new information provided by the investigator or otherwise available to the IRB that would alter the IRB’s prior determinations, particularly
with respect to the IRB’s prior evaluation of the potential benefits or risks to the participants. The IRB also should assess whether there is any new information that would necessitate revision of the protocol and/or the informed consent or HIPAA documents.

If research does not satisfy all of the criteria for initial review (SOP 403: Initial review – Criteria for IRB Approval) at the time of continuing review, the IRB must require changes that will result in research satisfying these criteria, defer taking action, or disapprove the research.

1.3.2 When conducting continuing review and evaluating whether research continues to satisfy the criteria for IRB approval of research, the IRB should pay particular attention to the following four aspects of the research:

A. Risk assessment and monitoring;
B. Adequacy of the process for obtaining informed consent;
C. Investigator and institutional issues; and
D. Research progress.

1.3.3 If any of the following are true, the IRB shall obtain verification from sources other than the investigators that no material changes have occurred since previous IRB review:

A. The IRB has doubts about the veracity of the information provided by the investigator.
B. The information provided by the investigator is inconsistent with other information known to the IRB, and the inconsistencies are not resolved through communication with the investigator.
C. There was previous serious or continuing non-compliance with continuing review requirements.
D. There is any other reason an IRB member believes warrants such verification.

1.4 Possible Outcomes of Continuing Review

A. As an outcome of continuing review, the IRB may require:
   - that the research be suspended or terminated as per SOP 411: Suspension or Termination of IRB Approval, or
   - that any significant new findings that arise from the continuing review process that might relate to participants’ willingness to continue participation be provided to participants.

B. As an outcome of a continuing review that is not resolved after the IRB approval expiration date, the IRB Chair may administratively inactivate the research project.
   - For HSC, studies not resolved within 60 University business days after expiration of IRB approval may be administratively inactivated by the IRB Chair or IRB designee.
   - For NC, studies not resolved within 7 University business days after expiration of IRB approval may be administratively inactivated by the IRB Chair or IRB designee.
1.5 Expedited Review for Renewal

For Continuing Review studies that qualify for expedited review, the Primary reviewer will receive and review all information that the convened IRB would have received. See SOP 402: Expedited Review.

1.6 Data Monitoring Reports

Investigators acting as sponsors and who hold the IND for the research project have additional reporting requirements to the FDA. The investigator is required to submit an annual report to the FDA and a copy to the IRB. Compliance with this requirement is monitored by the IRB via the continuing review application.

2. SCOPE

This SOP applies to all research submitted to the IRB.

3. RESPONSIBILITY

3.1 Investigators are required to submit a Continuing Review/Final Report before the expiration of the research project or as specified by the IRB, but at least once per year.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer the review to another IRB with primary and secondary reviewers with the relevant expertise or obtain that expertise from a special consultant.

3.3 The IRB Chair or IRB designee and the IRB Administrator are responsible to check each item on the agenda to determine whether a special consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context or knowledge, or experience in working with special populations.

3.4 The primary and secondary reviewers are responsible to conduct an in-depth review of all materials.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

3.6 The HRPP Director is responsible for establishing and implementing processes for making research renewal decisions.

3.7 The IRB is responsible for timely and thorough review of the Continuing Review/Final Report, communicating to the investigator any needed changes, and taking action prior to the approval expiration date.

3.8 If a participant has been enrolled since previous IRB review, the investigator is responsible for submitting a copy of the last-signed consent and HIPAA documents, as applicable, with the name of the participant redacted at the time of continuing review.

3.9 The IRB is responsible to verify that the correct consent documents are being utilized by the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108,111
5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 301: Research Submission Requirements
SOP 308: Reporting to Regulatory Agencies and Institutional Officials
SOP 402: Expedited Review
SOP 403: Initial Review – Criteria for IRB Approval
SOP 411: Suspension or Termination of IRB Approval

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 The IRB’s electronic information system will generally notify investigators to submit their Continuing Review/Final Report. However, it is the investigator’s responsibility to ensure the Continuing Review/Final Report is submitted by the deadline.

7.2 Upon submission of the Continuing Review/Final Report by the investigator, the IRB staff will verify that all necessary documents are received per SOP 301: Research Submission Requirements.

7.3 The IRB will conduct continuing review of research at intervals appropriate to the degree of risk to the participant, but not less than once per year. The review and approval must occur on or before the one-year anniversary date of the previous IRB review date.

7.4 At the time of approval, the IRB will give the research project an approved-through date that is entered in the IRB’s electronic information system. The approval period is determined at initial review and depends on the level of risk.

The IRB must receive the Continuing Review/Final Report by the appropriate board meeting deadline, prior to expiration of the research project. Prior to the expiration date, the IRB’s electronic information system provides notice within 60 University business days to the investigator.

7.5 Continuing review reports from the IRB’s electronic information system are generated based on the approved expiration date. The report lists the continuing reviews due by the month of expiration.

7.6 Federal regulations do not allow for a grace period or extension of the approval period. For studies subject to continuing review, if the Continuing Review/Final Report is not reviewed and approved by the end of the approval period, the investigator may not continue enrollment or
other research activities. The investigator is responsible for notifying the IRB in writing if there is a need to continue medical treatment of current participants for their safety and well-being.

7.7 As an outcome of a continuing review that is not resolved after the expiration date, the IRB Chair or IRB designee may administratively inactivate the research project.

For HSC, studies not resolved within 60 University business days after expiration may be administratively inactivated by the IRB Chair or IRB designee.

For NC, studies not resolved within 7 University business days after expiration may be administratively inactivated by the IRB Chair or IRB designee.

7.8 All expedited Continuing Review/Final Reports are given to the IRB Chair or IRB designee for review. The Continuing Review/Final Report for the convened IRB is added to the next appropriate meeting agenda for review.

7.9 IRB members will have access to all documents included with the Continuing Review/Final Report and study file, such as the Continuing Review/Final Report, protocol, consent documents, Research Authorization forms, and all documents as outlined in the Continuing Review/Final Report.

7.10 Review by the Convened IRB: The convened IRB will review all documents at the meeting and make recommendations for approval, contingent approval, deferral, or disapproval as follows:

A. Approval: If the IRB approves the Continuing Review/Final Report without revisions, the IRB Administrator will generate an approval letter for signature by the IRB Chair.

B. Contingent Approval: If the IRB determines that minor changes are required, the IRB Administrator will generate a Contingent Approval outcome letter notifying the investigator of the requested changes. When the investigator returns the changes, the IRB Administrator will review the changes for completeness. The IRB Administrator will note any deficiencies or discrepancies for the IRB Chair and forward the continuing review process response to the IRB Chair for review. If the Board’s requested changes are not received before the research approval expiration date, the IRB Administrator will generate a Notice of Expiration letter.

C. Deferral: The IRB may determine that substantive clarifications or modifications regarding the protocol or informed consent documents are required. In these cases, the IRB will defer approval, pending subsequent review by the convened IRB of responsive material. The IRB Chair will contact the investigator concerning the details of the deferral and drafts the deferral letter to be sent.

Once the investigator returns the changes, the IRB Administrator will place the Continuing Review/Final Report on the next appropriate meeting agenda. The IRB Administrator will evaluate whether there will be a lapse in IRB approval. If there will be a lapse in IRB approval, the IRB Administrator will send the Notice of Expiration letter to the investigator.

D. Disapproval: The IRB may identify serious concerns for participant safety or investigator compliance. In these cases, the IRB will disapprove the research. The IRB Chair will draft the disapproval letter, and the IRB Administrator will generate and send the disapproval letter to the investigator. The process for reporting in accordance with SOP 308: Reporting to Regulatory Officials, will be instituted.

7.11 Expedited Review of Continuing Reviews: The IRB Chair or IRB designee will review all continuing review documents received and either approve or contingently approve the Continuing Review/Final Report. The IRB Chair or IRB designee may also determine that the
Continuing Review/Final Report should be presented for review by the convened IRB. The IRB Chair or IRB designee may not disapprove a Continuing Review/Final Report.

A. **Approval:** If the IRB Chair or IRB designee approves the Continuing Review/Final Report without changes, the IRB Administrator will generate and sends an approval letter.

B. **Contingent Approval:** If the IRB Chair or IRB designee determines that minor changes are required, the IRB Administrator will notify the investigator of the contingent approval and the revisions required by the IRB Chair or IRB designee. If the IRB Chair or IRB designee determines that the convened Board should review the Continuing Review/Final Report, the IRB Administrator will assign the item to the next appropriate meeting agenda.

APPROVED BY: _________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 405: MODIFICATIONS

1. POLICY

Modifications to a previously approved research project, such as modifications to the inclusion/exclusion criteria, research project population, research project procedures, or consent process, requested by the investigator or sponsor must be approved by the IRB before the modifications are implemented. Such modifications are also known as amendments, protocol modifications, revisions, or changes.

Specific Policies

1.1 General Provisions

Modifications in approved research during the period for which approval has been given may not be initiated without prior IRB approval, except where necessary to eliminate apparent immediate hazards to participants.

Modifications to approved research that are initiated without IRB approval in order to eliminate apparent immediate hazards to the participant must be promptly (no longer than 30 calendar days) reported to the IRB by submitting the campus-appropriate report form. The IRB shall review said modifications to determine whether each change was consistent with ensuring the participants’ continued welfare.

Investigators shall submit requests for modifications to the IRB. Upon receipt of the submission, the IRB Chair or IRB designee shall determine if the modification meets the criteria for minimal risk. If the modification represents more than a minimal risk to participants, it must be reviewed at a convened meeting of the appropriate IRB. Minor modifications involving no more than minimal risk to the participants may be reviewed in accordance with the expedited review process (SOP 402: Expedited Review).

The investigator must submit modification requests by completing an IRB Modification/Notification Form with a clear description of the requested changes. The investigator shall include documentation with the completed form indicating the requested modification(s) or for any minor modifications that involve more than minimal risk.

In evaluating the IRB Modification/Notification Form and the documentation, the IRB Chair or IRB designee shall consider expedited review or review by the convened IRB. Expedited review shall be utilized only for minor modifications involving minimal risk. Review by the convened IRB is required for any major, controversial, or questionable modification(s) or for any minor modifications that involve more than minimal risk.

The criteria for approval of modifications to previously approved research are the same as those for initial review (SOP 403: Initial Review - Criteria for IRB Approval).

The Primary and Secondary reviewer model is used for review of modifications to currently approved research projects that require convened IRB review (SOP 203: Duties of IRB Members).

The IRB may require that any significant new findings that arise from the modification and that might relate to participants’ willingness to continue participation be provided to participants.
1.2 Definitions of Minor Modifications

Minor modifications to previously approved research are those that meet all of the following criteria:

- Involve the addition of no more than minimal risk to participants.
- All added procedures are eligible for initial review using the expedited procedure, if considered independently of the research.

Examples of minor modifications include, but are not limited to:

- Addition of research activities that would be considered exempt or expedited, if considered independently from the main research protocol;
- Minor increases or decreases in the number of participants;
- Changes in the compensation to participants;
- Revisions to improve the clarity of statements in the informed consent documents, research privacy forms, or protocol to correct typographical errors, provided that such changes do not alter the content or intent of the statement;
- Changes in Key Study Personnel.

1.3 Other Criteria

The IRB may require verification of information submitted by an investigator to provide necessary protection to participants, when deemed appropriate by the IRB.

2. SCOPE

This SOP applies to all HRPP and IRB staff, investigators, research staff, and IRB members.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for initial identification of submissions that may qualify for review by the convened IRB. The IRB Administrator coordinates with the IRB Chair or IRB designee to assign Primary and Secondary reviewers and forward these assignments to those reviewers providing or obtaining the tools and resources the IRB members need to complete its research reviews.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer the review to another IRB with Primary and Secondary Reviewers with the relevant expertise or obtain consultation for that expertise.

3.3 The IRB Chair or IRB designee and the IRB Administrator are responsible to check each item on the agenda to determine whether a consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context, or knowledge or experience in working with special populations.

3.4 Primary and Secondary reviewers are responsible to conduct an in-depth review of all materials and present their findings at the convened IRB.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.
3.6 The HRPP Education Coordinator is responsible for the initial and continuing education of the IRB members.

4. APPLICABLE REGULATIONS AND GUIDELINES
   45 CFR 46.109
   21 CFR 56.109

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 203: Duties of IRB Members
   SOP 301: Research Submission Requirements
   SOP 402: Expedited Review
   SOP 403: Initial Review - Criteria for IRB Approval

6. ATTACHMENTS
   203-A   HSC Reviewer Checklist
   203-A-1 NC Reviewer Checklist
   301-C   Modification/Notification Form

7. PROCESS OVERVIEW
   7.1 The IRB staff verifies all necessary documents are received per SOP 301: Research Submission Requirements.
   7.2 The IRB staff conducts pre-review of the submission and forwards the item to the IRB Administrator for processing. The IRB Administrator checks the modification/notification form for accuracy of information and to verify that all required documents are submitted. An initial assessment of the modification request or notification is conducted to determine if it requires review by expedited procedures or a convened IRB. The submission is either assigned to the next appropriate IRB agenda or assigned to the IRB Chair or IRB designee for review.
   7.3 The IRB Chair or IRB designee reviews the content with respect to the risk/benefit analysis, research project design, selection of participants, and the inclusion of required elements in the informed consent document according to applicable federal law and regulations, the Belmont Report, and applicable local and state requirements. If the submission requires convened IRB review, the IRB Chair or IRB designee returns the submission to the IRB Administrator, who assigns the submission to the next appropriate IRB agenda.
   7.4 The IRB Chair or IRB designee may require verification of information submitted by an investigator. This information may be obtained from third parties such as the sponsor, other institutions participating in the research, and other IRBs reviewing the research. The IRB Chair or IRB designee will document this verification in the IRB’s electronic information system.
   7.5 Prior to the meeting, the IRB Chair designates the Primary and Secondary reviewers for each submission on the agenda. The IRB Administrator assigns the Primary and Secondary reviewers who are reflected in the agenda.
   7.6 The IRB Administrator provides to IRB members the agenda and previous IRB meeting minutes prior to each convened IRB meeting.
   7.7 The IRB Primary and Secondary reviewers summarize their findings on the reviewer checklists provided in the IRB’s electronic information system. All IRB members are encouraged to provide information from their review of agenda items using the IRB’s electronic information system. The
IRB reviewers determine whether special considerations exist that may influence the review of the submission and whether evidence exists or is needed for third party verification of submitted information. The IRB reviewers present a summary of findings and recommendations at the convened IRB meeting. The IRB Administrator records the conclusions in the IRB meeting minutes.

7.8 All submissions eligible for expedited review shall follow the expedited review process outlined in SOP 402: Expedited Review.

APPROVED BY: ___________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 406: DETERMINATION OF HUMAN RESEARCH AND
PROTOCOL DEVELOPMENT

1. POLICY

The IRB shall evaluate research projects initiated by Key Study Personnel to determine whether the projects involve the use of human participants or “Experimental Subjects” (Department of Defense-funded projects) and/or qualify as research. The investigator shall submit the Determination of Human Research Worksheet (DHRW) to the IRB. The IRB Chair or IRB designee shall review the DHRW to determine whether human participants are involved and/or whether the project constitutes research.

Specific Policies

1.1 Human Participant Research Determination

If it is determined that the project involves human participants and the investigator desires to proceed, the research project shall be submitted to the IRB per SOP 301: Research Submission Requirements, and reviewed by the IRB per applicable SOP 401: Research Exempt from IRB Review; 402: Expedited Review; or 403: Initial Review – Criteria for IRB Approval.

The project shall be concurrently reviewed for compliance with the Health Insurance Portability and Accountability Act (HIPAA) per SOP 1001: HIPAA Privacy Rule.

1.2 Not-Human Participant Research Determination

If it is determined that human participant research is not proposed, the IRB, acting as the Privacy Board, shall review the research project for HIPAA compliance, per SOP 1001: HIPAA Privacy Rule. If the project is HIPAA-compliant, the investigator may initiate the project without further involvement of the IRB or Privacy Board. The usual types of activities that may be initiated without prior involvement of the IRB include:

A. Classroom evaluation activities when assessment involves regular classroom activities and the results of the evaluation process are intended to be used for the sole purpose of enhancing teaching practices of the instructor.

B. Quality improvement activities designed to enhance functionality of a department or campus program provided that results are not intended to be shared outside of the University.

C. Program evaluations.

D. Public health practice surveillance activities.

1.3 Research vs. Non-Research Determination

The investigator shall complete the DHRW and submit it to the IRB for a determination of whether the project constitutes human research. Projects that meet the definition of human research must be submitted, per SOP 301: Research Submission Requirements, to the IRB and prospectively reviewed by the IRB per applicable SOP 401: Research Exempt from IRB Review; 402: Expedited Review; or 403: Initial Review – Criteria for Approval.

There are limited types of non-research activities that may be initiated without prior submission to the IRB. (These activities may still be subject to HIPAA, however. The investigator is responsible for compliance.) These activities include:
A. Requirements of a course that are being conducted only for the purpose of learning research skills.

B. Case studies involving no more than two (2) separate cases, provided that the case studies are void of private identifiable information. This activity is not to be confused with thesis or dissertation projects, which do require prospective IRB review and approval.

C. Training exercises wherein humans are taught job/position-related responsibilities.

D. Public health practice surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority.
   i. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, disease outbreaks, or conditions of public health importance.
   ii. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health.

E. Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

F. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

G. Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

1.4 Other Applicable Standards for Not-Human Participant or Non-Research Projects

All projects conducted at the University shall be subject to other standards of review as determined by University policy and/or procedure.

All projects conducted at the University shall be subject to the same ethical standards as IRB-approved projects.

Any change to a research project that was initially deemed not-human participant or non-research shall be resubmitted to the IRB for review to determine whether the change alters the original determination of not-human participant or non-research.

1.5 Protocol Development (Norman Campus Only)

Investigators may have received external grants that include funding for the development of the research protocol and data collection instruments. In order to receive these funds from the Office of Research Services, the investigator must complete and submit the Norman Campus Protocol Development form in the IRB’s electronic information system and upload relevant supporting documents.

In these instances, protocols must be submitted to the IRB with as much information as is available. The protocols must include assurances that additional information will be submitted when developed and, in the case of training grants, that all trainees will submit individual protocols if human participants are to be used. Grant Proposals lacking definite plans for research participant involvement may include the following:
• Research training programs or grants in which the activities involving human participants remain to be selected or designed.

• Research, pilot, or developmental projects in which the involvement of human participants depends on such factors as the completion of instruments or prior studies.

The IRB will issue a protocol development letter that can be given to the investigator in order to have external funding released from ORS for research activities. After the protocol has been developed and the investigator is ready to begin human research activities, the investigator must submit an application for a new research project using the IRB’s electronic information system (See SOP 403: Initial Review – Criteria for IRB Approval).

2. SCOPE

This SOP applies to all on-going and planned human participant research projects at the University.

3. RESPONSIBILITY

3.1 The investigator is responsible for seeking IRB determination as to whether a proposed project meets the definition of research and involves humans as participants and, either by utilizing the DHRW or by contacting the IRB.

3.2 The investigator is responsible for seeking IRB determination as to whether any changes to on-going not-human participant or non-research projects alter the need for additional IRB review.

3.3 The IRB Administrator is responsible for processing submissions in the IRB’s electronic information system, forwarding the submission to the IRB Chair or IRB designee for review, and drafting and sending a determination letter to the investigator.

3.4 The IRB Chair or IRB designee is responsible for determining whether the research project involves humans as participants and whether the project is considered research.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102
21 CFR 50.603
DoD Directive 3216.02

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 1001: Health Insurance Portability and Accountability Act (HIPAA Privacy Rule)
SOP 301: Research Submission Requirements
SOP 304: Documentation and Document Management
SOP 401: Research Exempt from IRB Review
SOP 402: Expedited Review

6. ATTACHMENTS

406-A Determination of Human Research Worksheet
7. PROCESS OVERVIEW

7.1 The investigator will complete the DHRW for the appropriate campus and submit it to the IRB for determination regarding whether the proposed research project involves human participants and/or whether the project meets the definition of research.

Norman Campus: If applicable, the investigator shall complete the Protocol Development Form and submit it to the IRB for approval. The IRB Administrator shall communicate the IRB Chair’s determination to the investigator via the IRB’s electronic information system. The investigator will provide the IRB protocol development approval letter to the ORS.

The IRB Administrator will direct the DHRW to an appropriate IRB Chair or IRB designee for determination.

The IRB Chair will review the submission and indicate his/her determination on the Reviewer Checklist.

The IRB Administrator will communicate the IRB Chair’s determination to the investigator via the IRB’s electronic information system.

Documentation of the submission and determination is maintained in the IRB’s electronic information system (see SOP 304: Documentation, Document and Data Management, for details).

7.2 If the IRB Chair or IRB designee determines that the project does not involve human participants or is not considered research, the IRB Administrator will notify the investigator that the project may be initiated without IRB review.

If the IRB Chair or IRB designee determines that the project involves humans as participants and that the definition of research is met, the IRB Administrator will notify the investigator of this determination and instruct the investigator to complete and submit a Study Application along with applicable supporting documents to the IRB for approval, per SOP 301: Research Submission Requirements.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

Protocol deviations and unanticipated problems may be discovered in a variety of ways, including but not limited to discovery by research staff, IRB Staff, or IRB Reviewers; Quality Improvement (QI)/Evaluation processes; communications with research participants; or communications from related University administrative units.

Major Deviations: Despite the method of discovery, investigators are required to promptly report to the IRB any event that may represent a major protocol deviation and/or unanticipated problem as described below.

Minor Deviations: At the time of Continuing Review, Investigators shall report to the IRB minor protocol deviations and other harms caused to research participants that do not constitute an unanticipated problem.

Specific Policies

1.1 PROTOCOL DEVIATIONS

1.1.1 Protocol Deviation: A protocol deviation is any change, divergence, or departure from the research study approved by the IRB.

Upon discovery, the Principal Investigator is responsible for reporting major protocol deviations as described in Section 1.1.3 below to the IRB within five (5) University business days using the Protocol Deviation form available on the IRB electronic information system.

1.1.2 Minor Protocol Deviation: A minor protocol deviation is any change, divergence, or departure from the approved research protocol that has not been approved by the IRB and that DOES NOT have a major impact on the participant's rights, safety, or well-being or on the completeness, accuracy, and reliability of the research project data. (Examples include, but are not limited to: study procedure or participant visit conducted out of time frame, blood samples obtained at times close to but not at the time specified in the IRB approved protocol, having participants sign a non-stamped consent document, and not providing the participant with copies of the consent documents.)

Changes or alterations in the conduct of the research project that do not have a major impact on the participant's rights, safety, or well-being, or on the completeness, accuracy, and reliability of the research project data are considered minor protocol deviations.

For studies that require Continuing Review, minor protocol deviations shall be reported to the IRB by the Investigator at the time of Continuing Review. For studies that do not require Continuing Review, the investigator should maintain a log of minor protocol deviations for inspection during site visits and evaluations.

1.1.3 Major Protocol Deviation: Some examples of major protocol deviations are described below. Investigators are encouraged to contact the IRB to determine on a case-by-case basis whether a major protocol violation has occurred. Major protocol deviations falling into the following categories shall be considered Unanticipated Problems that require IRB
review as determined by the IRB Chair, IRB designee or Board:

I. The deviation has harmed or posed a significant or substantive risk of harm to a research participant (this is also an unanticipated problem).

Examples:
- A research participant received the wrong treatment or incorrect dose.
- A research participant met withdrawal criteria during the research project but was not withdrawn.
- A research participant received an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the research project.

Examples:
- A research participant was enrolled but does not meet the protocol's eligibility criteria.
- There was a failure to treat research participants per protocol procedures that specifically relate to primary efficacy outcomes (if it involves patient safety, it meets the first category above).
- There was a change the protocol without prior IRB approval (except where necessary to eliminate an apparent immediate hazard to the participant).
- Inadvertent loss of samples or data.

III. The deviation is a willful or knowing breach of human participants research protection regulations, policies, or procedures on the part of the investigator(s).

Examples:
- Failure to obtain informed consent prior to initiation of research project-related procedures.
- Research or medical records were falsified.
- Tests or procedures were performed beyond the individual's professional scope or privilege status (credentialing).

IV. The deviation involves a serious or continuing noncompliance with federal, state, local, or University human subjects research protection regulations, policies, or procedures.

Examples:
- Work conducted under an expired professional license or certification.
- Failure to follow federal and/or local regulations and intramural research or University policies.
- Repeated minor deviations.
V. The deviation is inconsistent with the HRPP’s research, medical, or ethical principles.

Examples:
- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

1.2 Review of Protocol Deviations

The investigator must track all protocol deviations on the Protocol Deviation Summary Report. All major protocol deviations must be submitted to the IRB within five (5) University business days upon discovery in the campus-appropriate report forms.

For studies subject to continuing review, the Protocol Deviation Summary Report must be attached to the Continuing Review Form.

The IRB will review the reported deviations and determine whether the events meet the criteria of an unanticipated problem involving risks to participants or others or resulted from serious or continuing noncompliance.

1.3 Unanticipated Problems Involving Risks to Participants or Others

An unanticipated problem is any incident, experience, or outcome that meets all three of the following criteria: (1) is unanticipated or unexpected; (2) is related or possibly related to the research; and (3) places participants or others at greater risk of harm than previously known or recognized.

Investigators are required to submit to the IRB within five (5) University business days of discovery any unanticipated problems (both internal and external) involving risks to participants or others. This is accomplished by answering the questions within the applicable report form for the investigator’s reviewing campus. If all three criteria are answered “YES,” the event may constitute an unanticipated problem; however, only the convened IRB can make this determination.

If any of the three criteria in the form are not answered “YES,” the investigator must log this event (both internal and external) in the Summary of Participant Harms Report. For studies subject to Continuing Review, this report must be submitted to the IRB at Continuing Review.

There is a high probability that the following problems/events represent some of the types of unanticipated problems involving risks to participants or others:

- Any harm experienced by a participant that in the opinion of the Investigator, is both unexpected and related to the research, regardless of whether the harm was an on-site or off-site adverse event and regardless of whether the harm was a serious or non-serious adverse event.
- Information that indicates a change to the risks or potential benefits of the research. For example:
  - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different from that initially presented to the IRB.
A paper is published from another study that shows that the risks or potential benefits of the research may be different from that initially presented to the IRB.

- A breach of confidentiality of the research project data.
- A change to the protocol made without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Incarceration of a participant who is enrolled in a protocol not approved to enroll prisoners.
- A sponsor-imposed study suspension due to risk to participants.
- A complaint by a participant when the complaint indicates unexpected risks or when it cannot be resolved by the research team.
- A change in FDA labeling or FDA withdrawal from marketing of a drug, device, or biologic used in the research protocol.
- An unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application [including a supplementary plan or application], or any other unanticipated serious problem associated with a device that relates to the rights and welfare of participants).

1.4 Determination of an Unanticipated Problem Involving Risks to Participants or Others

The IRB Chair or IRB designee determines whether the reported problem/event may represent an unanticipated problem involving risks to participants or others or the problem/event resulted from serious or continuing noncompliance.

NOTE: The intended mis-classification of a Serious Adverse Event as an “anticipated” event constitutes serious non-compliance. See SOP 903: Noncompliance/Scholarly Misconduct for more information.

The IRB shall report Unanticipated Problems in accordance with SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

If the IRB Chair or IRB designee determines the problem/event is NOT an unanticipated problem involving risks to participants or others and did not result from serious or continuing noncompliance, the IRB will note the report and will request the Investigator to log this event in the Summary of Participant Harms and submit it to the IRB at Continuing Review.

1.5 Possible Actions Required by the IRB for Protocol Deviations and Unanticipated Problems

The IRB may require additional corrective actions including, but not limited to:

- Requiring the investigator to modify the protocol.
- Modifying the information disclosed during the consent process.
- Providing additional information to past participants.
- Notifying current participants when such information might relate to participants’ willingness to continue to take part in the research.
- Requiring that the current participants re-consent to participation.
• Modifying the continuing review schedule.
• Monitoring the research.
• Monitoring the consent process and documentation.
• Suspending the research.
• Terminating the research.
• Referring to other organizational entities (e.g., VA Research and Development Committee, Radiation Safety Committee).
• Obtaining additional information.

It is within the authority of the IRB to initiate a For-Cause Evaluation or to require IRB Education or QI/Evaluation visits to promote research integrity if the IRB receives an excessive number of reported protocol deviations or unanticipated problems involving risks to participants or others or if the IRB independently suspects investigator noncompliance or improprieties on the part of the investigator and/or research personnel.

Note that the IRB may determine an Unanticipated Problem occurred even though the investigator did not submit a form for determination. Refer to SOP 901: Quality Improvement Program for more information.

1.6 Unanticipated Problems Involving Risks to Participants or Others and Unanticipated Serious Adverse Events in VA Research Projects

For reporting, review, and determination of unanticipated problems involving risks to participants or others and unanticipated serious adverse events in VA research projects, see SOP 603A: Veterans Affairs Health Care System.

2. SCOPE

This SOP applies to all research submitted to the IRB.

3. RESPONSIBILITY

It is the responsibility of the HRPP Director and IRB Chair to review all events submitted as unanticipated problems involving risks to participants or others to determine if the event should be reported in accordance with SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

The IRB Chairs are responsible to review reports of unanticipated problems involving risks to participants and others and protocol deviations and forward them to the convened IRB when appropriate.

The IRB Chair or IRB designee is responsible for selecting one Primary and one Secondary reviewer with the relevant expertise to review protocol deviations and/or unanticipated problems. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtain consultation to obtain that expertise.
Investigators involved in human participant research shall report all protocol deviations, per Section 1.1 of this policy. Investigators involved in human participant research shall report all suspected unanticipated problems involving risks to participants or others to the IRB, per Section 1.3 of this policy.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103,109
21 CFR 56.108,109
OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects and Others and Adverse Events (Jan. 2007)

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 308: Reporting to Regulatory Agencies and Institutional Officials
SOP 901: Quality Improvement Program
SOP 903: Noncompliance/Scholarly Misconduct

6. ATTACHMENTS

407-A NC Unanticipated Problem Report
407-B NC Protocol Deviation/Violation Report
407-C HSC Incident Report Form
407-D Summary of Participant Harms
407-E Protocol Deviation Summary Report

7. PROCESS OVERVIEW

The IRB Staff confirms that all documents are reviewed for submission per SOP 301: Research Submission Requirements.

7.1 Review Procedures for Protocol Deviations

If the IRB Chair or IRB designee determines and documents in the reviewer checklist that the deviation is NOT an unanticipated problem and the deviation was not a result of serious or continuing noncompliance, the IRB Chair or IRB designee shall note the event in the IRB’s electronic information system. The IRB Administrator will update the IRB’s electronic information system and send an outcome letter to the investigator.

If the IRB Chair or IRB designee determines and documents on the reviewer checklist that the deviation may represent an unanticipated problem involving risks to participants or others or that the deviation resulted from serious or continuing noncompliance, the IRB Administrator shall place the deviation report on the agenda of the next available IRB meeting for review.

The IRB Reviewer will present the protocol deviation to the convened IRB for discussion and possible action(s). See Section 1.5 of this policy for possible IRB actions.

Following review, the IRB Administrator will notify the investigator of the IRB’s action via the IRB’s electronic information system.
7.2 Review Procedures for Unanticipated Problems Involving Risks to Participants or Others:

If the IRB Chair or IRB designee determines and documents in the reviewer checklist that the event is NOT an unanticipated problem and the event was not a result of serious or continuing noncompliance, the IRB Chair or IRB designee shall note the event in the IRB’s electronic information system. The IRB Administrator will notify the investigator of the IRB’s action via the IRB electronic information system.

If the IRB Chair or IRB designee determines and documents on the reviewer checklist that the problem/event may represent an unanticipated problem involving risks to participants or others or the problem/event resulted from serious or continuing noncompliance, the IRB Administrator will place the event on the agenda of the next available convened IRB meeting for review.

The IRB Reviewer will present the unanticipated problem to the convened IRB for discussion and IRB action(s). See Section 1.3 of this policy for possible IRB actions.

Following review, the IRB Administrator will notify the investigator of the IRB’s action via the IRB’s electronic information system.

7.3 Reporting Requirements for Unanticipated Problems Involving Risks to Participants or Others, and Protocol Deviations

If the convened IRB determines that an event is an unanticipated problem involving risks to participants or others, the IRB staff will forward a copy of the report and the IRB letter to the Director of HRPP for reporting to regulatory agencies and Institutional Officials per SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

APPROVED BY:_________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 408: RESEARCH PROJECT COMPLETION

1. POLICY

The completion, premature completion, or termination of a research project is a change in activity that must be reported to the IRB. The investigator shall report completion, premature completion, or termination of a research project to the IRB.

Specific Policies

1.1 Determining When a Project is to be Closed

Research projects may be closed when individually identifiable follow-up data are no longer being collected about participants and analysis that could indicate new information has been completed.

1.2 Closure of Studies

The investigator may close a research project by submitting the Continuing Review/Final Report form requesting inactivation or closure. The investigator may close an Exempt research project by submitting an Exempt Study Closure Report form requesting closure.

2. SCOPE

This SOP applies to all human research projects submitted to the IRB.

3. RESPONSIBILITY

The IRB Administrator is responsible for verifying all research project completion documentation is received and reviewed by and presented to the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109
45 CFR 46.103, 46.109

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 401: Research Exempt from Federal Regulations
SOP 402: Expedited Review

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
408-A Exempt Study Closure Report

7. PROCESS OVERVIEW

Upon receipt of the closure documentation submission, IRB Staff will conduct a pre-review to confirm all documents are reviewed for submission, per SOP 301: Research Submission Requirements.

The IRB Administrator will forward the submission to the IRB Chair or IRB designee for review.
7.1 Convened Board and Expedited Research Projects

7.1.1 The investigator will submit the Continuing Review/Final Report to the IRB within 30 University business days after completion or termination of the research project. The IRB Administrator will review the submission for completeness and, if needed, request further information from the investigator to obtain missing data or to clarify any questions that arise. The IRB Administrator will then forward the submission to the IRB Chair or IRB designee for review.

7.1.2 The IRB Chair or IRB designee will review the submission the Continuing Review/Final Report form in accordance with SOP 402: Expedited Review. The IRB Administrator will post the research project closure to the next appropriate IRB agenda and generate a letter to send to the Investigator. The IRB Administrator will then change the research project status to “Inactive-Principal Investigator.”

7.2 Exempt Projects

The Exempt Study Closure Report form will be accepted at any time by the IRB at the time of study closure.

The investigator will submit the Exempt Study Closure Report form. The IRB Administrator will review the submission for completeness and forward the submission to the IRB Chair or IRB designee, who will review it in accordance with SOP 401: Research Exempt from IRB Review. The IRB Administrator will post the research project closure to the next appropriate IRB agenda and generate a letter to send to the investigator. The IRB Administrator will then change the research project status to “Inactive-Principal Investigator.”

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 409: CATEGORIES OF ACTION

1. POLICY

The IRB may approve or disapprove research submissions. Except when the expedited review procedure is used, these actions shall be taken by a vote of the convened IRB. When the expedited review procedure is used, the IRB Chair or IRB designee may approve or contingently approve a submission.

Specific Policies

1.1 Determinations

The IRB will make one of the following determinations as a result of its review of research submitted for initial, modification/notification, or continuing review:

1.1.1 Approval: The IRB approves the research project and accompanying documents as submitted. Participants must not be recruited into the research project until final approval has been issued.

For research reviewed by the convened Board, final approval is effective on the day the research project is approved by the convened IRB, and the approval period is based on the date of the convened meeting at which the IRB approved the submission.

When the expedited review procedure is used, approval is effective on the day the submission is approved by the IRB Chair or IRB designee, and the approval period is based on the date the IRB Chair or IRB designee approved the submission.

For research determined by the IRB to be exempt from regulations, the effective date of the determination is the day the submission is approved by the IRB Chair or IRB designee. There is no expiration date associated with research exempt from regulations.

1.1.2 Contingent Approval: The IRB may stipulate revisions to a research project or accompanying documents, no matter the level of review (convened board or expedited).

1.1.2.1 Convened IRB Review

The stipulations and terms of the approval are voted upon during the IRB meeting.

Specific stipulations are clearly outlined by the IRB, and the IRB informs the investigator of the required revisions and/or requested information via the IRB’s electronic information system. The investigator must provide the IRB with the revised submission materials or information before the IRB will grant final approval. The revised submission can be reviewed by the IRB Chair or IRB designee on behalf of the IRB.

1.1.2.2 Expedited/Exempt Review

When the expedited review procedure is used or when research is determined to be exempt from regulations: The stipulations are from the IRB Chair or IRB designee on behalf of the Board.

An investigator has 60 University business days to respond to the IRB. If the requested information and/or revisions are not received within that time period, the submission may be administratively withdrawn by the IRB.
A. For research reviewed by the convened IRB: The IRB Chair or IRB designee has the authority to review the investigator’s response and revised documents submitted via expedited review unless the IRB requires, or the IRB Chair or IRB designee decides, that the investigator response, revised materials, or information must be reviewed by the convened IRB. Upon satisfactory review of the investigator’s response and revised documentation, the IRB Chair or IRB designee approves the research project on behalf of the IRB. The IRB approval date is the date that the submission was approved by the IRB Chair or IRB designee. However, the expiration date of IRB approval is based on the date of the convened meeting at which the IRB approved the research with modifications.

1.1.3 Deferral (Convened IRB Action): The IRB defers a submission when there are significant questions regarding the submission or when the information provided is inadequate to assess risk/benefit ratio. The deferral and accompanying stipulations are voted upon during the IRB meeting.

The IRB informs the investigator through the IRB’s electronic information system of the IRB’s concerns and requests for additional information. The investigator has the opportunity to respond to the IRB with the revisions or information. The investigator’s response shall be reviewed by the convened IRB. The convened IRB shall reconsider the submission after additional substantive information is received from the investigator.

An investigator has 60 University business days to respond to the IRB. If the requested information is not received within this time period, the submission may be administratively withdrawn by the IRB.

1.1.4 Disapproval: The IRB disapproves submissions that fail to meet one or more criteria for approval of human participant research. Disapproval cannot be determined through the expedited review process and shall be determined only by a convened IRB.

The IRB informs the investigator through the IRB’s electronic submission system of the IRB’s determination. The investigator has the opportunity to respond to the IRB regarding the IRB’s disapproval. The investigator’s response shall be reviewed by the convened IRB. University administration shall not overturn the IRB’s disapproval of a submission.

2. SCOPE

This SOP applies to all research projects submitted to the IRB.

3. RESPONSIBILITY

The IRB Chair and HRPP Director are responsible for complying with all University and regulatory requirements.

The IRB Chair or IRB designee is responsible for the appropriateness of all IRB decisions and actions.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111, 56.113
45 CFR 46.109

5. REFERENCES TO OTHER APPLICABLE SOPS

None
6. ATTACHMENTS
None

7. PROCESS OVERVIEW

7.1 As a result of its review of a research submission, the IRB will decide to approve, contingently approve, disapprove, or defer the submission. These actions are taken by a vote of the convened IRB.

7.2 When the submission is reviewed via expedited review, the IRB Chair or IRB designee may approve or contingently approve that submission. The IRB Chair or IRB designee shall not defer or disapprove a research project. To pursue a potential deferral or disapproval, the IRB Chair or IRB designee must refer the submission to the convened Board.

7.3 The IRB Administrator updates the IRB’s electronic information system with the actions and determinations made during the convened IRB meeting or during the expedited review. For items reviewed by the convened Board, the IRB Administrator records the voting results, including the number for, against, and abstentions; and records the names of members making the motions.

7.3.1 Approval:

A. For items previously contingently approved by the convened Board:

The IRB approves the revised submission and accompanying documents after the investigator addresses all stipulations. “Approved by Board” is the action designated by the IRB Administrator in the IRB’s electronic information system.

The IRB Chair or IRB designee approves the revised submission and accompanying documents under expedited review after the investigator addresses all stipulations. “Approved by Chair/Designee” is the action recorded by the IRB Administrator in the IRB’s electronic information system.

Approval is effective on the day the new research project is approved by the convened IRB, and the approval period is based on the date of the convened meeting at which the IRB approved the research. The expiration date is calculated as the last day of the eleventh month from the date of IRB approval.

B. For items approved via expedited procedures:

When the expedited review procedure is used, approval is effective on the day the research project is approved by the IRB Chair or IRB designee, and the approval period is based on the date the IRB Chair or IRB designee approves the research project. The IRB Administrator records the approval date and expiration date in the IRB’s electronic information system and generates an approval letter. The investigator is notified of the IRB’s action through the IRB’s electronic information system.

7.3.2 Contingent Approval: When the IRB stipulates minor revisions to the research project and accompanying documents, the IRB must clearly define the minor revisions. The changes submitted by the investigator may be reviewed under the expedited review procedure by the IRB Chair or IRB designee.

A. For items contingently approved by the convened Board:

The IRB votes on the minor revisions and terms of approval during the convened IRB meeting. The IRB Administrator updates the IRB’s electronic information system with the actions and determinations made by the convened IRB as “Contingent Approval.”
The IRB Administrator is responsible for recording the contingent approval date and for generating a contingent approval letter. The investigator is notified of the IRB’s action through the IRB’s electronic information system.

The IRB Chair or IRB designee has the authority to review the information via expedited review unless the IRB requires or the IRB Chair or IRB designee decides that the investigator response, revised submission materials, or information must be reviewed by the convened IRB. The information requested by the IRB and received from the investigator must provide the IRB with all of the required changes or information in order for approval to be granted. However, the expiration date of IRB approval is based on the date of the convened meeting at which the IRB approved the research with revisions. When the expedited review procedure is used, approval is effective on the day the research project is approved by the IRB Chair or IRB designee, and the approval period is based on the date the IRB Chair or IRB designee approves the research project. Participants must not be recruited into the research project until IRB approval has been issued.

B. For items contingently approved via expedited procedures:

For studies contingently approved by the IRB Chair or IRB designee under expedited review procedures, the IRB Chair or IRB designee communicates to the IRB Administrator their concerns, requests for additional information, and/or stipulations for minor revisions in the IRB’s electronic information system. The IRB Administrator forwards the requests for additional information, minor revisions, and/or stipulations to the investigator. An investigator has 60 University business days to respond to the IRB. If the requested information and/or revisions are not received within that time period, the project may be administratively withdrawn by the IRB. When revised submissions are approved, the IRB approval letter is issued as of the date that the submission is approved. “Approved by Chair/Designee” is the motion recorded by the IRB Administrator in the electronic information system.

7.3.3 **Deferral:** The IRB makes a motion of deferral at a convened Board meeting when significant questions are raised regarding the submission or when the information provided is inadequate to assess risk/benefit ratio. The deferral action is designated in the IRB’s electronic information system as “Deferred.” The IRB Administrator is responsible for recording the deferral date in the IRB’s electronic information system. The IRB Chair or IRB designee is responsible for promptly contacting the investigator and for preparing the deferral stipulations. An investigator has 60 University business days to respond to the IRB. The investigator’s response shall be reviewed by the convened IRB. If the requested information is not received within that time period, the submission may be administratively withdrawn by the IRB. The IRB Administrator is responsible for notifying the investigator of the IRB’s action through the IRB’s electronic information system.

7.3.4 **Disapproval:** The IRB makes a motion of disapproval at a convened Board meeting when the submission fails to meet one or more criteria used by the IRB for approval of human participant research. Disapproval cannot be decided through the expedited review process; it may be decided only by the convened IRB. A disapproval by the IRB is considered final and cannot be overturned by University administration.

The action of disapproval is designated in the IRB’s electronic information system as “Disapproved.” The IRB Administrator is responsible for recording the date of disapproval in the IRB’s electronic information system. The IRB Chair or IRB designee is responsible
for promptly contacting the investigator and for communicating the reasons for disapproval. The IRB Administrator is responsible for notifying the Investigator of the IRB’s action through the IRB’s electronic information system. Any response from the investigator shall be reviewed by the convened IRB.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 410: RESEARCH PROJECT RECRUITMENT

1. POLICY

Generally, the IRB discourages investigators from recruiting or enrolling themselves, their students, or their employees in their own studies, but the IRB will review such situations on a case-by-case basis. The IRB shall consider the degree of risk and likelihood of benefit to the participants and the protections for participants from coercion or undue influence.

The IRB does not allow investigators or key personnel to accept bonus payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”). Payments for referrals of potential participants (“finder’s fees”) are prohibited.

Potential research participants may be identified through any of the following methods:

Private Medical Information: Common resources for identifying potential research participants include medical records, clinical databases, patient registries, and psychosocial screening databases. These resources allow the investigator to review records and identify eligible participants. The IRB/Privacy Board shall approve all methods of obtaining private health information for study recruitment before the investigator may use them.

Referring Physicians: Referrals from treating physicians can be useful in identifying potential research participants. Referring physicians who have been provided with general information about a research project may inform their patients that a research project is available and provide the patients with contact information for patients to learn more about the project and whether they might be eligible. The IRB shall review in advance all materials sent to referring physicians about the research project.

Advertisements: The IRB and the FDA consider advertising for research project participants to be the start of the informed consent and participant selection process. Advertising that is intended to be seen or heard by prospective participants to solicit their participation in a research project is not, in and of itself, an objectionable practice. Investigators are required to submit to the IRB the final form of any advertising materials that will be used to recruit potential participants. At a minimum, advertising materials must include the title of the research project and the name and contact information of the investigator. In addition, investigators should include in their advertising materials a brief description of the research protocol, the length of time required to participate, the research project location and the University IRB assigned research project number.

Advertisements intended for prospective participants include, but are not limited to, the following mediums:

- Newspaper
- Radio
- TV
- Bulletin boards
- Posters
- Flyers
- Postings to group listserves, the University or PI’s website, Internet and/or Social Media
- Emails to participants not affiliated with the University
Mass Mail (OUMM) to groups of participants affiliated with OU. Investigators must review the OU Information Technology Target Emailing policy if they wish to use this form of advertising.

Direct advertisements do not include:

- Participant or investigator interviews;
- Communications intended to be seen or heard by health professionals, such as ‘Dear Doctor’ letters (or communication with other types of practitioners for the purpose of soliciting assistance in identifying research participants) or doctor-to-doctor letters (even when soliciting for research participants);
- News stories; or
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

To increase veterans’ access to non-VA research, the investigator may be allowed to post advertisements at the VA facility, provided the investigator obtains appropriate permission from the facility director.

NOTE: The VA facility may not advertise non-VA research on Facebook or other social media platforms.

Specific Policies

1.1 IRB Review of Research project Recruitment Methods and Advertisements

1.1.1 The IRB shall review research project recruitment methods and advertisements prior to their use by the investigator, usually as part of the approval of the research project. The investigator shall include recruitment methods in the IRB submission and upload the proposed advertisements at the time of the initial submission or as a modification of an approved protocol. The investigator shall not use the methods or advertisements in the recruiting process without IRB approval.

1.1.2 The IRB shall review direct advertising to assure that it is not unduly coercive and does not overstate the potential benefits of the research beyond what is outlined in the informed consent documents and the research protocol. This review is especially critical when a research project may involve participants who are likely to be vulnerable to undue influence. Advertisements shall be limited to the information necessary for potential participants to make an informed decision regarding participation.

1.1.3 If direct advertisements are not included in the initial project plan and are not submitted to the IRB at the time of initial submission, but the investigator later decides to advertise for participants, the investigator shall submit the documents to the IRB as a modification to the ongoing research project.

1.1.4 The IRB shall review the information contained in the advertisement, the mode of its communication, the final copy of printed or electronic advertisements, and/or the final audio/video taped advertisements.

1.1.5 The IRB shall review advertisements to make certain advertisements do not use terms, such as “new treatment,” “new medication,” or “new drug” without explaining that the test articles is investigational. The IRB shall review advertisements to make certain exculpatory language is not included in advertisements.
1.2 Advertisements to Recruit Participants May Include Only the Following:

1.2.1 The individual name or specific office or department and the accurate address and telephone number of the investigator, as well as the location of the research and the person to contact for further information;

1.2.2 Wording that effectively communicates the purpose of the research and, in summary form, the eligibility criteria that will be used to admit participants into the research project; and

1.2.3 A straightforward and truthful description of the benefits (payments or free treatment shall not be overstated or be the main focus) to the participant from participation in the research project, the duration of the research project, and the treatment.

1.2.4 When appropriately worded, the investigator may include the following in advertisements.

A. The name and address of the investigator and/or research facility;

B. The condition being studied and/or the purpose of the research;

C. In summary form, the criteria that will be used to determine eligibility for the research project;

D. A brief list of participation benefits, if any;

E. The time or other commitment required of the participants; and

F. The location of the research and the person or office to contact for further information.

1.3 Advertisements to Recruit Participants SHALL NOT:

1.3.1 Mislead participants;

1.3.2 Claim, either explicitly or implicitly, that the drug or device is safe or effective for the purpose under investigation or that the drug or device is in any way equivalent or superior to any other drug or device;

1.3.3 Use terms such as “new treatment,” “new medication,” or “new drug” without an explanation that the test article is investigational;

1.3.4 Include exculpatory language;

1.3.5 Imply the research or investigator has a unique or special skill, remedy, or treatment;

1.3.6 Promise “free medical treatment,” when the intent is to say that participants will not be charged for taking part in the investigation. Advertisements may state that participants will be paid but shall not emphasize the payment or the amount to be paid by such means as larger or bold type.

1.3.7 Include monetary amounts as rewards or inducements to participate (they may, however, mention there will be compensation for the participant’s time or travel). Exceptions to this prohibition may be considered by the IRB on a case-by-case basis.

1.4 Payment to Participants

1.4.1 The IRB requires payment to participants to accrue as the research project progresses and be prorated based on the number of research project visits completed by the participant. It should not be contingent upon the participant completing the entire research project. Any amount paid as a bonus for completion should be reasonable and
not so large as to unduly induce participants to remain in the research project when they would otherwise withdraw.

1.4.2 Compensation for participation in a research project offered by the sponsor must NOT be in the form of a coupon, good for a discount on the purchase price of the research product once it has been approved for marketing.

1.4.3 The IRB requires all information regarding payment, including the amount and schedule of payments, to be set forth in the informed consent documents.

1.5 Equal Opportunity Statement

All advertisements shall contain the following statement: “The University of Oklahoma is an equal opportunity institution.”

1.6 VA Research Projects

For additional requirements for VA research projects, see SOP 603A: Veterans Affairs Medical Center.

2. SCOPE

This SOP applies to all advertisements that pertain to human participant research.

3. RESPONSIBILITY

The IRB is responsible for reviewing recruitment methods and all direct advertisements submitted by the investigator that pertain to research projects involving human participants.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 56

5. REFERENCES TO OTHER APPLICABLE SOPS

301: Research Submission Requirements

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 Review of Advertisements by the IRB

7.1.1 The IRB reviewer shall review advertisements received with the submission.

7.1.2 The IRB reviewer shall review the information contained in the advertisement, the mode of its communication, the final copy of printed or electronic advertisements, and the final audio/video taped advertisements.

7.1.3 The IRB reviewer shall review advertisements to make certain that advertisements do not include language, as described in Section 1.3 of this policy.
7.1.4 The IRB reviewer shall review advertisements to make certain that advertisements do not include exculpatory language.

7.1.5 After the IRB reviewer completes the review, the IRB Administrator shall process the submission following the procedures outlined in SOP 301: Research Submission Requirements.

7.1.6 On the HSC campus, for approved email advertisements, the IRB Administrator shall forward an electronic copy of the email advertisement to the appropriate email distributor in accordance with current policy.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 411: SUSPENSION OR TERMINATION OF IRB APPROVAL

1. POLICY

Approved human research that is not conducted in accordance with IRB policies/procedures, federal/state/local regulations, and/or laws or that has been associated with unexpected serious harm to participants is subject to suspension or termination. Suspension is defined as a temporary or permanent halt to all research activities, including a temporary interruption in the enrollment of new participants, activities involving previously enrolled participants, or other research activities. Suspended research is still subject to Continuing Review. Termination is defined as a permanent halt to all research activities, including a permanent halt in the enrollment of new participants, activities involving previously enrolled participants, or other research activities. Terminated research is no longer subject to continuing review. Suspension and termination apply to interruptions related to concerns regarding the safety, rights, or welfare of human participants, investigators, Research Staff, or others.

The IRB may suspend or terminate approval of research that:

- Is not being conducted in accordance with the IRB’s requirements.
- Is associated with unexpected serious harm to participants.

The IRB may suspend or terminate research based on information received during its continuing review, from the findings of a Quality Improvement audit, or from participant (or other) complaints made to the IRB.

The IRB, IRB Chair, and IRB Vice-Chair have the authority to suspend or terminate research activities, giving consideration to protections necessary for current participants’ rights and welfare. Should the IRB Chair or IRB Vice-Chair act independently to suspend or terminate research activities, this action shall be reported to the IRB at the next convened meeting.

An investigator may decide to voluntarily suspend or terminate some or all research activities that are under current review or investigation. If an investigator voluntarily suspends or terminates any research activities, even following a verbal or written prompt by the IRB, IRB Chair, or IRB Vice-Chair, it is not considered a suspension or termination of IRB approval.

For purposes of suspensions and terminations of VA research projects, see 603A: Veterans Affairs Health Care System.

Specific Policies

1.1 Suspension/Termination by the IRB

The IRB shall review the information it receives to determine whether the investigator failed to comply with IRB-approved conduct of research or the research is associated with unexpected serious harm to participants. When research project approval is suspended or terminated by the IRB, the IRB must consider:

A. Actions to protect the rights and welfare of currently enrolled participants.

B. Whether procedures for withdrawal of enrolled participant considered their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher, and continuation in the research under independent monitoring).

C. Whether participants should be informed of the termination or suspension.
D. Whether to require any adverse events or outcomes to be reported to the IRB.

The IRB shall suggest a course of corrective measures and establish a time frame in which the corrective measures are to be implemented. The particular details of suspension and termination are documented in the Minutes, per SOP 303C: Meeting Minutes.

The IRB shall continue to monitor the investigator’s progress at resolving the suspension. If sufficient progress is not made and the issue has been unresolved longer than two (2) months, the IRB may immediately terminate the research.

1.2 Suspension by an IRB Chair or IRB Vice-Chair

An IRB Chair or IRB Vice-Chair is authorized to terminate a research project and authorized to suspend research and report the suspension to the convened IRB. The IRB will then monitor the investigator’s resolution of the suspension. If after two (2) months the suspension has not been resolved, the IRB Chair or IRB Vice-Chair shall bring the suspension before the IRB in order to proceed with research project termination.

2. SCOPE

This SOP applies to all research submitted to the IRB.

3. RESPONSIBILITY

3.1 The Institutional Official is responsible for creating and maintaining a coercion-free environment with respect to the ongoing review of research and any decisions that come from that review, whether the outcome is approval, contingent approval, deferral, suspension, or disapproval/termination.

3.2 The IRB Administrator is responsible for posting items to the IRB agenda, per SOP 303A: Meeting Agenda; following distribution procedures, per SOP 302: Administrative Review and Distribution of Materials; and creating IRB Minutes, per SOP 303C: Meeting Minutes. The IRB Administrator is responsible for coordinating with the IRB Chair or IRB designee the drafting, finalizing, and distributing of all IRB correspondence. The IRB and/or Quality Improvement (QI) Coordinator are responsible to monitor the resolution of all suspensions.

3.3 The IRB Chair or IRB designee is responsible for the review of all information received regarding the conduct of the research in question and whether the information supports a determination of suspension and/or termination. The IRB Chair or IRB designee is responsible for forwarding all issues of research termination to the IRB for review. The IRB Chair or IRB designee is responsible for contacting the investigator regarding decisions of suspension and/or termination prior to sending formal written IRB communication. If after two (2) months adequate progress has not been achieved with respect to research suspension, the IRB Chair or IRB designee will notify the IRB of the research and recommend termination of the research to the IRB.

3.4 VA Research – The IRB Chair or IRB designee is responsible for notifying the VA facility director in writing within five (5) University business days of any IRB termination or suspension of VA research. See SOP 603A: Veterans Affairs Health Care System for additional guidance.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50, 56
45 CFR 46
VHA Handbook 1058.01
5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 302: Administrative Review and Distribution of Materials
SOP 303A: Meeting Agenda
SOP 303C: Meeting Minutes
SOP 308: Reporting to Regulatory Agencies and Institutional Officials
SOP 603A: Veterans Affairs Health Care System

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The IRB Administrator receives, processes, and either posts the item to the appropriate agenda or forwards it to the appropriate IRB Chair or IRB designee for review.

7.2 The IRB or IRB Chair reviews the information and may suspend the research if the research has not been conducted as previously approved by the IRB. Research may be suspended if it is associated with unexpected serious harm to participants.

7.3 The IRB Chair or IRB designee contacts the investigator with a suspension determination. The IRB Chair or IRB designee, in conjunction with the IRB Administrator, drafts, finalizes, and sends a formal letter outlining the reason(s) for suspension and proposes corrective measures with completion timeline or requests corrective measures and completion timeline from the investigator.

7.4 The IRB Administrator monitors the progress of suspension resolution. If after two (2) months acceptable progress has not been made, the IRB Administrator notifies the IRB Chair or IRB designee and posts the research suspension item as a discussion item for IRB review.

7.5 The IRB may terminate the research. The IRB discusses provisions for the rights and safety of participants, appropriate follow-up care, and the risk(s) to current participants prior to terminating any research. Formal communication with the investigator and other entities is accomplished as per SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

APPROVED BY: _______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The Central Institutional Review Board (CIRB) Initiative is sponsored by the National Cancer Institute (NCI) in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The University participates in the NCI-CIRB Initiative for review and approval of NCI-approved Children’s Oncology Group (COG) Phase 2 and 3 protocols and pilot protocols and Adult Phase 3 Cooperative Group protocols.

The NCI CIRB serves as the IRB of record for the CIRB-approved studies conducted under the Authorization Agreement between the University and CIRB. The CIRB conducts initial and continuing review of these studies as well as review of local context considerations. The University with the cooperation with the HSC Component Institutions, Stephenson Cancer Center (SCC) and Jimmy Everest Center for Cancer and Blood Disorders in Children, is responsible for ensuring compliance with the NCI CIRB determinations and local institutional requirements and for monitoring the conduct of the research at the HSC affiliated sites named in the Authorization Agreement.

CIRB-approved research projects shall be reviewed by the HSC IRB if the HSC investigator plans to enroll prisoners; or if a participant becomes incarcerated during the course of the research, as the NCI CIRB is not constituted to review research projects involving prisoners.

Specific Policies

1.2 HIPAA

A. For research projects conducted under the HSC IRB, it is standard practice at the University for the informed consent form and HIPAA Authorization form to be separate documents. Although CIRB accepts the University’s boilerplate language to be included in the informed consent form for HIPAA Authorization, CIRB does not serve as a Privacy Board. Therefore, the HIPAA Authorization form for CIRB studies at HSC sites shall be reviewed by a designated HSC IRB chair on behalf of the HSC Privacy Board.
1.3 Monitoring

A. The HSC HRPP reserves the authority to monitor any aspects of the research conducted under the CIRB / University agreement.

2. SCOPE

This SOP applies to University investigators and their research staff participating in CIRB-approved research projects; to IRB staff; and to IRB members serving on behalf of the HSC Privacy Board.

3. RESPONSIBILITY

3.1 Division of Responsibilities

A. The Responsibilities of the NCI CIRB are to:

1. Maintain an NCI CIRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
   a. Post the roster of NCI CIRB membership on the public side of the NCI CIRB website;
2. Conduct initial, amendment and continuing review of studies as well as review of any other study-specific documents submitted by the Study Chair to the NCI CIRB;
3. Conduct review of local context considerations:
   a. As outlined in the following worksheets: the Annual Signatory Institution Worksheet About Local Context for NCI CIRB Review, the Annual Principal Investigator Worksheet About Local Context, and the Study-Specific Worksheet About Local Context.
4. Conduct review of potential unanticipated problems and/or serious or continuing noncompliance when the University or other entity reports an incident, experience, or outcome to the CIRB. The review includes the following step:
   a. Report any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA, and the NCI Signatory Official;
5. Conduct a review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or equivalent monitoring body;
6. Post all study-specific documents related to CIRB reviews to the restricted access side of the CIRB website;
   a. Notify research staff and University designees of all CIRB actions, per written procedures, via institution-specific correspondence, broadcast emails, and access to the restricted area of the CIRB website;
7. Notify HSC Institutional Official immediately if there is ever a suspension or restriction of the CIRB’s authorization to review a study; and
8. Post the NCI CIRB Standard Operating Procedures on the public side of the CIRB website.

B. The Responsibilities of HSC are to:

1. Comply with the NCI CIRB’s requirements and directives as noted in the CIRB SOP’s and on the CIRB website.
2. HSC HRPP will report to the NCI CIRB the names of any Component or Affiliate Institutions that rely on the Signatory Institution’s IRB.
a. Component Institutions are defined by the NCI CIRB as meeting all of the following criteria:
   - the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the component Institution;
   - the FWA number for the Component Institution is the same as the Signatory Institution;
   - the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
   - the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
   - the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.

b. Affiliate Institutions are defined by the NCI CIRB as meeting all of the following criteria:
   - the local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet about Local Context;
   - the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet about Local Context; and
   - the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

3. HSC HRPP with the cooperation of SCC and Jimmy Everest Center shall ensure the safe and appropriate performance of the research at the Signatory Institution and at all Components and Affiliates. This includes, but is not limited to:
   a. ensuring the initial and ongoing qualifications of investigators and research staff;
   b. overseeing the conduct of the research;
   c. monitoring protocol compliance;
   d. maintaining compliance with state, local, or University requirements related to the protection of human participants;
   e. providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
   f. investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the University must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences.
NOTE: As part of ensuring safe and appropriate performance of the University’s research, the University has the authority to observe any aspect of the research process including observing the consent process. The CIRB retains the authority to direct observation to be done when necessary.

4. Provide updates in a timely manner to the NCI CIRB whenever an HSC Principal Investigator is no longer the responsible party for a study under the purview of the NCI CIRB;

5. Notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review;

6. Complete and submit the Annual Institution Worksheet About Local Context, the Annual Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation;

7. HSC HRPP shall determine on a study-by-study basis whether to open the study through the NCI CIRB or to conduct its own local IRB full Board review. Indicate the decision to open a study through the NCI CIRB by submitting a Study-Specific Worksheet About Local Context;

8. In the local consent form:
   a. incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form.
   b. make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language;
   c. obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
   d. obtain NCI CIRB approval of translations of the consent form prior to implementation;

9. Maintain a regulatory file for each study under NCI CIRB purview as per University and sponsor policy; and

10. Conduct full board review of any study enrolling prisoners, since the NCI CIRB is not constituted to review studies enrolling prisoners.

4. APPLICABLE REGULATIONS AND GUIDELINES

   45 CFR 46.114
   21 CFR 21.114

5. REFERENCES TO OTHER APPLICABLE SOPS

   SOP 1001, HIPAA

   NIC CIRB SOPs: www.NCICIRB.org

6. ATTACHMENTS

   Study-Specific Worksheet About Local Context (PI)

   Annual Signatory Worksheet About Local Context (including boilerplate language to the model consent form) (HSC HRPP)

   Annual Principal Investigator Worksheet About Local Context (PI)
7. PROCESS OVERVIEW

7.1 Submission Procedures for Initial Review

A. Investigators who wish to open a CIRB-approved research project at HSC shall submit the following documents to the HRPP via the IRB electronic information system:
   1. CIRB-approved protocol
   2. Documentation of approval and any other University-required committee reviews (i.e., IBC, PRMC)
   3. Proposed HSC HIPAA Authorization form

B. The submission is received in the IRB Office. HRPP staff shall review the submission to confirm that HSC investigator(s) and KSP have met all HSC IRB education requirements.

C. The Administrator shall conduct a pre-review of the submission and verify all necessary documents have been submitted.

D. The Administrator shall assign the submission to the IRB Chair to review on behalf of the Privacy Board.

E. The IRB Chair reviews the submission to confirm accuracy of the HIPAA Authorization form and for any other issues that might require HSC IRB review.

F. The Administrator shall update the outcome of the HSC IRB Chair review, communicate the outcome and any stipulations to the investigator, and report the HSC IRB Chair review to the next appropriate HSC IRB agenda. The Administrator stamps the HSC IRB Approval stamp to the HIPAA Authorization form.

G. The Investigator shall upload the appropriate documents to CIRB, following CIRB procedures. CIRB becomes IRB of record at that time.

7.2 Closing the Study

A. The investigator shall submit a final closure request to the HSC IRB electronic information system to inform the University of the closure of the research project at the HSC component or affiliate sites.

7.3 Submission of CIRB Required Worksheets

A. CIRB required worksheets shall be completed and submitted to CIRB as follows:
   1. Annual Institution Worksheet About Local Context (including University approved boilerplate language to the model consent form): HSC HRPP office
   2. Annual Investigator Worksheet About Local Context: HSC investigator with copy to HSC HRPP office
   3. Study-Specific Worksheet About Local Context: HSC investigator
   4. Other CIRB worksheets/forms required by the NCI CIRB for participation: to be determined by the HSC HRPP office as needed.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. **POLICY**

The IRB shall review all research that involves special populations that is of minimal risk or that benefits these populations directly. The extent of protection required by the IRB depends upon the risk of harm and the likelihood of benefit to the special population members. The IRB shall give special consideration to recruitment methods, the consent process, and the research participant’s capacity to consent. The IRB may require investigators to periodically reevaluate the judgment of any participant who lacks autonomy.

The IRB shall invite members or consultants with special expertise and related competency to participate in the review when necessary.

The IRB minutes shall document the special population findings made by the IRB or the IRB reviewer, as required in 45 CFR 46 Subparts B, C, & D.

The inclusion of research participants from special populations does not, in and of itself, necessitate review by the convened IRB. The IRB shall consider the level of risk involved in determining whether review by the convened Board is required. For example, research involving children that poses minimal risk may be expedited under 45 CFR 46.404 and/or 45 CFR 46.110.

Special populations include:

- Pregnant Women, Fetuses, & Neonates
- Children
- Cognitively Impaired Persons
- Prisoners
- Traumatized and Comatose Patients
- Terminally Ill Patients
- Elderly/Aged Persons
- Minorities (e.g., Native Americans)
- Students, University Employees, Employees of the Sponsor or Investigator, and Healthy Volunteers
- Economically or Educationally Disadvantaged Persons

**Specific Populations**

1.1 **Prisoners**

Federal regulations require additional protections for prisoners involved in research. If prisoners will participate in the research projects or it is reasonable to expect that research participants may become incarcerated during the research project, the IRB review of the project must comply with federal, state, and local requirements for inclusion of prisoners as research participants. In addition, review of these studies must comply with the following:

NOTE: Department of Justice, Bureau of Prisons research that consists of pilot projects of programmatic or operational initiatives are not considered to be human participant research.
1.1.1 IRB composition: A majority of IRB reviewers shall have no association with the prison(s) involved. At least one reviewer shall be a prisoner or prisoner advocate with appropriate background and experience to serve in that capacity.

1.1.2 The IRB may approve research projects involving prisoners only if it finds that the research falls into one of the following categories:

A. Study of the possible causes and effects and the processes of incarceration and of criminal behavior, provided that the research project presents no more than minimal risk and no more than inconvenience to the participants;

B. Research of prisons as institutional structures or of prisoners as incarcerated persons, provided that the research project presents no more than minimal risk and no more than inconvenience to the participants;

C. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials on hepatitis, which is more prevalent in prisons), provided that the Secretary of DHHS or designee has published notice in the Federal Register of its intent to approve such research; or

D. The research under review involves solely research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases where prisoners may not benefit from the research because they are assigned to a control group in a manner consistent with the protocol approved by the IRB, the research project may proceed only after the Secretary of DHHS has consulted with experts and has published notice in the Federal Register of its intent to approve such research.

1.1.3 Any possible advantages accruing to the prisoner through participation in the research project, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, should not be of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.

1.1.4 The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

1.1.5 Selection procedures within the prison must be fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Unless the investigator provides the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of eligible prisoners for the research project.

1.1.6 Any information given to participants is presented in language that is appropriate for the participant population.

1.1.7 Adequate assurance must exist that parole board(s) will not take into account a prisoner's participation in the research project when making decisions regarding parole, and each prisoner must be clearly informed in advance in the informed consent process and related documents that participation in the research project will have no effect on his/her parole.

1.1.8 Where there is need for follow-up examination or care of participants after the end of their participation in the research project, adequate provision is made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing research participants of this fact.
1.1.9. For prisoner research conducted or supported by DHHS, the IRB determines that the research project meets the criteria in Section 1.1, documents that determination, and sends a copy of the research proposal to the Prisoner Research Contact Person at OHRP.

The research project shall not be initiated unless OHRP determines that the proposed research involves at least one of the categories of research permissible under 45 CFR 46.306(a)(2).

Studies previously authorized by OHRP with prisoner involvement do not require recertification if modified unless the change to the research alters the applicability of the approved category of research.

1.1.10 When a Participant Becomes a Prisoner During a Research Protocol:
The IRB shall comply with the following if a participant becomes a prisoner after enrollment in research:

A. The investigator must cease all research interactions and interventions with and obtaining identifiable private information about the participant. The investigator shall report this to the IRB immediately upon learning of the incarceration. In special circumstances in which the investigator asserts that it is in the best interests of the participant to remain in the research project while incarcerated, the IRB Chair or IRB designee may determine that the participant may continue to participate in the research until the requirements of 45 CFR 46 Subpart C are satisfied.

B. At the earliest opportunity after receiving the investigator’s notice or otherwise becoming aware of the incarceration of a research participant, the IRB shall review the protocol again with a prisoner representative as a member of the IRB. The IRB shall take special consideration of the conditions of being a prisoner when considering whether to let the participant continue in the research project.

C. When reviewing the continuation of research participation, the IRB can either (a) approve the continued involvement of the prisoner as a participant in the research project in accordance with this policy or (b) determine that the participant must be withdrawn from the research project.

D. Additionally, when appropriate, the IRB shall confirm that the informed consent documents include information regarding incarceration that may result in termination of the participant’s participation without regard to the participant’s consent.

1.1.11 VA research involving prisoners as participants is not approved unless a waiver has been granted by the VA Chief Research and Development Officer.

1.1.12 For Department of Defense-Sponsored Research, research with Prisoners of War (POW) is prohibited. This includes any person captured, detained, held, or otherwise under the control of Department of Defense personnel (military and civilian, or contractor employee). Such persons include Enemy Prisoners, Civilian Internees, Retained Persons, and Lawful and Unlawful Enemy Combatants. Such persons do not include Department of Defense personnel being held for law enforcement purposes. For the definition of Prisoners of War for the Department of Defense components, see SOP IV, Glossary.

For research involving prisoners not meeting the definition of POW, expedited review procedures are prohibited.
1.2 Children

1.2.1 Federal regulations require additional protections for children involved in research. The IRB shall consider the following when reviewing research involving children:

- **Determination of probable risks and associated discomforts:** Procedures that usually present no more than minimal risk to a healthy child include urinalyses, obtaining small blood samples, EEGs, allergy scratch tests, minor changes in diet or daily routine, and/or the use of standard psychological or educational tests. The assessment of the probability and magnitude of the risk, however, may be different in sick children and vary depending on the diseases or conditions of the child participants. For example, obtaining blood samples from a hemophiliac child may present more than minimal risk to the child. On the other hand, the IRB shall consider that children suffering from chronic illnesses who are accustomed to invasive procedures are placed at minimal risk by involvement in similar research procedures, in contrast to children who have not had such experiences. The IRB shall also consider the extent to which research procedures would burden any child, regardless of whether the child is accustomed to the proposed procedures.

Procedures that exceed the limits of minimal risk may be difficult for the investigator to define in the research protocol but should not be too difficult for the IRB to identify on a case-by-case basis. Riskier procedures might include biopsy of internal organs, spinal taps, or the use of drugs whose risks to children have not yet been established. Behavioral interventions likely to cause psychological stress may also exceed minimal risk.

- **Determination of possible benefits:** In assessing the possible benefits of research interventions, the IRB shall consider the variability in health statuses among potential participants. For example, a potential participant might be a normal, healthy child, or a child who has been exposed to a disease or a toxin (e.g., meningococcus or lead) where it is known that a percentage of the children exposed will actually experience untoward consequences. A child may also be in an early state of disease; e.g., an HIV-infected child, or may actually suffer from disease or other significant medical condition. Thus, the IRB must take into account the current health status of a child and the likelihood of progression to a worsened state without research intervention.

1.2.2 **Wards of the State:** The special protections for children set forth in Subpart D of 45 CFR 46 include additional limitations on some research involving children who are wards of the State or any other agency, institution, or entity. Where the research involves greater than minimal risk to the participants with no prospect of direct benefit to individual participants (45 CFR 46.406), or requires DHHS Secretarial approval (45 CFR 46.407), the research must either be related to their status as wards, or be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards (45 CFR 46.409). The IRB shall require, for each child who is a ward, appointment of an advocate for purposes of the research study in addition to any other individual acting on behalf of the child as a guardian.

1.2.3 **HIV-Infected Children:** The IRB is particularly concerned with the involvement of HIV-infected children who are in foster care, but who are also not wards of the State. The IRB shall give special attention to groups of children such as these who, while they need special protections, should not be denied the opportunity to participate in research that may potentially benefit them.
1.2.4. Institutionalized Children: When institutionalized children are involved in research, the IRB shall not allow the institutionalized children to be included as participants simply because of their availability to the investigator.

1.2.5. Determination of Risk: Federal regulations require the IRB to classify research involving children into one of four categories and to document the discussions of the risks and benefits of the research project. The minutes shall document how the research protocol meets the required criterion.

The four categories of research involving children based on degree of risk and benefit to individual participants are as follows:

1. **Research not involving greater than minimal risk.** (45 CFR 46.404, 21 CFR 50.51)

2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual participants.** (45 CFR 46.405, 21 CFR 50.52)

   Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the participant; and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach.

3. **Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.** (45 CFR 46.406, 21 CFR 50.53)

   Research in this category is approvable provided: (a) the risk represents only a minor increase over minimal risk; (b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participant's disorder or condition.

4. **Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** (45 CFR 46.407, 21 CFR 50.54)

   Research that is not approvable under categories one, two, or three may be conducted or funded by DHHS provided that the IRB and the DHHS Secretary, after consultation with a panel of experts convened in accordance with OHRP Guidance on the 46.407 review process, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles.

For FDA-regulated research: If the IRB determines that risk categories one, two, and three are not met, the research project may proceed under category four only if:

- a) The IRB finds and documents that the research project presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

- b) The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, determines either:
1) That the research project in fact satisfies the conditions of 21 CFR 50.51, 21 CFR 50.52, or 21 CFR 50.53, as applicable, or

2) That the following conditions are met:

   i.) The research project presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

   ii.) The research project will be conducted in accordance with sound ethical principles; and

   iii.) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in 21 CFR 50.55.

1.2.6 Parental Permission: Children may be research participants only if permission is obtained from the parent(s) or legal guardian. The IRB shall determine whether the permission of both parents is necessary and the conditions under which one parent may be considered not reasonably available. For additional information, see SOP 701, Consent Process and Documentation.

1.2.7 Assent of Children: The IRB shall determine whether adequate provisions are made for soliciting the assent of the children when, in the judgment of the IRB, the children are capable of providing assent (21 CFR 50.55). For additional information, see SOP 701, Consent Process and Documentation.

1.2.8 Waiver of Assent: The necessity of obtaining the assent of the child shall be determined by the IRB. For additional information, see SOP 701, Consent Process and Documentation.

1.2.9 VA Research: Research involving children as participants may not be approved unless a waiver has been granted by the VA Chief Research and Development Officer. Research involving children may not pose greater than minimal risk to the child.

1.3 Pregnant Women and Fetuses

1.3.1 Federal regulations require additional protections for pregnant women, fetuses, or neonates involved in research. The IRB may approve research involving pregnant women and fetuses only if the research satisfies all the conditions of 45 CFR 46, Subpart B, as follows:

   a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

   b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; OR, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

   c) Any risk is the least possible for achieving the objectives of the research;

   d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect
of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

e) If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.

f) Each individual providing consent under paragraph (d) or (e) above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of 45 CFR 46;

h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

j) Individuals engaged in the research will have no part in determining the viability of a neonate.

1.3.2 Research Involving Pregnant Women That Is Not Federally Funded:

The IRB may be flexible in applying Subpart B to non-federally funded research involving pregnant women that is social/behavioral in nature, presenting minimal risk to the pregnant women and fetus, and creates generalizable scientific knowledge.

1.3.3 Research involving neonates:

A. After delivery, neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

2. The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the neonate; and

3. The regulatory requirements have been met as applicable.

B. Neonates of uncertain viability: After delivery, and until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by federal regulations unless the IRB has determined one of the following additional conditions are met:

1. The research holds out the prospect of enhancing the probability of survival of the particular neonate to the point of viability, and any risk is the least possible for achieving the objectives of the research; or

2. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research.
Additionally, legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with 45 CFR 46 subpart A, unless altered or waived in accord with 45 CFR 46.101(i) or 45 CFR 46.116(c) or (d).

C. **Nonviable neonates:** After delivery, a nonviable neonate may not be involved in research covered by federal regulations unless all of the following conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with 45 CFR 46 Subpart A, except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d) do not apply. However, if one parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of the other parent will suffice to meet the requirements except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of a nonviable neonate will not suffice to meet the requirements of the regulations.

1.3.4 **Research involving after delivery:** the placenta; the dead fetus, fetal material; or cells, tissue, or organs excised from a dead fetus.

A. Research involving after delivery; the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable federal, state, or local laws and regulations regarding such activities.

B. Oklahoma law prohibits research on fetal tissue resulting from an abortion. An abortion is defined as the purposeful termination of a pregnancy with the intent other than to produce a live birth or remove a dead unborn child. 63 O.S. §1-735 and SOP 1101: Oklahoma State Laws Pertaining to Research

C. If information associated with material described in Section 1.3.3 above is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent regulations apply.

1.3.5 **VA Restrictions on Fetal and In Vitro Fertilization Research**

A. Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue), must not be conducted by VA investigators while on official duty, at VA facilities, or at approved off-site facilities.
B. Research related to in vitro fertilization must not be conducted by VA investigators while on official duty, at VA facilities, or at approved off-site facilities.

C. Research involving stem cells shall be governed by the policy set by NIH, “Guidelines for Human Stem Cell Research”.

D. Interventional research involving neonates is not allowed. Prospective observational or retrospective record review studies that involve neonates or neonatal outcomes are permitted.

E. Research involving the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in-utero under 45 CFR 46.208(a)(2) Section 498B of the Public Health Service Act (42U.S.C.289g(b)) cannot be conducted by VA investigators, at VA facilities, or at VA approved off-site facilities.

1.3.6 VA Research Involving Pregnant Women

VA research involving pregnant women as participants is not approved unless:

A. The research includes adequate provisions to monitor the risks to the participant and the fetus;

B. Adequate consideration has been given to the manner in which potential participants are going to be selected;

C. The facility where the research will be conducted has staff with sufficient expertise in women’s health to conduct the proposed research; and

D. Adequate provision has been made to monitor the actual consent process by procedures such as:

1. Overseeing the process by which the consent of individual is obtained either by:
   - Approving enrollment of each individual.
   - Verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity are being followed.

2. Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

1.3.7 DOD Research Involving Subpart B

A. The phrase “biomedical knowledge” must be replaced with “generalizable knowledge”.

B. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

C. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
1.4 Cognitively Impaired Research Participants

Although there are no federal regulations specifically written to address the needs of this special population, the IRB shall generally follow the recommendations governing the conduct of research in children and made by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

1.4.1 Cognitively impaired participants are defined as participants having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., intellectual disability) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical disabilities, may also be compromised in their ability to make decisions in their best interests and are therefore considered to be cognitively impaired.

1.4.2 Selection of Participants: When involving individuals who are cognitively impaired, the research should have a direct relationship to the participant’s illness or condition unless the IRB determines there is a possibility of direct benefit to the participant that cannot be obtained outside of the research project. Particular attention should be paid to institutionalized individuals, as issues of dependence (e.g., staff and interventions in the institution, addiction, and/or those legally authorized to give permission to be a research participant) and coercion may be factors that may compromise the voluntary nature of their participation in research. For this reason, participants should be recruited from among non-institutionalized populations whenever possible.

1.4.3 Risk Determination: The IRB or IRB reviewer shall determine the degree of risk of a research protocol involving cognitively impaired participants:

   A. A minor increase over minimal risk may be permitted in research involving those institutionalized as mentally disabled, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care.

   B. For research that does not involve beneficial interventions and that presents more than minimal risk, the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the participants’ disorder or condition.

1.4.4 Limiting Risks: To limit a participant’s exposure to risk, the investigator shall include in the protocol:

   A. A description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures.

   B. The specific diagnostic, symptomatic, and demographic criteria for participant recruitment.

   C. A description of methods for assuring adequate protections for the privacy of the participants and the confidentiality of the information gathered.

   D. Justification of plans to hospitalize research participants or extend hospitalization for research purposes.

   E. Measures to protect individually identifiable information.
F. Measures to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens.

1.4.5 Informed Consent: Generally, cognitively impaired adults who are competent to understand the process, risks, and benefits of being a research participant should be allowed to either refuse or consent to participate in a research project. Cognitive impairment alone should not disqualify a person from consenting to participate in research. The investigator shall also present specific evidence of cognitive impairment, such as one of the following items:

- Declaration of incompetence by a court of law
- Assessment by a physician not involved with the research project
- Scoring from a Mini Mental Health Exam or equivalent assessment instruments

The IRB shall respect and observe the objection or refusal of a cognitively impaired participant to participate in a research project, even if the intervention is expected to provide a direct health benefit to the participant and the intervention is available only in the context of the research. This is in keeping with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research’s recommendation that “despite the fact that consent may be obtained from a legally authorized representative or guardian, the feelings and expressed wishes of a ‘cognitively impaired’ should still be respected.”

The IRB may seek guidance from the Office of Legal Counsel to assess state law that might affect the participation of cognitively impaired persons and/or the role of guardians in the consenting process.

Studies involving participants who are cognitively impaired may take place over extended periods. The IRB shall consider whether periodic re-consenting of individuals is required to determine that a participant’s continued involvement is voluntary. The IRB may require that investigators re-consent participants after taking into account the research project’s anticipated length and the condition of the individuals to be included (e.g., participants with progressive neurological disorders). Additionally, the IRB shall consider whether and when it should require a reassessment of decision-making capacity and require re-consent of the participant.

1.4.6 VA Research Involving Persons Who Lack Decision-Making Capacity: Refer to SOP 603A: Veterans Affairs Health Care System.

1.5 Other Special Populations

Students and employees recruited as research subjects are more vulnerable to coercion because of the possibility that they may perceive grades, employment, or other benefits as dependent upon or affected by their participation in research. Students and employees are at greater risk of experiencing negative ramifications related to an inability to maintain strict confidentiality and because more information is known about these individuals than is collected during the course of the research project.

The IRB considers these individuals to be more vulnerable to coercion (real or perceived) and to issues related to confidentiality than individuals not affiliated with the University and, therefore, will apply additional safeguards to protect their rights and welfare.
1.5.1 Students as Research Participants

Note: For Classroom-Based Research Projects Conducted by University Students, refer to SOP 401: Research Exempt from Federal Regulations.

A. Justification for Targeting Students: Investigators who plan to conduct research with only students as participants must be able to provide a rationale, other than convenience, for restricting the research project population to students and must show that the recruitment method does not lead potential subjects to think they will be penalized by not participating or receive preferential treatment by participating. Examples of such rationale include: a) participation as a valuable educational experience demonstrated by a substantive plan for debriefing, b) the need for an alternative mechanism for research project compensation (e.g. class credit or extra credit) due to lack of monetary resources, c) the existence of a formal student subject pool and related departmental policy. Neither Investigators nor Class Instructors may impose penalties on students who fail to attend scheduled research-related appointments.

Recruitment materials must minimize the potential for undue influence or coercion.

B. Direct Recruitment: Investigators may make research project-related announcements (such as research project title and investigator contact information) or provide recruitment materials (such as fliers) to students in University classrooms, so long as the investigator is not also the class instructor. Recruitment methods must permit students to self-identify as potential research participants outside of the classroom so as to maintain confidentiality and minimize the potential for peer pressure. For example, students should be provided with contact information for a research project team member who they may contact after class, rather than be asked to express interest at the time of the announcement.

C. Indirect Recruitment: The investigator must obtain appropriate permission from University campus locations before posting IRB-approved recruitment materials.

D. (For Norman Campus only) Mass Email Recruitment: Investigators seeking approval to email recruitment materials or research project announcements to students must explain this recruitment method in the protocol and include this language: “The OU IRB has approved the content of this research recruitment message, but the investigator is responsible for obtaining authorization to distribute this research recruitment message by mass email.”

E. Consent: A student may not be compelled to participate in research as part of a course requirement. Investigators must ensure that students know that they may choose not to participate in the research and that their decision will not affect their grade, class standing, or relationship with any instructor. Similarly, research participants must be made aware that their participation will not lead to any preferential class-based treatment.

F. Course Credit: If research participation is required as part of the course assignments, an alternate means of earning equivalent course credit for an equivalent commitment of time and effort must be made available for those who cannot or choose not to participate in a research project.
If extra credit is offered for participation in a research project, the opportunity to participate must be made available to all students. The amount of extra credit must reflect the amount of time required for research participation and cannot exceed 5% of the overall course grade calculation.

G. **Use of Class Time:** IRB submissions proposing the use of class time for research should include an explanation of the benefit of the research to all of the students, especially those who choose not to participate in the research project. Specifically, the investigator should explain how participation in the research would be a learning experience for the students and how the research project is relevant to the course being taught in that class. An alternative activity should be provided for students who choose not to participate.

H. **Use of Class Assignments in Research:** Instructors who use their students’ class assignments (e.g., journals, term papers) in research projects will be required by the IRB to obtain consent from the students who are willing to be research participants. The investigator must make arrangement for the consent process to occur after the class grades are posted or to be conducted by another member of the research team.

I. Additional safeguards may be required to protect the privacy and confidentiality of University student research participants. Certain additional protections for students and parents are required by federal regulations. For example, the proposed use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA). If any University records of the research participants are to be used, then the research participant must give permissions for records access in the consent documents. It is the responsibility of the investigator to comply with any additional federal, state, or local regulations.

1.5.2 **Student Research “Pools”**

A. In some departments, University students are offered the opportunity to participate in research projects. Examples include participation for course credit as part of a course requirement, participation for “extra credit” in a course, or participation in exchange for compensation.

B. A University student may not be required to participate in research for course credit unless a comparable non-research alternative is also offered. To minimize the potential for coercion, alternatives to participating in research for course credit that are offered must be comparable in terms of time, effort, and fulfillment of course requirements. Examples may include reading and/or writing research papers, attending research presentations offered by faculty, or observing performance of research studies.

C. All research participants, including University students, must be free to withdraw from participation at any point in research project without penalty. University students who withdraw from a research project offered for course credit must receive the full course credit offered for participation. When compensation is offered, a pro-rated amount of compensation must be given to any University student who does not complete the entire research project.

D. Every University student participating in a research project must give informed consent for that specific research project as described by SOP 701: Consent Process and Documentation; federal regulations; and IRB policies. Parental permission and
assent are required for any University students (including high school students taking University courses) who meet the regulatory definition of minors.

1.5.3 Recruitment of Employees

A. Justification for Targeting Employees: Investigators who plan to include only University employees must be able to provide a rationale, other than convenience, for restricting the research project population to employees and must show that the recruitment method does not lead potential subjects to think they will be penalized by not participating.

B. Direct Recruitment: Investigators may make research project-related announcements or provide recruitment materials to employees at regular meetings. However, recruitment methods must permit employees to self-identify as interested in participation in a way that maintains confidentiality. For example, employees should be provided with contact information for a research project team member whom they may contact for more information.

C. Indirect Recruitment: The investigator must obtain appropriate permission from University campus locations before posting IRB-approved recruitment materials.

D. (For Norman Campus only) Mass Email Recruitment: Investigators seeking approval to email recruitment materials or research project announcements to employees must explain this recruitment method in the protocol and include this language: “The OU IRB has approved the content of this research recruitment message, but the investigator is responsible for obtaining authorization to distribute this research recruitment message by mass email.”

E. Consent: An employee may not be required to participate in research as a condition of employment. Investigators will ensure that employees know that they may choose not to participate in the research and that their decision will not affect their employment or benefits at the University. Similarly, research participants must be made aware that their participation will not lead to any preferential employment treatment.

1.5.4 Other Special Populations

A. There are other groups of persons that receive special consideration and may include traumatized and comatose patients, terminally ill patients, normal volunteers, minorities, participants in AIDS research, employees of the sponsor or investigator, the elderly, and American Indian tribes and tribal organizations. The IRB defines the elderly as 65 years of age and older. The IRB shall determine special protections necessary for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by University policies and state and federal laws.

B. For purposes of VA Research, individuals or populations that might be temporarily or permanently vulnerable include, but are not limited to, those who:

1. Are susceptible to coercion or undue influence (e.g., the homeless, prisoners, students, patients with limited or no treatment options, socially and economically disadvantaged).
2. Lack comprehension of the research and its risks (e.g., educationally disadvantaged, dementia, schizophrenia, or depression).

3. Have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault).

4. Are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status).

2. SCOPE

This SOP applies to all human research submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB Staff is responsible for maintaining adequate information for review of research pertaining to special populations based on applicable regulations and guidance.

3.2 The IRB Chair or IRB designee is responsible for informing IRB members of applicable regulations and guidance pertaining to special populations, for selecting IRB reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

3.3 The IRB reviewer is responsible for conducting appropriate review of research including special populations with attention to the assessment of potential for coercion or undue influence, in consultation with appropriate experts and resources as necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
45 CFR 46: Subparts A, B, C, D
45 CFR 46.101, 45 CFR 46.110, 46.115(B), 46.116, 46.122, 46.404, 46.405, 46.406, 46.407, 46.409
21 CFR 50: Subpart D 50.51, 50.52, 50.53, 50.54, 50.55, 50.56
21 CFR 56.111
OHRP Guidance Document, IRB Guidebook
OHRP Guidance on the Involvement of Prisoners in Research, May 23, 2003
Department of Veterans Affairs, VHA Handbook 1200.5
NIH Guidelines for Human Stem Cell Research, July 7, 2009

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP IV: Glossary
SOP 301: Research Submission Requirements
SOP 401: Research Exempt from Federal Regulations
SOP 402: Expedited Review
7. PROCESS OVERVIEW

7.1 Review Process

A. The IRB Administrator reviews the submitted documents for the inclusion of special populations.

B. Research projects that include special populations may require that the IRB or IRB reviewer stipulate that additional protective measures be included in the research project as described in this policy. The revised protocol will then be considered in light of the regulations in 45 CFR 46 A, B, C, and D (as applicable) prior to IRB approval of the research project.

C. Following this, the Review Process will be carried out as described in SOP 301: Research Submission Requirements.

7.2 Additional Review and Meeting Requirements

Research projects that include special populations have the following meeting requirements:

7.2.1 Prisoners: A prisoner representative must attend and participate in the discussion of and vote on research projects that recruit from or that include participants who become incarcerated during the conduct of the research project. All documents pertaining to the prisoner research project are provided to the prisoner representative prior to the IRB meeting. If the prisoner research project involves minors, attempts are made to obtain a child prisoner advocate if one is available. The IRB shall determine that all the conditions for approval are met.

Additionally, research involving prisoners may fall into one of three categories:

1. For research involving interactions with prisoners reviewed by the convened IRB:
   a. Minor modifications to research may be reviewed using the expedited procedure, as documented in SOP 402: Expedited Review and SOP 405: Modifications.
   b. Modifications involving more than a minor change reviewed by the convened IRB must use the same procedures for initial review including the responsibility of a prisoner representative to review the modification and participate in the meeting (as described above).
   c. Continuing review must use the same procedure for initial review including the responsibility of a prisoner representative to review the continuing review materials and participate in the meeting (as described above).

2. Research involving interactions with prisoners reviewed by the expedited procedure:
a. Research involving interaction with prisoners may be reviewed by the expedited procedure if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

i. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.

b. Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure, including the responsibility of a prisoner representative.

3. Research not involving interactions with prisoners (e.g., existing data, record review) reviewed by the expedited procedure:

a. Research that does not involve interaction with prisoners may be reviewed by the expedited procedure if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

b. Review by a prisoner representative is not required. However, the prisoner representative may review the research as a reviewer or consultant if so designated by the IRB Chair.

7.2.2. Children: Research projects requiring a convened IRB review are assigned to an IRB with individuals who have expertise with this population. Alternatively, the IRB will consult with a child expert. The IRB or IRB reviewer shall determine the risk category and appropriate level of review.

7.2.3. Pregnant Women, Fetuses, and Neonates: The IRB shall determine the risk category and appropriate level of review.

7.3 Additional Minutes Requirements

Studies that include the following special populations have the following documentation requirements for the minutes:

7.3.1 Prisoners: The minutes shall reflect (1) the presence of the prisoner or prisoner advocate; (2) that all the seven considerations of 45 CFR 46 Subpart A were met; (3) the level of review for the research project; and (4) the protocol-specific findings justifying the IRB’s determination.

7.3.2 Children: The minutes shall reflect (1) that one of the four approval categories of research for children 45 CFR 46 Subpart D were met; (2) the level of review for the research project; and (3) the protocol-specific findings justifying the IRB’s determination.

7.3.3 Pregnant Women, Fetuses, and Neonates: The minutes shall reflect (1) that all of the conditions of 45 CFR 46 Subpart B was met; (2) the level of review for the research project; and (3) the protocol specific findings justifying the IRB’s determination.

7.4 Additional Procedures for Research Involving Prisoners

7.4.1 If the research is conducted or supported by DHHS and is approved under 46 CFR 46.306(a), category iii or iv (see Section 1.1, 1 above), the IRB Administrator generates a letter to the investigator stating that the research requires approval from OHRP prior to participant recruitment.
7.4.2 The IRB Administrator forwards the research project documents along with the IRB correspondence to the IRB Director. The IRB Director sends the IRB approved protocol, any relevant HHS grant application or proposal, any IRB submission materials required by the IRB, and any other information requested or required by the IRB to be considered during IRB review to OHRP Prisoner Research Contact Person.

7.4.3 DHHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to the IRB on behalf of the Secretary in accordance with 45 CFR 46.306(a)(2). The IRB Director notifies the investigator that the research project has been either approved or disapproved. If OHRP approves the research project, the IRB Administrator generates an approval letter noting the OHRP approval and forwards it to the investigator.

APPROVED BY: ___________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall review all human participant research involving investigational drug studies. Investigational drug studies typically pose greater than minimal risk and therefore require convened IRB review.

The category of research covered by this policy involves methodology that requires additional considerations or for which there are federally mandated determinations that IRBs are required to make and document.

All investigational drugs or agents used in human participant research shall be stored, handled, and dispensed in accordance with University policy and state and federal laws and regulations. If an investigational pharmacy is not utilized for dispensing the investigational drugs and agents, the investigator shall assure that dispensing is in accordance with University policy and state and federal laws and regulations.

Specific Policy

1.1 Clinical Research Involving Investigational Drugs

The review of most studies involving investigational drugs requires convened IRB review. Additional review by other University committees may be required.

1.1.1 Determination of a Valid Investigational New Drug (IND)

When research involves the use of a drug other than a marketed drug in the course of medical practice, the drug shall have an IND unless the protocol meets one of the following FDA exemptions from the requirement to have an IND. The IND goes into effect 30 days after the FDA receives the IND, unless the sponsor receives earlier notice from the FDA. The IRB requires investigators to provide documentation of the IND number for the investigational drug when submitting new research projects for investigator-initiated or industry-sponsored research by submitting a letter from the FDA, a letter from the sponsor, or a commercial protocol with the IND number.

Exemption 1 (all must be true)

- The drug product is lawfully marketed in the United States.
- The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
- The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- The investigation is conducted in compliance with 21 CFR 50 and 56.
The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

Exemption 2
A clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:

- Blood grouping serum.
- Reagent red blood cells.
- Anti-human globulin.
- The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- The diagnostic test is shipped in compliance with 21 CFR 312.160.

Exemption 4
A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.

1.1.2 Investigator Responsibilities for Investigational Drug Dispensing and Accountability
An investigator shall administer the investigational drug only to participants under the investigator's personal supervision or under the supervision of a Sub-investigator responsible to the investigator.

The investigator shall not supply the investigational drug to any person not authorized to receive it.

The investigator shall maintain adequate records of the disposition of the investigational drug, including usage, dates, quantity received, and use by the participants.

If the research is terminated, suspended, discontinued, or completed, the investigator shall return the unused supply of the investigational drug to the sponsor or otherwise provide for the disposition of the unused investigational drug consistent with the terms of the underlying research agreement.

The initial research project submission shall include the location where the drug will be stored and who will dispense it (i.e., the hospital pharmacy, the out-patient pharmacy, the investigator's office). If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions to prevent theft or diversion of the investigational drug. This includes storage of the investigational drug in a secure, well-constructed cabinet or other securely locked, well-constructed enclosure with limited access. The pharmacist member or designee of the IRB shall review the plan to store and dispense drug for adequacy.

Investigators shall have access to training in investigational drug storage, dispensing, and accountability in the Good Clinical Practice course in CITI. Investigators are responsible for making themselves familiar with and complying with all requirements of the Oklahoma Bureau of Narcotics and Dangerous Drugs, the Drug Enforcement
Agency, and any other agencies having jurisdiction over the investigational drug or the investigator’s license to use it.

For VA Research: The investigator shall inform the VA pharmacy service that IRB and Research and Development Committee (R&D) approval has been obtained through the use of VA Form 10-1223. The investigator shall provide the pharmacy with the currently approved protocol, a signed copy of the VA Form 10-1086 to document each participant’s consent to participate in the research project, documentation of IRB approval (including continuing review approval, if applicable) or other relevant approvals, a copy of VA Form 10-9012, if applicable, copies of sponsor-related correspondence specific to the appropriate drugs, and copies of all correspondence addressed to the investigator from the FDA specific to the investigational drug(s). The investigator shall inform the Chief, Pharmacy Service, and the R&D Committee, when the research has been terminated, suspended, or closed. The investigator shall comply with all dispensing requirements and with all documentation requirements and make relevant records accessible to the investigational drug pharmacist upon request.

1.1.3 Investigational Use of Marketed Drugs

Investigational use is the use of an approved drug in the context of a clinical study protocol. When the principal intent is to expand the drug’s safety or efficacy, an IND application may be required. However, according to 21 CFR 312.2, the clinical investigation of a marketed drug may not require submission of an IND if all five of the following conditions are met:

(A) it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;

(B) it is not intended to support a significant change in the advertising for the product;

(C) it does not involve a route of administration or dosage level, use in a research project population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

(D) it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];

(E) it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and it does not intend to invoke 21 CFR 50.24.

All investigator-initiated research in which a drug is being used for its approved indication may not require submission of an IND application to the FDA. The FDA may grant an exemption or may assign an IND number. When the investigator holds the IND, additional reporting responsibilities are required of the investigator. These reporting requirements include an annual report to the FDA.

The investigator considers whether or not an IND is indicated when s/he fills out the IND sub-form. The IRB considers whether or not an IND is indicated when reviewing the IND sub-form the investigator provides. In the event of a disagreement, the investigator will be requested to submit the study for IND review with the FDA, which will have final say.

1.1.4 Investigational Drug Protocols

An investigational new drug is a drug that is used in a clinical investigation and that has not been approved by the FDA to be marketed or that has not been approved by the FDA for the indication(s) the investigator will study.
The IRB shall carefully scrutinize the following for all investigational drug studies:

A. Scientific soundness – research validity and value.
B. Research project design for the research project population, trial phase, and mechanism for data analysis and surveillance.
C. Risk/benefit analysis and review of the procedure for obtaining informed consent.
D. Investigator qualifications – investigator experience and resources to carry out the protocol.
E. Conflicts of interest that must be addressed.
F. Confidentiality safeguards – how information will be handled.
G. Data and safety monitoring – the level of monitoring for the level of risk.
H. Participants must be advised in the informed consent and HIPAA form that the FDA may access their medical records as they pertain to the research project.

1.1.5 International Investigational Drug Research

For FDA-regulated research involving an investigational drug conducted outside of the United States, an IND is not required provided the research is conducted under the Declaration of Helsinki (1989) and Good Clinical Practice guidelines. If, however, the investigation is intended to be reported to the FDA as a well-controlled study in support of a new indication for use, intended to be used to support any other significant change in the labeling for the drug or intended to support a significant change in the advertising for the product, then an IND would be required under FDA regulations.

2. SCOPE

This SOP applies to all research studies involving investigational drugs submitted to the IRB.

3. RESPONSIBILITY

3.1 The HRPP Director or IRB designee is responsible for maintaining up-to-date review tools for review of this type of research.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.3 The IRB Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with appropriate experts and resources.

3.4 Communication with the FDA is the responsibility of the IRB, the sponsor, and the sponsor-investigator as appropriate.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

203-A  HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
603A-C VA Form 10-9012 Investigational Drug Information Record

7. PROCESS OVERVIEW

7.1 The investigator submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submissions with all applicable documents are made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as required, including documentation of a valid IND, investigator’s brochure or drug package insert. The IRB Administrator also verifies if additional University committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any addition information and /or reviews. If the research project is investigator-initiated, the investigator shall forward to the IRB a copy of all communications with the FDA regarding the IND.

7.4 The IRB Administrator assigns the submission either to the appropriate Board agenda or to the IRB Chair/IRB designee.

7.4.1 If to an IRB agenda, the process follows SOP #403: Initial Review – Criteria for IRB Approval

7.4.2 If to the IRB Chair / IRB Designee, the process follows SOP #402: Expedited Review

7.5 If an IND is required, final IRB approval shall not be granted until the IND process is complete and the necessary documents are received.

7.6 Following review of the submission, the IRB Administrator updates the outcome of the IRB review then communicates the outcome and any stipulations to the investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda.

7.7 Enrollment into the research project may not commence until all required University committees have completed their review and the research contract is signed, if applicable.

APPROVED BY: _______________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall review all human research involving biologics. These studies pose greater than minimal risk and therefore require convened IRB review.

The category of research covered by this policy involves methodologies that require additional considerations or for which there are federally mandated determinations that IRBs are required to make and document.

All investigational biologics used in human research shall be stored, handled, and dispensed in accordance with applicable University policy and state and federal laws and regulations. If an investigational pharmacy is not utilized for dispensing the investigational biologics, the investigator shall assure that dispensing is in accordance with applicable University policy, and, state and federal laws and regulations.

Specific Policy

1.1 Clinical Research Involving Biologics

The review of studies involving biologics requires convened IRB review. Additional review by other University committees may be required.

1.1.1 Determination of a Valid IND

When research involves the use of a biologic other than a marketed biologic in the course of medical practice, the biologic shall have an IND unless the protocol meets one of the following FDA exemptions from the requirement to have an IND.

Exemption 1 (all must be true)

- The drug product is lawfully marketed in the United States.
- The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
- The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- The investigation is conducted in compliance with 21 CFR 50 and 56.
- The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

Exemption 2

- A clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
  - Blood grouping serum.
  - Reagent red blood cells.
- Anti-human globulin.
- The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- The diagnostic test is shipped in compliance with 21 CFR 312.160.

Exemption 3

A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND

The IRB requires investigators to provide documentation of the IND number when submitting new projects to the IRB for investigator initiated or industry-sponsored research by submitting a letter from the FDA, a letter from the sponsor, or a commercial protocol with the IND number.

1.1.2 Investigator Responsibilities for Biologic Dispensing and Accountability

The investigator shall administer the biologic only to participants under the investigator’s personal supervision or under the supervision of a sub-investigator responsible to the investigator.

The investigator shall not supply the investigational biologic to any person not authorized to receive it.

The investigator shall maintain adequate records of the disposition of the biologic, including dates, quantity, and use by the participants.

If the research is terminated, suspended, discontinued, or completed, the investigator shall return the unused supply of the biologic to the sponsor or otherwise provide for the disposition of the unused supplies of the biologic, consistent with the terms of the underlying research agreement.

All investigational biologics shall be stored in the pharmacy or other location designated.

The IRB shall approve the plan submitted by the investigator to the IRB for storing, dispensing, and disposing of the investigational biologic, which shall be consistent with the underlying research agreement.

Investigators are responsible for making themselves familiar with and complying with all requirements of the Oklahoma Bureau of Narcotics and Dangerous Drugs, the Drug Enforcement Agency, and any other agencies having jurisdiction over the biologic drug or the investigator’s license to use it.

1.1.3 For VA Research:

VA human research involving biologic drugs, as regulated by the Food, Drug, and Cosmetic Act, must be conducted in accordance with all applicable VA and other Federal requirements including, but not limited to VHA Directive 1200.05, VHA Handbook 1108.04, and FDA regulations. This applies to investigator conduct and IRB approval of biologic drug research projects, as well as to storage and security procedures for biologic drugs. The investigator must:

(A) Provide the VA Pharmacy Service or Research Investigational Pharmacy information on each research participant receiving a biologic drug through the electronic medical record (CPRS) or other locally approved means. Documentation is to include allergies, toxicities, or adverse drug events related to the biologic drug, or the potential for interaction with other drugs, foods, or dietary supplements, i.e., herbals, nutriceuticals (see VHA Handbook 1108.04).
(B) Ensure the local VA Pharmacy Service or Research Service Investigational Pharmacy receives:

(a) Documentation of initial and subsequent IRB approvals, and any other relevant approvals;
(b) Documentation of R&D Committee approval;
(c) A copy of VA Form 10-9012, Investigational Drug Information Record, when applicable;
(d) A copy of the current approved protocol;
(e) A copy of the informed consent documents for each research participant with all appropriate signatures;
(f) Documentation of the IRB continuing review approval;
(g) Copy of current or updated Delegation of Authority form;
(h) Copies of sponsor-related correspondence specific to the drug(s) as appropriate; and
(i) Copies of all correspondence addressed to the investigator from the FDA (and other involved authorities) specific to the biologic drug(s) as appropriate.

(C) Inform the Chief of the Pharmacy Service, the research pharmacy when applicable, and the IRB in writing when a research project involving biologic drugs has been suspended, terminated, or closed.

(D) Comply with all dispensing requirements.

(E) Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested (VHA Handbook 1108.04).

(F) Comply with all VHA pharmacy requirements regarding receiving, dispensing, storing, and record keeping for investigational and/or biologic drugs.

1.1.4 Investigational Use of Marketed Biologics

All investigator-initiated research in which a biologic is being used for other than its approved indication requires submission of an Investigational New Drug (IND) application to the FDA. The FDA may grant an exemption or may assign an IND number. When the investigator holds the IND, additional FDA reporting responsibilities are required of the investigator.

The investigator considers whether or not an IND is indicated when s/he fills out the IND sub-form. The IRB considers whether or not an IND is indicated when reviewing the IND sub-form the investigator provides. In the event of a disagreement, the investigator will be requested to submit the study for IND review with the FDA, which will have final say.

The IRB requires investigators to provide documentation of the IND number when submitting new research projects to the IRB for investigator-initiated or industry-sponsored research.

1.1.5 Investigational Biologic Research Projects

An investigational new biologic is a new product or biologic that is used in a clinical investigation and that has not been approved by the FDA to be marketed.

The IRB shall review the following for all studies involving the use of biologics:

A. Scientific soundness – research validity and value.
B. Research project design to the research population, trial phase, and mechanism for data analysis and surveillance.
C. Risk/benefit analysis and review of the procedure for obtaining informed consent.
D. Investigator qualifications – investigator experience and resources to carry out research project.
E. Conflicts of interest that must be addressed.
F. Confidentiality safeguards – how information will be handled.
G. Data and safety monitoring – the level of monitoring for the level of risk.
H. Research participants must be advised in the informed consent documents and HIPAA form that the FDA may access their medical records as they pertain to the research project.

1.1.6 Gene Transfer

The Institutional Biosafety Committee, prior to IRB approval, must approve all gene transfer research projects. All gene transfer research projects require review by the convened IRB.

2. SCOPE

This SOP applies to all biologics research projects regarding biologics submitted to the IRB.

3. RESPONSIBILITY

3.1 The HRPP Director or IRB designee is responsible for maintaining up-to-date review tools for review of biologics research.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.3 The IRB Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with appropriate experts and resources.

3.4 Communication with the FDA regarding biologics research is the responsibility of the IRB, the sponsor, and the sponsor-investigator, as appropriate.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
21 CFR 312.2(b), 312.7
OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 403: Initial Review – Criteria for IRB Approval
6. ATTACHMENTS
   203-A HSC Reviewer Checklist

7. PROCESS OVERVIEW
   7.1 The investigator or investigator staff submits a new study application and uploads all applicable
documents into the IRB electronic information system.

   7.2 The submission is received in the IRB Office and processed (see SOP 301: Research
Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The
submissions with all applicable documents are made available to all IRB members.

   7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary
documents are received as required, including documentation of a valid IND and an
Investigator’s Brochure or drug package insert. The IRB Administrator also verifies if additional
University committee review or information is required. The IRB Administrator communicates
with the investigator and/or research staff to obtain any additional information and/or reviews. If
the research project is investigator-initiated, the investigator shall forward to the IRB a copy of
all communications with the FDA regarding the IND.

   7.4 The IRB Administrator assigns the submission either to the appropriate Board agenda or to the
IRB Chair/IRB designee.
      7.4.1 If to an IRB agenda, the process follows SOP 403: Initial Review – Criteria for IRB
Approval
      7.4.2 If to IRB Chair / IRB Designee, the process follows SOP 402: Expedited Review

   7.5 If IBC review is required, final IRB approval shall not be granted until documentation of IBC
approval has been received.

   7.6 Following review of the submission, the IRB Administrator updates the outcome of the IRB
review and communicates the outcome and any stipulations to the investigator. The IRB
Administrator posts the final IRB approval to the next appropriate IRB agenda.

   7.7 Enrollment into the research project may not commence until all required University committees
have completed their review and the research contract is signed, if applicable.

APPROVED BY _______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

All human participant research involving devices is reviewed by the IRB in accordance with applicable laws and regulations. For policy information concerning Humanitarian Use Devices, refer to SOP 502F.

The Health Sciences Campus IRB requires that all investigational devices used in human participant research be stored, handled, and dispensed in accordance with governing regulations, University policy, and state and federal law. If the Investigational Pharmacy is not utilized for the dispensing of investigational devices, it is the responsibility of the investigator to assure that dispensing is in accordance with University policy and state and federal law.

Specific Policy

1.1 Clinical Research Involving Devices

1.1.1 Determination of a Valid IDE

When research is conducted to determine the safety or effectiveness of a device, the device has an IDE issued by the FDA, or

The device fulfills the following requirements for an abbreviated IDE:

- The device is not a banned device.
- The sponsor labels the device in accordance with 21 CFR 812.5.
- The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval.
- The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator’s care, consent under 21 CFR 50 and documents it, unless documentation is waived by the IRB.
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

The device fulfills one of the IDE exemption categories:

- A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the
indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

- A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
  - Is noninvasive.
  - Does not require an invasive sampling procedure that presents significant risk.
  - Does not by design or intention introduce energy into a participant.
  - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

- A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.

- A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

As applicable, the IRB requires investigators to provide documentation of an investigational device exemption (IDE) when they submit new research projects for investigator-initiated or industry-sponsored research. The IRB requires investigators to provide documentation of a valid IDE number by submitting a letter from the FDA, a letter from the sponsor, or a commercial protocol with the IDE number.

1.1.2 Definitions

**Significant Risk Device** is defined at 21 CFR 812.3 (m) as a device that presents a potential serious risk to the health, safety, or welfare of a participant and:

A) is intended as an implant;

B) is used in supporting or sustaining human life;

C) is of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise prevents impairment of human health; or,

D) otherwise presents a potential for serious risk to the health, safety, or welfare of the participant.

**Non-Significant Risk Device** is defined at the FDA Information Sheet Guidance, Significant Risk and Non-Significant Risk Medical Device Studies, January 2006, as a device that does not meet the definition above for a significant risk device. These devices pose minimal risk to participants.

1.1.3 **Significant Risk (SR) Device vs. Non-Significant Risk (NSR) Device Studies**

- The difference between NSR device and SR device studies is that NSR device studies have fewer regulatory controls than SR device studies. The IRB acts as the agent of the FDA with respect to review and approval of NSR device studies.

- When an investigator or a sponsor proposes the initiation of a presumed NSR investigation to the IRB, if the IRB agrees that the device is NSR and approves the research project, the investigation may begin without submission of an IDE application to the FDA. However, if the IRB determines that the device is SR, the research project cannot proceed. The sponsor must notify the FDA that the IRB
has considered the device SR. The research project may proceed as an SR research project following FDA approval of an IDE application and IRB approval. The FDA ultimately determines if a device protocol is SR or NSR.

C) To aid in the determination of the risk status of the device, the IRB shall review information such as reports of prior investigations conducted with the device, the protocol, a description of the participant selection criteria, and monitoring procedures. The sponsor must provide to the IRB the rationale used in making its risk determination. The risk determination is based on the proposed use of a device in the investigation, not on the device alone.

D) The Investigator considers whether or not an IDE is indicated when s/he fills out the IDE sub-form. The IRB considers whether or not an IDE is indicated when reviewing the IDE sub-form the Investigator provides. In the event of a disagreement, the investigator will be requested to submit the study for IDE review with the FDA, which will have final say.

E) The IRB requires investigators to provide the IDE number when submitting new research projects for investigator-initiated or industry-sponsored research.

1.1.4 Investigator Responsibilities for Device Dispensing and Accountability

An investigator shall permit an investigational device to be used only with participants who are under the investigator’s supervision. An investigator shall not supply an investigational device to any person not authorized to receive it.

Upon completion or termination of a clinical research project or the investigator’s part of the investigation, or at the sponsor’s request, the investigator shall return to the sponsor any remaining device, consistent with the terms of the underlying research agreement.

The following accurate, complete, and current records shall be maintained by the investigator:

A) all correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports

B) records of receipt, use, or disposition of the device which relate to:

- type and quantity of the device, dates of receipt, and the batch number or code mark
- names of all persons who received, used, or disposed, of each device
- why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of

The initial research project submission must include a plan for storing, dispensing, and returning (if applicable) the investigational device that is consistent with the underlying research agreement.

2. SCOPE

This SOP applies to all device research submitted to the IRB.

3. RESPONSIBILITY

3.1 The HRPP Director or IRB designee is responsible for maintaining up-to-date review tools for review of research pertaining to devices based on new and evolving applicable regulations and guidelines.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members with adequate submission review training and ongoing guidance and for selecting one Primary and one
Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation to obtain that expertise.

3.3 The IRB Chair or IRB designee is responsible for conducting appropriate review of research involving devices in consultation with appropriate experts and resources.

3.4 The IRB Reviewer is responsible for conducting appropriate review of research involving devices in consultation with appropriate experts and resources and for utilizing the Reviewer Checklist in reviewing the research project.

3.5 The IRB is responsible for verifying investigators have followed proper procedures for procuring an IDE, IDE exemption/waiver, or HDE, especially for SR devices. It is also responsible for notifying the investigator, the sponsor, or FDA, if applicable, of pertinent information regarding device significant risk.

3.6 The IRB Administrator is responsible for requesting changes to the study protocol from the investigator, based on the IRB review and sending the response of the IRB review to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812
21 CFR 50, 56

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 403: Initial Review - Criteria for IRB Approval
SOP 502F: Humanitarian Use Devices

6. ATTACHMENTS

203-A HSC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 The investigator or investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as required, including information about the device, the sponsor’s assessment of SR or NSR, and documentation of an IDE, if applicable. The IRB Administrator also verifies if additional University committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any additional information and/or reviews.

7.4 The IRB Administrator assigns the submission either to the appropriate Board agenda or to the IRB Chair/IRB designee.

7.4.1 If to an IRB agenda, the process follows SOP 403: Initial Review – Criteria for IRB Approval.
7.4.2 If to IRB Chair / IRB Designee, the process follows SOP 402: Expedited Review.

7.5 In addition to the requirements outlined in SOP 403, the IRB shall make the following assessments:

7.5.1 If the sponsor indicates the device is NSR, the IRB or IRB Chair / IRB designee shall make a determination of whether to concur with the NSR determination.

7.5.2 The IRB or IRB Chair/Designee evaluates all new device protocols initiated by sponsor-investigators for elements of investigational use of a marketed device.

7.5.3 If a sponsor-investigator is utilizing a marketed device to “expand the device’s safety or efficacy,” the IRB or IRB Chair/Designee understands that a FDA IDE may be required and makes appropriate inquiries with the sponsor-investigator and/or the FDA during review of the research project to determine if an IDE is required.

7.6 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB approval to the next appropriate agenda.

7.7. If an IDE is required, final IRB approval shall not be granted until the IDE process is complete and the necessary documents are received.

7.8 Enrollment into the research project may not commence until all required University committees have completed their review and the research contract is signed, if applicable.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall review all human participant research prior to the investigator’s collection of data from medical records, charts, and case reports. The IRB shall give consideration to the protection of the privacy of the participants, purpose of the research, and the investigator’s ability to meet the objectives of the research project.

Specific Policy

1.1 Medical Records and Chart Reviews

The IRB shall review all requests for access to medical records and chart reviews for research. Inappropriate use of private, confidential information can result in harm to a human research participant.

1.1.1 Potentially Exempt Research Activities

A. Research utilizing information available in public documents in the United States (i.e., court records, police records) is not “human participant research” if the activity does not involve the collection of private identifiable information. Since “private information” is defined as “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public,” most research utilizing information available in public documents in the United States, is not “human participant research.” Human participant research that involves the collection of existing public information is not FDA-regulated and may be exempt, regardless of whether the information is recorded in such a way that participants can be identified directly or through linkage. All use of public documents from another country for a research project is subject to the applicable laws and regulations of that country, and the investigator is responsible to assure compliance with those laws and regulations.

B. Human participant research that involves the collection of retrospective data (records that exist prior to the start of the research project) from medical records can be exempt from IRB review if the information is recorded by the investigator in such a manner that the participants cannot be identified, directly or through identifiers linked to the participants.

C. Research that involves collection of data from medical records of patients no longer living is not considered human participant research, provided a related living person is not put at risk (as in some types of infectious disease or genetics research). Note, however, that these records remain subject to and protected by HIPAA for 50 years from the patient’s death.

1.1.2 Potentially Expedited Research Activities

A. Research implemented with reasonable and appropriate protections so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

B. Research limited to the review of data that has been (or will be) collected solely for the purpose of medical treatment or diagnosis (non-research purposes).

1.2 Case Reports
Retrospective review of three (3) or more medical case reports qualify as a research project and must be submitted to the IRB for review.

Publication of one (1) medical case report that will include the addition of a procedure that is outside of standard of care qualifies as research and must be submitted to the IRB for review.

2. SCOPE

This SOP applies to all research projects involving medical records, chart reviews, and case report research projects submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for conducting pre-review and assigning the research project to the IRB Chair or IRB designee for evaluation of type of initial review, if unclear. If the research project qualifies for “expedited” review, the IRB Administrator processes the submission in the IRB’s electronic information system for expedited review by the IRB Chair or IRB designee. If the submission qualifies for “full board” review, the IRB Administrator posts the submission on the next available IRB meeting agenda for review.

3.2 The HRPP Director or IRB designee is responsible for maintaining up-to-date review tools for review of this type of research.

3.3 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance, and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.4 The IRB Reviewer is responsible for conducting appropriate review of research planned for this category in consultation with appropriate experts and resources and for utilizing the IRB reviewer checklist to review the submission of the proposed research project.

3.5 The IRB is responsible for verifying appropriate measures are instituted for the protection of human rights and confidentiality.

3.6 Communication with the FDA is the responsibility of the IRB, the sponsor, and the sponsor-investigator as appropriate. The IRB Staff is responsible for assisting the IRB, the IRB Reviewer, and the investigator with the appropriate HIPAA form for the research project. The IRB Staff shall elicit guidance on HIPAA questions from the University Privacy Official, as necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 401: Exempt Review
SOP 402: Expedited Review

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
7. PROCESS OVERVIEW

Typically, medical record/chart reviews and case reports are minimal risk and may be approved under the expedited or exempt categories. However, the IRB Chair or IRB designee has the option of forwarding any request to the convened IRB for consideration.

7.1 The investigator or investigator's staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403 – Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all required documents are received including the appropriate HIPAA authorization or request for waiver of authorization form.

7.4 The IRB Administrator assigns the submission either to (1) the appropriate Board agenda or (2) to the IRB Chair/IRB designee (b).

7.4.1 If to an IRB agenda, the process follows SOP 403: Initial Review – IRB Criteria for Approval.
7.4.2 If to IRB Chair / IRB Designee, the process follows SOP 401: Exempt Review, or SOP 402: Expedited Review.

7.5 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda.

7.6 Enrollment into the research project may not commence until all required University committees have completed their review and the research contract is signed, if applicable.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 502E: TREATMENT USE OF INVESTIGATIONAL NEW DRUGS/DEVICES

1. POLICY

Treatment use, compassionate use, and expanded access for treatment use refer to the use of an investigational drug or device when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition rather than to obtain the kind of information about the drug that is generally derived from clinical trials. The primary intent of treatment use protocols is not to obtain information about the safety or effectiveness of a drug. Rather, treatment use protocols involve use of a drug or device that is not approved for marketing but that is under clinical investigation for a serious or immediately life-threatening disease or condition in patients for whom no comparable or satisfactory alternative drug, device, or other therapy is available.

The IRB shall review human research project submissions for the treatment use of investigational new drugs/devices. The investigator must meet FDA requirements under 21 CFR 312.34 and 21 CFR 312.35 prior to IRB approval. The investigator must obtain legally effective informed consent from the participant prior to treatment use of the investigational new drug/device.

Treatment use is defined as use of a drug or device that is not approved for marketing but is under clinical investigation for a serious or immediately life-threatening disease condition in patients for whom no comparable or satisfactory alternative drug/device or other therapy is available.

Specific Policies

1.1 Treatment IND/IDE

A treatment IND/IDE is a mechanism established by the FDA for providing eligible participants with investigational drugs/devices for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments.

The IRB may approve a treatment IND/IDE after the investigator has demonstrated that sufficient data have been collected to show that the drug/device "may be effective" and does not have unreasonable risks to participants. Because data related to safety and side effects are collected during a treatment IND investigation, treatment IND/IDEs also expand the body of knowledge about the drug/device.

There are four FDA requirements that the investigator must demonstrate before the IRB can approve a treatment IND/IDE:

1) the drug/device is intended to treat a serious or immediately life-threatening disease;
2) there is no satisfactory alternative treatment available;
3) the drug/device is already under investigation, or trials have been completed; and
4) the trial sponsor is actively pursuing marketing approval.

Treatment IND/IDE studies require prospective IRB approval and informed consent from the participants.

1.2 Exceptions to IRB Approval
Test articles given to human participants under a treatment IND/IDE require prior IRB approval, with two exceptions:

1. If a life-threatening emergency exists, as defined by 21 CFR 56.102(d), the procedures described in 56.104(c) ("Exemptions from IRB Requirement") may be followed.

2. The FDA may grant the sponsor or sponsor/investigator a waiver of the IRB requirement in accord with 21 CFR 56.105. However, the IRB may still choose to review the research project, even if the FDA has granted a waiver. SOP 502G: Emergency Use of FDA Regulated Products describes the process an investigator must follow for obtaining informed consent and the documentation requirements for situations requiring exceptions.

Such waivers noted above do not apply to the informed consent requirement.

1.3 Consent of the Participant

The IRB requires that the research team obtain legally effective informed consent prior to conducting any research project-related procedure or intervention, including for investigational new drugs and devices, from each research participant or from his/her legally authorized representative.

2. SCOPE

This SOP applies to all prospective treatment use research projects involving investigational drug and device protocols submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB administrative staff is responsible to facilitate the review of the treatment use of investigational new drugs/devices.

3.2 The IRB Administrator is responsible for posting the research project to the next available IRB meeting agenda and providing appropriate review sheets to the IRB Chair and IRB Reviewers.

3.3 The HRPP Director is responsible for maintaining up-to-date review tools for review of treatment use of investigational new drugs/devices.

3.4 IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.5 The IRB Reviewer is responsible for conducting appropriate review of research planned for this category in consultation with appropriate experts and resources.

3.6 The IRB is responsible for conducting a thorough discussion of this type of research project to verify that all regulations have been followed.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24, 50.25

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 301: Research Submission Requirements
   SOP 403: Criteria for Approval – Initial Review
   SOP 502G: Emergency Use of FDA Regulated Product

6. ATTACHMENTS
   203-A     HSC Reviewer Checklist

7. PROCESS OVERVIEW
   7.1 The investigator or investigator staff submits a new study application and uploads all applicable documents into the IRB electronic information system. Applicable documents might include consent document(s), the protocol provided by the sponsor, FDA documentation approving the treatment use, documentation of an IND or IDE number, Investigator’s Brochure or drug package insert or device information, etc.
   7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members
   7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as required, including documentation from the FDA approving the treatment use, Investigator’s Brochure, or drug package insert or device information. The IRB Administrator also verifies if additional University committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any additional information and/or reviews.
   7.4 The IRB Administrator assigns the submission to an appropriate Board agenda and follows the process detailed in SOP 403: Initial Review – Criteria for IRB Approval.
   7.5 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the investigator.
   7.6 Treatment use of the drug or device may not commence until all required University committees have completed their review and the research contract is signed, if applicable.

APPROVED BY ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

As defined in the Federal Food, Drug, and Cosmetic Act, and updated by the 21st Century Cures Act, a Humanitarian Use Device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.” A Humanitarian Device Exemption (HDE) is the approval process provided by the FDA that allows a medical device to be marketed without requiring evidence of effectiveness. An HDE is granted, even though the efficacy of the device has not been tested or proven, because it is not financially feasible to do the usual clinical testing when so few individuals are affected.

The IRB shall review all submissions for HUDs, even though the use is not considered research. Before using a HUD, the investigator must obtain IRB approval, unless an emergency situation exists. HUDs are subject to continuing review by the IRB.

NOTE: An IRB approved use of a HUD at a facility to treat or diagnose patients does not mean the IRB has approved investigational use of the HUD (i.e., in a clinical investigation) for the collection of safety and effectiveness data.

Specific Policies

1.1 HUD

Humanitarian use of investigational devices must be prospectively reviewed by the IRB, except for an emergency use situation. The investigator shall submit a new submission for IRB review that must include evidence that the investigator/sponsor has obtained a Humanitarian Device Exemption (HDE) from the FDA.

a. HUD projects are not considered research. However, HUD projects are subject to continuing review requirements at the University.

b. Generally, a HIPAA Authorization form for research is not required unless the use of the HUD is clinical and is for obtaining safety or efficacy data.

c. If the IRB suspends or terminates approval of the HUD project, the investigator shall notify the HDE holder.

1.2 Consent of the Patient

The investigator shall obtain informed consent from the patient or the patient’s legally authorized representative, as applicable. If obtaining such consent is not possible, both the investigator and a physician who is not otherwise participating in the treatment or care of the patient shall certify in writing all of the following:

a. The patient is confronted by a life-threatening situation necessitating the use of the HUD;

b. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the patient;

c. Time is not sufficient to obtain consent from the patient’s legally authorized representative; and

d. No alternative method of approved or generally recognized therapy is available that provides and equal or greater likelihood of saving the life of the patient.
1.3 Emergency Situations

If a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, the investigator may use a HUD without prior approval by the IRB. Within five University business days after the use of the device, the physician must provide written notification to the IRB that includes:

- The identification of the patient involved;
- The date the device was used; and
- The reason for the use.

See SOP 502G: Emergency Use of FDA Regulated Products for more information.

2. SCOPE

This SOP applies to all HUDs submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB administrative staff is responsible for facilitating the review of the HUD.

3.2 The IRB Administrator is responsible for assigning the submission to the next available IRB meeting and for providing the Reviewer Checklist in the IRB’s electronic information system.

3.3 The HRPP Director or designee is responsible for maintaining up-to-date review tools for review of HUD submissions.

3.4 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.5 The IRB Reviewer is responsible for conducting appropriate review of HUD submissions planned for this category in consultation with appropriate experts and resources.

3.6 The IRB is responsible for conducting a thorough discussion of this type of research project to verify that all regulations have been followed.

3.7 The investigator is responsible for notifying the HDE holder upon the IRB’s suspension or termination of the HUD project. See SOP 801 Investigator Qualifications and Responsibilities for additional guidance.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 814 Subpart H, Humanitarian Use Devices

FDA Information Sheets, Guidance for IRBs and Clinical Investigators, 1998 Update

FDA Humanitarian Device Exemptions; Final Guidance

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
7. PROCESS OVERVIEW

7.1 Processing a HUD submission is similar to processing other submissions for research involving human research participants. The IRB Administrator shall process new submissions and revisions to currently approved HUDs and continuing review of HUDs per SOP 301: Research Submission Requirements, and SOP 403: Initial Review – Criteria for IRB Approval.

7.2 The investigator submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.3 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403 – Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.4 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as required, including documentation of the HDE, package insert, or device information. The IRB Administrator also verifies if additional University committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any additional information and/or reviews.

7.5 The IRB Administrator assigns the submission to an appropriate Board agenda and follows the process as detailed in SOP #403: Initial Review – Criteria for IRB Review.

7.6 The IRB Reviewers review the HUD submission to verify that it falls within the criteria stated in the regulations.

7.7 Modifications may be required before final approval. When the modifications are received by the IRB, the IRB Administrator verifies all changes are made before assigning the submission to the IRB Chair or IRB designee for final review.

7.8 When IRB review is completed, the IRB Administrator generates the appropriate letter to notify the investigator of the results of the review and reports the final approval by posting to the next IRB agenda.

7.9 Enrollment may not commence until all required University committees have completed their review and the contract is signed, if applicable.

APPROVED BY: ______________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 502G: EMERGENCY USE OF FDA REGULATED PRODUCTS

1. POLICY

“Emergency use” is defined in 21 CFR 56.102(d)\(^1\) as the use of a test article with a human participant in a life-threatening situation for which no standard acceptable treatment is available and there is not sufficient time to obtain IRB approval.

The HSC IRB allows a one-time emergency use of an investigational drug, device, or biologic test article by an investigator without prior IRB approval, as permitted under FDA regulations at 21 CFR 56.104(c), provided that the emergency use is reported to the IRB within **5 University business days**. Any subsequent use of the test article requires prior IRB review.

The investigator must obtain written informed consent from each individual or legally authorized representative prior to the use of a test article, in accordance with FDA regulations at 21 CFR 50, unless the circumstances meet the exception to the requirement for consent at 21 CFR 50.23(a)-(c).

Under DHHS regulations, patients receiving a test article via emergency use, as defined by FDA regulations, may not be considered to be a research participant and do not permit data obtained from patients to be classified as human participants research, nor permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations. However, under FDA regulations, emergency use of a test article meets the FDA definition of a clinical investigation,\(^2\) and the patient receiving the test article meets the FDA definition of a human participant.\(^3\) Therefore, a patient in such case is a research participant as defined by FDA regulations.

Note that the FDA may require data from an emergency use to be reported in a marketing application.

Specific Policies

1.1 Emergency Use of an Unapproved Drug or Biologic

A drug or biologic may be used in an emergency prior to IRB review, provided that the following criteria are met:

- The participant is in a life-threatening situation for which no standard acceptable treatment is available, and
- There is not sufficient time to obtain IRB approval, and
- The use will be reported to the IRB within five University business days as outlined in Section 1.5 of this SOP, and
- Any subsequent use of the test article by an investigator is subject to IRB review.

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\(^1\)Life threatening, for the purposes of 21 CFR section 56.102(d), includes the scope of both life-threatening and severely debilitating, as defined as follows: Life threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the participants must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. Severely debilitating means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

\(^2\) 21 CFR 56.102(c).

\(^3\) 21 CFR 56.102(e).
If the intended participant does not meet the criteria for an existing research project protocol or if an approved research project protocol does not exist, the investigator must contact the manufacturer to determine if the drug or biologic can be made available for the emergency use under the manufacturer’s IND.

If the manufacturer does not allow the investigator to reference its IND, the investigator must contact the FDA directly at 301-796-3400 for an IND (note that this phone number is subject to change). The FDA requires an Investigational New Drug number (IND) for emergency use and does not allow a waiver of its policy.

1.2 Emergency Use of an Unapproved Device

FDA guidance documents state that emergencies that qualify for use of an unapproved device exist where an unapproved device may offer the only possible life-saving alternative and (1) an IDE for the device does not exist, or (2) the proposed use is not approved under an existing IDE, or (3) the investigator or institution is not approved under the IDE.

An investigator may use an unapproved device in such an emergency, provided that each of the following requirements is met to justify the use:

- The patient is in a life-threatening condition that needs immediate treatment;
- There is no generally acceptable alternative available for treating the patient; and
- Because of the immediate need to use the device, there is not time to use existing procedures to obtain FDA approval for the use.

Prior to using the device, the investigator must obtain authorization from the IDE holder, if an approved IDE for the device exists. If an IDE does not exist or if the IDE holder does not authorize the use, the investigator shall notify the FDA of the emergency use and provide FDA with a written summary of the conditions constituting the emergency, participant protection measures, and results. The contact telephone number for the Center for Devices and Radiological Health (CDRH) is 301-796-5640 (subject to change).

The FDA expects the physician to follow as many participant protection measures as possible. These include:

- Obtaining an independent assessment by a physician not involved in the patient’s care; (see 1.3.2)
- Obtaining informed consent from the patient or a legal representative;
- Notifying institutional officials as specified by institutional policies;
- Notifying the Institutional Review Board (IRB); and
- Obtaining authorization from the IDE holder, if an approved IDE for the device exists.

1.3 Informed Consent

1.3.1 Informed Consent Requirements for Emergency Use Situations

The investigator shall obtain informed consent from the patient or the patient’s legally authorized representative, as applicable, using a consent document that contains the elements of informed consent (as described in 21 CFR 50.25). The investigator is encouraged to utilize the Sample Consent Form for Emergency Use that is available on the IRB website. In emergent situations, the informed consent document will not be reviewed or approved by the IRB, unless the investigator has time to notify the IRB prior to the use of the test article.
1.3.2 Exception from Informed Consent Requirements

If obtaining informed consent is not possible, both the investigator and a physician who is not participating in the research project must certify in writing all of the following:

A. The patient is confronted by a life-threatening situation necessitating the use of the test article;
B. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the patient;
C. Time is not sufficient to obtain consent from the patient’s legally authorized representative; and
D. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the patient.

If, in the investigator’s opinion, immediate use of the test article is required to preserve the patient’s life and time is not sufficient to obtain an independents physician’s determination that the above four conditions apply, the investigator shall make the determination and, after the use of the test article, have the determination reviewed and evaluated in writing by a physician who is not participating in the research project.

The investigator must submit to the IRB a copy of the independent physician’s evaluation within 5 University business days after the use of the test article.

1.4 Prior Notification to the IRB

The investigator should attempt to notify the IRB prior to an emergency use. If an investigator notifies the IRB of the intent to use a test article on an emergency basis in a life-threatening situation without prior IRB review, the IRB Chair or IRB designee shall review the use (including informed consent or the exception from the requirement for informed consent) to determine whether the circumstances of the emergency comply with FDA regulations. However, this notification and subsequent IRB Chair acknowledgement should not be considered an IRB approval.

1.5 Reporting Requirements

1.5.1 Requirement for Five-Day Follow-up Report to the IRB

The emergency use must be reported to the IRB within 5 University business days after emergency use of a test article. Failure to comply with this requirement is considered non-compliance with the IRB. The report must include the following:

- One-time Emergency Use of a Test Article Form;
- Case history of the patient;
- Therapeutic protocol, including reference material and;
- Copy of the executed informed consent document or a copy of the independent physician’s determination that the conditions for exception from informed consent as described in Section 1.3.2 above were met and the emergency use was necessary to preserve the participant’s life.

\[4 \text{ 21 CFR 50.23.}\]
1.5.2 Report of an Unapproved Device to the Sponsor or FDA

After using an unapproved device in an emergency, and if an IDE does exist, the investigator shall notify the sponsor of the emergency use.

After using an unapproved device in an emergency, and if an IDE does not exist, the investigator shall provide the FDA with a written summary of the conditions constituting the emergency use, the participant protection measures followed, and the results of the use. Note that the FDA requires that data generated from the use be used in reports of the research activity to the FDA.

1.6 Subsequent Use

FDA regulations allow for one emergency use (single use with one participant) of a test article without prospective IRB review, provided that the emergency use is reported to the IRB within five University business days after such use. Subsequent use is considered a second use with that participant or another participant. The investigator must evaluate the likelihood of a similar need and, if future use is likely, initiate efforts to obtain IRB approval and an approved IND or IDE from the FDA for subsequent use.

1.7 Planned Emergency Research

Planned emergency research is defined as planned research in a life-threatening emergency where the requirement to obtain prospective informed consent has been waived as covered by 21 CFR 50.24. The research plan must be approved in advance by the FDA (or DHHS) and the IRB, and the project, as well as its results, must be publicly disclosed to the community in which the research is conducted.

Oklahoma law does not allow for an exception to the waiver of consent in emergency research. Therefore, the IRB cannot waive the requirement to obtain informed consent for planned emergency research, and no planned emergency research shall be conducted at OU.

Refer to SOP 701: Consent Process and Documentation, Section 1.4 C for more information regarding waiver of informed consent.

1.8 VA Requirements

A patient in a VA research project receiving a test article in an emergency use that is regulated by FDA is not considered to be involved in research and is not a research participant. VA regulations pertaining to research involving human participants do not permit data obtained from patients to be classified as human participants research, nor may the outcome of such care be included in any report of a research activity subject to VA regulations pertaining to research involving human participants.

2. SCOPE

This SOP applies to all emergency use protocols submitted to the IRB, whether prior or subsequent to the use.

3. RESPONSIBILITY

3.1 The investigator is responsible for consulting with the IRB Chair prior to use of the test article, if time allows, and must submit a One-Time Emergency Use of a Test Article Submission Form to the IRB within 5 University business days after emergency use of the test article.

3.2 The IRB staff is responsible for processing the submission and forwarding it to the appropriate IRB Chair for review and adding the item to the next available IRB meeting agenda.

3.3 IRB Reviewers are responsible for verifying that the use of the test article in an emergency falls within the emergency use criteria, conducting a thorough review of the use of the test
article, securing appropriate consulting expertise as needed, and making appropriate approval recommendations for consideration by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24, 50.25
21 CFR 56.102(d)-(e), 56.104(c)

FDA Information Sheet, Guidance for IRBs and Clinical Investigators, 1998 Update

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 701: Consent Process and Documentation
SOP 903: Non-Compliance/Scholarly Misconduct

6. ATTACHMENTS

301-E HSC One-Time Emergency Use of a Test Article
203-A HSC Reviewer Checklist
502G-A Sample Consent Form for Emergency Use

7. PROCESS OVERVIEW

7.1 If time allows, an investigator shall notify the IRB of an intent to use a test article on an emergency basis in a life-threatening situation without prior IRB review and the IRB Chair or IRB designee shall review the use (including informed consent or the exception from the requirement for informed consent) to determine whether the circumstances of the anticipated emergency use will comply with applicable regulations. The IRB Chair may assist the investigator in efforts to follow as many participant protection measures as possible. However, this notification and subsequent IRB Chair acknowledgement or assistance will not be considered an IRB approval.

7.2 Within 5 University business days of the use of the test article, the physician shall submit a new application in the IRB electronic information system, indicating One-Time Emergency Use of a Test Article, and upload all applicable documents into the IRB electronic information system.

7.3 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.4 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received including: (1) New Application with the One Time Emergency Use of a Test Article subform, (2) documentation from the FDA authorizing the use of the test article for this single use, (3) copy of the consent form signed by the patient (or explanation of why consent could not be obtained in the emergency situation), and (4) assessment from an independent physician. The IRB Administrator also verifies that the report is received within 5 days of the use of the test article.

7.5 The IRB Administrator assigns the submission to the next appropriate Board agenda. The process follows SOP 403: Initial Review – Criteria for IRB Approval.

7.6 The IRB reviews the submission at the convened meeting to verify that the use falls within the criteria stated in the regulations and makes any recommendations necessary. The IRB may require the investigator submit a follow-up status report and to report unanticipated problems to the IRB.
7.7 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the physician / investigator.

7.8 If the use of the test article did not meet the emergency use criteria, or if the investigator fails to submit a New Application with the One Time Emergency Use of a Test Article sub-form to the IRB within five working days, this may represent reportable non-compliance subject to SOP 903, Non-Compliance / Scholarly Misconduct. The investigator, the Department Chair and the Director of Compliance will be informed in writing that the use of the test article did not meet the criteria and is subject to investigation.

APPROVED BY: _______________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall review all research projects involving the collection and/or storage of any human biologic specimen for use in future research studies. An investigator must have an approved research project to collect and bank such specimens and a separately-approved research project for the distribution of these specimens.

The IRB shall review all human participant research projects involving genetic testing. The type of review is at the discretion of the IRB Chair or IRB designee based on the level of risk to the participant. Generally, the greatest risk for participants who participate in genetic research (except for gene therapy research) involves breach of confidentiality.

Gene transfer research projects shall be reviewed independently by the convened IRB and the Institutional Biosafety Committee (IBC).

Specific Policy

1.1 Clinical Research Involving Banking of Biologic Specimens

Research projects involving the collection and banking of human biologic specimens may be approved under either expedited or convened IRB review, depending on the design of the research project and the degree of potential risk for participants. Research projects that are principally drug-treatment in design but have a specimen-banking component are also subject to this SOP.

The IRB adopts the Office for Human Research Protection’s (OHRP) recommendation that recipient-investigators not be provided access to the identities of donors or to information through which the identities of donors may be ascertained in clinical research involving banking of biologic specimens.

1.2 Genetic Testing of Biologic Specimens

The IRB shall review all research projects involving genetic testing and modifications to approved research projects that include genetic testing. The IRB Chair or IRB designee shall determine the type of review based on the level of risk to the participant using the following table as a general guideline:

<table>
<thead>
<tr>
<th>LEVEL OF ANONYMITY</th>
<th>RESEARCH PROJECT DESIGN</th>
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</thead>
<tbody>
<tr>
<td>Anonymous / Anonymized</td>
<td>RETROSPECTIVE</td>
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<td>Usually Full Board</td>
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<tr>
<td>Identified (direct identifiers)</td>
<td>Expedited/Full Board</td>
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<td>Usually Full Board</td>
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</table>
1.3 Gene Transfer

The convened IRB and the IBC shall review gene transfer studies independently. Such studies may also require review by external microbiologists, virologists, molecular biologists, or other consultants with relevant expertise to provide guidance to the IRB and IBC. If the research project involves gene transfer to human participants for other than clinical purposes, the National Institutes of Health Recombinant DNA Advisory Committee (RAC) must approve the research project prior to IRB approval.

1.4 GINA-Genetic Information Nondiscrimination Act

GINA is a Federal law that prohibits discrimination in health coverage and employment based on genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or from using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions and for any decisions regarding terms of employment.

Given that GINA has implications regarding the actual or perceived risks of genetic research and an individual's willingness to participate in such research, investigators and the IRB should be aware of the protections provided by GINA, as well as the limitations in the law's scope and effect. The IRB shall consider the provisions of GINA when assessing whether genetic research satisfies the criteria required for IRB approval of research, particularly whether the risks are minimized and reasonable in relation to anticipated benefits and whether there are adequate provisions in place to protect the privacy of participants and maintain the confidentiality of their data. GINA is also relevant to informed consent. When investigators develop and the IRB reviews the consent processes and documents for genetic research, they shall consider whether and how the protections provided by GINA should be reflected in the consent document's description of risks and in the provisions for assuring the confidentiality of the data.

2. SCOPE

This SOP applies to all research involving banking of biologic specimens, genetic testing, and gene transfer.

3. RESPONSIBILITY

3.1 The HRPP Director or designee is responsible for maintaining up-to-date review tools for review of this type of research.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.3 The IRB Reviewer is responsible for conducting appropriate review of research planned for this category, in consultation with appropriate experts and resources.
3.4 The IRB is responsible to assure there are adequate safeguards for the confidentiality and safety of the participant.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
OHRP Guidance Document, IRB Guidebook
Office for Protection From Research Risks-Issues to Consider in the Research Use of Stored Data or Tissues, November 7, 1997

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 403: Initial Review – Criteria for IRB Approval

6. ATTACHMENTS

203-A HSC Reviewer Checklist
701-A Informed Consent Template
701-C Tissue Consent Template
701-D Patient Information Sheet – Tissue Banking

7. PROCESS OVERVIEW

7.1 The investigator or investigator staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403 – Initial Review – Criteria for IRB Approval).

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received as applicable, including documentation of a valid IND and investigator’s brochure or drug package insert (if applicable), or if additional institutional committee review or information is required. The IRB Administrator communicates with the investigator and/or research staff to obtain any addition information and / or reviews.

7.4 The IRB Administrator assigns the submission either to (1) the appropriate Board agenda or (2) to the IRB Chair/IRB designee.

7.4.1 If assigned to an IRB agenda, the process follows SOP 403: Initial Review – Criteria for IRB Approval.

7.4.2 If assigned to IRB Chair / IRB Designee, the process follows SOP 402: Expedited Review

7.5 Modifications may be required before final approval. When the modifications are received by the IRB, the IRB Administrator verifies all changes are made before assigning the submission to the IRB Chair or IRB designee for final review.
7.6 When IRB review is completed, the IRB Administrator generates the appropriate letter to notify the investigator of the results of the review, and reports the final approval by posting to the next IRB agenda.

7.7 Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall review research utilizing human cell lines or cloned DNA and RNA from which the
original donors may be readily identified, including materials that retain links, such as a code, to the
original source material.

The IRB / Privacy Board reviews research involving established human cell lines and human cloned
DNA/RNA from which the identity of the donor(s) can be readily ascertained by the investigator.
See SOP 1001 for Privacy Board policy information.

Specific Policies

1.1 Identifiable Human Cell Lines or Human Cloned DNA/RNA

Research involving human cell lines or human cloned DNA/RNA where the donor(s) may be
readily identified, including materials that retain links, such as a code to identifying information is
generally considered human participant research because the donors are human participants.
IRB approval is required for such research.

1.1.1 Cell Lines Research NOT Considered Human Participant Research

In vitro research and research in animals using already established human cell lines or
human cloned DNA/RNA that retain a link to identifying information ordinarily would not
be considered human participant research if:

(1) the investigator and the University do not have access to identifiable private
information related to the cell line or cloned DNA/RNA; and

(2) a written agreement is obtained from the holder of the identifiable private information
related to the material stating that such information will not be released to the
investigator under any circumstances.

In this case, the research may be considered not to involve human participants because
the identity of the donor(s) could not be readily ascertained by the investigator or
associated with the material. In these cases, IRB review of research using the cell line or
cloned DNA/RNA is not required.

1.1.2 When Coded Cell Lines Research IS Considered Human Participant Research

In some cases, an investigator who obtains coded private information or specimens
about living individuals that have not previously required IRB review may:

(1) unexpectedly learn the identity of one or more living individuals or,

(2) for unforeseen reasons now believe that it is important to identify the individuals.

If, as a result, the investigator knows or may be able to readily ascertain the identity of
the individuals to whom the previously obtained private information or specimens
pertain, then the research activity now involves human participants and requires IRB
approval before continuation.

1.2 Unidentifiable Human Cell Lines or Human Cloned DNA/RNA

In Vitro research and research in animals using unidentifiable cell lines or unidentifiable human
cloned DNA/RNA is not subject to IRB review.
2. SCOPE

This SOP applies to all research that involves cell lines and cloned DNA/RNA.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for maintaining up-to-date review tools for review of research pertaining to cell lines and cloned DNA/RNA based on new and evolving applicable regulations and guidelines and must notify the appropriate entities if the IRB disapproves the research project.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members with adequate submission review training and ongoing guidance and for selecting primary and secondary reviewers with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.3 The IRB Chair is responsible for conducting appropriate review of research planned for this category in consultation with any appropriate experts and resources.

3.4 The IRB is responsible to assure there are adequate safeguards for the confidentiality of the participant.

3.5 The IRB Administrator is responsible to request changes from the investigator and send the results of the IRB review to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 301: Research Submission Requirements
SOP 403: Initial Review – Criteria for IRB Approval
SOP 1001: Health Insurance Portability and Accountability and Accountability Act (HIPAA Privacy Rule) – Privacy Board

6. ATTACHMENTS

301-A IRB Application
203-A HSC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 Research involving human cell lines and cloned DNA / RNA is submitted to the IRB using the electronic information system and indicating the use of human cell lines.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The IRB
Administrator conducts a pre-review of the submission and verifies all necessary documents are received.

7.3 The IRB Chair or IRB designee reviews the research project submission on behalf of the IRB to determine the risk level of the research and potential health information disclosures. The IRB Chair or IRB designee determines if the investigator’s assessment of potential review by the Institutional Biosafety Committee (IBC) is appropriate. If the IRB Chair or IRB designee determines IBC review is required, the IRB Administrator notifies the investigator and the IBC of this determination.

7.4 The IRB review process is not finalized until the IRB receives notification of IBC review. The IRB Administrator then forwards the research project submission and IBC determination to the IRB Chair or IRB designee for final approval.

7.5 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the investigator. The IRB Administrator posts the final IRB determination to the next appropriate IRB agenda.

7.6 Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The IRB shall review social/behavioral research involving human participants. Methods employed to carry out this type of research often involve direct/indirect participant observation, questionnaires or surveys, interviews, or review and analysis of existing data.

Specific Policy

1.1 Social/Behavioral Research

The review of studies involving social/behavioral research may be appropriate for either expedited review or convened IRB review. Additional review by other University committees, such as the Stephenson Cancer Center Scientific Review Committee (SRC), may be required.

The IRB considers the methods used in the research project and storage of data. If audiotaping, videotaping, and photography may be used, plans to store and, ultimately, to destroy these forms of data must be clearly described in the research protocol and in the informed consent documents.

1.2 Deception

Deception in social research is a method sometimes used in social/behavioral research. Generally, deception falls into one of two categories:

1. Concealment, which involves withholding information about the specific purpose or procedures of the research without providing false or misleading information to the research participant, or

2. Direct Deception, which involves providing false or misleading information to the research participant.

In studies in which deception is proposed, the IRB considers the following when determining risk related to the use of deception in the research:

A. The scientific value and validity of the research. For example, does the deception improve the internal or external validity of the research project?

B. The ability to obtain the information without the use of deception. Why is deception a necessary and unavoidable component of the experimental design?

C. Whether deception will influence the participants’ willingness to participate.

D. The possibility of harm to the participants because of exposure to the deception.

E. The quality of the plan for debriefing, which must be conducted as soon as possible after the conclusion of the research project. Debriefing must include a full explanation of the purpose of the research project. At the debriefing, participants shall be given the opportunity to withdraw their consent to participate in the research project by requesting that any data collected from them be destroyed.

F. The possibility that the deception may cause invasions of privacy.

The Norman Campus IRB allows for studies that involve concealment to be reviewed by expedited procedures, provided that the study involves no greater than minimal risk and does not involve protected groups or special populations. However, the IRB reviewer has the option of requesting that a determination of the type of deception be made by a convened IRB.
Debriefing is always required in cases of direct deception; however, it may not be required in cases of concealment.

The debriefing is to be provided to the participants at completion of the research project and shall include a full explanation of the purpose of the research project. At the debriefing, the participant is given the opportunity to withdraw participation by means of requesting that his/her data be withdrawn from the research project.

Deception is a method sometimes used in social/behavioral research. The IRB considers the following when reviewing research that involves deception:

- The scientific value and validity of the research.
- The ability to obtain the information without the use of deception.
- Whether deception will influence the participants’ willingness to participate.
- The possibility of harm to the participants and a plan for debriefing, which must be conducted as soon as possible after the conclusion of the research project. As a component of debriefing, participants shall be given the opportunity to withdraw from the research project. After debriefing, the participant may request that any data collected from them be destroyed.
- The possibility that the deception may cause invasions of privacy.

1.3 Community-Based Participatory Research (CBPR)

The HRPP is committed to supporting the active engagement of communities in University research and to promoting research designed to engage the communities served by the University. Community-based participatory research (CBPR) is a form of community engaged research involving a collaborative approach for protocol development, community member participation, shared decision-making, dissemination of research results, and mutual ownership in all aspects of the research process among communities affected by the issue being studied, investigators, and organizational representatives.

IRB members and/or consultants with CBPR expertise review community-based participatory research projects. The IRB reviewer will consider regulatory requirements related to investigator engagement, performance sites, and involvement of special populations, including, as appropriate:

1. Key study personnel training requirements
2. Reliance agreements and/or individual investigator agreements
3. Involvement of community advisory boards
4. The process for conducting a formative assessment with community members to develop the research protocol
5. Involvement of participant advocates
6. Establishing collaborations with community-based organizations
7. Discussion in the research protocol of the processes that will be used to disseminate any changes to the research project, any protocol deviations or unanticipated results, and the research results.

1.4 Types of Risks Found with Social/Behavioral Research

A. Breach of confidentiality
B. Violation of privacy
C. Validation of inappropriate or undesirable behaviors of participants
D. Presentation of results in a way that does not respect the participants’ interests
E. Possible harm to individuals not directly involved in the research, but about whom data are obtained indirectly (secondary participants), or who belong to the class or group from which participants were selected
F. Harm to participants’ dignity, self-image, or innocence as a result of indiscreet or age-inappropriate questions in an interview or questionnaire that results in embarrassment, harassment, or stigmatization
G. Harm to a participants because of exposure to potential criminal or civil liability and/or damage to financial standing or employability

1.5 Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research-Application of Subpart B in Social Behavioral Research

For additional guidance on pregnant women in social/behavioral research, see SOP 501: Special Populations.

2. SCOPE

This SOP applies to all social/behavioral research.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for maintaining up-to-date tools for review of this type of research and to notify the appropriate entities if the IRB disapproves the human research protocol.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtain consultation for that expertise.

3.3 The IRB Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with appropriate experts and resources.

3.4 The IRB Administrator is responsible for requesting changes to the study protocol from the investigator and sending the results of the IRB review to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements.
SOP 402: Expedited Review
6. ATTACHMENTS

203-A    HSC Reviewer Checklist
203-A-1   NC Reviewer Checklist
502J-A-1  NC Debriefing Template

7. PROCESS OVERVIEW

7.1 The investigator or investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received.

7.4 The IRB Administrator assigns the submission either to the appropriate Board agenda or to the IRB Chair/IRB designee.

    7.4.1 If assigned to an IRB agenda, the process follows SOP 403: Initial Review – Criteria for IRB Approval.

    7.4.2 If assigned to IRB Chair / IRB Designee, the process follows SOP 402: Expedited Review.

7.5 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda.

7.6 Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

A. Research conducted by University investigators in foreign countries must provide the same or equivalent protections to the rights and welfare of participants as research conducted in the United States (U.S.). Protections should encompass the ethical principles of respect for person, beneficence, and justice. The foreign participant protections need not be identical to those provided in the U.S. but must be equal in function or effect. Participant autonomy and dignity should be respected.

B. Both the U.S. and host country standards for protecting human participants must be respected within the research design and considered during the IRB approval process and during the conduct of the research. Where the two sets of standards present a conflict, the research must meet the higher standard.

C. The level of knowledge about the local context and laws required for research project approval is based on the degree of risk to potential research participants. Researchers must pay special attention to maintaining sensitivity to local cultural, political and socio-economic factors, religious norms, and applicable laws. Research methods that have minimal risk in the U.S. might have greater than minimal risk when conducted at international sites. For example: Questions considered innocuous in the U.S. could be offensive or more sensitive at the international location; assuring and maintaining confidentiality may be difficult in other countries; and a breach of confidentiality in the research locale could have potentially dangerous consequences. The IRB will confirm the qualifications of the researchers and research staff for conducting research in the country in question. Researchers and research organizations must follow the requirements of that country’s laws.

D. The research project should include details regarding issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and participant literacy level.

Export Controls/Embargoed Countries

E. In some circumstances, the University may be required to obtain prior approval from a U.S. government agency before allowing foreign nationals to participate in research, collaborating with a foreign company, or sharing research results with foreign nationals. For example, the Treasury Department’s Office of Foreign Assets Control (OFAC) regulates trade embargoes, sanctions, and travel restrictions and restricts exportation of information and research articles to embargoed entities and persons. Researchers are encouraged to consult with the University’s Office of Export Control for further guidance.

1.1 Specific Policies

a) Local Research Approval:

The investigator may be required to provide some form of documentation of research project approval by an IRB with a foreign FWA, a local review body equivalent to the IRB, or an independent local community expert or leader, in this order. Documentation of local approval must include an attestation to the host country standards for human participant protection and the research project’s conformity to those standards. Details about this requirement are described in Section 1.2 of this SOP.
b) Research Resources and Facilities:
The investigator and research hosts at the international site are responsible for providing evidence ensuring that the resources and facilities are appropriate for research at each international site where the research will be conducted. The IRB may require the investigator to provide a letter of cooperation from each international site where the research will be conducted. Examples include NGOs, universities, schools, or other institutions. In some instances (such as anthropological research in smaller tribal communities), investigators will be asked to provide details about an established local contact. Investigators should provide the IRB with an explanation of how they will be invited into the community.

c) International Research Involving Children:
The legal and ethical standards for what is appropriate for informed consent, parental permission, and child assent may differ in international research settings. The research project involving children should document that consideration was given to:
1. In the locale of the research, when a child is considered an adult.
2. The relationship between parents and their children in the specific country
3. Acceptable and effective parental permission processes.
4. Whether child assent is acceptable/permitable by local custom.
5. Whether there are laws pertaining to orphans.

d) Cross-Cultural Issues and the Consent Process:
The research project must include an informed consent process and, if applicable, consent documents that are meaningful in terms of the local research setting and that comports with international standards of ethical research. Special attention must be given to language issues, local customs, cultural and religious norms in reviewing written consent documents or proposed alternative consent formats. The IRB does not exempt research projects conducted in foreign countries from the legally effective consent requirement, but it can waive the requirement for written documentation of consent.

e) HIPAA Applicability:
HIPAA regulations do not apply to health information obtained and held at international sites; however, researchers must comply with all applicable local privacy laws. If identifiable health information is collected at an international site by or on behalf of the University or is collected by a non-covered, non-contracted entity but is stored within a University HIPAA health care component, it is subject to HIPAA regulation.

1.2. IRB Criteria for Local Review and Approval
There are four ways for the IRB to demonstrate that the research project has been reviewed for conformance with local human research protections and research conduct standards for international research sites. When submitting local IRB or equivalent project approval, language barriers may need to be addressed through the submission of documents in their original form and with an English translation that includes an attestation from a translator who is not an investigator.

a) If the research project is approved by an IRB designated under an approved foreign Federal Wide Assurance (FWA) in the country where the work will be done, then no other review is needed other than that of the OU IRB. The investigator must submit the notice of approval and a copy of the research project that was reviewed.
b) For international research where it is not possible to have the work reviewed under a foreign FWA, then a local review body such as a local ethics committee or a tribal council that is equivalent to an IRB within the country of the research site can review the project. The investigator should describe in the application the qualifications of the local review body (e.g., source and scope of authority, location, membership).

c) If no local review body is available, the IRB may require the investigator to provide some documentation from an independent local community expert or leader (e.g., NGO director, university professor) indicating that the research project is in keeping with local social standards and expectations. This leader or expert should be familiar with the culture, mores, and attitudes of the community from which participants will be drawn and must not be associated with the conduct of the research. This local community leader or expert may not receive compensation of any kind from the investigator for the review of the research project. A local community leader or expert cannot provide approval if the country has promulgated human research standards and an IRB with a foreign FWA or a local review body.

d) On a case-by-case basis, the IRB may determine that no international review of research is possible. In this situation, the IRB must demonstrate that it has obtained necessary information about the local research context through written materials and at least one of the following at the discretion of the IRB: personal knowledge of the local research context on the part of one or more IRB members or discussions with appropriate consultants.

e) Written materials may include, for instance, peer-reviewed research publications that provide relevant information about the local research context that would assist the IRB in making its determinations. Written materials alone are not sufficient for a greater than minimal risk research project but may be submitted as supporting information.

f) Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended, direct experience with the subject population and their environment.

g) Appropriate consultant referrals to individuals with personal knowledge of the research site, such knowledge having been obtained through extended, direct experience with the subject population and their environment, and who are, in the estimation of the IRB qualified to provide an informed and independent review. It is not acceptable for the consultant to have a Conflict of Interest (SOP 104B: Conflict of Interest IRB Members) or a collaborator on research projects or grants of the investigator(s), anyone who has personal/professional ties with the investigator(s) that precludes him or her (in the opinion of the IRB) from speaking independently and objectively about the research project, or anyone who in the estimation of the IRB is not qualified to conduct the review.

h) The investigator will provide the consultant(s) with application materials for the research project to make a determination. The consultant will be asked to verify that, in his or her judgment, the research project design is appropriate to the social/political/cultural conditions of the research site and (as applicable):

i. the selection of subjects is equitable;

ii. informed consent is sought in a language understandable to the subject(s) and consent is obtained under conditions that minimize the possibility of coercion or undue influence;

iii. appropriate safeguards protect the rights and welfare of vulnerable subjects.
i) The consultant’s review is submitted to the IRB and the review will be held confidential to the IRB. The IRB will take under advisement any concerns the investigator may have about confidentiality, proprietary information, or other sensitive issues relating to his/her research. Final determination of whether to approve or not approve a research project remains with the IRB regardless of what a consultant may advise.

1.3 IRB Criteria for Informed Consent/Assent

Legally effective informed consent is required from each international human research participant, unless a waiver of the requirement is approved by the IRB. When approving international research projects (see SOP 701: Consent Process and Documentation) criteria must be followed; however, there are additional protections that will be required. The investigator should consult, if possible, with a local culture expert to determine an appropriate informed consent process and related documentation, or any issues related to language. Surrogate consent/permission may not be substituted for a subject's informed consent unless the IRB has approved an alteration or waiver to the consent process.

If the investigator or local expert or leader has indicated that written informed consent is not standard or appropriate in the host country, alternate consent procedures (for example: use of pictures, video, or computers, or alternate forms of documentation such as thumbprints) should be considered. The researcher may also request a waiver of documentation of informed consent and use an oral consent process. Oral consent is appropriate when the local community uses no written language or considers the signing of documents problematic. If these alternatives are not possible, the investigator may request a waiver of informed consent. For both waivers of documentation of consent and waivers of consent, the research protocol must include explanations of cultural norms or conditions requiring such a waiver.

1.4 Compensation to International Participants

In any human research project, every effort should be made to minimize opportunities for coercion and to ensure that participation is truly voluntary. If a person is to be paid in cash or goods at a value that far surpasses what would be commonly available in the local community, such payment could be coercive. The investigator must consider the appropriateness of any incentives or reimbursements to be paid to international participants and include a justification that describes the relative value of the compensation based on the local context. (Example: The investigator may report the prevailing hourly wage of the participants in the local research context. The compensation should be commensurate with other compensation the participant could receive for the same amount of time in wage-based employment.) Additional guidance on compensation is provided in SOP 410: Study Recruitment and Advertisements.

1.5 Sponsoring Organizations

Investigators seeking to conduct research outside the United States that is sponsored by a federal agency or external organization should be aware of additional special requirements that may apply (See VHA Directive 1200.05 for additional guidance). The VA and DOD requirements are provided below. The investigator must consult with funding organizations to learn of any special requirements that may apply.

a) VA Research Requirements for International Research

VA international research is defined as any VA-approved research conducted at international sites (not within the U.S., its territories, or Commonwealths); any VA-approved research using either human biological specimens (identified, de-identified,
or coded) or human data (identified, de-identified, or coded) originating from international sites; or any VA-approved research that entails sending such specimens or data out of the U.S. NOTE: This includes sending such specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site). It also includes a VA’s serving as a coordinating center for an international research project. The VA facility director must ensure all international research is approved explicitly in a document signed by the facility director, except for Cooperative Studies Program activities which must be approved by the CRADO. Multi-site trials are covered under this definition if any of the following apply:

1. VA is a sponsor;
2. VA functions as the coordinating center;
3. VA subcontracts to a foreign site;
4. The PI for the total study is a VA investigator; or
5. The VA investigator is specifically collaborating with an international investigator and the VA investigator sends data or human biological specimens outside the U.S. or receives data from outside the U.S.

NOTE: This requirement does not apply if the VA is only one of the participating sites and the trial does not meet the preceding conditions.

i. All individuals who participate as subjects in VA Research at international sites must be provided appropriate protections that are in accord with those given to research subjects within the U.S., as well as protections considered appropriate by local authority and customs (38 CFR 16.101(g)). All VA international researchers must obtain permission from the Chief Research and Development Officer (CRADO), Office of Research and Development (ORD), or designee, prior to initiating research.

ii. This applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including agreements, MOU, Cooperative Research and Development Agreements (CRADA), grants, or contracts. The CRADO, or designee, will not grant permission for an international research study involving prisoners as research subjects.

iii. All VA Research international sites must hold an international FWA, and the research must be approved by the IRB or Research Ethics Board of the participating site(s) that are listed on the international FWA. In addition to VA facility Director responsibilities delineated in VHA Directive 1200.05, the facility Director is responsible for:

- Approving the request for permission to conduct international research prior to forwarding it to the CRADO for action.
- Ensuring permission has been obtained from the CRADO, or designee, for the international research prior to its initiation by an investigator at the facility.

NOTE: Information on how to request permission from the CRADO may be referenced at: https://www.research.va.gov/resources/policies/guidance/intl-research.pdf.
iv. In addition to the PI responsibilities delineated in VHA Directive 1200.05, the PI is responsible for:

- Obtaining approval from the Facility Director.
- Obtaining permission from the CRADO, or designee, in writing before initiating an international research study.
- Conducting research in compliance with this VHA Directive 1200.05, and all other applicable VA and other Federal requirements including those for protecting human subjects, tissue banking, use of databases, Federal criminal laws, and the Standards of Ethical Conduct for Employees of the Executive Branch.

1.6 Communication with Home Institution

The investigator must make adequate provisions for communication from the international site to the University. The research protocol must include descriptions of the following:

a) How communication by the investigator will occur with the IRB and the local site organization, host, or supervisor.

b) How ongoing review, modifications, or reporting of unanticipated problems/adverse events non-compliance or complaints will be handled by the investigator and communicated to the IRB.

c) Local contact information if the investigator cannot be reached.

d) For student researchers, the extent of the student's knowledge of the country and how the student will communicate with the faculty sponsor.

e) The investigator shall provide the IRB the contact information for the local IRB or research counsel for communication and coordination purposes.

1.7 Monitoring of Approved International Research

In certain cases, the IRB may require the following documentation:

a) Continuing IRB/Ethics Committee approval from the international institution or site;

b) Continuing cooperation from the international institution or site if the institution or site is not engaged in the research;

c) Verification from sources other than the researcher that there have not been any substantial changes in the research since the last continuing review; and/or

d) Inclusion of an independent monitor/body as part of the data safety/monitoring plan.

2. SCOPE

This policy applies to all international human participant research conducted at the University.

3. RESPONSIBILITY

A. Training Programs:

The investigator should submit as part of the application materials verification that all KSP (including all those recruited from the research site) who are participating in the international research project have received human research training. The training options are:

1. CITI online training
2. Local training program
If local research participants are not proficient in English, the assistance of a translator may be required. If the locally recruited KSP elect to use a local training program, documentation from the provider of that training program must be provided to the IRB. This training is in addition to any specific research project instructions that the IRB may require the investigator to provide to any KSP recruited from the research site.

B. Local Research Assistants/Translators:
In instances where the data to be collected has the potential to cause social stigmatization, investigators should use care in selecting an appropriate field assistant or translator to ensure that participant confidentiality is maintained. Graduate students from a regional University are sometimes hired in this role, provided that they are sufficiently external to the community of interest to assure confidentiality. In other cases, local customs require that the translator/field assistant be drawn from the community. In this case, the investigator should train the field assistant in the confidentiality requirements of the research project and train the assistant about not unduly influencing a participant to respond to questions that s/he may otherwise not wish to answer.

C. Location of Data Collection:
The collection of data must comply with local law relating to data privacy and security, as well as applicable U.S. law. Researchers should consider the appropriateness of locations where any interactions with participants will occur, considering whether or not there may be issues related to being seen speaking to the researchers or the possibility of being overheard.

1. Securing Data and Enhancing Participants’ Privacy.
Depending on the nature of the data to be collected and its sensitivity in the local culture, the research protocol may need to include a range of suggested data protection measures, for example:

2. Paper files:
Secure data in the research field by means of a lock box or locking file cabinets whenever possible. In some remote sites, physically securing records may be difficult so alternate approaches such as maintaining records in English in an area where English is not understood can be more effective. Use of notebooks interspersed with random travel notes may hinder unauthorized access to respondent data.

3. Electronic Data:
The collection of data must comply with local law relating to data privacy and security, as well as applicable U.S. law. As a matter of best practices under U.S. law, researchers and other IRB-approved key study personnel should use only password-protected computers and encrypted files and devices and should limit access to necessary key study personnel. If the information to be collected is politically sensitive either in the country or in the U.S., researchers may wish to consider storing data by uploading encrypted data files to University servers and then securely deleting the files from the laptop on-site to avoid unlawful or unauthorized confiscation of data. Researchers should use caution in connecting through unsecure connections such as Internet cafes. U.S. export control laws may affect the ability to travel outside the United States with laptops and other electronic storage devices. Similarly, U.S. Customs may control re-importation of these devices.

4. APPLICABLE REGULATIONS AND GUIDELINES

Biomedical research - international guidelines: e.g., The Declaration of Helsinki, the International Conference of Harmonization – Good Clinical Practice (E6) Guidelines, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects published by the Council for International Organizations for Medical Sciences (CIOMS).

Department of Defense: Instruction 3216.02 6 para. 3.a.(4); SECNAVINST 3900.39D, para. 6i
Veterans Administration: VHA Directive 1200.05, 4, 5, 56

U.S. export controls and sanctions laws apply to international research activities. Contact the University Office of Export Control for information about legal, procedural, and practical matters related to international travel of faculty, staff, researchers, and students. Further information is available on ORIA’s export controls website.

5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 104B: Conflict of Interest IRB Members
SOP 403: Initial Review – Criteria for IRB Approval
SOP 404: Continuing Review
SOP 405: Modifications/Notification
SOP 410: Study Recruitment and Advertisements
SOP 701: Consent Process and Documentation
SOP 801: Investigator Responsibilities

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The investigator or investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies that all necessary documentation is included in the submission regarding local research approval, research resources and facilities, research involving children, and the type of local review and approval.

7.4 The IRB Administrator assigns the submission either to the appropriate Board agenda or to the IRB Chair/IRB designee.

7.4.1 If assigned to an IRB agenda, the process follows SOP #403: Initial Review – Criteria for IRB Approval.

7.4.2 If assigned to IRB Chair / IRB Designee, the process follows SOP #402: Expedited Review.
G. Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda.

H. Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY: ________________________________  DATE:  09/03/2019

NEXT ESTABLISHED REVIEW DATE:  AUGUST 2020
SOP 502L: INTERNET/SOCIAL MEDIA-BASED RESEARCH

1. POLICY

Internet/social media-based research projects are reviewed by the IRB just as any other research projects, except that there are additional considerations related to the establishment and protection of human research participants’ identity and research data security concerns that must be addressed by the investigator.

Investigators should be aware of any research-related restrictions on the use of the internet/social media site through which they intend to conduct their research activities. The IRB cannot take responsibility for ensuring that the terms and conditions for conducting research on internet/social media sites have been met. Failure to acquire appropriate permissions could result in consequences that may include loss of the data collected, reputational harm to the investigator and the University and, in the worst case, legal action by the site manager or research participants against the investigator and/or the University.

When conducting internet and social media research, the investigator is responsible for knowing the University Information Technology, Information Security, and HIPAA policies concerning (but not limited to) Privacy, Terms of Use of University Equipment, Data Security, and Disposal of Electronic Media and Hardware.

Because the nature of research involving these technologies continues to evolve, it is not possible to identify every circumstance or type of research activity. If there are circumstances that are unique to a research project, the IRB will review the research project on a case-by-case basis.

Specific Policies

1.1 Passive Data Collection

Passive data collection from internet/social media sources may not constitute human participant research if the research project does not involve any interaction or intervention with the individual about whom data is being collected (examples: Twitter feeds; Facebook profiles or wall postings; information from open chat rooms, whether the data is collected through silent observation or from archives).

Typical examples of internet/social media-based research projects that are not human participant research include:

1.1.1 The individual user or internet/social media site has not placed any restrictions on access to information about himself/herself (e.g., information available on a public website, blog, Twitter feed, chat room,) OR
1.1.2 The data are officially and publicly archived and are not protected by a password or login, AND
1.1.3 The site policy does not prohibit the direct quotation of material from the site (or prohibit research more generally).

For passive data collection on internet or via social media archives, the investigator shall ensure that all the information on an individual is de-identified and that research results are presented in aggregate.
1.2 Active Data Collection

1.2.1 An expectation of privacy has been established and the research will be considered Human Participant Research that requires IRB approval if:

- An individual has restricted access to the internet/social media data in any way (for example, the investigator has to request or seek access from the individual or from the group that the individual belongs to or if the investigator has to belong to, be invited to, or invite others to a particular “interest” or “friend” group), or
- The internet/social media site has restrictive provisions in its terms of service.

1.2.2 Additionally, if research is being done on a site or chat platform that requires consenting to a EULA (End User License Agreement), TOS (Terms of Service), or other site or platform rules, users must follow the internet provider guidelines. If this includes requiring permission from the host site’s administrator(s), investigators must first obtain consent from the administrator(s).

1.2.3 Individuals must be made aware that they are participating in a research project that involves an experimental manipulation. Deception research projects can be conducted using internet/social media-based research projects; however, individuals must consent to participate (see SOP 502J: Categories of Research Social/Behavioral for further guidance on deception studies).

1.3 Special Types of Research Participants

1.3.1 Online identities: Personas or avatars and their corresponding character names established in online communities should be treated just like real persons. These personas and their reputations can usually be traced back to real individuals who are the human controller. If an investigator wishes to use names of personas or real participant names in publications, it is normally sufficient to consent the human controller or to recognize consent from the personas as a proxy for the controller, although in some cases consenting both the virtual persona and the human controller may be more appropriate.

1.3.2 Collateral research participants: During data collection, investigators may gather information not only about and from the individual specifically recruited for the research project, but also about individuals connected to the recruited participant’s social network (e.g., his/her “friends” on Facebook) by accessing the information that those individuals have made available to the recruited participant.

Information made available by “friends” on the “wall” or another public place on the recruited participant’s social network may be considered to belong to the participant and can be included without the explicit consent of the “friend”. Investigators must exercise caution to protect the identity of such “friend” participants and report results in aggregate as much as possible.

1.3.3 Individuals Who Decline to Participate: Investigators may not collect any information from any individual who declines to participate in the research project. Exception: if the process for making an accept/decline decision is the subject of the research project; the investigator must acknowledge the deception in a subsequent debriefing process and, when possible, allow the individual the opportunity to withdraw her/his response. (see SOP 502J: Categories of Research Social/Behavioral).

1.3.4 Individuals Who May Be Deductively Re-identified: Research projects may include collection of data that individuals may not realize is accessible (e.g., data left on directories that are accessible via use of a web crawler), investigators should regard data as private unless they can demonstrate that data is sufficiently de-identified.
1.3.5 Individuals Whose Identity is Accidentally Revealed During Passive Data Collection: Passive and active data collection practices may make it possible for the information to be combined in such a manner that the identity of the group or individuals can be readily ascertained. Research projects that include the risk of accidental identification need to be approved by the IRB as human participant research.

For more information, see Glossary entry: Data Mining, Scraping, and Mashing

1.4 Recruitment

Investigators should be aware that in internet/social media-based research settings, the potential participant population may not be entirely under the investigator’s control. For example, the recruitment information can be forwarded or otherwise accessible to other individuals who may not be part of the intended participant pool. Investigators should therefore exercise caution to appropriately identify the target participant population in the research protocol and in recruitment messages. Investigators must ensure safeguards are in place for screening children, prisoners, and other special populations, unless these populations are the intended participants of the research project.

The research protocol should include procedures to authenticate potential participants, if appropriate. For example, investigators can provide each participant (in person or by regular postal mail or email) with a Personal Identification Number (PIN) to be used for authentication in subsequent internet/social media-based research data collection. The PIN used must not be one that could be used by others to identify the individual (e.g. Social Security number, etc.).

1.5 Compensation of Internet/Social Media-Based Research Participants

The use of compensated research panels, such as Amazon Mechanical Turk (mTurk), as a recruitment method for human participant studies continues to grow. Panels such as mTurk often advertise for panel participants as a “marketplace for work,” and individuals who take part in the activities (called “HITS”) on this site are referred to as “workers.” The consent document should explicitly mention that the research project is “research” and not a “job.” The compensation for the tasks accomplished is typically very small, usually less than $1.00.

Depending on the nature of the research, the IRB may request that methods of incentives and/or compensation allow participants to receive remuneration either without revealing their identities or without connecting their identities to survey responses. For example: Using gift certificates from online retailers and displaying the unique certificate redemption number to respondents at the completion of an online survey. This allows participants to receive an incentive without revealing their identity.

1.6 Consent

1.6.1 The IRB does not allow passive consent for human participant research participation (See SOP 701 Consent Process and Documentation for details about alternative consent processes). The process of requesting consent should not disrupt the normal activity of an internet/social media-based research site that is not expressly set up for research purposes and for which the investigator is not the site administrator.

1.6.2 In real-time environments (including chatrooms, virtual worlds, multiplayer gaming “MMOG”, etc.) the process of requesting consent publicly is often perceived as disruptive. In such cases, investigators should consider announcing publicly that they are conducting research. Investigators may then request that people contact them via PM (private messaging using the site or platform in question), IM (instant messaging on another platform), email, website, etc. for more information about the research project and the process to become a participant.

1.6.3 When a waiver of consent documentation is requested, the information sheet used for consent
must appear as the first page of the online survey website and an Accept or Decline checkbox is usually acceptable. Online consent forms should include a link to download the consent document, or the investigator should provide the participant with instructions for how to print or obtain a copy of the consent document when they are completing the online survey.

1.6.4 Depending on the level of risk, a single checkbox to Accept/Decline may not be acceptable. Since internet culture is such that people often check such boxes without reading the content, the investigator cannot assume that participant consent is legally effective. Instead of a single checkbox at the end of a consent form, investigators may use a checkbox for each item in the consent form, taking subjects through each step of the informed consent process. It is also possible that investigators will be required to obtain signed print copies of consent in some circumstances.

1.6.5 For surveys sent to and returned by participants through email, investigators should include an information sheet with consent information and inform participants that submitting the completed survey implies their consent. If PHI is included as part of content, the email must comply with HIPAA Privacy and Security regulations and University HIPAA policy.

1.6.6 For greater than minimal risk research, if the IRB does not approve a waiver of documentation of consent, the consent form can be mailed or emailed to the participant who can then sign the form and return it via fax, postal mail, or as an email attachment. If PHI is included as part of content, the email must comply with HIPAA Privacy and Security regulations and University HIPAA policy.

1.6.7 Some survey vendors and/or software packages provide a means to record whether a respondent has consented to participate before beginning the survey (e.g., a date/time stamp feature). Investigators should consider the use of this functionality.

1.6.8 Investigators subject to the Children’s Online Privacy Protection Act (16 CFR Part 312) are prohibited from collecting personal information from a child under 13 years of age without posting notices about how the information will be used and without getting verifiable parental permission. For research that excludes minor participants, the IRB may ask the investigator to describe the procedures to be employed to authenticate that the participants are adults.

1.7 Consent Document: Confidentiality Section Addition

For internet/social media-based research, additional language must be added as part of the confidentiality statement in the consent document provided to the participant.

A disclosure included in the informed consent information provided to the participant stating, “Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with the University and with its own privacy and security policies that you can find at its website.”

AND/OR: “This is an academic not-for-profit research project. Data collected using the [Amazon Mechanical Turk] data collection tool resides on the [Amazon] servers and no assurance can be made as to its use for purposes other than the research or privacy.

AND/OR: “Although every reasonable effort has been taken, confidentiality during actual Internet or email communication procedures cannot be guaranteed.”

AND/OR: “Your confidentiality will be kept to the degree provided by the technology being used. No guarantees can be made regarding the interception of data sent via email or the Internet by any third parties.”

AND/OR: “Data may exist on backups or server logs beyond the timeframe of this research project.”

1.8 Consent Document: Voluntary Nature Section Addition
Survey question responses must be voluntary unless the consent document clearly indicates that answering a question is a requirement and reminds prospective participants that they may choose not to participate or stop participation in the research at any time.

If the participant completes an anonymous survey and then submits it to the investigator, the investigator may not be able to extract/remove/delete their specific data from the database should the participant wish it withdrawn. The consent document should inform prospective participants of this limitation.

1.9 Consent Document: Opt-in for Permission to Quote or Paraphrase Participants

1.9.1 If the research is not greater than minimal risk, the consent form may include an opt-in allowing quotation. Investigators are encouraged to omit or modify participant provided information that would be harmful if revealed so that the individual’s identity cannot be linked to other publicly available data or re-identified.

1.9.2 For greater than minimal risk research, quotes from participants should be paraphrased so that they are not searchable. Searchable data may be traced back to individuals, thereby putting them at risk.

1.9.3 In some social media environments, the participants may have a persona with a pseudonym or may request that a pseudonym be used to protect the participant’s identity. Pseudonyms and real names may be used with permission of individual participants.

1.9.4 Since individuals using social media may use pseudonyms to conceal their identities, investigators should avoid eliciting information from other sources to establish the real identity of these individuals and must exercise caution to ensure that accidental revelation of their identity does not occur.

1.9.5 For greater than minimal risk research, pseudonyms and other identifying information (place, organizational affiliation, institutional names, etc.) should be changed. Additionally, false details may be deliberately introduced by the investigator to further protect research subjects.

1.10 Mobile Devices and Emerging Technologies

Additional considerations apply to research that involves the collection of data via social media applications that are networked with mobile devices or that involves installing applications on a person’s mobile device to collect data:

Investigators must not collect location information or other data that is not explicitly approved by the research participant in the consent document.

If the research involves installing an application (app) on a person’s mobile device for the purposes of data collection, the investigator must describe how the app will be deactivated at the conclusion of the research project. This should be done either by making the deactivation part of the research project’s exit procedures, or by providing instructions to participants on how to deactivate the app. Additionally, investigators should describe plans to ensure they do not continue to collect data once the research project is complete, in case a participant does not effectively deactivate the app.

If the research project involves the use of a mobile device provided by the investigator, the investigator should explain the confidentiality safeguards that are in place (e.g., how s/he will ensure the data is under the research team’s control and that third parties do not have access to it), as appropriate to the research project.

1.11 Technology-Assisted Survey Administration

Investigators can use a variety of software programs to conduct internet/social media-based
research. These options fall within one of the following three broad categories:

1. Commercial or third-party survey creation and data collection hosting services. In these cases, the investigators often enter into a contract through the University with the vendor to provide some or all of the services related to the creation and management of the internet surveys. Investigators are advised to therefore collect data using third-party survey software, with known policies for data security and anonymity.

2. Surveys developed either internally or by using survey development software and hosted on web servers managed by investigators or by University IT services.

3. Surveys that are conducted via email, because the nature of the transmission to and from respondents may carry additional risks to confidentiality.

1.12 Data Security

1. Collecting data over the internet can increase potential risks to confidentiality because of third-party internet sites, the risk of interception by non-authorized persons when transmitting data across a network, and the impossibility of ensuring that data are completely destroyed once the research project is complete.

When conducting internet/social media-based research, if the investigator is not using a third-party internet site that has been previously approved by the University IT for use, then the investigator must demonstrate that the following minimum standards are met:

1. A standard encryption technology such as SSL is used.
2. The server is administered by a professionally-trained person with expertise in computer and Internet security.
3. Access to the data hosted on the server is limited to key project personnel and configured to minimize the possibility of external access to the server data.
4. How the security of the web server is being ensured to prevent unauthorized access.
5. The server is subject to periodic vulnerability assessments to determine that the server is configured and patched according to industry best practices.

1.12.2 For certain studies that present greater than minimal risk to the participation, the IRB may elect to require additional protections, such as certified digital signatures for informed consent, technical separation of identifiers and data, or a higher level of encryption.

1.13 Data Management, Storage, and Destruction

Investigators are encouraged to keep the research participant’s personal identifying information separate from the research data and to de-identify the research data set promptly after data collection. Both sets of data should be stored in encrypted format on an encrypted device or server.

Data backups must be stored in accordance with University IT data security and cloud storage security standards and other applicable Information Technology security policies. Encryption of backup data is also recommended. The investigator should consult with the Information Technology representative who is assigned to their academic department for assistance.

Competent data destruction services should be used to ensure that no data can be recovered from obsolete electronic media. Investigators should contact the University Information Technology office for services related to destruction of media content. It is advisable that the investigator receive assurance of the procedures used for the destruction of the materials and instruction on how to monitor the service.
2. SCOPE

This SOP applies to all human participant research conducted by investigators who conduct research under the auspices of the University.

3. RESPONSIBILITY

The investigator is responsible for verifying that any third-party internet sites that are to be used for research participant recruitment, consent, data collection, or data storage, or from which data will be transmitted to the investigator are approved by University IT Security.

If the investigator wishes to use a third-party internet site for research participant recruitment, consent, data collection, or data storage, or from which data will be transmitted to the investigator that has not already received University approval, the IRB administrator is responsible for providing a checklist to be completed by a representative of the third-party internet site. After satisfactory review of the third-party internet site provider by the IRB in consultation with Information Technology and Legal Counsel, as appropriate, the investigator and a representative from the third-party internet site are responsible for signing the Non-OU Employee Collaborator Assurance document provided by the IRB. The investigator is responsible for uploading the executed agreement into the IRB’s electronic information system prior to approval of the research project.

The HRPP Director is responsible for reviewing the third-party internet site response to the checklist with other OU offices, as appropriate, in order to determine if the investigator will be allowed to use the proposed third-party internet site. The determination will be communicated to the IRB administrator.

The IRB administrator is responsible for providing the Non-OU Employee Collaborator Assurance document to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

University’s Information Technology Office for Information Security policies and in particular, the Media Sanitization Policy and the Technology Hardware Disposal Service.

HIPAA Security policies

HIPAA Privacy policies

Children’s Online Privacy Protection Rule (COPPA) 16 CFR Part 312

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 502J: Social Behavioral Research

SOP 701: Consent Process and Documentation

6. ATTACHMENTS

Third-party Internet Site Checklist

Non-OU Employee Collaborator Assurance

7. PROCESS OVERVIEW

7.1 Research submission processing will follow normal procedures in the applicable SOPs referenced in Section 5 of this SOP.

7.2 Based on the information provided by the investigator in the submission, the IRB Administrator will determine if the research involves internet or social media.
For studies involving internet/social media-based research, the reviewer will inform the investigator that an additional statement regarding internet/social media-based research must be included in the Confidentiality section of the informed consent document.

7.3 Based on the information provided by the investigator in the submission, the IRB Administrator will determine if the research involves a third-party internet site.

For studies involving human participant research activities hosted on a third-party internet site, the IRB administrator will confirm that the third-party internet site is on the University approved list. If not, the IRB administrator will provide the investigator with the checklist to be completed by a representative from the third-party internet site and returned to the IRB by the investigator using the IRB’s electronic information system.

7.4 The HRPP Director reviews the third-party internet site response to the checklist with other OU offices as appropriate in order to determine if the investigator will be allowed to use the proposed third-party internet site. The HRPP Director will communicate the determination to the IRB administrator.

7.5 Once the IRB Administrator has determined that the third-party internet site is on the University approved list, they provide the investigator with the Non-OU Employee Collaborator Assurance document.

7.6 The research project can be approved when the signed Assurance document has been uploaded into the IRB’s electronic information system.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 601: IRB COMMUNICATION AND NOTIFICATION

1. POLICY
The IRB shall notify the Institutional Officials and investigators in writing of all decisions made by the IRB. Open and frequent communication shall be maintained among the IRB, the Institutional Officials in the Offices of the Senior Vice President and Provost, the investigator, and the investigator’s research team.

The IRB shall foster open communication with the investigator regarding questions, concerns, and suggestions that pertain to the HRPP program. The IRB shall answer questions as promptly as possible. Concerns and suggestions that cannot be satisfactorily addressed by HRPP or IRB staff shall be addressed in a meeting with the appropriate administrative individuals.

Opportunity for improvement in the IRB review process is based upon voluntary feedback of investigators and, as such, Investigators are encouraged to offer suggestions and discuss concerns regarding the HRPP program and IRB review process.

Specific Policies

1.1 New Research Projects

1.1.1 All submissions shall be processed per SOP 301: Research Submission Requirements; and SOP 302: Administrative Review and Distribution of Materials.

1.1.2 Once a research project is reviewed by the convened IRB, the IRB shall forward a letter to the investigator regarding the decision of the IRB to approve, contingently-approve, defer, or disapprove the project.

1.1.3 After the IRB Chair or IRB designee reviews and approves research projects meeting one of the Expedited Review Categories, the IRB Administrator shall forward a letter to the investigator regarding the approval of the project. If the IRB Chair or IRB designee requires revisions to or submission of the research project to the convened IRB, the IRB Administrator shall notify the Investigator via the IRB’s electronic information system.

1.1.4 If the research project receives a contingent approval status and is pending receipt and review of requested revisions and/or information from the Investigator or Sponsor, the IRB shall receive a response from the Investigator within 60 calendar days of the date of notification; however, this period may be extended by the IRB Chair or IRB designee if the Investigator/Sponsor communicates a need to the IRB for an extension. If the Investigator does not respond to the requested revisions and/or information within 60 calendar days, the IRB staff shall inform the investigator that the research project may be administratively withdrawn.

1.1.5 If the research project is deferred or disapproved by the convened IRB, the IRB Chair shall notify the investigator (by telephone and/or by electronic communication) of the IRB’s decision immediately following the IRB meeting, followed by written notice per 1.1.2.

1.2 Submissions Involving On-Going Research Projects

For submissions related to on-going research projects, the IRB shall notify the investigator of all review decisions. These decisions may include:

- All revisions, additions, or deletions to a research project.
- An impending continuing review and the outcome of the research project once it is reviewed.
- Actions to withdraw or inactivate a research project and the reason such action is being taken.
- Status of all adverse events reports submitted for review.
- Necessity to conduct an audit as described in SOP 903: Non-compliance/Scholarly Misconduct.

1.3 Appeal of IRB Action

An investigator may appeal the revisions required by the IRB to the human research protocol and/or informed consent documents. This appeal shall be in writing and submitted to the IRB office via email. Investigators may also appeal an IRB decision to disapprove a research project. Any such appeal shall be in writing or in person and shall be reviewed by the convened IRB. If the IRB denies the appeal and disapproves the research project, the University shall not override the IRB’s decision.

1.4 Pending Items Over 60 Days

The IRB Administrator shall send a pending withdrawal letter to the investigator after the submission has been in pending status for 60 days.

1.5 Notification to Institutional Offices and Officials

The IRB shall make available, IRB minutes, including findings and actions to the Office of the Senior Vice President and Provost as the Institutional Official.

1.6 Questions, Concerns, and Suggestions Regarding the Human Research Participant Protection Program

Investigators can direct questions, concerns, and suggestions regarding the Human Research Participant Protection Program to the HRPP Director. Investigators can direct questions, concerns, and suggestions regarding the Human Research Participant Protection Program that are not satisfactorily addressed by the HRPP Director to the Director of Compliance for the NC or the HSC VPR for HSC or the Institutional Official.

1.7 Determination of Human Research and Protocol Development

Determination of Human Research or Protocol Development submissions are reviewed according to SOP 406: Determination of Human Research and Protocol Development. The outcome of each determination is communicated to the investigator via the IRB electronic information system.

2. SCOPE

This SOP applies to all research submitted to the IRB.

3. RESPONSIBILITY

3.1 The HRPP Director or designee is responsible for overseeing all internal and external IRB communications.

3.2 The IRB Administrator is responsible for generating appropriate correspondence in response to IRB meetings and decisions and for distributing IRB correspondence to appropriate parties.

3.3 The IRB Chair or IRB designee is responsible for contacting the Investigator in the event of an IRB action of deferral or disapproval and for drafting the letters for the IRB Administrator to send to the Investigator.

3.4 The HRPP Director is responsible for all communication with OHRP, FDA, and University officials.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.113
5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 302: Administrative Review and Distribution of Materials
SOP 304: Documentation and Document Management
SOP 401: Research Exempt from IRB Review
SOP 402: Expedited Review
SOP 403: Initial Review – Criteria for IRB Approval
SOP 404: Continuing Review
SOP 903: Non-compliance/Scholarly Misconduct

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The IRB Administrator shall process new research projects, revisions to currently approved research, and continuing review of research documents per SOP 301: Research Submission Requirements; and SOP 302: Administrative Review and Distribution of Materials.

7.2 The IRB review is conducted per SOP 401: Research Exempt from IRB Review; SOP 402: Expedited Review; or SOP 403: Initial Review – Criteria for IRB Approval, as appropriate.

7.3 The Investigators shall submit IRB requested revisions to the IRB within 60 University business days of receiving written IRB notification.

7.4 The IRB Administrator shall conduct periodic review of outstanding items, including telephone calls and/or emails to investigator regarding outstanding issues.

7.5 IRB Administrator shall consult with the HRPP Director or designee for items outstanding more than 60 University business days; a pending withdrawal notification shall be sent to the investigator for new research project submissions and protocol modifications.

7.6 For of outstanding continuing review items the IRB shall follow, SOP 404: Continuing Review.

7.7 The IRB Administrator shall forward Investigator appeals of requested revision(s) to the IRB (for the next available meeting agenda) or the IRB Chair for review.

7.8 The Investigator shall adhere to final IRB determinations; the University cannot overrule final IRB determinations.

7.9 All documentation shall be retained per SOP 304: Documentation and Document Management.

7.10 Investigators with questions, suggestions, or concerns should visit the IRB website contact page.

7.11 IRB staff will make available the approved IRB meeting minutes for each IRB to the Institutional Officials.

APPROVED BY: ____________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 602A: OFFICE OF COMPLIANCE

1. POLICY

The University’s Office of Compliance, under the direction of the Director of Compliance, shall be responsible to oversee, monitor, and assist the University in its efforts to (i) raise awareness regarding ethical issues; (ii) improve compliance training and quality improvement and review functions; and (iii) obtain adherence to the highest standards of conduct.

The NC Office of Human Research Participant Protection (HRPP) operates under the direction of the Director of Compliance. The HSC HRPP operates under the direction of the Vice President for Research and may seek guidance from the Director of Compliance. All HRPP policies shall be reviewed and approved by the Joint IRB Executive Committee and the Director of Compliance prior to implementation. The HRPP Director shall initiate and implement approved policies and policy revisions.

The Office of Compliance shall identify and disseminate new information that may affect human research protection. This information may include new or revised state or federal laws, regulations, or guidance, as well as University policies and procedures.

The Office of HRPP shall function independently and free from outside influence. The HRPP and IRB staff, through the HRPP Director, shall report incidents of influence that directly affect the review process and the protection of human participants to the Director of Compliance. The Director of Compliance shall investigate allegations of undue influence and report findings to the appropriate University official.

Specific Policies

1.1 Compliance Issues

Compliance issues are addressed in SOP 903: Non-Compliance/Scholarly Misconduct.

1.2 Office of HRPP

The Director of Compliance reviews HRPP policies, assists the HRPP Director in policy development, and serves on the IRB Executive Committee.

2. SCOPE

This SOP applies to interactions between the Office of Compliance and the Offices of HRPP.

3. RESPONSIBILITY

3.1 For the NC the Director of Compliance shall be responsible to oversee the Office of HRPP. For HSC the Vice President for Research shall be responsible to oversee the Office of HRPP.

3.2 The Director of Compliance advises the HRPP Director on compliance issues. The HRPP Director informs the Director of Compliance and the HSC Vice President for Research for HSC matters regarding noncompliance issues and implements policies pertaining to the HRPP Program.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 56

University of Oklahoma, Compliance and Quality Improvement Program
5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 903: Non-compliance/Scholarly Misconduct.

6. ATTACHMENTS
   None

7. PROCESS OVERVIEW
   7.1 Compliance
   Refer to SOP 903: Non-compliance/Scholarly Misconduct, for process overview.

   7.2 Office of HRPP
   One of the IRB Chairs or the Director of Compliance acts as the Chair of the IRB Executive Committee meetings. The Director of Compliance is a member of the IRB Executive Committee. These meetings are generally held once each month to review and update HRPP policy as needed. The HRPP Director or designee is responsible for meeting preparation and completion of the meeting minutes.

   APPROVED BY:_____________________________ DATE: 09/03/2019

   NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 602B: OFFICE OF LEGAL COUNSEL

1. POLICY

The University’s Office of Legal Counsel shall, upon request, provide legal guidance to the HRPP Director or designee and IRB Chairs in the conduct of the Office of Human Research Participant Program activities. Legal Counsel shall be available to interpret and provide advice to the HRPP Director or designee and IRB Chairs regarding relevant laws and policy pertaining to research involving human participants. Relevant law and policy may include federal and Oklahoma case law, federal and Oklahoma statutes, other applicable law and regulations, and University policy.

Specific Policies

1.1 Consultation

The HRPP Director or designee and IRB Chairs may consult Legal Counsel when issues arise that require legal or policy interpretation or resolution of conflicts of laws. Legal Counsel shall, upon request, provide advice to the HRPP Director or designee and IRB Chairs when new law or policy may affect research. In doing so, Legal Counsel assists the HRPP Office in remaining compliant with applicable University policies, laws, and regulations.

1.2 Records Requests

The HRPP Office shall respond to requests from Legal Counsel for Open Records Requests as well as other requests for information concerning research activity conducted at the University.

1.3 Notice to the Office of Legal Counsel

The HRPP staff shall notify the Office of Legal Counsel of audits or investigations conducted by state or federal agencies or law enforcement that involve the HRPP or IRB and will include the Office of Legal Counsel in any responses to such agencies.

2. SCOPE

This SOP applies to all aspects of the HRPP Program.

3. RESPONSIBILITY

3.1 The HRPP Director or designee may bring issues for discussion to Legal Counsel and provide information to Legal Counsel at their request.

3.2 The IRB Chairs discuss issues with the HRPP Director or designee and consults with Legal Counsel as needed.

3.3 Legal Counsel, upon request, advises the HRPP Director or designee and IRB Chairs with respect to University policy, federal and Oklahoma case law, federal and Oklahoma statutes, other applicable law and regulations, and University policy as well as conflicts of law.

3.4 The HRPP Office cooperates with Legal Counsel in records requests and other requests for information involving human participant research activity.

3.5 The HRPP staff shall, as soon as possible, notify the Office of Legal Counsel of audits or investigations conducted by state or federal agencies or law enforcement that involve the HRPP or IRB and will include the Office of Legal Counsel in any responses to such agencies.
4. **APPLICABLE REGULATIONS AND GUIDELINES**
   
   45 CFR 46.101 (f)

5. **REFERENCES TO OTHER APPLICABLE SOPS**
   
   None

6. **ATTACHMENTS**
   
   None

7. **PROCESS OVERVIEW**

   7.1 The HRPP Director designee meets with Legal Counsel as legal or policy issues or audits or investigations arise. Issues such as acceptable language for informed consent documents, determinations regarding exculpatory language, and local and state laws are among the items for which legal advice may be requested.

   7.2 The HRPP Director or designee acts upon or disseminates the advice of Legal Counsel to the HRPP Office and IRB chairs. The HRPP Director or designee documents advice given by Legal Counsel for reference as needed.

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**APPROVED BY:** ________________________________ **DATE:** 09/03/2019

**NEXT ESTABLISHED REVIEW DATE:** AUGUST 2020
SOP 602C: OFFICE OF RESEARCH ADMINISTRATION - OUHSC

1. POLICY

The Office of Research Administration (ORA) shall serve as a central resource to promote the research, education, and service missions of the OUHSC. ORA shall provide information and administrative assistance to faculty and staff for preparing and submitting proposals to external sponsors and managing post-award administration of sponsored research awards. ORA requires that the Human Research Participant Protection (HRPP) requirements shall be addressed in all agreements with sponsors involving human participant research prior to finalizing the agreements. ORA and HRPP shall work together to ensure all University and sponsor approvals and contracts are in place prior to the initiation of sponsored research involving human participants.

Specific Policies

1.1 Just-in-Time Policy for IRB Submissions

The NIH just-in-time policy that allows grant applications to be submitted to NIH for peer review without prior IRB approval has been extended by University policy to all OUHSC grant proposals where the granting agency does not require IRB approval at the time the proposal is submitted. Investigators are required to submit a new study application only to the IRB through the electronic information system and promptly upon receipt of a favorable priority ranking from the granting agency. The investigator shall ensure IRB approval is obtained before the award is accepted and research begins.

1.2 Grant Proposals Lacking Definite Plans for Human Participant Involvement at the Time of Submission to Funding Agency

The IRB recognizes that certain types of grant applications, cooperative agreements, or contracts are submitted to funding agencies with the knowledge that human participants may be involved within the period of support, but definite plans are not set forth in the initial application or proposal. The IRB does not require review of these applications prior to an award being made; however, a supporting agency may require IRB review and certification.

Grant proposals lacking definite plans for human participant involvement at the time of submission may include the following:

- Research training programs or grants in which the activities involving human participants will be selected or designed during the course of the program.
- Research, pilot, or developmental projects in which the involvement of human participants depends on such things as the completion of pre-clinical animal studies.
- Research projects that are designed in collaboration with the funding agency only after the award has been made to HSC. Once the research project has been designed by the investigator and funding agency, it shall be submitted to the IRB for a determination.

Involvement of human participants in any research project supported by these awards shall be permitted only after the IRB has approved the research project.

1.3 Research Proposals Without the Initial Intent of Human Participant Involvement

Occasionally, research activities are designed without the intention of human participant involvement, but human participant research is proposed later. The newly proposed research activity involving human participants shall be approved by the IRB before initiation of the research involving human participants.
1.4 Research Requiring a Contract with the Sponsor or Funding Agency

All human participant research projects approved by the IRB at HSC that are sponsored and/or funded by industry (i.e., pharmaceutical and biotechnology companies) require the execution of a contract detailing both parties’ responsibilities prior to the initiation of the research project. In addition, human participant research projects funded by other agencies (i.e., state, foundation, federal) require the execution of a contract between HSC and the other party prior to the initiation of the research project. When a contract between HSC and the other party is required by University policy, the investigator shall not begin research project activities prior to the execution of a contract through ORA.

1.5 Unique IRB Number Assignment For Each Funded Research Project

HSC policy requires that each research project involving human participants be submitted to the IRB for approval and be assigned a unique IRB number. Therefore, every funded research project shall have a corresponding IRB application with a unique IRB number and individual approval, whether internally (departmental) or externally funded. Federal regulations under 45 CFR 46.103 (f) mandate that each federally-funded research project be reviewed and approved, in entirety, by an assured IRB.

1.6 Communication Mechanisms Between IRB and ORA

Regular communication between the IRB and ORA is essential in order for the IRB to fulfill its functions relative to human participant research.

The ORA shall have access to the electronic information system in order to check the status of a research project.

1.7 Human Research Participant Protection Requirements with Sponsors

1.7.1 Adherence to Policies

The University requires a formal agreement between the HSC and the industry sponsor of a clinical trial. Agreements and other sponsored awards administered through ORA shall indicate that the HSC will conduct human participant research in accordance with the IRB-approved protocol, and applicable law.

Requests from sponsors for HSC HRPP to deviate from its policies and procedures shall not be accepted.

1.7.2 Medical Care for Research-Related Injury

Contracts and/or funding agreements must indicate who will provide care and who is responsible to pay for it. ORA reviews each clinical trial agreement for research participant injury language and notifies the investigator if the agreement language contradicts the informed consent document language. If research participant injury language is included in a clinical trial agreement, such language shall not refer to billing a research participants’ insurance company first for the injury or require the research participant to be financially responsible for the research-related injury. The HRPP will not include such language in the informed consent form or permit sponsor to do so. ORA shall notify the investigator if the informed consent document contains language that contradicts the agreed upon language in the clinical trial agreement.

The IRB shall review each consent document and require that it include an explanation of who to contact for answers to questions about the research, research participants’ rights, and research-related injuries.
1.7.3 Reporting Requirements of the Sponsor

ORA reviews each clinical trial agreement for language indicating the sponsor will promptly report (within 30 days) to the HSC HRPP any information contained within a routine or urgent data and safety monitoring report that could affect the rights, safety, or welfare of the research participants or their willingness to continue in the research project, influence the conduct of the research project or alter the IRB’s approval to continue the research project.

The HRPP shall review each informed consent for required language that participants will be notified of new information relevant to their participation in the research project. Clinical trial agreements shall also indicate the time frame after closure of the study during which the Sponsor will communicate such findings to the University but shall not be any less than two years after closure.

1.7.4 Communication to Research Project Participants

The HRPP through the investigator provides research project participants with significant new findings developed during the course of the research that may affect their willingness to continue their participation.

The IRB through the investigator notifies both current and past participants when they are at increased risk of a problem that was not identified at the time the research project was initially designed. In order to fulfill this obligation, ORA shall require the sponsor to include language in the clinical trial agreement indicating the sponsor shall promptly communicate to the IRB through the investigator any significant or unexpected research project results that may alter the willingness of research project participants to continue participation in the research project.

1.7.5 Publications or Disclosure of Results

ORA shall review each clinical trial agreement for language providing for the publication rights of the investigator. ORA shall make every effort to ensure that investigators retain the right to publish the data and/or results of a sponsored research project in accordance with the terms of the agreement.

1.7.6 Warranty or Disclaimer

ORA reviews each clinical trial agreement for warranty or disclaimer language and, if warranty or disclaimer language is found that goes to the study drug or device (other than efficacy), ORA negotiates with the sponsor to remove or revise the language in compliance with IRB policy, as follows: The IRB shall review each consent document and shall not allow any language that disclaims or limits the warranty of drugs or devices except with regard to the efficacy of the drug or device. Exceptions to this policy will be handled on a case-by-case basis as described below in Section 7.7.6 (B)

2. SCOPE

This SOP applies to all human participant research projects performed at HSC.

3. RESPONSIBILITY

IRB and ORA staff are responsible for facilitating communication and notification between their offices.

4. APPLICABLE REGULATIONS AND GUIDELINES

 NIH Notice OD-00-031 Release Date May 1, 2000
45 CFR 46
21 CFR 56
5. REFERENCES TO OTHER APPLICABLE SOPS
SOP 301: Research Submission Requirements

6. ATTACHMENTS
701-A Informed Consent Template (HSC)
701-A-1 Informed Consent Template (NC)

7. PROCESS OVERVIEW
7.1 Just-in-Time Policy for IRB Submissions
7.1.1 Upon receipt of a favorable priority ranking from the funding agency, the investigator submits an IRB Application, Grant Proposal, and other required submission documents per SOP 301: Research Submission Requirements, to the IRB for review.
7.1.2 If the priority ranking of the project is unfavorable, it is not necessary for the investigator to contact the IRB. If the priority ranking is favorable, the investigator shall promptly submit the research project to the IRB.

7.2 Grant Proposals Lacking Definite Plans for Human Participant Involvement at the Time of Submission to Funding Agency
7.2.1 The IRB does not require review of grant applications lacking definite plans for human participant involvement prior to an award being made. If review is required by a supporting agency, the investigator submits an IRB Application, Grant Proposal, and other required submission documents to the IRB for review.

7.3 Research Proposals Without the Initial Intent of Human Participant Involvement
7.3.1 The IRB does not require review of research proposals when the initial intent of the research does not involve human participants. If proposed research activities are later revised to include involvement of human participants, the investigator submits an IRB Application and required documents to the IRB for approval before involvement of human participants in the research.

7.4 Research Requiring a Contract with the Sponsor or Funding Agency
7.4.1 HSC research projects involving human participants that are sponsored and/or funded by pharmaceutical and biotechnology companies (industry sponsored) require both IRB approval and a fully executed contract between the HSC and the company prior to initiation of the research activities.
7.4.2 The investigator indicates on the IRB Application that the research project is industry-sponsored (i.e., providing drug, device, and/or funding). Upon final approval of the project by the IRB, the approval date of the project is available for review by ORA in the IRB’s electronic information system.
7.4.4 The IRB approval letter instructs the investigator that they are not to begin the project until the contract is signed by ORA. ORA does not execute the contract until IRB
approval is granted unless the contract indicates the research may not begin until IRB approval is obtained.

7.5 Unique IRB Number Assignment Per Funded Proposal

7.5.1 The IRB’s electronic information system assigns a unique IRB number upon receipt by the IRB of a research project submission for every new IRB application submitted to the IRB.

7.5.2 The IRB number is used in all reports, minutes, agendas, correspondence with the investigator, and communications with ORA, the sponsor, and federal agencies.

7.5.3 The Sponsored Program Administrator in ORA accesses the IRB electronic information system to verify that the IRB number, title, and sponsor designated in the IRB electronic information system correspond to the IRB number, title, and sponsor provided by the investigator to ORA on the grant proposal and ORA routing form.

7.6 Communication Mechanisms Between IRB and ORA

7.6.1 The IRB electronic information system is available to ORA for review of IRB research project status.

7.6.4 ORA notifies the HRPP Director or designee of any discrepancy discovered by ORA.

7.6.5 If discrepancies in the sponsor, investigator, and project title cannot be resolved between the IRB and ORA, the IRB seeks clarification from the investigator.

7.6.6 If necessary, the IRB requests the investigator to submit a modification form as outlined in SOP 302: Administrative Review and Distribution of Materials.

7.7 Human Research Participant Protection Requirements with Sponsors

7.7.1 Adherence to Policies

Requests to the IRB or ORA from sponsors for the HSC HRPP to deviate from HRPP policies and procedures are not accepted by ORA. ORA must bring such requests to the attention of the HRPP Director or ORA Associate Director for response to the sponsor.

7.7.2 Medical Care for Research-Related Injury

A. The Sponsored Program Administrator of ORA reviews each clinical trial agreement for inclusion of research participant injury language. ORA notifies the investigator if the agreement language does not agree with the informed consent document language.

B. The IRB Member reviews each informed consent document for inclusion of the following elements as described in the IRB informed consent templates: an explanation of whom to contact for answers to questions about the research, research participants’ rights, and research-related injuries.

7.7.3 Reporting Requirements of the Sponsor

A. The Sponsored Program Administrator of ORA reviews each clinical trial agreement for language indicating the sponsor must promptly report to the HSC HRPP any information contained within a monitoring report that could affect the rights or welfare of the research participants or their willingness to continue in the research project or alter the IRB’s approval to continue the research project. Each clinical trial agreement shall be reviewed for language indicating the time frame after closure of the study during which the Sponsor will communicate such findings to the University.
B. The IRB Administrator reviews each informed consent document for inclusion of language, as described in the consent form templates, that participants will be notified of new information relevant to their participation in the research project.

7.7.4 Communication to Research Project Participants

A. The investigator provides research project participants with significant new findings developed during the course of the research that may affect their willingness to continue their participation.

B. In order to fulfill this obligation, the sponsor is required via contract to notify the IRB through the investigator when new findings developed during the course of the research may affect the participants’ willingness to continue their participation.

C. The IRB requires the investigator to notify both current and past participants when they are at increased risk of a problem that was not identified at the time the research project was initially designed.

D. ORA requires that the sponsor include language in the clinical trial agreement indicating the sponsor, through the investigator, shall promptly communicate significant or unexpected research project results that may affect the willingness of research project participants to continue participation in the research project to the IRB. The clinical trial agreement shall indicate the time frame after closure of the study during which the Sponsor will communicate such findings to the University which shall not be any less than two years after closure.

7.7.5 Publications or Disclosure of Results

A. The Sponsored Programs Administrator of ORA reviews each clinical trial agreement for language providing for the publication rights of the investigator.

B. ORA shall make every effort to ensure that investigators retain the right to publish or disclose the data and/or results of a sponsored research project in accordance with the terms of the agreement.

7.7.6 Warranty or Disclaimer

A. The Sponsored Programs Administrator of ORA reviews each clinical trial agreement for warranty or disclaimer language. The IRB reviews each consent document and does not allow any language that disclaims or limits the warranty of drugs or devices other than of efficacy, in compliance with IRB policy. If the Sponsored Programs Administrator of ORA finds warranty or disclaimer language beyond efficacy in the Phase III or IV clinical trial agreement, ORA negotiates with the sponsor to modify or remove the language.

B. Exceptions to this policy are handled on a case-by-case basis through a subcommittee comprised of the Associate Director of ORA or designee, Director of the IRB or designee, and the IRB Chair. The Office of Legal Counsel may be consulted.
1. POLICY

The Office of Research Services (ORS) and Outreach Sponsored Programs (OSP) shall serve as a central resource to promote the research, education, and service missions of the University. ORS and OSP shall provide information and administrative assistance to faculty and staff for developing and submitting proposals to external sponsors and negotiating awards and post-award support. Consistent with NIH policy, access to funding of projects involving the use of human research participants shall be contingent upon IRB approval, including compliance with requirements for continuing review.

The ORS and OSP shall track all projects involving human research participants and request current information on the status of research project approval from the IRB. Open communication among the IRB and the ORS and OSP is essential in order for each entity to fulfill its function.

Specific Procedures

1.1 Submission to IRB After an Award Acceptance

The revised NIH policy of May 2000 that allows grant applications to be submitted to NIH for peer review without prior IRB approval is extended to all Norman Campus (NC) grant proposals where the granting agency does not require IRB approval prior to their review process. An investigator will be required to submit an IRB application “just in time” only for award acceptance and funds access.

1.2 Research Proposals With Delayed Human Participant Involvement

Occasionally, research activities are funded but human participant involvement will occur after protocol development. The investigator must receive approval from the IRB for protocol development in order for ORS to release research funds. Additional guidance about receiving IRB approval to develop the human research protocol is provided in SOP 406: Determination of Human Research and Protocol Development.

1.3 IRB Project Quality Assurance

Investigators often seek funding from various sources. To save time, some investigators may submit only one research project for IRB approval. When investigators receive feedback from granting agencies, they may “tweak” the protocol in order to receive a higher rating/score. Sometimes the titles remain the same as the title originally submitted and approved by the IRB, but the content/mechanics of the protocol have changed. This becomes a problem if the investigator does not re-submit the revised protocol for IRB approval and is contrary to University and federal policy. Investigators who revise protocols per funding agency requirements must submit the protocol with an application to the IRB as a new submission.

Each research project is assigned a unique IRB number based on grantor/sponsorship information; i.e., one IRB number for each grant proposal/sponsor. This numbering system assures that each federally funded project has been reviewed, in entirety, by an assured IRB as mandated in the federal regulations under 45 CFR 46.103 (f).
2. SCOPE

   This SOP applies to human participant research projects routed through the IRB and ORS or OSP at OU-NC.

3. RESPONSIBILITY

   If there is an outstanding project that requires IRB approval and has not begun the review process, ORS or OSP notifies the investigator as well as the HRPP office. ORS or OSP employees also contact the HRPP office periodically in order to check on project titles, approval dates, and continuing review dates.

4. APPLICABLE REGULATIONS AND GUIDELINES

   45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

   SOP 301: Research Submission Requirements
   SOP 302: Administrative Review & Distribution of Materials
   SOP 406: Determination of Human Research and Protocol Development

6. ATTACHMENTS

   None

7. PROCESS OVERVIEW

   7.1 The investigator submits a research project to the IRB, and the IRB Administrator processes per SOP 301: Research Submission Requirements; and 302: Administrative Review & Distribution of Materials.

   7.2 The IRB staff communicate and resolve issues related to the Investigator's research project with ORS or OSP.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 602E: MEDICAL BILLING COMPLIANCE OFFICE

1. POLICY
The OUHSC Medical Billing Compliance Office (MBC) is a central resource in promoting education and monitoring regulatory compliance for medical and dental documentation, coding, and billing. The MBC Office assists in identifying and eliminating potential risk areas by activities which include but are not limited to providing education and training on regulations from federal, state and other regulatory agencies affecting professional billing; conducting compliance validation reviews; recommending any needed changes or additions to billing policies and procedures; researching inquiries concerning proper billing practices; reviewing, investigating and responding to reports of potential non-compliance; and recommending remedial actions for non-compliance.

The MBC Office shall review questions or concerns from the IRB regarding billing compliance issues for human participant research projects.

Specific Policies

1.1 Evaluation of Billing Questions or Concerns
The IRB shall refer billing questions or concerns related to human participant research projects to the MBC Office for review and evaluation.

The MBC Office shall evaluate billing questions or concerns related to human participant research projects and shall contact the Investigator, if applicable and assist the PI to resolve the concerns of the IRB.

2. SCOPE
This SOP applies to billing issues related to human participant research.

3. RESPONSIBILITY
3.1 The investigator is encouraged to contact MBC to discuss or clarify potential billing questions or concerns for new research projects prior to submitting the research project to the IRB.

3.2 The MBC Office is responsible for providing assistance to the investigator to resolve billing questions or concerns referred from the IRB.

3.3 The investigator is responsible for responding to the MBC Office when presented with IRB concerns regarding billing in the research project.

4. APPLICABLE REGULATIONS AND GUIDELINES
None

5. REFERENCES TO OTHER APPLICABLE SOPS
None

6. ATTACHMENTS
None

7. PROCESS OVERVIEW
7.1 The IRB Administrator shall refer billing questions or concerns related to research projects to
the MBC Office in writing for evaluation.

7.2 The IRB Administrator shall document in the IRB’s electronic information system billing issues that are referred to the MBC Office for evaluation.

7.3 The MBC Office shall evaluate billing questions or concerns related to research projects that are referred from the IRB.

7.4 The HBC shall assist the Investigator to address the IRB concerns and provide written notice of resolution to the IRB.

7.5 Final IRB approval of any research project is contingent on the resolution of the IRB’s billing questions or concerns.

7.6 The IRB will make decisions regarding the inclusion of payment information in the informed consent documents.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 602F: INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

1. POLICY

The IRB shall not grant final approval of human participant research projects involving recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins until the project has been reviewed and approved by the Institutional Biosafety Committee (IBC).

The IBC shall review all human participant research involving recombinant or synthetic nucleic acid molecules (recombinant DNA), gene transfer, microorganisms, viruses, or biological toxins. The IBC review shall include a scientific review and determination on whether research projects involving recombinant DNA activities meet the requirements of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and other health and safety guidelines. All projects involving gene transfer shall also be reviewed by the National Institutes of Health Recombinant DNA Advisory Committee (RAC), which serves a critical role in the oversight of federally funded research involving recombinant DNA. The RAC review process is to be initiated by the sponsoring entity, and if such a review has not been initiated prior to adding the University of Oklahoma as a clinical trial site, the University must initiate this process.

Specific Policies

1.1 Committee Interaction

Reciprocal communication on a regular basis between the IRB and the IBC is essential in order for the IRB to fulfill its functions relative to human participant research. The IRB shall notify the IBC when an IRB application is received involving recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins. The IBC shall notify the IRB of its decision regarding approval of human participant research projects using recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins.

If the IRB reviews the research project before the IBC, the IBC may invite a representative from the IRB that reviewed the research project to the corresponding IBC meeting. If the IBC reviews the research project before the IRB, the IRB may invite a representative of the IBC to attend the corresponding IRB meeting.

Any modification to the protocol, informed consent documents, or personnel or other significant change during or after the review process shall be reviewed and approved by both the IRB and IBC before the research project modification is initiated.

2. SCOPE

This SOP applies to all human participant research that involves the use of recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins.

3. RESPONSIBILITY

3.1 The investigator is responsible for submission of human participant research projects that involve the use of recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins to the IBC.

3.2 The IRB and IBC independently review the research project and may do so concurrently. The IRB Administrator is responsible for verifying IBC approval or review before assigning the research project to the IRB Chair or IRB designee for final approval by the IRB. The IRB Administrator is responsible for obtaining documentation of IBC approval before finalizing the IRB approval.
4. APPLICABLE REGULATIONS AND GUIDELINES
   NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 301: Research Submission Requirements
   SOP 302: Administrative and Distribution of Materials
   SOP 401: Research Exempt from Federal Regulations
   SOP 402: Expedited Review
   SOP 403: Initial Review – Criteria for IRB Approval

6. ATTACHMENTS
   602F-A    Institutional Biosafety Approval letter

7. PROCESS OVERVIEW
   7.1 The investigator shall submit all research projects that involve recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins to the IBC for review.
   7.2 Upon approval, the IBC shall issue an approval letter to the investigator and shall forward the letter to the IRB.
   7.3 The investigator shall submit the research project to the IRB. The IRB Administrator shall review the documents per SOP 301: Research Submission Requirements; and SOP 302: Administrative Review and Distribution of Materials. The IRB Administrator shall initiate communication between the IRB Administrator or IRB Chair or IRB designee and the investigator if IBC review is indicated.
   7.4 Review of the research project by the IRB shall be accomplished per applicable SOP 401: Research Exempt from IRB Review; SOP 402: Expedited Review; or SOP 403: Initial Review – Criteria for IRB Approval.
   7.5 The IRB Administrator shall verify IBC approval before forwarding the research project to the IRB Chair or IRB designee for final approval by the IRB.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 602G: DETERMINATION OF REVIEWING OU CAMPUS IRB

1. POLICY

Investigators at the University often engage in research projects involving participants or testing procedures that may fall under the purview of multiple OU campus IRBs. The Human Research Participant Protection (HRPP) Director evaluates the role of the OU researchers and determines the appropriate OU campus IRB of record.

Research Involving Multiple OU IRBs: Human research projects involving IRBs from both the Health Sciences (HSC) and Norman campuses (NC) may include research projects that recruit participants from both campuses, involve investigators from both campuses, and/or utilize resources from both campuses. Research projects that target a specific patient population or utilize research procedures that may result in elevated physical risk may require HSC IRB approval, as determined by the HSC IRB Chair or IRB designee.

Specific Policies

1.1 Determination of Reviewing OU Campus

The investigator will submit the original application materials to the University IRB on the campus of his or her academic program. The initial determination of which IRB will be the IRB of record will be made according to the following guidelines:

1.1.1 All medical, clinical, FDA-regulated, and VA studies involving human participants will be reviewed by the OUHSC IRB unless an IRB with medical and clinical expertise is reviewing the research protocol. For example, if OU NC faculty, staff, or students conduct research in a hospital setting and the IRB from that facility will conduct an independent IRB review, OUHSC IRB review is not required.

1.1.2 Studies that include a research procedure that may result in greater than a minimal level of physical risk or that targets research participants with a specific medical diagnosis or clinical intervention may be evaluated by the IRB Chairs at both the HSC and NC campuses to determine why such participants are at increased physical risk from participation compared to a healthy population.

1.1.3 Either University IRB can require review of a research submission by an investigator whose academic program it oversees.

1.1.4 When the University investigator’s campus of record will not serve as the IRB of record, the IRB from the originating campus shall cooperate in response to requests from the IRB of record for additional information and reporting requirements, adequately support the designated IRB in its function, and abide by the designated IRB decisions. No University IRB shall administratively overrule disapprovals by another University IRB of proposed projects.

1.2 Reciprocal Campus IRB Review Policy

The University of Oklahoma Norman Campus and the University of Oklahoma Health Sciences Center shall sign and maintain a Cooperative Memorandum of Understanding (MOU) that specifies
which IRB is designated with sole IRB oversight when a research project involves both campuses and when research proposed by OU NC faculty, staff, or students requires medical oversight. At a minimum, the Cooperative MOU shall provide:

1.2.1 Unless otherwise stipulated in Section 1.1, when participants of a research project will be recruited primarily at one University campus, that campus shall be assigned IRB oversight for the research project.

1.2.2 When participants of a research project will be recruited from both University campuses, IRB Chairs at both campuses will confer to determine which IRB should retain sole oversight, taking into consideration the scope of the research.

1.2.3 If the originating University IRB determines it does not possess the necessary expertise to review a particular research project, it shall transfer the IRB review process to an IRB on the other campus.

2. SCOPE
This SOP applies to all research that involves investigators or research participants from multiple University campuses.

3. RESPONSIBILITY
The HRPP Director or the IRB Chair of the originating campus is responsible for providing initial review and recommendation concerning the appropriate campus IRB to retain oversight.

4. APPLICABLE REGULATIONS AND GUIDELINES
None

5. REFERENCES TO OTHER APPLICABLE SOPS
SOP 301: Research Submission Requirements

7. PROCESS OVERVIEW
7.1 When a research project involves multiple University campuses, one campus IRB shall be designated as the IRB of record, as described above in Section 1.1.

7.2 The IRB Administrator reviews submitted documents per SOP 301: Research Submission Requirements.

7.3 The IRB Chairs from both campuses may confer to determine which IRB is responsible for regulatory oversight. The determination will be documented in the study file.

7.4 The IRB Administrator or IRB Chair notifies the investigator regarding determination of IRB oversight.

7.5 The investigator will submit the forms that are applicable to the assigned campus IRB.

APPROVED BY:________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020

Version No. 11
Effective Date: 09/03/2019
Supersedes Document: 08/31/2018
SOP 602G
SOP 602H: STEPHENSON CANCER CENTER
PROTOCOL REVIEW AND MONITORING COMMITTEE

1. POLICY
The Protocol Review and Monitoring Committee (PRMC) of the Stephenson Cancer Center (SCC) shall review cancer-related research for scientific merit and SCC priority prior to IRB review. The PRMC shall provide review and feedback to investigators, who will forward PRMC-approved submissions to the IRB for review of research participant protection issues.

Specific Policies
1.1 PRMC & IRB Interaction
The IRB shall review cancer-related research projects following review by the PRMC. The PRMC approval letter shall be included as part of the IRB submission. PRMC deliberations shall not be shared with the IRB unless specific participant protection issues are raised by the PRMC. The PRMC letter shall either indicate approval or state issues of concern raised by the PRMC.

2. SCOPE
This SOP applies to all cancer-related human participant research.

3. RESPONSIBILITY
3.1 The investigator is responsible for submitting all new cancer-related research projects to the PRMC prior to submission to the IRB.
3.2 The PRMC will forward the PRMC approval letter to the investigator and to the IRB once the PRMC review is complete.

4. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46.111
21 CFR 56.111

5. REFERENCES TO OTHER APPLICABLE SOPs
SOP 301: Research Submission Requirements
SOP 302: Administrative Review & Distribution of Materials
SOP 401: Research Exempt from IRB Review
SOP 402: Expedited Review

6. ATTACHMENTS
305-C Reviewer Checklist
602H-A Cancer Center PRMC Approval Letter
7. PROCESS OVERVIEW

7.1 The investigator submits all cancer-related research projects to the PRMC for review. If this procedure has not taken place prior to submission to the IRB, the IRB Administrator returns the submission to the investigator for completion of PRMC review.

7.2 Following PRMC review, the PRMC forwards a letter to the investigator indicating PRMC approval or areas of concern, with copy to the HRPP Office.

7.3 The investigator submits the approved cancer-related project to the IRB in accordance with SOP 403. The HRPP Office processes submitted documents per SOP 301: Research Submission Requirements; and SOP 302: Administrative Review and Distribution of Materials.

7.4 The project is reviewed per SOP 401: Research Exempt from IRB Review; SOP 402: Expedited Research; or SOP 403: Initial Review Criteria for IRB Approval, as applicable.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 602I: RADIATION SAFETY OFFICE

1. POLICY
The Radiation Safety Office (RSO) shall review all human research that involves the use of ionizing radiation when the research is performed solely as part of the research and is not standard of care and shall provide its knowledge and expertise to the IRB.

Specific Policies
1.1 Committee Interaction
Following review of a research project, the Radiation Safety Office will provide written recommendations to the IRB. The IRB shall consider these recommendations when conducting its review.

RSO review should be conducted prior to IRB review. If time is a factor, however, the IRB will allow concurrent review by the IRB and the RSO. Final IRB approval of the project shall be contingent upon IRB receipt and review of the RSO written recommendations.

2. SCOPE
This SOP applies to human participant research that involves the use of ionizing radiation when the research is performed solely as part of the research and is not standard of care, as indicated by the investigator.

3. RESPONSIBILITY
3.1 The investigator is responsible for submitting human participant research projects that involve the use of ionizing radiation to the RSO and the IRB when such radiation is performed solely as part of the research and is not standard of care.

3.2 The IRB Administrator is responsible for obtaining the RSO written recommendations before submitting the research project to the IRB Chair or IRB designee for final IRB approval.

4. APPLICABLE REGULATIONS AND GUIDELINES
None

5. REFERENCES TO OTHER APPLICABLE SOPS
None

6. ATTACHMENTS
305-C Reviewer Checklist
602I-A Radiation Safety Approval Letter

7. PROCESS OVERVIEW
7.1 Submission Procedures
7.1.1 When an IRB submission involves the use of ionizing radiation performed solely as part of the research project (or as requested by the IRB or the RSO on a case-by-case basis) and not as standard of care, the investigator will indicate this on the IRB application and
describe in the informed consent document the risks to participants as a result of the exposure to ionizing radiation.

7.1.2 The investigator must also complete the Application for Human Use of Radiation or Radioactive Materials (available as a sub-form within the IRB electronic information system).

7.2 IRB Review Procedure

7.2.1 The IRB Administrator reviews the investigator’s submission documents for the use of ionizing radiation.

7.2.2 The IRB Administrator notifies the IRB reviewer that the submission will need to be reviewed by the convened IRB. The IRB Administrator will assign the RSO as an additional consultant/ad hoc reviewer on the file.

7.2.3 If the RSO review is not available at the time of research project submission to the IRB, the research project can be reviewed by the convened IRB with notification to the IRB members that the RSO review results are pending.

7.2.4 The convened IRB reviews the RSO recommendations and suggested modifications to the protocol and/or consent documents.

7.2.5 If the RSO recommendations and suggested modifications qualify as minimal modifications, the IRB may request that the investigator revise the project according to both RSO and IRB requested stipulations. Once the investigator submits the IRB and RSO requested revisions, the IRB Chair or IRB designee reviews the revisions and, if the revisions are satisfactory, grants final IRB approval for the project through the expedited review process.

If the RSO recommends modifications that are more than minimal, the IRB may request that the PI submit revised protocol and consent documents, as applicable, and forward the modifications to the RSO for a subsequent review. If a second review by the RSO is requested by the IRB, the updated RSO recommendations and suggested modifications will be reviewed by the convened IRB to make a determination on the IRB submission.

7.3 RSO Review Procedure

7.3.1 The RSO will review the ionizing radiation component of the research project. If the RSO reviewer has questions, s/he may contact the investigator directly. If the RSO reviewer requires additional information or documentation, the investigator will receive notification of the RSO reviewer’s stipulations via the IRB’s electronic information system.

7.3.2 When the ionizing radiation component of the IRB submission review is completed, the RSO documents their recommendations and suggested modifications to the protocol or to the consent documents, as applicable, in the IRB’s electronic information system for action by the IRB Chair or IRB designee.
SOP 602J: USE OF SINGLE IRB (SIRB) IN MULTICENTER RESEARCH

1. POLICY

This policy establishes the requirements governing when OU investigators collaborate with non-OU institutions and/or non-OU investigators in multicenter human research.

The OU HRPP retains oversight of human subjects research conducted by OU faculty, staff, and students. As part of the OU HRPP, the OU IRB provides IRB review and oversight unless an alternate IRB has been designated via a formal IRB Reliance Agreement between OU and the alternate IRB.

The OU IRB will consider serving as the IRB of record for non-OU sites and/or non-OU researchers when an OU researcher will serve as the Lead Investigator. When the OU researcher is not the Lead Investigator, the University will consider deferring IRB oversight to a collaborating institution’s IRB or external IRB.

Under certain circumstances, the University may be required to either rely on an outside IRB or serve as an outside IRB in order to participate in multicenter research. Examples include:

1. Use of the Central Institutional Review Board for National Cancer Institute studies (NCI CIRB);
2. Studies that fall under the NIH Policy on the Use of Single IRB for Multi-Site Research;
3. Revised Common Rule mandate that requires single IRB oversight for cooperative research (effective January 19, 2020);
4. A research consortium’s mandate to use a single IRB.

There may be other circumstances when the University may decide to defer to an outside IRB for a study led by an OU investigator; i.e., when the University has an institutional conflict of interest; when an outside IRB may have a particular expertise of the proposed research, or when OU IRB oversight of a particular study or group of studies is not feasible. The IRB will make a determination regarding which IRB shall serve as the relying IRB on a case-by-case basis.

The University shall not approve research subject to a Reliance Agreement if it has not been approved by the designated Reviewing IRB.

Specific Policies

1.1 WHEN OU IRB SERVES AS THE REVIEWING IRB

The OU IRB may serve as the reviewing IRB for multicenter studies in which the Lead Investigator of the research is faculty, staff, or student of OU or an OU affiliate and has direct responsibility for the conduct of the research or of the human subjects.

The OU investigator must provide the OU IRB with a communication and oversight plan for the collaborating sites. The plan shall outline what research activities will occur at each site, the communication plan with the sites, and the plan for ensuring study and regulatory compliance of each site, and local site policy updates. The OU investigator must also provide information about the local context of the relying sites, including the relying site’s PI.

An approved Reliance Agreement must be fully executed between the University and the relying site prior to the site’s participation in the IRB-approved research.
1.2 WHEN OU IS THE RELYING INSTITUTION

The University may rely on a non-OU IRB under the conditions below. OU will take into consideration the Accreditation status of the outside IRB when making a determination of whether to rely on the outside IRB.

1. OU is “engaged” in the proposed research as defined by OHRP.
2. The outside IRB must have an approved and active FWA with OHRP.
3. All non-IRB local context issues must be addressed by the OU investigator, including University ancillary committee reviews (IBC, RSO, SRC, etc.), COI, University HRPP training requirements, and ORA/ORS contract/grant negotiations.
4. The OU investigator must submit an External IRB application into the IRB electronic submission system prior to participating in the multicenter research.
5. A Reliance Agreement must be fully approved and executed between the University and the reviewing IRB prior to the OU investigator’s participation in the multicenter research.

1.3 WHEN OU EXTENDS ITS FWA TO COLLABORATING, NON-OU INVESTIGATORS

The OU investigator may be collaborating on a research project with an individual who is not affiliated with any FWA covered institution. If the OU investigator plans to include a non-OU researcher who is unaffiliated with an FWA-covered institution and that non-OU researcher will be engaged in OU research as defined by OHRP, the University will consider extending its FWA to cover that non-OU researcher.

The following information/actions are required:

1. The OU investigator must provide documentation describing the research activities in which the non-OU collaborating investigator will engage. Examples: The statement of work from a funding arrangement, detailed description in the research protocol, and/or OU IRB application.
2. Copy of the non-OU collaborator’s credentials (i.e., curriculum vitae) to determine if the non-OU collaborator is qualified to conduct assigned research activities.
3. The non-OU collaborator must complete OU IRB education requirements, or equivalent, as deemed appropriate by the OU HRPP.
4. The OU investigator must directly and appropriately supervise all of the collaborative research activities to be performed by the non-OU collaborating investigator.

The University will negotiate an Individual Investigator Agreement (IIA) with the non-OU collaborator. The signed agreement will be added to the IRB study file.

The University retains the right to revoke an IIA at any time. The collaborating investigator must cease all research activities at the time of revocation of the IIA.

2. SCOPE

This SOP applies to all HRPP staff, IRB members, OU staff, researchers, and non-OU researchers who are involved in human participant research that engages the University.
3. **RESPONSIBILITY**

3.1 **The HRPP Director**, after consulting with the OU IRB Chair and the Institutional Official (at NC) or the Vice-President for Research (at OUHSC), is responsible for determining whether the OU IRB will be the relying IRB or will rely on an outside IRB, and for communicating that decision to the OU investigator and University officials.

3.2 **The OU investigator** is responsible for contacting the HRPP to request (1) OU IRB to be the Reviewing IRB for multicenter research or (2) OU to rely on a non-OU IRB as the IRB of record.

If a determination is made for OU to serve as the Reviewing IRB with the OU investigator serving as the lead PI, the OU investigator is responsible for complying with the requirements as described in the applicable Reliance Agreement.

The OU investigator is responsible for complying with SOP 801: Investigator Qualifications and Responsibilities, providing adequate oversight of the collaborating sites, communicating this plan to the Reviewing IRB, and ensuring that all items requiring IRB review are submitted to the Reviewing IRB.

If the OU investigator serves as a relying site investigator, the OU Investigator is responsible for submitting the External IRB application into iRIS for HRPP tracking and complying with local context requirements. The OU investigator is responsible for complying with the Reviewing IRB’s protocol determinations and lead study site’s requirements, as described in the applicable Reliance Agreement.

3.3 **The Reviewing IRB** is responsible for the review and approval of human participant research, including initial, continuing review, modifications, and unanticipated problems involving risks to participants or others, in accordance with applicable laws and SOPs. Additional responsibilities may include, but are not limited to:

- Reviewing additional study sites to previously approved studies, considering the local context of the research;
  - **NOTE:** Such changes may be considered minor modifications reviewed in accordance with the expedited review process documented in SOP 402: Expedited Review. See SOP 405: Modifications for a definition and examples of minor modifications.
- Notifying relying institutions of the Reviewing IRB’s determinations;
- Making available relevant IRB minutes, SOPs, and other documents to the relying institution upon request;
- Conducting scientific review;
- Reviewing potential non-compliance, including complaints, deviations, and results of audits
  - Deciding whether allegations of non-compliance are based in fact;
  - Determining whether an incident of non-compliance is serious or continuing;
  - Reporting serious or continuing non-compliance, unanticipated problems, and suspensions or terminations of IRB approval;

  **Note:** This responsibility may necessitate negotiation between the two sites, as the Relying Site may require their own non-compliance responsibility.
• Obtaining additional approvals from DHHS when then research involves pregnant women, fetuses, and neonates; or children; or prisoners;

• Managing organizational conflicts of interest for research of the Reviewing site;
• Meeting other requirements as defined by the applicable Reliance Agreement.

3.4 **The Relying Institution** is responsible for conducting the research as approved by the Reviewing IRB and complying with requirements, as defined by the applicable Reliance Agreement. The Relying site is also responsible for notifying the Reviewing IRB when local policies that impact IRB review are updated. Additionally, the Relying site is responsible for managing organizational conflicts of interest of research of the Relying site.

3.5 In the event that termination of a reliance agreement occurs, the Reviewing and Relying sites will work together to ensure that one party is clearly responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of studies.

3.6 **Non-OU Collaborating Researcher** is responsible for complying with the standards and requirements in the Belmont Report; OHRP rules and guidance (or other internationally recognized equivalent institutions); the FWA and applicable terms of the FWA for the assured institution; the relevant institutional policies and procedures for the protection of human subjects of the assured institution; and all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects research.

4. **APPLICABLE REGULATIONS AND GUIDELINES**
   OHRP Policy and Guidance
   NIH Policy on the Use of Single IRB Policy for Multi-Site Research

5. **REFERENCES TO OTHER APPLICABLE SOPS**
   SOP 402: Expedited Review
   SOP 405: Modifications
   SOP 801: Investigator Qualifications and Responsibilities

6. **ATTACHMENTS**
   602J-A Non-OU Employee Collaborator Assurance Form (NC)
   602J-B Local Context Form for Relying Sites
   602J-C Communication Plan Template
   602J-D Relying Institution Checklist Template
   602J-E OUHSC Reliance Agreement Template
   602J-F OUHSC Individual Investigator Agreement Template

7. **PROCESS OVERVIEW**
   When the OU IRB is to be the Reviewing IRB:
7.1 The OU PI should consult with the HRPP for guidance upon becoming aware that a multicenter study proposal may require single IRB oversight by OU IRB.

7.2 The OU PI must submit the proposed study to the OU IRB via iRIS and indicate the study will involve multiple non-OU sites.

7.3 The HRPP will consult with the IRB Chair and appropriate University officials to obtain concurrence for OU IRB to serve as IRB of record.

7.4 If concurrence is reached, the HRPP will work with the OU PI and relying sites to begin the reliance agreement process.

7.5 The OU PI may begin the study when (1) all OU requirements have been met, (2) the Reliance Agreement is fully executed, and (3) the Reviewing IRB has approved the protocol and the OU site to participate in the study.

When OU relies on a non-OU IRB

7.6 The OU PI should consult with the HRPP for guidance upon becoming aware that a proposal may require non-OU IRB oversight.

7.7 The OU PI must submit a request to rely on an External IRB form to the HRPP (available on the HRPP website), along with the protocol.

7.8 The HRPP Office will review the request and identify the status of the non-OU IRB, including its accreditation status and registration with OHRP.

7.9 The HRPP will consult with an OU IRB Chair and University officials to obtain concurrence to rely on the non-OU IRB.

7.10 If concurrence is reached, the HRPP will work with the OU PI and the non-OU IRB to begin the reliance agreement process, and provide a HRPP Acceptance letter.

7.11 The OU PI will submit an External IRB Application into iRIS.

7.12 The OU PI may begin the study when (1) all OU requirements have been met, (2) the Reliance Agreement is fully executed, and (3) the Reviewing IRB has approved the protocol and the OU site to participate in the study.

APPROVED BY: ____________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY (Applies to HSC Only)

Under an agreement between the Board of Regents of the University of Oklahoma Health Sciences Center (HSC) and Oklahoma City VA Health Care System (OKCVAHCS), the HSC Institutional Review Board (IRB) is designated as an IRB of record for review of human participant research conducted at the OKCVAHCS. The agreement establishes the provision of services provided by the IRB to the OKCVAHCS and outlines the responsibilities of the IRB and OKCVAHCS.

Under a separate agreement between HSC and the Eastern Oklahoma VA Health Care System (EOVAHCS), the HSC IRB is designated as an IRB of record for review of human participant research conducted at the EOVAHCS. The agreement establishes the provision of services provided by the IRB to the EOVAHCS and outlines the responsibilities of the IRB and EOVAHCS.

The OKCVAHCS and EOVAHCS each have a separate agreement with the VA Central IRB (VA-CIRB) in Washington DC for the approval of VA-funded multisite research. The VA-CIRB is listed on all applicable FWAs.

It is the policy of the HSC IRB to apply the requirements of 38 CFR Parts 16 and 17 and all applicable Veterans Health Administration (VHA) Handbooks, Directives, Guidance, and provisions that the OKCVAHCS and/or EOVAHCS make available to it for all VA-regulated research for which it acts as the IRB of record.

Veterans Affairs (VA) research is defined as research that is conducted by investigators (serving on VA compensated, without compensation [(WOC)], or Intergovernmental Personnel Agreement [(IPA)] appointments) while on VA time or on VA property. The research may be funded by VA or by other sponsors or be unfunded. VA research must have VA Research and Development Committee (R&DC) approval before it is considered VA Research and before it can be initiated. All research activities approved by the VA R&D Committee are considered VA Research.

Non-VA research cannot be conducted in VA space. If a non-VA investigator is proposing to conduct research in VA space, the investigator must also have a VA appointment that allows the research to be conducted at the VA. If a non-VA investigator is proposing to conduct research in leased space, the space is not considered to be VA space and the activity is not VA research.

VHA does not conduct or permit VA investigators to conduct planned emergency research (see 21 CFR 50.24) or classified research involving human subjects.

Additionally, international VA research must be approved by the OKCVAHCS Director before research may begin.

Specific Policies

1.1 OUHSC IRB and VA Research and Development

1.1.1 Proposed research to be conducted at the OKCVAHCS or EOVAHCS requires prospective approval by both the HSC IRB and the OKCVAHCS R&DC, per applicable SOPs 401: Research Exempt from Federal Regulations; SOP 402: Expedited Review; or SOP 403: Initial Review – Criteria for IRB Approval. The EOVAHCS has a separate agreement with the OKCVAHCS to use its R&DC.
1.1.2. Continuing review of and modifications to on-going research conducted at the OKCVAHCS or EOVAHCS are subject to SOP 404: Continuing Review; and SOP 405: Modifications; respectively.

1.1.3. Research projects involving international research are subject to SOP 502K and VHA Directive 1200.05.

1.2. International Research

1.2.1 VA international research is defined as any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S. This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including MOUs, CRADAs, grants, contracts, or other agreements. NOTE: VA does not consider research conducted at U.S. military bases, ships, or embassies to be international research.

a. Sending specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the U.S. or Puerto Rico and accessed via a secure connection is not considered international research.

b. International research includes multi-site trials involving non-U.S. sites where VA is the study sponsor, a VA investigator is the overall study-wide PI, VA holds the Investigational New Drug (IND), or the VA manages the data collection and the data analyses.

c. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator).

1.2.2. Before approving international research involving human participants, the IRB must ensure that human participants outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S. (see OHRP guidance at http://www.hhs.gov/ohrp/international/index.html).

NOTE: The VA medical facility Director must approve participation in the proposed international research (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).

1.2.3. All international research must also be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities, which must be approved by the CRADO.

1.3 General VA Consent and Recruitment Requirements for VA Research Projects

1.3.1 Consent Documentation Requirements

A. VA Form 10-1086

1. For VA Research, local consent is documented through the use of VA Form 10-1086, VA Research Consent Form. The requirement to utilize VA Form 10-1086 to document informed consent applies to all VA-approved research including, but not
limited to, studies in which VA investigators working on VA research enroll subjects at the affiliate hospital or other sites outside VA (e.g., community centers or shopping malls).

2. The local VA Form 10-1086 must include all elements required by the Common Rule, as well as any additional elements required by the IRB. It includes VA required language and the requirements for the signature and date of the participant and the person obtaining consent. The signature and date of the witness may be included if required by the sponsor, IRB, the investigator, or others. The witness is required to observe only the participant’s or participant’s legally authorized representative’s (LAR’s) signature, not the consent process, unless the Sponsor or IRB requires the witness to observe the consent process. The witness cannot be the person who obtained consent from the participant but may be another member of the study team, someone unrelated to the research study, or a family member. A witness signature is always required when a short form consent is employed (see subparagraph. 18b(2) VHA Directive 1200.05).

3. The most current IRB-approved and stamped version of VA Form 10-1086 for each study (or the most current IRB-approved and stamped electronic version of VA Form 10-1086) must be used as the informed consent document. The only exception to requiring the use of VA Form 10-1086 is that a DoD consent document may be employed for active duty military personnel participating in VA research at DoD sites when VA-specific language is not necessary, as determined by DoD.

4. IRB approval of the VA informed consent document is documented through the use of a stamp on each page of the VA Form 10-1086 that indicates the date of the most recent IRB approval. The IRB approval must be documented in the IRB minutes or IRB research project files for those studies reviewed by the expedited process. IRB correspondence with the investigator will indicate which version of the informed consent document has been approved. The IRB approval date will be documented by the use of a stamp or preprinted box on each page of the informed consent documents. The IRB will maintain a copy of the approved informed consent documents in its records.

B. Electronic Consent

Documentation of consent may be obtained electronically so long as the informed consent process meets the VA requirement for use of electronic signatures.

C. Additional consent elements:

1. In addition to the elements for informed consent required under the Common Rule and FDA regulations, the VA requires the following elements for informed consent:
   a) The name of the study.
   b) The name of the PI and, in multi-site studies, the name of the Local Site Investigator (LSI).
   c) The sponsor of the study.
   d) Any payments the participant is to receive for participating in the study.
   e) Any real or apparent conflict of interest by investigators where the research will be performed.
   f) If the participant will be re-contacted for future research, whether within VA or outside VA.
2. A veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with federal law; certain veterans are required to pay co-payments for medical care and services provided by VA. Pursuant to 38 CFR 17.102, participants in VA-approved research cannot be charged, nor can their insurance be billed, for research-related interventions or procedures (e.g., tests, drugs, clinic visits, hospital admissions, transportation) that are required by the research project. If medical services are furnished to a person who is not eligible for medical services as a Veteran, the medical care appropriation will be reimbursed from the research appropriation.

3. All regulations pertaining to the participation of veterans as participants, including requirements for indemnification in case of research-related injury, pertain to non-veteran participants enrolled in VA-approved research.

4. Photographs, voice or video recordings: If the research involves photographs or voice or video recordings, the consent document must include a discussion of why photographs or voice or video recordings are being taken for the research, the individuals who will have access to them, and what their disposition will be after the research is completed.

5. The original or digitalized signed and dated informed consent form (see subparagraph 5g.(12), VHA Directive 1200.05) must be filed in the investigator’s research file for that participant so that it is readily accessible for auditing. A copy of the signed and dated informed consent documents must be provided or made available to the person signing the document (38 CFR 16.117(a) & VHA Directive 1200.05 18a.). Where applicable, a copy of the signed and dated informed consent documents must be placed in the medical record in accordance with VHA Directive 1200.05 and VHA Handbook 1907.01.

6. VA Requirements for Written Consent Document (Short Form):
   If approved by the IRB, the consent may be in the form of a short form written consent document stating that the elements of informed consent required in 38 CFR 16.116 have been presented orally to the subject or the subject’s LAR (38 CFR 16.117(b)(2)). When this method is used, this process includes the following:
   1. There must be a witness to the oral presentation (38 CFR 16.117(b)(2)).
   2. The IRB must approve a written summary of what is to be said to the subject or the LAR (38 CFR 16.117(b)(2)).
   3. Signatures are to be obtained as follows:
      a) The short form is to be signed by the witness, and the subject or LAR (38 CFR 16.117(b)(2)).
      b) The copy of the summary is to be signed by the witness and the person actually obtaining consent (38 CFR 16.117(b)(2)).
      c) The IRB cannot waive the requirement for a witness or witness signature when the short form consent is employed.
   4. A copy of the summary and a copy of the short form are to be given to the subject or the LAR (38 CFR 16.117(b)(2)).
   5. The original signed short form and summary must be filed in the investigator’s research file for that subject.
6. Where applicable (see VHA Handbook 1907.01), a copy of the signed short form must be placed in the medical record in accordance with VHA Handbook 1907.01.

7. The investigator must file all original signed and dated short forms in the investigator's research file for that subject, so that they are readily accessible for auditing.

1.3.2. Requirements to Delegate Obtaining informed Consent

If the investigator does not personally obtain informed consent, the investigator must delegate this responsibility in writing (e.g., by use of a delegation letter) to research staff sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective subjects and questions about the ethical basis of the informed consent process and the study (see subparagraph 5g.(10) VHA Directive 1200.05).

1.3.3. Non-Veteran Enrollment

Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment, but only when there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45, 17.92). The investigator must justify including non-Veterans, and the OKCVAHCS R&DC must review the justification and provide specific approval for recruitment of non-veterans. They may be recruited for studies that will generally benefit Veterans and their well-being but would not include veterans as subjects. Examples include surveys of VA providers, studies involving veterans’ family members, and studies including active duty military personnel.

Non-veterans may not be entered into VA studies simply because a non-veteran population is easily accessible to the investigator. Investigators must follow VHA Handbook 1605.04, Notice of Privacy Practices, to provide notice of privacy practices and acknowledgement for any non-Veteran enrolled in the approved protocol. All VA regulations and policies related to veterans as research subjects apply to non-Veterans entered into VA research.

Although active duty military personnel are not considered veterans, they should be included in VA studies whenever appropriate. In addition to the non-Veterans referenced above, active duty military personnel may be entered into VA research conducted jointly by VA and DoD or within DoD facilities.

Outpatient Care for Research Purposes. Any person who is a bona fide volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.92).

Hospital Care for Research Purposes. Any person who is a bona fide volunteer may be admitted to a VA hospital when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45).

1.3.4 VA Research Involving Adults Who Lack the Ability to Consent/Surrogate Consent

A. Under appropriate conditions, the VA does allow investigators to obtain consent from the LAR of a subject (i.e., surrogate consent).

An investigator must seek such informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and
consider whether or not to participate and that minimize the possibility of coercion or undue influence.

If an Investigator is likely to approach adults who lack decision-making capacity, the IRB will evaluate the following:

- the proposed plan for the assessment of the capacity to consent is adequate,
- whether assent of the participant is a requirement and if so, whether the plan for assent is adequate, and
- whether a re-consenting process is necessary for participants with fluctuating decision-making capacity or for those with decreasing capacity to give consent.

**B. Investigators’ Responsibilities for Surrogate Consent-Investigators**

Investigators must:

1) Provide the IRB with a description of the procedures to ensure that subjects’ LARs are well informed regarding their roles and obligations to protect persons who lack decision-making capacity and provide an explanation of the appropriate procedures for respecting their dissent.

2) Provide information and disclosures (i.e., informed consent process and HIPAA authorization) to the subjects’ LARs that would ordinarily be required by VHA Handbook 1200.05 to be made to the subjects themselves if they had decision-making capacity. The LAR shall be advised that the LAR’s obligation is to try to determine what the participant would do if able to make an informed decision. If the prospective participant’s wishes cannot be determined, the LAR shall be advised that the LAR is responsible for determining what is in the participant’s best interest.

3) If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives (i.e., if they dissent). Under no circumstances may a subject be forced or coerced to participate in a research study, even if the LAR has provided consent.

**C. Capacity to Consent**

1) For VA research, an individual is presumed to have decision-making capacity unless the prospective participant is incompetent or has impaired decision-making capacity, as determined and documented by one or both of the following:

   a. A qualified practitioner documents in the individual’s medical record in a signed and dated progress note that the individual lacks capacity to make the decision to participate in the proposed study. **NOTE: The qualified practitioner may be a member of the research team.** Or

   b. The individual has been ruled incompetent by a court of law.

**D. Who Can be an LAR**

1) For VA research, the LAR is defined as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, LAR means an individual recognized by
VA policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research. The LAR may be the following persons in the following order of priority:

a Health care agent (i.e., an individual named by the potential participant in a Durable Power of Attorney for Health Care, Advanced Directive, or another appropriate legal document. (38 CFR17.32(a)(iii));

b Legal guardian or special guardian;

c Next of kin.

NOTE: The VA order of priority for next-of-kin differs from the order of priority under Oklahoma law. Check with VA Regional Counsel for state or local requirements for surrogate consent for research that may supersede VA requirements.

2) An individual who is qualified as an LAR to provide informed consent on behalf of a prospective research subject may not always qualify as a personal representative for purposes of consent to use or disclose a human subject’s PHI (i.e., signing a HIPAA authorization). Therefore, in circumstances involving authorization for use or disclosure of a human subject’s PHI, the investigator must ensure the LAR meets the requirements of a personal representative (legal guardian or power of attorney) in HIPAA and the Privacy Act of 1974 prior to the LAR’s signing a HIPAA authorization (A personal representative is a person who, under applicable law, has authority to act on behalf of another individual. This may include an advanced directive, power of attorney, durable power of attorney, legal guardianship of an individual, the executor of an estate of a deceased individual, or someone under Federal, state, local, or tribal law with such authority (e.g., the parent of a minor) (See VHA Handbook 1605.1).

E. When Capacity is Questionable

1) If there is any question as to whether or not a potential adult subject has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision making capacity, and the individual has not been ruled incompetent by a court of law, the investigator must consult with a qualified practitioner (who may be a member of the research team) about the individual’s decision-making capacity before proceeding with the informed consent process.

2) The IRB requires that the determination that a participant is incompetent or has an impaired decision-making capacity to be made by a legal determination or by a practitioner, after appropriate medical evaluation, that the prospective participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.

3) Individuals who, because of a known condition, are at high risk for temporary (e.g., head trauma) or fluctuating (e.g., schizophrenia) lack of decision-making capacity must be evaluated by a qualified practitioner (who may be a member of the research team) to determine the individual’s ability to provide informed consent. This evaluation must be performed as described in the IRB-approved research project. If the individual is deemed to lack decision-making capacity at the time of participation in the research project, a LAR must provide informed consent. If the research participant regains decision-making capacity, the
investigator or investigator’s designee must repeat the informed consent process with the research participant and obtain consent to continue with the research project.

4) The IRB requires that, when feasible, the practitioner explain the proposed research to the prospective participant, even when the surrogate gave consent.

F. Criteria to Enroll Subjects Who Lack Capacity to Consent

1) No individual who lacks decision-making capacity may participate in VA research until the IRB has reviewed and approved that individual’s, or that class of individuals’, participation in a given research project. Individuals who lack decision-making capacity may be enrolled in a VA research project if:

a. The proposed research entails:
   i. No greater than minimal risk to the participant as determined by the IRB; or
   ii. If the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant; or
   iii. Greater than minimal risk and no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participant’s disorder or condition that is of vital importance for the understanding or amelioration of the participant’s disorder or condition.

b. The disorder (e.g., Alzheimer’s) leading to the individual’s lack of decision-making capacity is being studied whether or not the lack of decision-making capacity itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a research project studying cardiovascular effects of a stroke), but only if the research project cannot be performed with only persons who have decision-making capability.

c. The subject of the research project is not directly related to the individual’s lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the research project (e.g., transmission of methicillin-resistant Staphylococcus aureus [(MRSA)] infections in a nursing home where both individuals with, and those without, decision-making capacity are affected).

d. If the enrollment criteria mentioned above are met, the IRB may approve the inclusion of individuals who lack decision-making capacity in VA research studies on the basis of informed consent from LARs. Before approving the research project, the IRB must:
   i. Ensure the research project includes appropriate procedures for respecting dissent;
   ii. Consider whether or not the research project needs to include procedures for obtaining assent; and
   iii. Determine whether any additional safeguards need to be used (e.g., consent monitoring).
2) The IRB must document in the IRB minutes its deliberations and the enrollment
criteria used to approve inclusion of individuals who lack decision-making
capacity.

1.4. Reporting Requirements

1.4.1 Unanticipated problems involving risks to participants or others or unanticipated
serious adverse events

The OUHSC follows VHA Handbook 1058.01 for identification, assessment, and reporting
of unanticipated problems or unanticipated serious adverse events.

A. Reporting Local Unanticipated Problems:

Within five business days of becoming aware of any local (i.e., occurring in the
reporting individual’s own facility) unanticipated problems involving risks to
participants or others or any unanticipated serious adverse events in VA research,
members of the VA research community are required to ensure the problem or event
has been reported in writing to the IRB.

1. This requirement is in addition to other applicable reporting requirements (e.g.
reporting to the sponsor under FDA requirements).

2. The unfounded classification of a serious adverse event as “anticipated”
constitutes serious non-compliance.

3. Examples of serious unanticipated problems involving risks to participants or
others include:

- Interruptions of participant enrollments or other research activities due to
  concerns about the safety, rights, or welfare of human research
  participants, research staff, or others.

- Any work-related injury to personnel involved in human research, or any
  research related injury to any other person, that requires more than minor
  medical intervention (i.e., basic first aid), requires extended surveillance of
  the affected individuals, or leads to serious complications or death.

- Any VA National Pharmacy Benefits Management (PBM) Bulletins or
  Communications (sometimes referred to as PBM Safety Alerts) relevant to
  one or more of the VA facility’s research projects.

- Any data monitoring committee, data and safety monitoring board, or data
  and safety monitoring committee report describing a safety problem.

- Any sponsor analysis describing a safety problem for which action at the
  VA facility might be warranted.

- Any unanticipated problem involving substantive harm, or a genuine risk of
  substantive harm, to the safety, rights, or welfare of human research
  participants, research staff, or others.

- Any problem reflecting a deficiency that substantively compromises the
  effectiveness of the VA facility’s HRPP.

B. Reporting Serious Unanticipated Problems:

Within five business days after a report of a serious unanticipated problem involving
risks to participants or others, or of a local unanticipated serious adverse event, the
convened IRB or IRB Chair/IRB designee shall determine and document whether the
reported incident was serious and unanticipated and related to the research.

1. If the problem or event is determined to be serious, unanticipated, and related to
the research, the IRB chair or IRB designee shall notify the VA Regional Office
of Research Oversight (ORO) via telephone or e-mail within 48 hours of the IRB
determination and report the unanticipated problem or event within five business
days after the determination to:
   • VA Medical Center Director
   • Associate Chief of Staff for Research (ACOS/R)
   • Research and Development Committee (R&DC)
   • The Office of Research and Development (ORD), if VA-funded
   • ORO RO
   • The VA Privacy Office, when the event involves unauthorized use, loss, or
disclosure of individually identifiable patient information. (UP)
   • The VHA Information Security Officer when the event involves violations of
   VA information security requirements. (UP)

2. If the IRB or IRB Chair/IRB designee determines that the problem or event was
serious, unanticipated, and related to the research, the IRB shall also determine
if additional action is required (e.g., suspension of activities, notification of
participants) necessary to prevent an immediate hazard to participants in
accordance with VA regulations.
   • “Related” for purposes of VA research means the event or problem may
reasonably be regarded as caused by, or probably caused by, the research.

3. Any determinations of the IRB Chair/IRB designee shall be reported at the next
convened IRB meeting. If the IRB determined that the problem or event is
serious, unanticipated, and related to the research, the convened IRB must
determine and document:
   a) Whether a protocol or consent document modification is warranted.
   b) Whether previously enrolled participants must be notified of the
   modification.
   c) When such notification must take place and how such notification must be
documented.

1.4.2 Serious or Continuing Non-compliance:

The OUHSC IRB follows VHA Handbook 1058.01 and Directive 1200.05 for identification,
assessment and reporting of serious or continuing non-compliance.

A. Within five business days of becoming aware of any apparent or possible serious or
continuing non-compliance or with any other possible serious or continuing
noncompliance with VA or other federal requirements related to human research or
with IRB requirements or determinations, the investigator and research staff are
required to ensure that the non-compliance has been reported to the IRB in the IRB
electronic submission system, as well as to the ACOS/R&DC. The IRB shall review the
report of non-compliance at its next convened meeting.
B. Should the IRB determine that the reported incident constitutes serious non-compliance or continuing non-compliance, within five business days after the determination by the IRB, the HRPP Director shall notify the Oklahoma City VA Medical Center Director directly and copy the ACOS/R&DC, the RCO, and the R&DC, and to the VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information and to the VHA Information Security Officer when the report involves violations of VA information security requirements).

1. The IRB must reach a determination that serious or continuing non-compliance did (or did not) occur within 30-45 days after receiving a report of apparent non-compliance.

2. Remedial actions involving a specific study or research team must be completed within 90-120 days after the IRB’s determination.

3. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the IRB’s determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

1.4.3 Other Reportable Events
For VA research projects involving other reportable events, the HRPP Director shall notify the Oklahoma City VA Medical Center Director and copy the ACOS/R&DC, the RCO, and the R&DC within five business days after the determination of the following:

A. When the IRB determines an event is an unanticipated problem involving risks to participants or others (UP);

B. When IRB accreditation problems, to include failure to obtain accreditation or any change in the IRB’s accreditation status, occur; or

C. When suspension of IRB approval, termination of IRB approval, or interruptions of subject enrollments or other research activities due to concerns about the safety, rights, or welfare of human research participants, research staff, or others occurs. This does not include a lapse of IRB approval from continual review.

1.4.4 Reporting HIPAA/Privacy Events
The VA research community shall notify the VA Information Security Officer (ISO), VA Privacy Officer (PO), ACOS/R&DC, and RCO immediately upon becoming aware of any:

A. Unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information, or confidential information, as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C. §§5701, 5705, and 7332;

B. Suspension or termination of VA research related to concerns about research information protection;

C. Findings of noncompliance related to research information security or privacy regarding VA Research;

D. Other deficiency(ies) that substantively compromise the effectiveness of the VA facility’s research information protection program.

1.4.5 Research Misconduct
Any allegation of research misconduct involving VA research or VA researchers shall be reported to the ORO via telephone or email promptly.
1.4.6 Expired Research
For VA research that expires because continuing review is not completed, all research activities must stop. The PI must then immediately submit to the IRB Chair a list of research participants who could be harmed by stopping study procedures. The IRB chair shall determine within two business days whether participants on the list may be continued in the research interventions.

1.4.7 Suspensions and Terminations of IRB Approval
A. Reporting Suspensions and Terminations
1. Any termination or suspension of research (e.g., by the IRB or other research review committee, or by the associate chief of staff or research or other VA facility official) related to concerns about the safety, rights, or welfare of human research participants, Research Staff, or others must be reported in writing within five business days after the termination or suspension occurs to:
   a. Medical center director at the involved VA facility.
   b. Associate chief of staff for research (ACOS/R) at the involved VA facility.
   c. R&DC at the involved VA facility.
   d. IRB.
   e. Other relevant research review committee(s) at the involved VA facility.
2. IRB approval of suspensions and terminations shall be promptly reported by the HRPP Director or HRPP designee to:
   a. The VA Office of Research and Development, if VA-funded.
   b. The VA Regional ORO.
   c. The VA PO, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information.
   d. The VA ISO when the report involves violations of information security requirements.

1.4.8 The VA medical center director must report all unanticipated problems, serious or continuing non-compliance or termination or suspension of IRB approval to the appropriate ORO research officer within five business days after receiving such notification.

1.5 Additional VA Requirements

1.5.1 Updating VHA Health Records
VA Researchers are required to follow VHA Directives and Handbooks with regard to creating and updating VHA health records for research participants.

1.5.2 Trainees
A. Students and other trainees (residents, fellows, post-docs, etc.), including VA employees, from schools with an academic affiliation agreement consistent with current VHA policy, may serve as Investigator, but not as a PI, within a VA facility. Trainees as defined above may conduct research at a VA facility and serve as a sub-investigator. They may also use VA data, or use human biological specimens that have been collected within the VA for clinical, administrative, or research purposes. Trainees who do not fulfill the requirements specified above cannot participate in VA
research unless the VA medical facility Designated Education Officer seeks a waiver from the Chief Academic Affiliations Officer or designee and the CRADO.

Trainees are defined as a subset of employees who are:

1. Appointed under trainee authority (38 U.S.C. 7405 or 7406), and
2. Enrolled in one of two types of training programs:
   (a) Enrolled in an accredited training program sponsored by an affiliated educational institution under a current and existing academic affiliation agreement (e.g. VA Form 10-0094A-J), or
   (b) Enrolled in a VA sponsored training program (either accredited or non-accredited). Examples of these VA sponsored training programs include Office of Academic Affiliation (OAA)-funded advanced fellowship programs, OAA-funded Chief Residents in Quality and Safety, or OAA-funded and VA-sponsored accredited training programs.

B. Trainees must have a VA Investigator sufficiently experienced in the area of the trainee’s research interest to serve as the PI. The PI is responsible for ensuring that the trainee:

1. Complies with all applicable local VA medical facility, VA, and other Federal requirements including those related to human subjects or animal safety, use of radioactive substances, information security, privacy, and other research processes;
2. Completes or terminates the study in an orderly fashion prior to leaving VA in accordance with all applicable local, VA, and other Federal requirements;
3. Provides the VA Research Office with an inventory of all research records to be retained at VA in accordance with the Record Control Schedule 10-1.

1.5.3 Records Retention

Research records must be retained for a minimum of six years.

Codes, or keys linking participant data to identifiers must be retained as part of the research record for at least six years.

If a protocol is inactivated without participant enrollment, IRB records must be retained for at least five years.

2. SCOPE

This SOP applies to all research involving human participants conducted at the VAMCs located in Oklahoma City and Muskogee, unless the research is reviewed and approved by the VA-CIRB.

3. RESPONSIBILITY

3.1 The OUHSC IRB is Responsible For:

3.1.1 Protecting the rights and welfare of human participants who participate in VA-regulated research.

3.1.2 Including two or more VA employees as voting members of the IRB on each IRB that reviews VA research. The OKCVAHCS will provide two or more VA employees to serve as voting members of the IRBs that review its research, and the EOVAHCS will provide two or more VA employees as voting members of the IRBs that review its research. One
of these members from each VAMC for each IRB must have scientific expertise, and at least one member must be present at a convened IRB meeting during the review of their respective facility’s research. Attendance via video or telephone conferencing or similar is permissible.

3.1.3 Reporting to the VA with regard to VA Research:

A. The OUHSC IRB conducts initial and continuing review of research and reports its findings and actions to the investigator, ACOS/R&D, and the R&DC. After the IRB has approved a study, the study must not be initiated until the investigator has been notified in writing by the ACOS/R&DC that all applicable approvals have been obtained and the study may be initiated;

B. The IRB must notify in writing the investigator and the OKCVAHCS and EOVAHCS VA Research Service, as appropriate, of the IRB’s decision to approve, disapprove, or require modifications to approve any submissions;

C. The IRB must notify in writing the investigator, the R&DC, and the OKCVAHCS and EOVAHCS VA Research Service, as appropriate, of the IRB’s decision to approve any VA research including pregnant women, human fetuses, noninvasive monitoring of neonates, children, prisoners, or international research. This VA research requires VA medical facility Director certification. For VA research involving prisoners, a waiver from the Chief Research and Development Officer (CRADO), Office of Research and Development (ORD). VA facility director must approve any request for permission to conduct prisoner research prior to forwarding it to the chief research and development officer;

D. If IRB approval expires and the investigator submits a list of research subjects who could be harmed by stopping research project procedures, the IRB Chair or IRB designee determines if subjects on the list may continue participating in the research interventions or interactions;

E. The IRB Chair or IRB designee must notify the facility director within 5 business days after the determination to suspend or terminate any VA research project activities due to concerns related to safety, rights, or welfare of subjects or others. The report must be made in writing, with a simultaneous copy sent to the ACOS/R and the RCO;

F. The IRB Chair or designee must notify the ORO via telephone or e-mail within 2 business days and in writing, with a simultaneous copy sent to the facility Director, ACOS/R, and the RCO, of any determination of a local unanticipated and related death;

G. The IRB Chair or designee must notify the facility director within 5 business days from the IRB’s determination and in writing, with a simultaneous copy to the ACOS/R and the RCO, of any determination of an unanticipated problem involving risks to subjects or others or Serious and/or Continual Noncompliance;

H. The IRB Chair or designee must notify the facility director within 5 University business days and in writing, with a simultaneous copy sent to the ACOS/R and the RCO, following any determination of serious or continuing noncompliance;

3.1.4 Determining that the investigator and key personnel have met all HSC IRB educational requirements.

3.1.5 Reporting to the appropriate VHA facility Information Security Officer and VA Privacy Official immediately (i.e., within one hour) upon becoming aware of any unauthorized use, loss, or disclosure of individually identifiable participant information or protected
health information. Information security incidents related to VA research, including any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI. The report must be made in writing, with a simultaneous copy sent to the ACOS/R and the RCO.

3.1.6 Preparing a confidentiality agreement for the VAMC R&D members to sign prior to providing copies of the HSC IRB meeting minutes to the VAMC R&D.

3.1.7 Providing copies of the HSC IRB meeting minutes to the VAMC R&DC for review upon approval by the IRB.

3.2 VAMC R&DC is Responsible For:

3.2.1 Assisting the VA Medical Center director in fulfilling responsibilities for the facility’s research program.

3.2.2 Ensuring the effective operation of the research program through oversight of the R&DC’s subcommittees and making appropriate recommendations, including space and resource needs, to the VA Medical Center director based on the R&DC’s oversight and evaluation of the research program.

3.2.3 Identifying and recommending qualified VA employees to serve on the HSC IRB.

3.2.4 Providing the VAMC Research Compliance Officer (RCO) to serve as a non-voting consultant to the HSC IRB, as needed. The RCO may not serve as a voting or nonvoting member of the IRB. The RCO may attend meetings of the IRB when requested by the IRB.

3.2.5 Approving HSC IRB minutes for VA-regulated research projects.

3.2.6 Establishing policy to ensure that all research in which the VAMC is to be engaged has been reviewed and approved for the ethical use of human participants; protection of human participants (including privacy and confidentiality); and the implementation of adequate safety measures for research participants and personnel and security of VA data and VA sensitive information, as well as acting on any findings of non-compliance.

3.2.7 Providing a final VA Approval Memorandum from the ACOS/R and Chair R&DC to investigators after formal approval from the VAMC R&DC is secured.

3.2.8 Providing a copy of the VA R&DC Approval Memorandum to the HSC IRB.

3.2.9 Monitoring VA-regulated research activities.

3.2.10 Reviewing conflicts of interests for VA Research.

3.2.11 Serving as the Privacy Officer, as required, for HIPAA and GDPR compliance.

3.3 Investigators Proposing to Conduct VA-Regulated Research are Responsible For:

3.3.1 Prospectively submitting research projects, including exempt determinations for review, to the VAMC R&DC prior to submission to the HSC IRB.

3.3.2 Submitting research projects to the HSC IRB once VAMC R&DC has been submitted.

3.3.3 Not initiating VA research until after the IRB has approved the research project and the investigator has been notified in writing by the ACOS/R&D that all applicable approvals have been obtained.

3.3.4 Disclosing all conflict of interest to the HSC IRB and VA R&DC.
3.3.5 Ensuring the research has adequate resources.

3.3.6 Ensuring all research project personnel are qualified to perform their research project duties and have been approved by the HSC IRB and VA R&DC.

3.3.7 Promptly reporting all changes to the approved research to the HSC IRB before implementing those changes and notifying the R&DC of the IRB’s approval.

3.3.8 Overseeing the research and all research project staff. The PI is the investigator solely responsible for the conduct of the research.

3.3.9 Implementing the research as it is approved and maintaining adequate and accurate research records, to include the original informed consent documents and HIPAA Authorization. The PI will make available these records for audit as requested by the RCO, IRB, R&DC, research project sponsor, and any other entity charged with oversight of the research.

3.3.10 Using the appropriate VA form 10-1086 consent document and local VA HIPAA Authorization for Research to consent VA Research participants.

3.3.11 Ensuring appropriate telephone contact with participants. Research team members are prohibited from requesting Social Security numbers by telephone. No “cold calling” is allowed. During the recruitment process, the PI is responsible for ensuring the research team makes initial contact with the potential participant in person or by letter prior to initiating any telephone contact, unless there is written documentation that the participant is willing to be contacted by telephone about the research project in question or a specific kind of research (e.g., if the potential participant has diabetes, the participant may indicate a desire to be notified of any diabetes-related research studies). The initial contact must provide a telephone number or other means that the potential participant can use to verify the research project constitutes VA research.

3.3.12 Reporting modifications, continuing reviews, problems, deviations/violations, AEs/SAEs, unanticipated problems or others, and any other issue related to VA research in accordance with local SOPs and VHA regulations.

3.3.13 Completing training and education in the ethical principles on which human research is to be conducted before participating in human participants research as outlined in SOP 102B: Key Study Personnel Education.

4. APPLICABLE REGULATIONS AND GUIDELINES

38 CFR 16, 17
Department of Veterans Affairs, VHA Directive 1058.01, ORO Oversight
Department of Veterans Affairs, VHA Directive 1200.01, R&D Committee
Department of Veterans Affairs, VHA Directive 1200.02(1), Research Business Operations
Department of Veterans Affairs, VHA Directive 1200.05, Req for the Protection of Human Subjects in Research
Department of Veterans Affairs, VHA Handbook 1200.12
Department of Veterans Affairs, Office of R&D Program Guide 1200.21
Department of Veterans Affairs, VHA Handbook 1907.01
Department of Veterans Affairs, VHA Handbook 1605.01
5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 301: Research Submission Requirements
   SOP 302: Administrative Review and Distribution of Materials
   SOP 401: Research Exempt from Federal Regulations
   SOP 402: Expedited Review
   SOP 403: Initial Review – Criteria for IRB Approval
   SOP 404: Continuing Review
   SOP 405: Modifications

6. ATTACHMENTS
   603A-A VA R&D Approval Memorandum
   603A-B VA Form 10-1086 Consent Form Template
   603A-C VA Form 10-9012 Investigational Drug Information Record
   603A-D VA Memorandum of Understanding-OKCVAHCS
   603A-E VA Memorandum of Understanding-EOVAHCS
   305-C New Study Approval Checklist

7. PROCESS OVERVIEW
   7.1 The VA investigator prospectively submits a research project to the VAMC R&DC when the
       investigator utilizes VA resources and/or recruits VA patients as participants in the project. This
       may be done concurrently with submission to the HSC IRB.
   7.2 The IRB processes documents submitted to the IRB per SOP 301: Research Submission
       Requirements; and SOP 302: Administrative Review and Distribution of Materials.
   7.3 If review of the research per SOP 401: Research Exempt from Federal Regulations; and SOP
       402: Expedited Review; indicates the research project qualifies for convened IRB review, the
       IRB Administrator processes the research project per SOP 403: Initial Review – Criteria for IRB
       Approval, and forwards the agenda to the VAMC RCO.
   7.5 The VAMC RCO audits VAMC-regulated research projects to ensure VA regulations have been
       followed and ensures that the VAMC research projects have been submitted to the VAMC
       R&DC for review. The RCO may attend IRB meetings in a consultant capacity upon IRB request
       to suggest changes to VAMC research projects in order to assist the IRB in complying with VHA
       regulation.
   7.6 Final IRB approval is issued when all requested changes have been made and verified by the
       IRB Administrator and the IRB Chair or IRB designee.
   7.7 IRB meeting minutes are forwarded to the Research Administration Officer and R&DC Manager
       for presentation to the VA R&DC no more than three weeks after each IRB meeting.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 603B: Office for Human Research Protection (OHRP)

1. POLICY

The Common Rule for the protection of human participants at Section 103(a) of 45 CFR 46 Subpart A requires that each institution "engaged" in federally-supported human participant research file a Federal-wide Assurance (FWA) of protection for human participants. The Assurance formalizes the institution’s commitment to protect human research participants. The IRB operates under DHHS regulations 45 CFR 46, OHRP guidance documents, and the Belmont Report.

For research projects funded by the Department of Defense (DoD) or that include research participants who are members of the U.S. military, a DoD Addendum to the FWA may be required, and if so, is signed by the Institutional Official.

Institutions engaged in human participant research that is conducted or supported by DHHS must provide written Assurances of Compliance to DHHS describing the means they employ to comply with the applicable DHHS Regulations. OHRP negotiates and approves the Assurances on behalf of the Secretary of DHHS. An Assurance approved by OHRP commits the institution and its personnel to full compliance with the applicable regulations. The University shall maintain Assurances with OHRP and uphold its Assurances as filed.

Specific Policies

1.1 Assurances

The University shall maintain Assurances for both the Health Sciences Center (HSC) IRB and the Norman Campus (NC) IRB and uphold its Assurances as filed with OHRP. A copy of the Assurance for each campus shall be maintained in the offices of the HRPP Directors and on the HRPP website.

In order to maintain an active Assurance approved by OHRP, all information provided under the Assurance shall be updated at least every 36 months, even if no changes have occurred. The HRPP Director for each campus shall report promptly to OHRP all amendments to the Assurance. Amendments to the Assurance include changes to the IRB membership rosters, the addition or deletion of an IRB Chair, and a change in the signatory official.

The University is the IRB of record for a number of affiliate institutions through a-- written agreements signed by the Institutional Official. The HRPP Director of the respective campus for these affiliate institutions maintains the written agreements.

1.2 DHHS Regulations

The University shall uphold the ethical principles of the Belmont Report and apply DHHS regulations (45 CRF 46, including Subparts A, B, C, & D) to all research involving human participants regardless of the source of funding.

1.3 Noncompliance and Participant Safety

The HRPP Director for each campus shall act as the liaison between OHRP and the University and shall report incidences of serious or continuing noncompliance, unanticipated problems involving risk to participants or others, and/or suspension or termination of research. Refer to SOP 407: Protocol Deviations and Unanticipated Problems; SOP 903: Non-Compliance/Scholarly Misconduct; or SOP 411: Suspension or Termination of IRB Approval; respectively, regarding the reporting of these occurrences.
1.4 OHRP Compliance Oversight Evaluations
The University and the HRPP office shall cooperate fully in the event of a compliance oversight evaluation. Refer to SOP 902: Audits by Regulatory Agencies.

1.5 Guidance from OHRP
The HRPP shall communicate with OHRP for guidance as needed in all matters of human research.

2. SCOPE
This policy applies to interactions between OHRP and the Office of HRPP.

3. RESPONSIBILITY
3.1 The HRPP Director for each campus is responsible to report to OHRP incidences of serious or continuing noncompliance, unanticipated problems involving risk to participants or others, and/or suspension or termination of research.

3.2 The HRPP Director for each campus is responsible for maintaining the FWA with DHHS and for updating it at least every 36 months. When maintaining and updating the FWA, the HRPP Director is also responsible for registering IRBs, as required by regulatory agencies.

3.3 The HRPP Director is responsible for providing guidance to HRPP and IRB staff, IRB members, and investigators regarding applicable DHHS regulations.

3.4 The HRPP Education Coordinator includes information regarding DHHS regulations and research in the education program.

4. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46
21 CFR 50 and 56
OHRP Compliance Oversight Procedures for Evaluating Institutions, 10/14/09

5. REFERENCES TO OTHER APPLICABLE SOPS
SOP 407: Protocol Deviations and Unanticipated Problems
SOP 411: Suspension or Termination of IRB Approval
SOP 603F: Department of Defense
SOP 902: Audits by Regulatory Agencies
SOP 903: Non-Compliance/Scholarly Misconduct

6. ATTACHMENTS
603B-A Federal-wide Assurance-HSC Campus
603B-C Federal-wide Assurance–Norman Campus

7. PROCESS OVERVIEW
7.1 The HRPP Directors maintain their respective campus’ assurance with OHRP and negotiate authorization agreements with approved affiliate institutions. The HRPP Directors seek review of such agreements by the Office of the Legal Counsel. The assurance and authorization
agreements are signed by the Institutional Official for the respective campus and filed with the respective HRPP Director.

7.2 The HRPP Directors review and update the Assurance for their campus periodically as needed, or at least every 36 months. All information provided under the FWA must be renewed or updated at least every 36 months, even if no changes have occurred, in order to maintain an active FWA.

The University shall complete a DoD addendum to its FWA when human research is conducted or funded by the DoD. See SOP 603F: Department of Defense.

7.3 The HRPP Directors discuss and review incidences of unanticipated problems involving risks to participants or others, serious or continuing noncompliance, and suspension or terminations with the Director of Compliance for NC incidences and to the HSC Vice President for Research for HSC incidences, per SOP 407: Protocol Deviations and Unanticipated Problems; SOP 903: Non-Compliance/Scholarly Misconduct; or SOP 411: Suspension or Termination of IRB Approval.

7.4 The HRPP Directors communicate with OHRP to evaluate research proposals when appropriate and to seek guidance as needed. The HRPP Directors may seek guidance from the University’s Office of Legal Counsel and/or the Director of Compliance or the HSC VPR for HSC, as needed. The HRPP Directors and/or the Director of Compliance or the HSC VPR shall consult with the Office of Legal Counsel prior to communicating compliance issues with OHRP.

7.5 When OHRP initiates a compliance oversight evaluation, SOP 902: Audits by Regulatory Agencies, is followed.

7.6 All correspondence to and from OHRP is filed with the respective campus’ HRPP Director.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 603C: Food and Drug Administration (FDA)

1. POLICY

The Institutional Review Board shall operate pursuant to the regulations of the United States Food and Drug Administration (FDA) in the review of human research involving investigational drugs, biologics, or devices.

The purpose of IRB review is to assure, both in initial and by continuing review that appropriate steps are taken to protect the rights and welfare of humans participating in the research. In accordance with FDA regulations, the IRB has the authority to approve, require modifications of (to secure approval), or disapprove research.

The definition of research encompasses activities that are “clinical investigations” and involve “human subjects” as those terms are defined by FDA regulations.

“Research” is any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms “research,” “clinical research,” “clinical study,” “study,” and “clinical investigation” are synonymous for purposes of FDA regulations.

“Human subject” means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

The HSC IRB shall review all FDA-related research for all University campuses. SOP 403: Initial Review provides additional guidance.

Specific Policies

1.1 FDA Regulations

The HSC IRB shall operate pursuant to the FDA regulations 21 CFR Part 50, 54, 56, 312, 600, 601, and 812.

1.1.1 Noncompliance and Participant Safety

The Human Research Participant Protection (HRPP) Director or designee shall act as the liaison between the FDA and the University. The HRPP Director or designee shall report incidences of serious or continuing non-compliance or unanticipated problems involving risk to participants or others to the FDA per SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

1.1.2 Guidance from the FDA

A representative of the HRPP Office may communicate with the FDA to evaluate research projects when appropriate or to seek guidance as needed.
1.1.3 **FDA Audits**

The FDA has the authority to audit the IRB records and/or investigators on a routine basis or for cause. FDA field investigators may interview University officials and examine the IRB records to determine compliance with FDA regulations.

When the FDA notifies the University of an IRB site visit, the HRPP Director or designee shall notify the Director of Compliance, the Institutional Official, and the Office of Legal Counsel.

2. **SCOPE**

This SOP applies to interactions between the FDA and the HRPP Office.

3. **RESPONSIBILITY**

3.1 The HRPP Director or designee is responsible to provide guidance regarding FDA regulations to IRB staff, IRB members, and investigators.

3.2 The IRB staff is responsible to immediately notify the HRPP Director or designee when contacted by the FDA for an audit or site visit. The HRPP Director or designee is responsible to immediately notify the Director of Compliance, the Institutional Official and Legal Counsel.

3.3 The HRPP Education Coordinator includes information regarding the FDA regulations and research in the HSC IRB education program. Investigators are responsible for making themselves familiar with these regulations.

3.4 The investigator is responsible to copy the IRB on all correspondence to and from the FDA.

4. **APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 50 and 56.

21 CFR 312, 600, 601 and 812.


5. **REFERENCES TO OTHER APPLICABLE SOPS**

SOP 308: Reporting to Regulatory Agencies and Institutional Officials

SOP 403: Initial Review

6. **ATTACHMENTS**

603-C-A Government Agents and Compliance Policy – June 24, 2019, Memorandum from Anil Gollahalli, University Vice President and General Counsel

7. **PROCESS OVERVIEW**

7.1 The HSC IRB reviews all FDA-regulated research in accordance with the applicable FDA regulations.

7.2 The HRPP Director or designee acts as the liaison between the FDA and the University.

7.3 The HRPP Director or designee may communicate with the FDA to evaluate research projects when appropriate or to seek guidance as needed. The HRPP Director shall consult the Director of Compliance prior to communicating compliance issues with the FDA and include the Director of Compliance in telephone calls with the FDA as appropriate.
7.4 The HRPP Director or designee is the point of contact for an FDA Audit. The HRPP Director notifies the Director of Compliance of the FDA audit and directs IRB staff as indicated.

7.5 The HRPP Directors or designee retain written form FDA-483, if such a form is drafted. The HRPP Director or designee informs the Director of Compliance of the FDA preliminary findings of audit.

7.6 The HRPP Directors maintain FDA documents on file at the IRB Office in accordance with the State Universities and Colleges General Records Disposition Schedule.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 603D: COMMUNICATION WITH RESEARCH PARTICIPANTS

1. POLICY

Communications received from prospective or current research participants shall be promptly directed to the HRPP Director for prompt response. The HRPP Director shall provide a safe, confidential, and reliable means for participants, whether past, present, or prospective, to voice concerns or questions regarding their participation in a research project or to request information regarding a research project.

Participants who have questions, comments, or complaints related to their participation will be directed to the HRPP Director or to a designee who is unaffiliated with the research project.

When the investigator reports findings from a research project that indicate that participants may be at an increased risk that was not anticipated at the time of research project approval, the IRB shall request that the investigator provide written notification to current and past participants regarding the increased risk and verify their willingness to continue participation, if applicable.

Specific Policy

1.1 Prospective Participant Request for Information

All communications from prospective participants shall be directed to the HRPP Director or designee for review.

1.2 Current Research Participants

1.2.1 The HRPP and IRB Staff shall notify the HRPP Director or designee of participant correspondence pertaining to concerns or problems a participant encountered while participating in a research project promptly.

1.2.2 The HRPP Director or designee shall receive and maintain the information in a manner that is secure and confidential.

The HRPP Director or designee may direct the participant to other University officials who are unaffiliated with the research project so that the participant may discuss concerns specific to the officials’ duties.

1.2.3 The HRPP Director or designee shall report research participant allegations that suggest research noncompliance or scholarly misconduct to the Director of Compliance as described in SOP 903: Noncompliance/Scholarly Misconduct. In the absence of the HRPP Director or designee, the HRPP and IRB Staff shall promptly forward all such communication from participants to the Director of Compliance.

2. Scope

This SOP applies to all human participant research.

3. Responsibility

3.1 The HRPP and IRB Staff are responsible for promptly directing all research participant communication to the HRPP Director.

3.2 The HRPP Director or designee is responsible for documenting all participant complaints received.
3.3 The HRPP Director or designee is responsible for promptly addressing potential or current research participant communications, notifying the Director of Compliance, HSC Vice President for Research, FDA and OHRP as necessary.

3.4 The Norman Campus Senior Vice President and Provost or the HSC Vice President for Research is responsible for addressing noncompliance and/or scholarly misconduct allegations raised by research participants.

4. Applicable Regulations and Guidelines
   45 CFR 46.116
   21 CFR 50.25

5. References to Other Applicable SOPS
   SOP 407: Protocol Deviations and Unanticipated Problems
   SOP 903: Non-Compliance/Scholarly Misconduct

6. Attachments
   None

7. Process Overview
   7.1 If the HRPP or IRB staffs receive communication from a prospective, current or former research participant, they shall notify the HRPP Director or designee promptly. If an individual presents to the IRB office, the IRB will provide direct access to HRPP Director or designee.

   7.2 The IRB will maintain the confidentiality of any prospective or current participant communication(s).

   7.3 For participant correspondence that involves research projects that are covered under FDA regulations, the HRPP Director or designee notifies the Compliance Officer of the FDA and/or requests site evaluation as required in SOP 407: Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations; or SOP 903: Non-Compliance/Scholarly Misconduct, as applicable. The HRPP Director works with the Compliance Officer of the FDA, as required.

   7.4 The HRPP Director, in conjunction with the Director of Compliance as required, works to resolve participant issues.

   7.5 The HRPP Director documents communications with participants, directs the participants to appropriate University officials and federal agencies as indicated, and retains the documentation of all communications on file at the HRPP Office.

APPROVED BY:___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 603E: PARTICIPANT OUTREACH PROGRAM

1. POLICY

The University shall provide educational information to the community through an outreach program concerning human research in general and specifically the human research participant program of the University.

Specific Policy

1.1 The purpose of the Participant Outreach Program is to provide information to individuals in the community about research involving humans, what constitutes ethical research, and who to contact with questions about research. The University shall accomplish this purpose through:

A. Contact Telephone Number

The IRB shall require that all participants receive a contact telephone number in their informed consent documents as well as a statement about who to contact with questions concerning research participant rights.

B. Internet Web Site

The HRPP shall maintain an internet web site as a resource for prospective, current, or former research project participants. The web site shall provide a range of educational information from the history of research involving human participants to current research opportunities available. Links to other entities’ web pages may also be included in the website.

C. Educational Activities

HRPP shall make available educational activities for the community. Educational activities shall be announced to the community on the IRB website. The curriculum of the educational activities shall be developed to foster an understanding of research within the community.

1.2 The HRPP Director, the HRPP Education Coordinator, and the Quality Improvement Specialist shall periodically evaluate the Participant Outreach Program activities and implement improvements as necessary.

2. Scope

This SOP applies to all human research projects.

3. Responsibility

The HRPP Director is responsible for providing support and direction for the management of the IRB Outreach Website and for acting on comments of outreach participants, whether positive or negative. The HRPP Director will provide the outreach participants’ feedback to the Director of Compliance.

The Director of Compliance is responsible for addressing serious concerns of research misconduct raised by research participants participating in the Participant Outreach Program.

4. Applicable Regulations and Guidelines

45 CFR 46.116

45 CFR 56.108(b), 56.113
5. References to Other Applicable SOPS
   SOP 701: Consent Process and Documentation

6. Attachments
   None

7. Process Overview
   7.1 Information contained in the informed consent documents is reviewed per SOP 701: Consent
       Process and Documentation, to assure that contact numbers are available to participants in the
       case of injury or for questions regarding being a research participant.
   7.2 IRB website information is maintained by the HRPP Director or designee.
   7.3 Feedback from participants received by the HRPP or IRB staff is directed to the HRPP Director.
       The HRPP Director notifies the Director of Compliance as indicated.
   7.4 The HRPP Education Coordinator makes available educational activities for the community.
       Educational materials are provided free of charge.

APPROVED BY:__________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

Research supported by the Department of Defense (DoD) and involving a human as an experimental participant, as defined in SOP IV, Glossary, is subject to the Federal regulations for the protection of human participants in research, the Common Rule in Subpart A of 45 CFR 46 under 32 CFR 219. The University shall apply additional requirements outlined in DoD Directive 3216.02 when human research is conducted or supported by a DoD component (an organizational entity within the DoD).

The DoD applies the provisions in 45 CFR Part 46, Subparts B, C, and D, for research governing the protection of vulnerable classes of participants with the following specifications:

- For purposes of applying Subpart B, the phrase “biomedical knowledge” is replaced with “generalizable knowledge.”
- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.
- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

Non-exempt classified research must be conducted following the requirement of DoD Instruction 3216.02. 13. Note: Classified research involving human participants cannot be approved by the VA IRB or performed at a VA facility, including space leased to and used by the VA.

For DoD-supported non-exempt research involving human participants that also involves classified information reviewed by a non-DoD IRB, the involvement of classified information may be limited to:

- Information needed for IRB approval and oversight of the research;
- Information needed to inform the human participants during the consent process; and
- Information provided by human participants during the course of the research.

The University’s Federal-wide Assurance (FWA) with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP) meets the DoD requirement that the University maintain a federal assurance of compliance. The University shall complete a DoD addendum to its FWA when human participant research is conducted or funded by the DoD. The DoD addendum outlines the unique DoD component requirements that are not specifically included in the FWA.

The definition of the minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” must not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain). The involvement of DoD personnel in the conduct of the research must be secondary to that of the non-DoD institution.

The DoD component must conduct an appropriate administrative review of the research involving human subjects. The DoD component administrative review must be conducted before the research
involving human subjects can begin, to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of a foreign country when the research is conducted in a foreign country.

Civilian researchers attempting to access military volunteers should collaborate with a military researcher familiar with service-specific requirements.

Specific Policies

1.1 Multi-Site Research

When conducting multi-site research, a formal agreement between institutions is required and must specify the roles and responsibilities of each party in accordance with all legal requirements. This agreement must be approved by the DoD component prior to the University’s engagement in the research.

1.2 Survey Research

Survey research involving DoD personnel, including U.S. military personnel, typically requires DoD approval. The IRB must approve the research project prior to DoD approval. When a survey crosses DoD components, additional review is required by the applicable DoD components.

1.3 Department of Defense Addendum

The Senior Vice President and Provosts or designee for each campus have signatory authority for the DoD addendum to the University’s FWA when human participant research is conducted or funded by the DoD.

1.4 Education

For research sponsored by the DoD, initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participant research.

In accordance with SOP 102B: Key Study Personnel Education, all key study personnel (KSP) involved in research must complete initial and continuing IRB education requirements regarding human participant research protection issues.

There may be specific DoD educational requirements or certification required of KSP involved in DoD-sponsored research. These requirements will be dictated by the specific sponsoring DoD component involved. The DoD component may evaluate the HRPP education program to ensure KSP are qualified to perform the research, based on the complexity and risk of the research.

DoD education requirements pertain to IRB staff, IRB Chairs and Vice-Chairs, and IRB members. The IRB will identify the required education for the sponsoring DoD component involved and conduct education sessions appropriate for these individuals.

1.5 Records

DoD-sponsored research may require submitting records to the DoD for archiving. The investigator shall submit the relevant IRB records to the DoD component sponsoring or supporting the research. As appropriate, the HRPP Director or designee shall provide additional information pertinent to IRB review to the DoD.
1.6 Research Monitor

Appointment of an independent research monitor is required for research projects involving greater than minimal risk, although the IRB may also require appointment of a research monitor for a portion of the project or for studies involving no more than minimal risk. There may be more than one monitor required if additional skills or experience are needed.

- The independent research monitor shall be appointed by name by whom?. The research monitor may be the ombudsman or a member of a data and safety monitoring board.
- The duties of the research monitor are determined on the basis of specific risks or concerns about the research.
- The research monitor has the authority to stop a research project in progress, remove individuals from the research project, and take any steps to protect the safety and well being of participants until the IRB can make an assessment of the monitor's concerns.

1.7 Research Involving Prisoners

1.7.1 Research involving prisoners of war (POW) is prohibited for DoD-sponsored research. See SOP IV, Glossary, for the definition of POW.

1.7.2 Research involving prisoners cannot be reviewed by expedited review procedures.

1.7.3 In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
  - The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
  - The research presents no more than minimal risk.
  - The research presents no more than an inconvenience to the participant.

1.7.4 When a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component Office review the IRB's approval to change the research protocol.

Otherwise, the IRB chair must require that all research interactions and interventions with the prisoner-participant (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, must promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner participant’s confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner participant to continue to participate in the research. This approval is limited
to the individual prisoner-participant and does not allow recruitment of prisoners as participants.

1.7.5 Research involving a detainee as a human participant is prohibited. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to U.S. military personnel in the same location for the same condition.

1.8 Research Involving International Populations
For DoD-sponsored research involving international populations, the following additional safeguards are required:
- The organization or investigator has permission to conduct research in that country by certification or local ethics review.
- The investigator follows all applicable local laws, regulations, customs, and practices.
Additional safeguards may not be applicable to social-behavioral research involving no more than minimal risk.

1.9 Research Involving U.S. Military Personnel
For DoD-sponsored research involving U.S. military personnel, the IRB shall require the investigator to provide a plan for recruitment that incorporates additional protections.

1.9.1 The following additional protections for military research participants shall be applied to minimize undue influence:
- Officers shall not influence the decision of their subordinates to participate in the research.
- Officers and senior non-commissioned officers shall not be present at the time of recruitment into the research.
- Officers and senior non-commissioned officers must have a separate opportunity to participate in the research.
- When recruitment involves a percentage of a unit, an independent ombudsman shall be present during the recruitment.

1.9.2 The limitations on dual compensation are as follows:
- An individual is prohibited from receiving pay of compensation for research during duty hours.
- An individual may be compensated for research if the individual is involved in the research only when not on duty.
- Federal employees while on duty and non-federal persons may be compensated up to $50 for each blood draw taken for research.
- Non-federal persons may be compensated for participating in research for other than blood draws in a reasonable amount approved by the IRB according to local prevailing rates and the nature of the research.

1.10 Provisions for Research-Related Injuries
For DoD-sponsored research, DoD components may have stricter requirements than the Common Rule requirements for research-related injuries. The IRB shall apply the stricter
requirements for research-related injuries as outlined by the DoD component conducting or supporting the research.

1.11 Consent Requirements

When following DoD requirements:

1. If consent is to be obtained from the legally authorized representative of the experimental subject, as defined in DODI 3216.02, the intent of the research must be to benefit each participant enrolled in the study.

2. The determination that research is intended to be beneficial to the individual experimental participant must be made by an IRB.

3. The consent document must include a statement that the DoD or a DoD organization is funding the study.

4. The consent document must include a statement that representatives of DoD are authorized to review research records.

1.12 Waiver of Consent Requirements

If the research participant meets the DoD definition of “Experimental Subject,” waiver of consent is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) under the following conditions:

- The research is necessary to advance the development of a medical product for the Military Services.
- The research may directly benefit the individual experimental subject.
- The research is conducted in compliance with all other applicable laws and regulations.

If the research participant does not meet the definition of Experimental Subject, the IRB may waive consent.

For classified research, waivers of consent are prohibited.

2. SCOPE

This SOP applies to all research involving human participants conducted or supported by the DoD.

3. RESPONSIBILITY

3.1 The investigator is responsible for the initial submission that must include the supplementary DoD research project information and the contact information for the DoD liaison. The DoD liaison is responsible for communicating to the IRB information about specific requirements of the DoD component and whether a DoD addendum will be required.

3.2 The HRPP Director or designee shall review the requirements of the DoD addendum when human participant research is conducted or supported by a DoD component. The HRPP Director is responsible for providing the DoD addendum to the Senior Vice President and Provost or designee for review and signature.

3.3 The Senior Vice President and Provost or designee shall review and sign the DoD addendum when human participant research is conducted or funded by the DoD.

3.4 The HRPP Education Coordinator is responsible for identifying the required education for the sponsoring DoD component involved and for conducting education sessions appropriate for KSP, IRB staff, IRB Chairs and Vice-Chairs, and IRB members.
3.5 **Department of Defense (DoD) Reporting Requirements**

For DoD supported research, the investigator must promptly report the following (no more than within 30 days) to the DoD human research protection officer:

3.5.1 IRB approval of significant changes to the research protocol.

3.5.2 The results of the IRB continuing review.

3.5.3 A change of the reviewing IRB.

3.5.4 Notification by any Federal department, agency, or national organization that any part of the University’s HRPP is under a for-cause investigation that involves a DoD-supported research project.

3.5.5 Any determinations of serious or continuing non-compliance of DoD supported research.

3.5.6 Any suspension or termination of DoD-supported research.

4. **APPLICABLE REGULATIONS AND GUIDELINES**

Department of Defense Directive, Number 3216.02, March 25, 2002, Certified Current as of April 24, 2007

Office of the Under Secretary of Defense (Personnel and Readiness) and Department of Defense Requirements, Version 22, March 2007

Department of the Navy, SECNAVINST 3900.39D, 6 November 2006

Army Regulation 70-25, 25 January 1990

10 USC 980

32 CFR 19

45 CFR 46, Subpart A

45 CFR 46, Subparts B, C, and D

5. **REFERENCES TO OTHER APPLICABLE SOPS**

SOP IV: Glossary

SOP 102B: Key Study Personnel Education

SOP 304: Documentation, Document, and Data Management

6. **ATTACHMENTS**

SOP 203-K, Reviewer Checklist

7. **PROCESS OVERVIEW**

At the time of submission to the IRB, the investigator shall identify on the IRB submission that the research is funded by the specific DoD component and provide contact information for the DoD liaison and supplementary DoD information concerning the research project.

7.1 **Multi-Site Research**

In order to ensure consistent protection of participants under DoD requirements, an investigator conducting DoD-sponsored multi-site research shall submit information to the IRB about the FWA(s) held by collaborating institutions, including the existence of any DoD addendum.
IRB staff shall be responsible for making sure that a formal agreement between collaborating institutions is completed that specifies the roles and responsibilities of each party.

7.2 Survey Research

Survey research projects conducted or supported by the DoD typically require DoD approval. The investigator, with assistance from IRB staff, shall identify any requirements for an additional level of DoD review of the research for DoD-sponsored survey research or survey research that involves DoD personnel, including U.S. military personnel.

The investigator shall submit surveys and all required documentation relevant to survey research review to the IRB for approval prior to submitting the survey to the DoD component for approval. When a survey crosses DoD components, additional review is required by each of the involved DoD components.

7.3 Department of Defense Addendum

After the investigator submits a research project to a DoD component, the University may receive notice from the DoD component that the sponsored research award includes a DoD addendum to the existing FWA.

The HRPP Director or designee shall review the requirements of the DoD addendum and shall provide the DoD addendum to the Senior Vice President and Provost or designee and the appropriate IRB Chair for review and signature. The HRPP Director shall also review and sign the DoD addendum.

7.4 Education

The HRPP Education Coordinator is responsible for identifying specific required education for the sponsoring DoD component involved. The HRPP Education Coordinator shall conduct the specific required education sessions appropriate for KSP, IRB staff, IRB Chairs and Vice-Chairs, and IRB members.

7.5 Records

7.5.1 IRB staff shall maintain IRB records for DoD-sponsored research in accordance with SOP 304: Documentation, Document, and Data Management. The IRB shall determine, in coordination with the investigator, whether the DoD component requires submission of IRB records to the DoD for archiving.

7.5.2 The investigator shall submit the relevant IRB records to the DoD component sponsoring or supporting the research, as appropriate.

7.5.3 The DoD may also request additional documentation to verify compliance with federal and DoD policies, including IRB meeting minutes related to the research. As appropriate, the HRPP Director or designee shall provide the additional information pertinent to IRB review to the DoD.

7.5.4 The investigator may not initiate the research until the human participants’ research protection officer within the sponsoring DoD component reviews and approves the IRB approval and other submitted documentation and notifies the University of such approval.

7.5.5 Records maintained that document compliance or non-compliance with DoD regulations must be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.
7.6 Research Monitor

7.6.1 The IRB shall require investigators to appoint an independent research monitor for DoD-sponsored research projects involving greater than minimal risk. The IRB may require appointment of a research monitor for a portion of a DoD-sponsored project or for projects involving no more than minimal risk if appropriate. The monitor may perform oversight functions such as observe recruitment, enrollment procedures, the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis. The research monitor may discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study. The monitor may also report observations and findings to the IRB or a designated official.

7.6.2 The investigator shall be responsible to appoint the independent research monitor and to provide the name of the research monitor to the IRB.

7.6.3 The IRB shall approve a summary of the research monitor’s duties, authorities, and responsibilities. The IRB Chair or Institutional Official will communicate with the research monitor to confirm these duties, authorities, and responsibilities.

7.6.4 The investigator shall provide to the IRB reports from the research monitor at intervals determined by the IRB.

7.6.5 The IRB shall review research monitor reports as provided and assess the progress of the research project if any further action or changes are necessary.

7.7 Prisoners of War in Research

The IRB shall review new research project submissions to determine the proposed research project population involved. Research with POWs is prohibited for DoD-sponsored research. The IRB shall not approve research with prisoners of war. See SOP IV: Glossary, for the definition of POW.

7.8 Research Involving International Populations

The IRB shall apply the following safeguards if the proposed research project involves international populations:

7.8.1 The IRB shall require the investigator to provide to the IRB the local applicable laws, regulations, customs, and practices for the country where the proposed research project will occur, along with an outline of how the investigator will follow those laws, regulations, customs, and practices.

7.8.2 The IRB will require the investigator to provide to the IRB evidence of permission to conduct research in that country by certification or local ethics review.

7.9 Research Involving U.S. Military Personnel

7.9.1 In order to minimize undue influence for DoD-sponsored research involving U.S. military personnel, the IRB shall require the investigator to apply the following additional protections:

- Officers shall not influence the decision of their subordinates to participate in the research.
- Officers and senior non-commissioned officers shall not be present at the time of recruitment into the research.
- Officers and senior non-commissioned officers must have a separate opportunity to participate in the research.
• When recruitment involves a percentage of a unit, an independent ombudsman shall be present during the recruitment.

7.9.2 The IRB shall require the investigator to apply the following limitations on dual compensation for DoD-sponsored research involving U.S. military personnel:

• An individual is prohibited from receiving pay from more than one position for more than 40 hours of work in one calendar week.
• The limitations on dual compensation include temporary, part-time, and intermittent appointments.

7.10 Provisions for Research-Related Injuries

The IRB staff, in coordination with the IRB Chair or IRB designee, shall review the DoD component requirements for research-related injury to determine if the requirements are stricter than the Common Rule requirements. The investigator shall include the stricter provisions in the informed consent documents.

7.11 Consent Requirements

The IRB makes the determination as to whether a research participant meets the definition of Experimental Subject per SOP IV, Glossary.

If a research participant meets the definition of, DoD regulations prohibit a waiver of consent unless a waiver of consent is obtained from the Secretary of Defense. The IRB shall not approve a waiver of consent unless the IRB has received a waiver issued by the Secretary of Defense.

If the research participant does not meet the definition of Experimental Subject, the IRB may waive consent when appropriate.

The IRB reviewer must also make a determination that research is intended to be beneficial to the individual experimental subject. If consent is to be obtained from the experimental subjects’ legally authorized representative, the IRB must determine that the research is intended to benefit the individual participant.
SOP 603G: OTHER FEDERAL AGENCIES

1. POLICY
Several of the federal agencies that have adopted the Common Rule have policies and regulations that differ from the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) Department of Health and Human Services (DHHS) requirements. The agency-specific requirements must be met when reviewing, approving, and conducting human research projects supported or funded by these specific federal agencies.

1.1 SPECIFIC POLICIES

A. Department of Defense (DoD) (see SOP 603F: Department of Defense)

B. Department of Education (ED)
   1. Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods and techniques.
   2. Children are persons enrolled in research not above the elementary or secondary education level who have not reached the age of majority as determined under applicable state law.
   3. The Family Educational Rights and Privacy Act (FERPA) applies when researchers obtain student records or personally identifiable education information from an education program (defined as any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education and adult education).
      a) Under FERPA, an educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is part of an agreement between organizations or researchers conducting studies for, or on behalf of, educational agencies or institutions to:
         1) Develop, validate, or administer predictive tests.
         2) Administer student aid programs.
         3) Improve instruction.
      b) A school district or postsecondary institution that uses an exception for this disclosure is required to enter into a written agreement with the University that specifies:
         1) The determination of the exception for this disclosure.
         2) The purpose, scope, and duration of the study.
         3) The information to be disclosed.
         4) That information from education records may be used solely to meet the purposes of the study stated in the written agreement and must contain the current requirements in ED regulations on re-disclosure and destruction of information.
5) That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the University with legitimate interests.

6) That the University is required to destroy or return all personally identifiable information when it is no longer needed for the purposes of the study.

7) The time period during which the University must either destroy or return the personally identifiable information.

c) Education records may be released without consent from the parent or eligible student under FERPA if all personally identifiable information has been removed, including:

1) Student’s name and other direct personal identifiers, such as the student’s Social Security number or student number.

2) Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address; personal characteristics or other information that would make the student’s identity easily traceable; and date and place of birth and mother’s maiden name.

3) Biometric records of the student, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

4) Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community who does not have personal knowledge of the relevant circumstances to identify the student with reasonable certainty.

4. For certain types of research directly funded by ED, the Protection of Pupil Rights Amendment (PPRA) applies.

a) PPRA prohibits students from being required, as part of a research project, to submit without prior consent* to surveys; psychiatric examination, testing, or treatment; or psychological examination, testing, or treatment in which the primary purpose is to reveal information concerning one or more of the following:

1) Political affiliations or beliefs of the student or the student’s parent.

2) Mental or psychological problems of the student or the student’s family.

3) Sex behavior or attitudes.

4) Illegal, anti-social, self-incriminating, or demeaning behavior.

5) Critical appraisals of other individuals with whom respondents have close family relationships.

6) Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.

7) Religious practices, affiliations, or beliefs of the student or student’s parent.

8) Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
*Prior consent: (1) prior consent of the student if the student is an adult or emancipated minor under applicable state law, or (2) prior written consent of the parent or legal guardian, if the student is not an adult or emancipated minor.

b) For certain types of research not directly funded by ED and conducted in a school that receives funding from ED, policies and procedures shall include a process to verify compliance with ED regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

1) The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.

2) Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.

3) Arrangements to protect student privacy that are provided by ED in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):

   i. Political affiliations or beliefs of the student or the student’s parent.
   ii. Mental or psychological problems of the student or the student’s family.
   iii. Sex behavior or attitudes.
   iv. Illegal, anti-social, self-incriminating, or demeaning behavior.
   v. Critical appraisals of other individuals with whom respondents have close family relationships.
   vi. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
   vii. Religious practices, affiliations, or beliefs of the student or the student’s parent.
   viii. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
   ix. All instructional material – including teachers’ manuals, films, tapes, or other supplementary instructional material – which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.
   x. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
   xi. The administration of physical examinations or screenings that the school or agency may administer to a student.
   xii. The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including
arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

xiii. The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.

xiv. Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

C. Department of Energy (DOE)

1. For research funded or supported by the DOE:

   a) Research involving human participants includes studies of the intentional modification of the human environment.

   b) When considering if a DOE project meets the definition of research, generalizable should be viewed in terms of the contribution to knowledge within the specific field of study. The term ‘generalizable’ includes:

      1) The study of tracer chemical, particles, or other materials to characterize airflow.

      2) Studies in occupied homes or offices that manipulate the environment to achieve research aims.

      3) Testing new materials

      4) Collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.

   c) No human participant research conducted with DOE funding at DOE institutions (headquarters or DOE sites/ laboratories, regardless of funding source) or by DOE employees and contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, shall be initiated without both a Federal-wide Assurance and approval by the cognizant IRB in accordance with 10 CFR Part 745.103.

      Note: OU researchers are required to consult with Office of Export Controls before initiating classified research.

   d) DOE employees and contractors are considered vulnerable participants. The IRB must consider if additional protections are required for research involving these individuals. For more information see SOP 501: Special Populations.

   e) The consent document must include the identity of the sponsoring agency, unless the sponsor requests that it not identified because doing so could compromise intelligence sources or methods; the research involves no more than minimal risk to participants; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.

Researchers are required to follow DOE requirements for the protection of personally identifiable information by completing and complying with the requirements of the “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in
Compliance with DOE Requirements” as outlined at: https://science.energy.gov/ber/human-subjects/.

2. Investigators must promptly (within 48 hours) report the following to the DOE Human Subject Research Program Manager:
   a) Any significant adverse events, unanticipated risks, and complaints about the research with a description of any corrective actions taken or to be taken.
   b) Any suspension or termination of IRB approval of research.
   c) Any significant non-compliance with HRPP procedures or other requirements.

Any compromise of personally identifiable information must be reported immediately upon discovery.

3. Classified Research:

Requirements for human participant protections for classified research apply to all research conducted or supported by the DOE, including contracts and including Human Terrain Mapping research.

Requirements for human participant protections and their accompanying Contractor Requirements Documents (CRDs) apply to all research conducted at DOE institutions regardless of funding source and to all research conducted by DOE employees/contractor personnel regardless of funding source of location conducted, and whether done domestically or in an international environment, and including Human Terrain Mapping Research.

DOE workers are considered vulnerable subjects and shall be afforded additional protections as determined by the IRB.

The use of exemptions is prohibited. The fact that research meets a particular exemption category may be noted, but review by a convened IRB is required.

The IRB must have a voting quorum of at least five members, which must include both a scientist and a non-affiliated member. The non-affiliated member must be a non-governmental member with the appropriate security clearances. This individual cannot be a current federal employee or contractor. Any IRB member can appeal a vote to approve research to the Institutional Official, Secretary of Energy, and Director of the Office of Science and Technology, in that order.

The IRB must determine whether participants need access to classified information to make a valid consent decision. The consent document must state the project is classified and what it means for the purposes of the research project.

For classified research, waivers of consent are prohibited.

D. Department of Justice (DOJ)

1. Bureau of Prisons: For research conducted within the Bureau of Prisons, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

   a) General Requirements
      1) The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
2) The University, IRB, Investigators, and Research Staff shall apply the requirements of 28 CFR 512 to human participant research, including:
   
   i. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
   
   ii. The research design must be compatible with both the operation of prison facilities and protection of human participants.
   
   iii. The Investigator must observe the rules of the institution or office in which the research is conducted.
   
   iv. Any Investigator who is a non-employee of the Bureau must sign a statement in which the Investigator agrees to adhere to the requirements of 28 CFR 512.
   
   v. All research proposals must be reviewed by the Bureau Research Review Board.

b) Confidentiality of Data

1) A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the DOJ.

2) Except as noted in the consent statement to the participant, the Investigator must not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

3) Except for computerized data records maintained at an official DOJ site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

4) If the investigator is conducting a study of special interest to the DOJ’s Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the Investigator may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

The following elements must be disclosed by the investigator to the participants:

   i. Identification of the researchers.
   
   ii. Anticipated uses of the results of the research.
   
   iii. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
   
   iv. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an Investigator may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself
or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.

v. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility

c) Participant Selection:
1) The selection of participants within any one institution must be equitable.
2) Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
3) Reasonable accommodations such as nominal monetary compensation for time and effort may be offered to non-confined research participants who are both:
   i. No longer in Bureau of Prisons custody, and
   ii. Participating in authorized research being conducted by Bureau employees or contractors.

d) Additional Investigator Requirements:
1) At least once a year, the investigator must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
2) At least 12 business days before any report of findings is to be released, the investigator must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director and the warden of each institution that provided data or assistance. The investigator must include an abstract in the report of findings.
3) In any publication of results, the investigator must acknowledge the Bureau's participation in the research project.
4) The investigator must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
5) Prior to submitting for publication the results of a research project conducted under this subpart, the Investigator must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
6) The investigator must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Investigator.

2. For National Institute of Justice (NIJ)-funded research:
   a) All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer.
   b) All investigators and research staff are required to sign employee confidentiality statements available from NIJ, which are maintained by the responsible investigator.
   c) The consent form for NIJ-funded research shall include:
      1) The name(s) of the funding agency(ies).
      2) A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by NIJ the research
participant should be informed that private, identifiable information will be kept confidential and will be used only for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained in confidence, the research participant needs to be explicitly notified.

3) If the investigator intends to disclose any information, the research participant needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.

4) Under an NIJ privacy certificate, researchers and staff are not required to report child abuse unless the participant signs another consent document to allow child abuse reporting. However, because Oklahoma state law does require reporting of actual or suspected child abuse, only those individuals who agree in advance to allow for such reporting and sign a separate consent document available from the IRB that acknowledges such reporting will occur may be enrolled in OU research funded by NIJ and subject to an NIJ privacy certificate.

5) The investigator shall ensure that a copy of all data is de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

E. Environmental Protection Agency (EPA)

1) For human participant research conducted or supported by the EPA:
   a) EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
   b) For observational research (i.e., research that does not involve intentional exposure to a substance), EPA requires application of 40 CFR 26 Subparts B, C and D to provide additional protections to pregnant women, fetuses, and children.
   c) EPA requires submission of IRB determinations and approval to the EPA human participant research review official for final review and approval before the research can begin.

2) For human participant research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:
   a) EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to substances.
   b) EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

3) Research involving children: The IRB may review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that:
   a) The intervention or procedure holds out the prospect of direct benefit to the individual research participants or is likely to contribute to the research participant’s well-being.
   b) The risk is justified by the anticipated benefit to the research participants.
c) The relation of the anticipated benefit to the risk is at least as favorable to the research participants as that presented by available alternative approaches.

d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR 26.406.

2. SCOPE

These policies and procedures apply to research involving human participants conducted or supported by the following federal agencies: Department of Energy (DOE), Department of Justice (DOJ), Environmental Protection Agency (EPA), and Department of Education (ED), all as applicable.

3. RESPONSIBILITY

The investigator is responsible for assisting the IRB with identifying applicable agency requirements and submitting relevant documentation to the IRB, implementing the research consistent with the agency requirements, and for complying with the specific agency human participant protection regulations. See the agency-specific responsibilities listed in Section 1.

The IRB, IRB Chair/Designee, and HRPP Director and staff are responsible for applying applicable agency requirements to the IRB review and approval process.

4. APPLICABLE REGULATIONS AND GUIDELINES

40 CFR 26.304
40 CFR 26.404 - 405
34 CFR 98, 99
34 CFR 350, 356
10 CFR 745
DOE O 443.1.B.
28 CFR 22
28 CFR 512
10 O.S. § 7103

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 603F: Department of Defense
SOP 202: Management of IRB

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
301-A Study Application
7. PROCESS OVERVIEW

7.1 The investigator reviews the requirements of the applicable agency to verify the agency specific requirements. At the time of submission to the IRB, the Investigator shall identify on the IRB application that the research involves one of the following agencies: DOE, DOJ, EPA, or ED and uploads supporting documents to comply with the specific requirements.

7.2 HRPP staff conducts a pre-review, identifies the agency-specific requirements, and forwards this information to the IRB Chair/Reviewer.

7.3 The IRB Chair/Reviewer reviews the research project against the following, as applicable:


4. Environmental Protection Agency (EPA) – (40 CFR 26)

7.4 The IRB documents findings as required by the applicable federal agency and communicates them to the Investigator.

7.5 The Investigator submits reports and documentation to the federal agency as required.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 701: CONSENT PROCESS AND DOCUMENTATION

1. POLICY

The IRB requires investigators to obtain legally effective informed consent from human research participants.

Informed consent is the process by which the research project is explained to the potential participant, and the potential participant then voluntarily agrees to participate in the research. Except as provided elsewhere in this SOP:

1. Before involving a human participant in research subject to IRB review, an investigator shall obtain the legally effective informed consent from the subject or the subject’s legally authorized representative.

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or legally authorized representative sufficient opportunity to discuss and consider whether to participate and that minimize the possibility of coercion or undue influence.

3. The information that is given to the subject or the legally authorized representative shall be in a language understandable to the subject or the legally authorized representative.

4. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights or that releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.

For research projects subject to the 2018 Common Rule, the following also applies:

5. The investigator must provide the prospective subject or the legally authorized representative with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and with an opportunity to discuss that information.

6. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

7. The informed consent process as a whole must include information in sufficient detail relating to the research, and the information must be organized and presented in a way that does not merely provide lists of isolated facts, but rather that facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.

Nothing in this policy is intended to limit the authority of a physician or other health care provider to provide emergency medical care, to the extent the physician or health care provider is permitted to do so under applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaskan Native tribe).

The informed consent requirements in the federal regulations are not intended to preempt any other applicable federal, state, or local laws that require additional information to be disclosed for consent to be legally effective (45 CFR 46.116(e)).
The IRB requires that a research team member must obtain legally effective informed consent, prior to conducting any research project-related activities. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with federal regulations.

Neither "passive" nor "implied" consent is recognized by the IRB, per HHS regulations.

*Note: Although “Broad Consent” is permitted by the 2018 regulations, OU will not implement this option at this time.*

**Specific Policies**

**1.1 Written Informed Consent**

The IRB requires documentation of informed consent by use of written informed consent documents approved by the IRB and signed and dated by the participant or the participant's legally authorized representative, the person obtaining consent, the investigator if required by the sponsor, and a witness when appropriate. The participant or the representative must be given adequate opportunity to read it before it is signed.

Signature may be electronic if the IRB has approved the use of electronic signatures in any particular study.

The informed consent documents must contain all federally required elements of informed consent plus additional federally required elements as indicated below.

A. Required Elements of Informed Consent

1. Consent is sought only under circumstances that provide the participant or the legally authorized representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.

2. Required Core Elements of Informed Consent:
   
   a. A statement that the research project involves research.
   
   b. An explanation of the purposes of the research.
   
   c. The expected duration of the participant's participation.
   
   d. A description of the procedures to be followed
   
   e. Identification of any procedures that are experimental.
   
   f. A description of any reasonably foreseeable risks or discomforts to the participant.
   
   g. A description of any benefits to the participant or to others who may reasonably be expected to benefit from the research.
   
   h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
   
   i. A statement describing the extent, if any which the confidentiality of records identifying the participant will be maintained and that noting the possibility that the IRB, HRPP, University regulatory offices and Food and Drug Administration (if applicable) may inspect the records.
   
   j. For research involving more than minimal risk, an explanation as to whether any compensation is provided for and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
k. An explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights and whom to contact in the event of a research-related injury to the participant.

l. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

For research subject to the 2018 Common Rule, the following elements are also required:

m. One of the following statements about any research that involves the collection of identifiable private information or identifiable private specimens:

(i) A statement that the participant’s identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional consent from the participant or legally authorized representative; or

(ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

NOTE: For DoD sponsored research, DoD may have stricter requirements than Common Rule requirements for research-related injury. See SOP 603F: Department of Defense.

3. Additional Elements of Informed Consent that May Be Required:

In Specified Circumstances or as Otherwise Appropriate:

a. When research involves investigational test articles or procedures with a risk profile that is not well known: A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) which are currently unforeseeable.

b. When there are known circumstances under which the individual’s participation may be terminated by the investigator or sponsor: A statement of anticipated circumstances under which the participant’s participation in the research project may be terminated by the investigator or the sponsor without regard to the participant’s consent.

c. When there are additional costs to the participant that may result from participation in the research: A statement of any additional costs to the participant that may result from participation in the research.

d. When significant new findings are likely to develop during the course of the research: A statement that significant new findings developed during the course of the research that may relate to the participant’s willingness to continue participation will be provided to the participant.

e. When the number of participants involved may affect an individual’s willingness to participate in the research: The approximate number of participants involved in the research project.

f. A description of the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant. Include the consequences of a participant’s decision to withdraw from the research.
when there are adverse consequences of a participant’s decision to withdraw from
the research project. Include procedures for orderly termination of participation by
the participant when such procedures are defined in the protocol.)

- When a participant withdraws from a study, the data collected on the
  participant to the point of withdrawal remains part of the study database and
  may not be removed. The consent document cannot give the participant the
  option of having data removed.

- The investigator may ask a participant who is withdrawing whether the
  participant wishes to provide continued follow-up and further data collection
  subsequent to their withdrawal from the interventional portion of the study.
  Under this circumstance, the discussion with the participant distinguishes
  between study-related interventions and continued follow-up of associated
  clinical outcome information, such as medical course or laboratory results
  obtained through non-invasive chart review, and address the maintenance of
  privacy and confidentiality of the participant’s information.

- The investigator must obtain the participant’s consent for this limited
  participation in the study (assuming such a situation was not described in
  the original consent document). The IRB or EC must approve the consent
  document.

- If a participant withdraws from the interventional portion of a study and
  does not consent to continued follow-up of associated clinical outcome
  information, the investigator must not access for purposes related to the
  study the participant's medical record or other confidential records
  requiring the participant's consent. However, the investigator may review
  study data related to the participant collected prior to the participant's
  withdrawal from the study, and may consult public records, such as those
  establishing survival status.

g. The amount and schedule of payments.

h. The following exact statement must be included in the informed consent documents of
   “applicable clinical trials:” “A description of this clinical trial will be available on
   http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include
   information that can identify you. At most, the Web site will include a summary of the
   results. You can search this Web site at any time.”

For research subject to the 2018 Common Rule, the following elements may also be
required:

i. A statement that the participant's biospecimens (even de-identified specimens) may
   be used for commercial profit and whether the participant will or will not share in this
   commercial profit.

j. A statement regarding whether clinically relevant research results, including individual
   results, will be disclosed to participants, and if so, under what conditions.

k. A statement regarding whether research involving biospecimens will (if known) or
   might include whole genome sequencing. (i.e., sequencing of a human germline or
   somatic specimen with the intent to generate the genome or exome sequence of the
   specimen).

B. Documentation of Informed Consent
1. Except as described below in Section 1.5, documentation of informed consent is required according to legal and regulatory requirements to conduct research studies involving human participants. Documentation of informed consent is required for all studies that involve more than minimal risk.

2. Format of written informed consent.
   a. Unless otherwise authorized in advance by the IRB, the consent document must use the format and template language provided in the sample on the IRB website.
   b. The OUHSC consent document must be in a question/answer format. (OU Norman Campus IRB does not require a question format for the consent template.)
   c. The consent document must be written in the second person.
   d. The consent document must be written in language understandable to the participant. All necessary medical or technical terms must be explained in lay terms.
   e. The consent document may not contain any exculpatory language through which the participant waives or appears to waive legal rights or releases or appears to release the investigator, the sponsor, or the University of Oklahoma from liability for negligence.
   f. The consent document may not contain any language that disclaims or limits the warranty of drugs or devices used in the research, except as to efficacy of the drug or device.
   g. The consent document must be signed and dated by the participant, the person obtaining consent, and the investigator (if required by the sponsor).
   h. The participant must be given a copy of the signed consent form. The original signed informed consent must be kept on file at the investigator's site and is subject to audit.
   i. The final approved consent document must be stamped by the IRB office with the date of approval and date of expiration. The expiration date will be no longer than 1 year after the last review by the convened Board or, if expedited review, by the IRB Chair. All participants must sign the currently approved IRB stamped document prior to participating in any research project-related activity.
   j. Investigators shall use the consent form template available on the University's IRB websites for documenting consent. For VA research, VA Form 10-1086, VA Research Consent Form, shall be used for documenting consent. See SOP 603A: Veterans Affairs Health Care System.

1.2 Electronic Informed Consent

Electronic informed consent refers to the use of electronic systems that may employ electronic media to convey information about a research project to obtain and document informed consent. As with written informed consent, electronic informed consent must contain all required elements of informed consent, must be presented in a language and manner understandable to the participant or the participant’s legally authorized representative, and allow a mechanism or opportunity for the participant to ask questions and interact during the consent process.

Unless the IRB waives the requirement for signed consent, a written consent must be given to and signed and dated by the participant or the participant’s legally authorized representative. An
electronic signature on a consent document may be used if the procedures for obtaining electronic signature are approved by the IRB. Electronic signature must be valid within the jurisdiction where the research is being conducted.

Oklahoma law recognizes the use of electronic signatures. The investigator is responsible for ensuring that any out-of-state participants complete the consent process in accordance with that state’s laws.

1.2.1. Special issues for the IRB to consider:

The IRB shall review all aspects of the electronic consent form, process, and documentation to ensure the rights and welfare of research participants are protected. The IRB will give special consideration to (1) how consent will be obtained and documented; (2) how confidentiality will be maintained; (3) site security and data use policies of the institution; (4) how new information that might affect a participant’s willingness to continue will be shared with participants; and (5) how electronic consent forms will be secured. No electronic consent forms may be maintained on unencrypted devices (laptops or smartphones) or in unencrypted storage locations, such as clouds or servers.

1.3 Obtaining Consent From Participants Who Are Blind, Illiterate, or Understand But Do Not Speak or Read English

DHHS regulations require that informed consent information be presented in a language understandable to the subject and, in most situations, that informed consent be documented in writing. Participants who understand but do not speak English should be presented with a consent document (a document that embodies all of the elements of the informed consent as required in Section 1.1 of this SOP) written in a language understandable to them. The IRB strongly encourages the use of this procedure whenever possible.

This document may be read to the participant or the participant’s legally authorized representative in their native language, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed.

Alternatively, oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally are permitted.

When oral presentation of informed consent information is used in conjunction with a short form:

a) The IRB must approve a written summary of what is to be said to the participant or the participant’s legally authorized representative.

b) The participant or the participant’s legally authorized representative must sign and date only the short form of the consent documentation.

c) There shall be a third-party witness to the oral presentation. The witness must be conversant in both English and the language of the participant.

d) The witness must sign and date both the short form and a copy of the IRB-approved summary. The person actually obtaining the consent must sign and date a copy of the summary. The original short form and summary must be filed in the investigator’s files in accordance with the sponsor’s requirements.

e) A copy of the signed and dated short form must be given to the participant or the participant’s legally authorized representative, along with a copy of the signed and dated summary.
The IRB shall also consider the use of the short form written consent document when the participant is blind or illiterate.

For written consent document (Short Form) requirements for VA research projects, see SOP 603A: Veterans Affairs Health Care System.

1.4 Waiver of Informed Consent:

A. The requirement for informed consent may be waived partially or entirely by the IRB or the IRB designee if the following conditions are met:
   1. There is no more than minimal risk (including confidentiality risks) to the participants;
   2. The research involves using identifiable private information or identifiable biospecimens and the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
   3. The waiver or alteration of consent will not adversely affect the rights and welfare of the participants;
   4. The research could not practicably be carried out without the waiver or alteration; and
   5. When appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

B. Examples of research that might qualify for a waiver of informed consent include but are not limited to:
   1. Retrospective chart reviews
   2. Observation of public behavior
   3. Research or demonstration projects that are conducted by or subject to the approval of state or local government officials and are designed to study, evaluate, or otherwise examine:
      a. Public benefit or service programs
      b. Procedures for obtaining benefits or services under public or service programs
      c. Possible changes in or alternatives to public or service programs or procedures, or
      d. Possible changes in methods or levels of payment for benefits or services under public or service programs, and
      e. The research is not subject to FDA regulations (the FDA has no provision for waiver or alteration of consent).

In addition, the research could not practicably be carried out without the waiver or alteration.

C. VA Research:
   Consent to take a photograph, video, or audio recording for research cannot be waived by the IRB.

D. Emergency exemption from informed consent to participate in research that would normally require consent (i.e., research involving more than minimal risk) is not provided for under Oklahoma law.

E. Department of Defense-Sponsored Research:
If the research participant meets the definition of “Experimental Subject,” as defined in SOP IV, Glossary, a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research participant does not meet the definition of Experimental Subject, the IRB may waive consent. See SOP 603F: Department of Defense.

1.5 Waiver of Documentation of Informed Consent

The IRB or IRB designee may waive documentation of informed consent partially or entirely if it finds:

1. That all of the following are true:
   - The only record linking the participant and research would be the informed consent document, and
   - The principal risk would be potential harm from a breach of confidentiality.
   - Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern, and
   - The research is not subject to FDA regulations; OR

2. That both of the following are true:
   - The research presents no more than minimal risk of harm to participants, and
   - The research involves no procedures for which written consent is normally required outside the research context.

3. Or that all of the following are true:
   a. The participant or legally authorized representative is a member of a distinct cultural group or community in which signing forms is not the norm, and
   b. The research presents no more than minimal risk of harm to the participants, and
   c. There is an appropriate alternative mechanism for documenting that informed consent was obtained.

An example of a type of research project that could qualify for a waiver of documentation of informed consent is a survey.

If the IRB waives the requirement of documentation of informed consent, the IRB may require the investigator to provide a written statement of the research to the participant. The informed consent documents approved by the IRB may also serve as the written statement.

1.6 Waiver of Informed Consent for Public Benefit and Service Programs

The IRB may partially or entirely waive the requirements for informed consent in research involving public benefit and service if the IRB finds and documents that:

A. The research or demonstration projects that are conducted by or subject to the approval of state or local government officials and are designed to study, evaluate, or otherwise examine:

   1. Public benefit or service programs,
   2. Procedures for obtaining benefits or services under public or service programs,
   3. Possible changes in or alternatives to public or service programs or procedures, or
4. Possible changes in methods or levels of payment for benefits or services under public or service programs, and

B. The research could not practicably be carried out without the requested waiver or alteration.

1.7 Waiver of Informed Consent Related to Screening, Recruiting, or Determining Eligibility

The IRB may approve research in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without informed consent if either of the following are met:

A. Information will be obtained through oral or written communication with the prospective participant or legally authorized representative; or

B. Identifiable private information or identifiable biospecimens will be obtained by accessing records or stored identifiable biospecimens.

1.8 Surrogate Consent by a Legally Authorized Representative

The IRB will not waive the requirement for informed consent for human participant research studies where informed consent is required. Under special circumstances, however, it may be appropriate to obtain surrogate consent to allow adult patients who, because of a medical condition, are incapable of giving informed consent for themselves to be enrolled in research studies. Such consent must be obtained from the legal guardian, attorney-in-fact, with health care decision authority, or family member (in order or priority as set by statute) in accordance with Oklahoma Statutes, Title 63 §3102A, when the impairment is a cognitive one. The intent of this SOP is to allow research of incapacitating conditions such as dementia, head trauma, coma, sepsis, and psychiatric disorders. Generally speaking, it is not intended to allow enrollment of incapacitated patients into research projects where competent patients are also to be enrolled (particularly randomized studies) unless the research project involves access to treatments that may be of direct benefit to the participant, but which are not available outside of the research context.

A. The use of surrogate consent for incapacitated participants in a research project must be approved by the convened IRB, whether a general permission or specific permission for an individual participant. In deciding whether it is appropriate to allow the use of surrogate consent, the IRB will consider:

1. Will participating in the research project directly benefit the participant?
2. Are there alternative standard/approved treatments available for this participant?
3. Could this research project be done in a less vulnerable population?
4. If there is no direct benefit to the individual participant, would the information gained result in a potential benefit for other patients with the same incapacitating condition?
5. If there is no direct benefit to the individual participant, is there more than a minimal risk to participation?
6. If the plan for the assessment of the capacity is adequate.
7. If the assent of the participant is a requirement, and, if so, whether the plan for assent is adequate.

B. The participant must be treated by a licensed physician OR someone who holds a faculty appointment at an accredited medical or osteopathic school. If the treating physician and the investigator are not the same person, then the investigator must get the approval of the treating physician for the individual’s participation.
C. No surrogate consent will be accepted if the experimental treatment is in contravention to the incapacitated person’s expressed permission or prohibition regarding such treatment. Surrogate informed consent may be obtained from a legal guardian, attorney-in-fact with health care decision authority, or a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage) when the IRB approves this type of consent and if the participant is incapable of giving informed consent. When the legal guardian or attorney-in-fact with health care decision authority provides consent, the investigator must obtain a copy of the guardianship papers.

D. If the individual previously refused to participate in the research (at a time when he/she was competent to make that decision), the legal guardian, attorney-in-fact, or family member cannot subsequently override his/her wishes after the individual becomes incompetent.

E. Individuals who are incompetent to give informed consent may be able to assent to participation. (The IRB may require or waive participant assent, depending on the level of incapacity.)

F. If the research project is a long-term study and the participant for whom surrogate consent was obtained regains competency during the project, the informed consent process should be repeated with the participant, as described in SOP 501: Special Populations.

G. Surrogate consent may be allowed in non-therapeutic research if the research entails no more than minimal risk to the participant.

H. Surrogate consent cannot be used for participants who, in addition to being incapacitated, are pregnant or are prisoners.

I. For surrogate consent involving VA patients, see SOP 603A: Veterans Affairs Medical Center.

J. Legally Authorized Representative:

For research involving experimental treatments, tests, or drugs conducted in Oklahoma under which federal law and Oklahoma law both apply, the following individuals in the following order can serve as a legally authorized representative and provide surrogate consent:

- a legal guardian
- attorney-in-fact with health care decision authority
- a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage).

For research involving experimental treatments, tests, or drugs that are not health care related conducted in Oklahoma, where federal law and Oklahoma law both apply, the following individuals in the following order can serve as a legally authorized representative and provide surrogate consent:

- legal guardian
- attorney-in-fact with health care decision authority

For research conducted outside of Oklahoma, individuals who meet the definition of a legally authorized representative are those individuals as described under the applicable law of the jurisdiction in which the research will be conducted. If recruiting a participant through a legally authorized representative, the investigator must report this category of participant on the IRB submission and provide to the IRB the definition of legally authorized representative for the applicable jurisdiction.
K. Children:

For research conducted in Oklahoma, where federal regulations and Oklahoma law both apply, individuals under the age of 18 are considered to meet the DHHS and FDA definition of “children.”

For research conducted outside of Oklahoma, individuals who meet the definition of a child are those individuals described under the applicable law of the jurisdiction in which the research will be conducted. If recruiting children outside of Oklahoma, the investigator must report this category of participant on the IRB submission and provide to the IRB the definition of child for the jurisdiction.

L. Guardian:

For research conducted in Oklahoma, where federal laws and Oklahoma law both apply, a guardian is an individual who is authorized to consent to the general medical care of a child or incapacitated person and therefore meet the DHHS and FDA definition of “guardian.”

For research conducted outside of Oklahoma, investigators must provide on the IRB submission the definition of a guardian in the jurisdiction in which enrollment will take place. Only those individuals will be able to provide consent for children or incapacitated person to participate in a research project.

For additional consent requirements for VA research, see Section 1.9 of this policy.

Legal Counsel may be consulted by the HRPP Director and IRB Chair for assistance in applying laws to research involving human participants.

For LAR requirements specific to VA research projects, see SOP 603A: Veterans Affairs Health Care System.

1.9 Informed Consent in Special Populations

A. Informed Consent in Children

"Assent" in research involving children means a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent. "Permission" in research involving children means the agreement of the parent(s) or guardian to the participation of their child or ward in research.

Children are defined as being less than 18 years old. Oklahoma law does not recognize the concept of an “emancipated minor” for the purposes of research.

Informed legal consent for children must meet the following:

1. In children, informed consent is obtained from the parent(s) or legal guardian.

2. Research involving more than minimal risk with or without the prospect of direct benefit requires both parents’ signatures when both are available. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

3. For some types of research where documentation of informed consent would normally be waived (such as surveys), documentation of parental permission may be required for children.

4. The IRB may waive the requirement for parental permission under the same conditions that it may waive informed consent described in Section 1.3 above, if it determines:
• the research project is designed to study conditions in children or a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children),

• there is an appropriate mechanism in place to protect the children, and

• the waiver is not inconsistent with federal, state, or local law.

5. Assent from the child is usually required unless:

a. The minor participant is too immature or incapacitated to be consulted.

b. The intervention/procedure involved in the research holds out the prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

c. The assent document would be the only link between the participant and the research and would pose a confidentiality risk.

Assent is documented depending on the age, maturity, and psychological state of the child:

iii. Age < 7 years old, assent is waived or verbal assent is obtained, as determined by the IRB.

iv. Age 7-12 years old, a simple assent statement is obtained.

v. Age 13-17, the IRB approved informed consent document is used, with a statement of assent added.

Assent may be obtained verbally or as a written document or a combination of both as appropriate to the age, maturity, and psychological state of the child, as well as the nature of the research project.

B. Informed Consent in Research Involving Pregnant Women and/or Fetuses

For research involving pregnant women and/or fetuses, consent must be obtained from both the pregnant woman and father unless:

1. The purpose of the research is to meet the health needs of the mother,

2. The identity or whereabouts of the father cannot reasonably be ascertained or he is otherwise unavailable, or

3. The pregnancy resulted from rape or incest.

C. Informed Consent in Research Involving Native Americans

1. Informed consent from the individual Native American participant is sufficient if the research project is not directed at or about Native Americans as a group.

2. For studies involving Native Americans as a group, informed consent is required from the individual participant and the appropriate tribal authority.

D. Informed Consent in Research Involving Prisoner Populations

1. The informed consent for research involving prisoner populations will be presented in language that is understandable to the prisoner population.

2. The informed consent document shall include language to clearly inform participants in advance that parole boards will not take into account a prisoner’s participation in research in making decisions regarding parole. See SOP 501: Special Populations.
E. Informed Consent in Research Involving Other Special Populations

Other special populations may include, but are not limited to: individuals with impaired decision-making capacity and economically or educationally disadvantaged persons, HIV+ participants, employees of the sponsor or investigator, terminally ill patients, and the elderly (65 years of age and older). The IRB will determine special protections for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by applicable University policies and state and federal law.

1.10 Re-consenting Participants

The investigator has a responsibility to inform research participants of any new information that might affect a participant’s willingness to continue participating in the research. Often, re-consent can be obtained verbally, with the investigator documenting in the research file that he/she has informed the participant of the new information. However, under certain circumstances, the investigator must obtain written documentation that the new information was conveyed to the participant and the participant agreed to continue in the research project. Written documentation of re-consent must be obtained by having the participant sign an updated version of the informed consent document or an addendum to the original consent form, as determined by the IRB.

A. Significant Changes: Written documentation of the participant’s willingness to continue to participate must be obtained if there is a significant change to the research project or the risk that directly affects what the research participant is being asked to do. Examples include:

1. The research project was originally going to last for 6 weeks but now the participants are going to be followed for 5 years.
2. The research project drug was originally to be given in randomized, double-blind fashion but now is going to be open label.
3. The drug was recently reported to cause liver failure.
4. The drug was originally intended to be given by peripheral IV but now requires a central line.
5. Blood originally stored for future analysis of unknown biomarkers will now be used for genetic testing.

B. Minor Changes: Notification of minor changes is required, but not written informed consent. Examples of minor changes include:

1. Research project required 5cc of blood but now requires 10cc of blood.
2. Surveys are changed (unless the new questions pose new risks; i.e., questions about illegal activity).
3. Final follow-up visit was originally scheduled in-office but now will occur via telephone.

C. Participants who were enrolled in research studies at a time when they were minors must be re-consented when they turn 18 years old if they are still actively participating or being followed in the research project.

D. Participants who were incompetent and were enrolled in a research project by a legally authorized representative must be re-consented when they regain competency (if they are still actively participating or being followed in the research project).
E. For Additional Consent Requirements for VA Research Projects see SOP 603A: Veterans Affairs Medical Center. Note: for VA Research, VA Form 10-1086, is required to be submitted to show documentation of consent.

1.11 Posting Consent Form for Clinical Trials

For research subject to the 2018 Common Rule:

A. The investigator shall post one IRB-approved consent form used to enroll participants to a publicly available Federal website (such as ClinicalTrials.gov) for each clinical trial conducted or supported by a Federal department or agency.

B. The investigator must post the consent form to the Federal website after the study is closed to recruitment, and no later than 60 days after the last study visit by any participant, as required by the protocol.

C. There may be circumstances in which the investigator thinks that certain information should not be made publicly available (e.g. confidential commercial information). In such cases, the investigator may request from the Federal department or agency appropriate redactions to the consent form, or in rare cases, an exception to the requirement to post the consent document. The investigator must obtain documentation of this approval from the Federal department to provide to the University’s ClinicalTrials.gov administrator.

2. SCOPE

This SOP applies to all research submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB shall verify that the consent documents allow for the signature of both parents in cases where research meets the regulations of 45 CFR §46.406 and 45 CFR §46.407.

3.2 The IRB shall determine which of the procedures at 45 CFR §46.117(b) is appropriate for documenting informed consent in the research projects that it reviews.

3.3 The IRB Chair or IRB designee shall designate whether informed consent exemptions or waivers of documentation of informed consent are applicable and appropriate with regard to research meeting expedited criteria.

3.4 The IRB Chair or IRB designee shall review consent documents or changes to consent documents meeting expedited review criteria.

3.5 The investigator is shall provide appropriately translated consent documents if there is the potential for or actual inclusion of non-English speaking participants. Translated consent documents must be accompanied by a letter from the translator attesting to the accuracy of the translated consent.

3.6 The investigator shall provide in the IRB submission a detailed description of the consent method, process, timing, and steps implemented to reduce undue influence.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24
21 CFR 56.109 (c), 56.109 (d)
38 CFR 16
45 CFR 46.116
45 CFR 46 Subpart A
45 CFR 46 Subpart B
5. REFERENCES TO APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 303C: Meeting Minutes
SOP 304: Documentation, Document and Data Management
SOP 501: Special Populations
SOP 603A: Veterans Affairs Health Care System
SOP 603F: Department of Defense

6. ATTACHMENTS

701-A Informed Consent Template (HSC)
701-A-1 Informed Consent to Participate in a Research Study (NC)
701-A-2 Informed Consent Information Sheet (NC)
701-A-3 Assent to Participate in a Research Study (NC)
701-B Child Assent Template
701-C Tissue Consent Template
701-D Patient Information Sheet – Tissue Banking
701-E Template for Informed Consent Addendum
701-F Translator Statement (NC)
502-G-A Sample Consent Form for Emergency Use
203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 Submitted items are processed by the IRB Administrator per SOP 301: Research Submission Requirements.

7.2 The IRB Administrator shall review the consent documents to ensure all required and additional elements are present, if applicable, prior to assigning the research project to the IRB reviewer.

7.3 For submissions that require a review of the consent process or of the consent documents, the IRB, the IRB Chair or IRB designee will review the proposed consent process, the content of the consent document, the presence/absence of required/additional elements, presence/absence of exculpatory language, and/or any language that disclaims or limits the warranty of drugs or devices beyond the efficacy of the drug or devices. The IRB will either approve the consent process/document as is or make recommendations for changes.

7.4 When the revised submission materials are returned by the investigator, the IRB Administrator will confirm that all of the changes have been made and will assign the materials to the IRB Chair or IRB designee for review. If the IRB Chair or IRB designee determines that convened
Board review is necessary, the IRB Administrator will post the item to the next appropriate meeting agenda.

7.5 In the event the consent process or consent document is in a language other than English, the IRB must receive appropriately translated documents and a signed attestation from the translator and then assess the consent process.

7.6 The IRB Administrator will document in the IRB meeting minutes, per SOP 303C: Meeting Minutes, the outcome of any IRB discussion related to the consent process or the consent document including, but not limited to:

- Use of non-English documents and use of translator
- Use of surrogate consent from a legally-authorized representative
- Consent requirements related to children, prisoners, pregnant women, and fetuses
- Waiver of consent, alteration or deletion of consent elements, or waiver of documentation of consent
- Letters of tribal support when research involves Native Americans/American Indians as a group

7.7 Once IRB has approved the consent documents, the IRB Administrator will apply the IRB stamp to each page of the consent document, assent document (if applicable), or short form (if applicable), per SOP 304: Documentation, Document and Data Management. The IRB Administrator will provide a stamped version of the consent document to the investigator and maintain a copy of the stamped consent document in the IRB’s electronic information system.

APPROVED BY: ________________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 801: INVESTIGATOR QUALIFICATIONS AND RESPONSIBILITIES

1. POLICY

The purpose of this policy is to outlines the qualifications and responsibilities of the principal investigator and key personnel, including student investigators, who are engaged in research involving human participants. All key personnel are qualified by training and experience for their roles and responsibilities in conducting research.

Principal investigators are obligated to design and conduct human participant research in accordance with the policies of the IRB, institutional policies, the ethical principles of the Belmont Report, and federal and state law and regulations.

Specific Policies

1.1 Qualifications for Serving as Principal Investigator.

The principal investigator of a research project involving human participants must hold a regular full- or part-time paid faculty or staff appointment. Employees of institutions under which the University’s IRB is the designated IRB and who will conduct research under the University’s FWA may also serve as principal investigators.

1.1.1 Sub-Investigators on the HSC Campus

Students, fellows, or residents may serve as a sub-investigator under the supervision of a faculty member but may not serve as a Principal investigator (nor as Co-Principal investigator) of a research project. Retired faculty with a Professor Emeritus status may also only serve as a sub-investigator.

1.1.2 Staff and Students on the Norman Campus

For staff on the Norman Campus to serve as a principal investigator or supervise graduate student researchers, staff must submit their research credentials for IRB review.

Graduate students on the Norman Campus may serve as a Principal investigator provided that the following criteria are met:

a. The research project must include a Faculty Sponsor who will provide assurance that the student meets the qualifications. The student must submit a “Student as Principal investigator” form as part of the submission requirements.

b. The graduate student must be:
   a. fully admitted and degree seeking in an academic program;
   b. in good academic standing, and
   c. enrolled in classes.

1.2 Additional Qualifications for Investigators Holding an IND/IDE.

Investigators holding an IND or IDE assume sponsor responsibilities for the conduct of the research, as described in 21 CFR 312 or 812 and Good Manufacturing Practices. Each research faculty and/or staff member signs a written attestation agreeing to abide by applicable federal regulations pertaining to IND/IDE research. For additional information regarding IND/IDE, refer to SOP 502A: Categories of Research Drugs.
When an investigator holds an IND/IDE, the investigator is responsible for adhering to sponsor responsibilities in addition to investigator responsibilities per SOP 802: Sponsor Responsibilities.

1.3 Education Responsibilities.

Investigators and key personnel engaged in research involving human participants must complete initial and continuing education regarding the responsible conduct and oversight of research. Refer to SOP 102B: Key Personnel Education.

1.4 Review of Research Conducted by Persons with University of Oklahoma Appointments at Non-University Facilities.

Research carried out by persons with University of Oklahoma affiliations impacts the University, even if it is not conducted at University facilities. Any individual who has a University appointment, whether full- or part-time, salaried or voluntary, staff or faculty, is required to notify the appropriate IRB of his/her plans to conduct human participants research. The IRB Chair or IRB designee shall review such activities and determine whether the rights and safety of the participants are adequately considered by another IRB (See SOP 602G IRB of Record for further information). If no IRB review has taken place, or if the IRB Chair or IRB designee has sufficient concerns about the research project, the research shall not proceed until those concerns have been adequately addressed by the IRB Chair or the convened IRB.

1.5 IRB Review of Research.

The principal investigator must obtain prior IRB approval before engaging in research involving human participants, except in the case of an emergency exemption from IRB review (See SOP 403: Initial Review - Initial Criteria for IRB Approval and SOP 502G: Emergency Use of FDA Regulated Products).

1.6 Responsible Conduct of Research.

Principal investigators engaged in research involving human participants are responsible for:

1.6.1 Designing protocols that minimize risks to participants and maximize benefit.

1.6.2 Providing for the safety and welfare of the participants enrolled.

1.6.3 Conducting the research in compliance with the IRB-approved research protocol, the applicable regulations, and in accordance with the principles of the Belmont Report.

1.6.4 Control of FDA test articles under investigation.

1.6.5 Personally conducting the research and supervising all sub-investigators and key research personnel involved in the research.

1.6.6 Reviewing and attesting to the accuracy of all electronic submissions submitted to the IRB for review prior to applying their electronic signature to the submission.

1.6.6 Complying with the Belmont Report, IRB policies, institutional policies, and applicable federal and state law and regulations.

1.6.7 Not enrolling participants prior to IRB approval or on or after expiration of IRB approval.

1.6.8 When the investigator is the lead investigator of a research project that involves multiple research institutions, the principal investigator must submit a multi-site management plan which documents plans for:

- communication process between sites; and
• The management of information obtained during the course of the research project, such as:
  o Unanticipated problems involving risks to participants or others
  o Protocol deviations
  o Interim results reporting
  o Protocol modifications

The IRB will evaluate the management plan as it relates to the protection of participants to assess that it is adequate.

For a VA multi-site research project, the investigator and the local site investigators must obtain written approvals from the relevant local VA facilities’ IRBs of record and all other local committees, subcommittees, and other approvals according to the respective and applicable local, VA and other federal requirements. A research project cannot be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local associate chief of staff for research and development.

1.6.9 If the principal investigator determines that the participant is to be removed from the research project for non-compliance, the investigator should notify the participant in writing of this action if the participant can be reached.

1.6.10 The principal investigator whose research is both sponsor-initiated and sponsor funded are responsible for performing their research in accordance with Good Clinical Practice (GCP) as defined by the Food and Drug Administration (FDA). GCP applies only for clinical research and it is not applicable to non-clinical research.

Investigators are subject to QI evaluations to determine knowledge and, if applicable, compliance with 21 CFR 312 or 812 and Good Manufacturing Practice.

1.7 Informed Consent

The investigator must obtain either an IRB approved informed consent prior to conducting any research activities or an IRB approved waiver of consent, per SOP 701: Consent Process and Documentation.

The investigator must use the informed consent documents and conduct the consent process as approved by the IRB.

1.8 Modifications

The principal investigator must submit in writing any proposed modifications in the research project or informed consent documents for IRB approval before initiating the change, except when necessary to eliminate apparent immediate hazards to human participants (as described in SOP 405: Modifications).

The principal investigator may not enroll more participants than approved by the IRB without obtaining IRB approval for increased numbers.

1.9 Continuing Review

For Expedited and Full Board studies, approval for a research protocol will be effective for only up to one year and is dependent on the risk involved with the research. The principal investigator must submit for approval a continuing review submission prior to the expiration of the research project (as described in SOP 404: Continuing Review).
1.10 Reporting Responsibilities

1.10.1 The principal investigator must promptly report to the IRB:

- any unanticipated problems involving risks to participants or others as described in SOP 407: Protocol Deviations and Unanticipated Problems. The sponsor must be notified, when applicable.
- protocol deviations as described in SOP 407: Protocol Deviations and Unanticipated Problems. Protocol deviations may or may not place participants at risk. The sponsor must be notified, when applicable.
- Any allegations of non-compliance and/or scholarly misconduct to the IRB as described in SOP 903: Non-Compliance/Scholarly Misconduct.

1.10.2 Principal investigators holding an IND/IDE must comply with the reporting requirements of the FDA under 21 CFR 312.32 (c) and 21 CFR 812.150 (b) (1) for serious adverse events and unanticipated device events related to the investigational article. Principal investigators must also comply with the annual reporting requirements of the FDA outlined by 21 CFR 312.33.

1.10.3 Principal investigators holding an IND/IDE will be subject to site evaluation as described in SOP 901: Quality Improvement Program in order to ensure compliance with federal regulations 312, 812 and Good Manufacturing Practices.

1.11 Record Keeping Responsibilities

The principal investigator must maintain appropriate research-related records. All research records must be available for inspection by authorized representatives of federal regulatory agencies, the sponsor, the University, and the IRB.

The principal investigator must maintain, as appropriate:

- A list of qualified persons to whom the principal investigator has delegated significant research-related duties
- Signed and dated consent documents
- Research privacy forms
- All records submitted to the IRB with evidence of approval
- All data collection forms
- All adequate records of the disposition of the drug or device
- Participant enrollment log
- Signed and dated CVs for all principal investigators and sub-investigators
- Signature sheet documenting signatures and initials of all persons authorized to make entries or corrections on data collection forms
- Monitoring reports to document findings of monitoring the research project
- All other research-related records related to study administration or data analysis

1.12 Conflict of Interest

The principal investigator is responsible for disclosing to the IRB all potential conflicts of interest for any member of the research team in compliance with SOP 104A: Conflict of...
Interest-Investigators. Conflicts of interest must be reported at initial submission and updated as appropriate.

1.13 Investigator Manual

The Investigator Manual is available on the OU HRPP website for additional information and guidance.

2. SCOPE

This SOP applies to all investigators involved in human participant research activities.

3. RESPONSIBILITY

3.1 HRPP Director or designee is responsible for tracking investigator compliance with IRB requirements stipulated during the IRB’s review of the investigator’s research and for implementing appropriate remedial action when investigators are not in compliance with IRB requirements.

3.2 IRB Chair or IRB designee is responsible for facilitating investigator compliance with IRB requirements through his/her management of IRB deliberations and providing investigators clear guidelines pertaining to compliance through IRB communications to the investigator.

3.3 The investigator is responsible for conducting research that is in compliance with the Belmont Report, IRB policies, federal law/regulations, state law/regulations, and institutional policy.

3.4 The investigator is responsible for ensuring research staff conduct research that is in compliance with the Belmont Report, IRB policies, federal law/regulations, state law/regulations and institutional policy.

3.5 The investigator is responsible for reporting any allegations of non-compliance with applicable laws, regulations, or policies and/or scholarly misconduct to the IRB as described in SOP 903: Non-Compliance/Scholarly Misconduct.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111
21 CFR 54
45 CFR 46.109, 46.111
21 CFR 312
21 CFR 812

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 102B: Key Personnel Education
SOP 104: Conflict of Interest-Investigators
SOP 403: Initial Review
SOP 404: Continuing Review
SOP 405: Modifications
SOP 407: Protocol Deviations and Unanticipated Problems
SOP 502A: Categories of Research Drugs
SOP 502G: Emergency Use of FDA Regulated Products
SOP 602G: IRB of Record
SOP 701: Consent Process and Documentation
SOP 802: Sponsor Responsibilities
SOP 901: Quality Improvement Program

6. ATTACHMENTS

801-A Investigator’s Manual
801-B NC Staff as Principal Investigator Form
801-C NC Student as Principal Investigator Form
801-D HSC Faculty Handbook- Section 3.25, Ethics in Research
801-E NC Faculty Handbook- Section 3.26, Ethics in Research
801-F University of Oklahoma Compliance and Quality Improvement Program- Section X, Response and Prevention

7. PROCESS OVERVIEW

7.1 Upon receipt of a new submission, IRB Staff confirms eligibility of key personnel to conduct research. The IRB will not accept new research project submissions that include key personnel who have not completed the required IRB education. Residents, fellows, and graduate students are not allowed to serve as principal or co-principal investigators at the HSC campus. Eligibility issues must be resolved prior to assigning the submission to an IRB reviewer.

7.2 The IRB Administrator assists investigators with preparing IRB submissions, securing initial and ongoing approval of research, and providing required reports to the IRB.

7.3 The HRPP Director provides guidance to the IRB Education Coordinator regarding curriculum development for training investigators and research team members.

7.4 The HRPP Program provides investigators and research team members with appropriate training on the responsibilities and conduct of human participant research.

7.5 The IRB Staff and IRB Chairs identify allegations of investigator non-compliance and report such immediately to the HRPP Director.

7.6 The QI Coordinator identifies areas of education improvement for investigators and research team members as a part of the ongoing evaluation process.

7.7 The QI Coordinator conducts periodic evaluations of all IND/IDE holding-investigators.

7.8 The QI Coordinator sends notices to all IND/IDE holding-investigators regarding annual reports to the FDA.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 802: SPONSOR RESPONSIBILITIES

1. POLICY

When an investigator holds an IND/IDE, the investigator acts as the sponsor of the study and is responsible for adhering to sponsor responsibilities in addition to investigator responsibilities.

The IRB expects the sponsor to adhere to ethical principles and monitor the conduct of the research in accordance with federal regulations and Good Clinical Practice as described by FDA when the research project is industry-sponsored and industry-funded.

Sponsors are responsible for selecting qualified investigators, providing them with the information necessary to conduct an investigation properly, monitoring the investigation(s), verifying that the investigation is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and informing the FDA and all participating investigators of unanticipated problems involving risk to participants or others with respect to the drug or device.

Specific Policies

1.1 IRB Review of Research

The sponsor must require that human participant research be reviewed and approved by the IRB before any research-related procedures or interventions are initiated.

1.2 Informed Consent

The sponsor must require investigators to obtain informed consent from participants before any of the research activities involving that participant are initiated. The sponsor shall require that investigators use the informed consent document approved by the IRB.

1.3 Reporting Requirements

The sponsor must report any unanticipated problems involving risks to participants or others to the investigator for prompt reporting to the IRB, including anticipated events occurring at a higher-than-expected frequency. Additionally, if the research project involves a Data Safety Monitoring Board (DSMB), the sponsor must provide periodic DSMB reports to the investigator for reporting to the IRB during the time the study is open and for two years following closure of the study or as otherwise indicated in the clinical trial agreement. Refer to SOP 407: Protocol Deviations and Unanticipated Problems, for reporting unanticipated problems involving risks to participants or others.

The sponsor must communicate with the investigator and IRB any information that may be contained in a monitoring report or that may be a summary of the sponsor’s assessment that could affect the rights or welfare of the research participants or their willingness to continue in the research project. Examples include, but are not limited to, major protocol deviations, failure to obtain informed consent, misuse of investigational drugs or devices, or fraud.

1.4 Modifications

The sponsor must provide any change in the research project or informed consent documents to the investigator for submission to the IRB for approval. Changes in approved research during the period for which approval has already been given may not be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to human participants. Any changes that are implemented prior to IRB approval are considered protocol deviations.
1.5 Continuing Review

The sponsor must verify that the investigator has obtained IRB continuing review approval prior to the expiration of the current approval. Additionally, if the sponsor has information that relates to research project results that could affect the risk/benefit of the research or willingness of participants to participate, the sponsor must provide that information to the investigator for submission to the IRB.

1.6 Communication with the Sponsor

If appropriate, the IRB may communicate directly with the sponsor. For example, the IRB will notify the sponsor in writing if the IRB suspends or terminates a research project.

2. SCOPE

This SOP applies to all human participant research activities.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for tracking sponsor compliance with IRB requirements and for notifying the HRPP Director and IRB Chair of non-compliance.

3.2 The IRB Chair is responsible for facilitating compliance with IRB requirements through his/her management of IRB deliberations and for providing sponsors with clear guidelines pertaining to that compliance through IRB communications to the sponsor.

3.3 The investigator is responsible for ensuring a written agreement containing the aforementioned requirements is executed prior to commencement of research activities as required in SOP 602C: Office of Research Administration-OUHSC.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111
21 CFR 54
45 CFR 46.109, 46.111

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 407: Protocol Deviations and Unanticipated Problems
SOP 602C: Office of Research Administration -OUHSC

6. ATTACHMENTS

None.

7. PROCESS OVERVIEW

7.1 The sponsor will provide the investigator with the protocol, consent documents, investigator Brochure, and any supporting documents. The investigator and/or research team will incorporate the sponsor’s consent template into the IRB consent documents. The investigator submits the research project materials to the IRB in the IRB’s electronic information system.

7.2 The investigator will utilize the consent documents approved by the IRB to obtain consent from participants of the research project. Any changes to the consent documents must be approved as a modification by the IRB prior to initiating any changes.

7.3 Unanticipated problems involving risks to participants or others are reported to the IRB by the investigator. Prompt reporting is essential, as unanticipated problems may require a change to the consent documents and/or protocol.
7.4 The investigator will submit the continuing review documents to the IRB. The sponsor is responsible to provide any DSMB information, publication information, and any risk information to the investigator for inclusion on this submission to the IRB.

7.5 The sponsor shall report to the IRB or University any findings of serious or continuing non-compliance detected during the monitoring process that could affect the safety of participants or influence the conduct of the research. Communication to and from the sponsor is typically channeled through the investigator. However, in some situations, it may be appropriate for the IRB and sponsor to communicate with one another directly.

APPROVED BY:______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The Human Research Participant Protection (HRPP) Quality Improvement (QI) Program monitors the effectiveness of the HRPP program. Effectiveness of the Program is measured through routine, for-cause, internal, and self-assessment evaluations, plus observation of the informed consent process for compliance with University policies and procedures, applicable federal regulations, and Oklahoma law. The primary tools used for conducting investigator evaluations, as well as the tool for investigator self-assessment, are the applicable regulations and Good Clinical Practice.

The goals of the Quality Improvement Program are to:

- Determine if the rights and welfare of research participants are being properly protected in accordance with the Belmont Report University policy, IRB policy, applicable federal law/regulations, and Oklahoma state law.
- Determine if research protocols are being implemented as approved by the IRB.
- Monitor the informed consent process to determine outcome and areas of needed improvement.
- Confirm all research team members have completed required HRPP training.
- Promote open communication between the IRB and the research team.
- Provide additional education to the research team.

The evaluations under the QI program are different from the IRB site inspection, as outlined in SOP 903: Non-Compliance/Scholarly Misconduct.

Specific Policies

1.1 Routine Evaluations

Routine QI evaluations of research sites are periodically performed through selection of protocols by the HRPP or at the request of the investigator.

Investigator-initiated studies in which the investigator holds an IND/IDE are given priority for routine evaluation. In these circumstances, the investigator is evaluated to ensure compliance with the additional regulatory requirements. These requirements are outlined in SOP 802: Sponsor Responsibilities. During routine evaluation of investigator-initiated studies in which the investigator assumes the role of the sponsor, the QI Coordinator evaluates whether the investigator is knowledgeable about the regulatory requirements of sponsors and is complying with those requirements.

Studies may be evaluated post-inactivation to ensure proper documentation is maintained and all study activities have ceased.

For VA research projects:

The IRB may also consider the routine Veterans Affairs’ Research Compliance Officer’s triennial compliance and quality improvement study evaluations and informed consent reviews, as applicable.
The IRB may require more frequent evaluations by the research compliance officer or by other means. The IRB also may require the research compliance officer to conduct more focused evaluations of one or more aspects of the study. The requirement to increase the frequency of evaluations or to evaluate specific aspects of the study might be based on considerations including, but not limited to:

- Involvement of vulnerable populations.
- Level of risk.
- Phase I or Phase II studies.
- Involvement of FDA approved drugs for which there has been a new safety warning issued or change in the labeling that indicates increased risks.
- Issues of noncompliance.
- Data confidentiality or security concerns.
- Studies that are not subject to Continuing Review.

1.2 For-Cause Evaluations

For-cause evaluations of research sites occur as a result of known or suspected problems in the conduct of human participant research. Results of for-cause evaluations will be promptly reported to the HRPP Director and to the IRB that requested the evaluation for review and determination.

1.3 IRB Internal Evaluations

Routine QI evaluations of IRB operations are conducted to review and assess the IRB records that include submissions, actions of the convened IRB or IRB Chair or IRB designee, membership rosters, and minutes.

Routine assessment of IRB SOPs is a function of the HRPP Director and/or Director of Compliance to determine if SOPs are in compliance with applicable federal and state law/regulations and University policy.

The HRPP shall measure and improve the program’s effectiveness; quality; and compliance with University policies and procedures and applicable federal, state, and local laws.

Improvements to the HRPP program shall be implemented based upon measures identified through routine evaluations of the program. These improvements include providing education programs, providing IRB member and staff training, revising policies and procedures, and making any necessary changes to the IRB’s electronic information system.

The improvements shall be monitored and measured by the HRPP program to determine the effectiveness. If necessary, additional improvements shall be implemented.

1.4 Investigator Self-Assessment Evaluations

Investigators may choose to evaluate effectiveness and improve quality of their research through a self-assessment, which allows investigators to identify areas needing improvement. Investigators may obtain the Self-Assessment Evaluation checklist from the IRB website. The checklist helps investigators identify areas of needed improvement by following an algorithmic approach. This model is offered as a resource for investigators to promote their own quality improvement at their research sites.
1.5 Observing Research Activities and the Consent Process

The IRB has the authority to observe, or have a third party observe research activities, including the informed consent process it has approved, and to verify that the research project is being conducted as required by the IRB and within the University policies and procedures and site- and agency-specific procedures, as appropriate. Before the IRB or third party observes the consent process, verbal consent of the participant must be sought. Mechanisms by which observation of the consent process might be implemented, utilizing the “Consent Form Observation Checklist,” include, but are not limited to, the following situations:

A. The HRPP Director or the IRB may choose to have research activities, including the consent process, observed as part of the QI Program for routine evaluation, for-cause evaluation, or education.

B. The IRB may determine it is necessary to observe research activities, including the informed consent process, in order to provide additional protections and may conduct informed consent observations in the following situations:
   1. Non-compliance per SOP 903: Non-Compliance/Scholarly Misconduct;
   2. Unanticipated problems involving risks to participants or others per SOP 407: Protocol Deviations and Unanticipated Problems;
   4. Participant complaints, or
   5. Any other situation the IRB deems appropriate where additional protections are necessary.

Additionally, investigators may be asked to submit copies of signed informed consent documents or other documents to ensure their compliance with IRB requirements. The IRB may conduct interviews with screened and/or enrolled research participants as deemed necessary.

Results from the Observation of the Informed Consent Process will be reported as outlined in Section 1.6 of this policy.

1.6 Reporting of QI Outcomes

All QI findings are confidential and are not disclosed to entities outside the University, unless otherwise required by applicable state or federal law. All QI evaluations are conducted for quality improvement purposes and should not be viewed as punitive. Findings/results from the evaluations are reviewed at least annually during IRB Executive Meetings, with emphasis on evaluation of the overall effectiveness of the HRPP program and suggestions for educational improvement. Any concerns about the QI program should be directed to the HRPP Director.

2. SCOPE

This SOP applies to all research being conducted under the University’s FWA.

3. RESPONSIBILITY

3.1 The HRPP Director and/or a QI Coordinator are responsible for identifying protocols for routine evaluations, including identifying those studies that are investigator-initiated in which the investigator holds the IND/IDE, and for identifying internal evaluation needs.
3.2 A QI Coordinator is responsible for conducting routine and for-cause evaluations to monitor and measure the effectiveness of HRPP.

3.3 A QI Coordinator is responsible for providing feedback of the evaluation to the investigator, HRPP Director, IRB Chair or IRB designee, and IRB Education Coordinator.

3.4 The IRB Chair or IRB designee is responsible for notifying the HRPP Director and the QI Coordinator of any for-cause evaluations requested by the IRB or as required under SOP 903: Non-Compliance/Scholarly Misconduct.

3.5 Investigators are responsible for conducting ethical and lawful research. Investigators are also required to grant access to research materials so that an evaluation can occur and to cooperate in such an evaluation.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56
38 CFR 16
45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 303C: Meeting Minutes
SOP 407: Protocol Deviations and Unanticipated Problems
SOP 701: Consent Process and Documentation
SOP 801: Investigator Qualifications and Responsibilities
SOP 802: Sponsor Responsibilities
SOP 903: Non-Compliance/Scholarly Misconduct

6. ATTACHMENTS

901-A HSC Quality Improvement Evaluation Form
901-A-1 NC Quality Improvement Evaluation Form
901-B Quality Improvement Self Assessment
901-C Consent Observation Checklist
901-D Inactivation Evaluation Form
901-E HRPP Evaluation Form
901-F HSC Meeting Minutes Checklist
901-F-1 NC QI Checklist for IRB Minutes

7. PROCESS OVERVIEW

7.1 Procedures for Routine Evaluation

7.1.1 A QI Coordinator, with input from the HRPP Director, will query the IRB’s electronic information system to determine those studies that are investigator-initiated studies using FDA regulated items (particularly those in which the investigator holds the
IND/IDE) or sponsored/non-sponsored studies considered to be high-risk to participants and/or the University.

7.1.2 From the studies identified, the QI Coordinator will select the study or group of studies to be evaluated. Then the QI Coordinator contacts the investigator to schedule the evaluation.

7.1.3 The evaluation of the study is conducted using an evaluation tool (attachment 901-A or 901-D) and may also include evaluating the consent process.

7.1.4 The QI Coordinator drafts a report documenting evaluation findings and reviews the report with the HRPP Director and/or IRB Chair prior to distributing to the investigator.

7.1.5 The report addresses positive findings, areas for improvement, and action items, if applicable. If investigator misconduct or non-compliance is identified during the evaluation, SOP 903: Noncompliance/Scholarly Misconduct, shall be implemented.

7.1.6 The QI Coordinator distributes a copy of the report to HRPP Director, IRB Chair, and IRB Education Coordinator. The Department Chair and applicable federal entities may also be notified, depending on evaluation findings.

7.1.7 Results of routine evaluations are reviewed at least annually during an IRB Executive Committee meeting to evaluate the overall effectiveness of the HRPP program.

7.1.8 The QI Coordinator maintains documentation of correspondence concerning the evaluation.

7.2 Procedures of a For-Cause Evaluation

7.2.1 The HRPP Director, IRB, or Director of Compliance, or other University administrator may request a for-cause evaluation of any study. Justification for the evaluation shall be documented in writing and must include all of the relevant information to support the need for the evaluation.

7.2.2 The investigator is contacted regarding the for-cause evaluation to schedule the evaluation. However, it may be necessary to conduct a for-cause evaluation without first notifying the investigator (for example, where there is or may be increased risk of harm to participants or others).

7.2.3 The evaluation of the study is conducted, which may also include evaluation of the consent process, in accordance with the IRB SOPs.

7.2.4 Results of For-Cause evaluations will be promptly reported to the HRPP Director and the requesting IRB for determinations.

7.2.5 Sponsors and/or sites may be asked to submit copies of the sponsor’s monitoring reports or to provide additional information regarding the research project and/or the research site.

7.3 Procedures for Routine Internal HRPP Program Evaluations

7.3.1 Internal HRPP evaluations are ongoing and may include the following activities conducted by the QI Coordinator and/or HRPP Director:

A. Review IRB meeting minutes using the applicable campus checklist to measure whether elements outlined in SOP 303C: Meeting Minutes, are included as appropriate. This includes:
1. Quorum
2. Recusal
3. Consultants
4. Protocol specific findings
5. Appropriate IRB actions.

B. Review random selection of research projects to measure the following:
   1. Accuracy of category selection for Exempt and Expedited research projects
   2. Use of checklists (by IRB staff and IRB reviewers)
   3. Accuracy and completeness of correspondence
   4. Actions appropriately posted to agenda

C. Evaluate pending items to close out and to identify areas of deficiencies.

D. Check file room to ensure the file system is organized and maintained in a functional manner.

E. Check Notice of Study Expiration letters to ensure prompt notification to the investigator of an expiration.

F. Evaluate IRB Member knowledge and application of regulations and policies and procedures:
   1. Monitor use of checklists for areas in need of improvement
   2. Educate IRB staff on areas in need of improvement
   3. Monitor outcomes and provide education as needed

G. Evaluate IRB Staff knowledge and application of regulations and policies and procedures.

H. Monitor and evaluate internal processes of IRB staff and their work product

I. Implement education to focus on areas in need of improvement

J. Monitor outcomes and develop or modify training programs to improve practice

K. Perform other evaluations as determined by HRPP Director

7.3.2 The objectives of internal evaluation exercises are to determine adherence to the Belmont Report, federal regulations, state law, University policy, and IRB policy. Outcomes of the internal evaluations are used to address educational issues involving IRB Administrators and IRB Chairs and Board members.

7.3.3 The QI Coordinator discusses internal evaluation findings with the HRPP Director at the conclusion of an evaluation exercise.

7.3.4 The HRPP Director or designee and/or Director of Compliance periodically review IRB SOPs for quality improvement.

7.4 Procedures for Investigator Self-Assessment Evaluations

7.4.1 Investigators may complete the QI Self-Assessment Form. It is not mandatory; it is a voluntary checklist the investigator is encouraged to download and complete
independently to determine areas of strength and weakness at the investigator’s research site.

7.4.2 The objectives for investigator self-assessment include, but are not limited to:

- Promote quality improvement at the University.
- Educate investigators on compliance with the Belmont Report, federal regulations, state law, University policy, and IRB policy.
- Foster open communication between the IRB and investigators regarding such law, regulations, and policies.

7.4.3 A QI Coordinator is available to the investigator to answer any questions the investigator may have at the conclusion of a self-assessment evaluation.

7.4.4 A QI Coordinator provides anecdotal feedback to the HRPP Director and/or IRB Education Coordinator as needed.

7.5 Procedures for Observing the Consent Process

7.5.1 The IRB shall observe the informed consent process to verify compliance or as part of the QI program. Site visits will be conducted in accordance with this policy.

7.5.2 During a consent process observation:

- The consent process shall be reviewed to determine outcome and areas of improvement.
- The consent process shall be reviewed to confirm consent is being conducted in accordance with the Belmont Report, applicable federal regulations, state law, University policy, and IRB policies.
- The informed consent documents shall be reviewed to ensure the most current IRB-approved version is being used.
- Any other materials shall be reviewed as necessary.

7.5.3 A third party may be asked by the IRB Chair or IRB designee to conduct the observation.

7.6 Overall evaluation of the HRPP program

The HRPP Directors shall conduct an evaluation of the HRPP program annually. The HRPP Evaluation Form shall be completed by the Education and Quality Improvement staff and evaluated by the HRPP Directors. The evaluation and proposed improvements shall be discussed with the Director of Compliance for the NC or the HSC Vice President for Research, as appropriate, and the relevant IRB Executive Committees. The Education and Quality Improvement staff shall implement changes and improvements under the direction of the HRPP Directors.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 902: AUDITS BY REGULATORY AGENCIES

1. POLICY

The University acknowledges that certain regulatory agencies have the responsibility and authority to audit the operations of IRBs and supports such audits as part of its continuing effort to maintain high standards for human participant research protection.

Entities that may audit IRBs include, but are not limited to, FDA, OHRP, and appropriate certified auditors of foreign countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

Specific Policies

1.1 Audit Preparation & Participation

Preparation includes notification of Institutional Officials; organization of all IRB documents; and allocation of staff, space, and equipment.

The HRPP Director or designee orients the auditor to the IRB Office and ancillary facilities. A daily and final exit interview is requested.

1.2 Follow-up after the Audit

The HRPP Director will provide reports of the audit, either verbal or written, to Institutional Officials or designees as soon as possible following the audit.

2. SCOPE

This SOP applies to both the HSC IRB and the Norman Campus IRB.

3. RESPONSIBILITY

The Institutional Official is responsible for answering to all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in response to and correction of audit findings.

The HRPP Director or designee and the Director of Compliance will serve as the key institutional contacts during such audits. In conjunction with the IRB Chair and/or the Director of Compliance, the HRPP Director will draft policy and procedural changes as indicated by such audit.

The HRPP Director or designee, with assistance from the Director of Compliance and/or IRB Chair, is responsible for all formal regulatory agency correspondence and interactions and for establishing logistical support during regulatory agency audits.

The IRB Chair, IRB members, and IRB staff are responsible for participating in regulatory agency audits as determined by the HRPP Director and for fully cooperating with government officials during their participation in such audits.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115
45 CFR 46.115

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

5. REFERENCES TO OTHER APPLICABLE SOPS

None.
6. ATTACHMENTS

None.

7. PROCESS OVERVIEW

Audit Preparation & Participation

7.1 For external audits involving OHRP or FDA or other regulatory agencies, the HRPP Director notifies the following individuals immediately:

- Senior Vice President and Provost or designee
- Director of Compliance (for the NC)
- HSC Vice President for Research
- IRB Chair
- Legal Counsel
- Sponsor of study, if required

7.2 The HRPP Director or designee will organize and make available to the auditor an organizational chart, IRB documents (i.e., membership rosters, policies, procedures, investigator manuals), IRB study files, agendas, and minutes.

7.3 The HRPP Director or designee will provide auditors with an adequate work area and necessary equipment (i.e., telephone, copy machine).

7.4 Senior Institutional Officials or designees and HRPP/IRB staff and members are available for interviews and/or to assist the auditor. HRPP/IRB staff and members make every reasonable effort to be available and to accommodate and expedite the requests of auditors.

7.5 Prior to being granted access to IRB documentation, inspectors and auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents. No entity or person other than those listed on the consent documents may access any document that includes participant identifiers, except as otherwise provided by law.

7.6 The HRPP Director provides the auditor a brief orientation of the IRB office system.

7.7 The HRPP Director or designee will ask the auditor to give the HRPP Director or designee a daily and final exit interview to provide an opportunity for the IRB to answer questions or address problems.

7.8 Only individuals authorized in writing by the HRPP Director or by law may copy documents and take them off-site. An additional copy of all documents provided to the auditor is made and kept in the IRB Office files.

7.9 If the auditor requests interviews with HRPP/IRB staff and/or IRB members, the HRPP Director or designee will receive the names of the interviewees and arrange for their presence.

7.10 Notes on the audit and copies of all documents that are reviewed will be placed in a folder or notebook so that responses can be made quickly and easily regarding any questions and/or concerns by the auditor.

7.11 Responses to the audit, either verbal or written, are addressed by the Senior Vice President and Provost or designee, with the assistance and support of the Director of Compliance for the NC, HSC VPR for HSC, HRPP Director, Legal Counsel, and/or IRB Chair, as soon as possible after the audit.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 903: NON-COMPLIANCE/SCHOLARLY MISCONDUCT

1. POLICY

The IRB takes seriously its role in assuring prompt reporting of violations of applicable laws and regulations, requirements or determinations of the IRB, and allegations of scholarly misconduct made about researchers, staff, students, other employees, and/or members or consultants of the IRB from the University as well as from other sites operating under the auspices of the IRB. All researchers, staff, students, other employees, and/or members or consultants of the IRB from the organization as well as from other sites operating under the auspices of the IRB shall report any allegations of violations of applicable laws and regulations, requirements or determinations of the IRB, and/or scholarly misconduct to the IRB and/or the appropriate University officials.

The IRB may address issues of human research non-compliance in SOP 407: Protocol Deviations and Unanticipated Problems, as well as in this policy. The University also addresses issues of research non-compliance as described in the University’s Ethics in Research and Compliance policies.

All credible reports of non-compliance and allegations of scholarly misconduct made to the IRB are referred to the Director of Compliance (for Norman Campus (NC) allegations) or the Health Sciences Center (HSC) Vice President for Research (for HSC allegations), as appropriate, and reported to the Senior Vice President and Provost or designee for the applicable campus.

Reports of non-compliance or scholarly misconduct may come from any source including IRB members, investigators, participants, University personnel, the media, anonymous sources, or the public.

The IRB has the authority to suspend or terminate approval of human research that is not being conducted in accordance with the IRB policies; is not in compliance with local, state, federal or foreign law and/or regulations; has been associated with unexpected serious harm to participants; or involves allegations of scholarly misconduct.

It is the responsibility of the IRB staff and IRB members to act on information or reports received from any source that indicates a human research project being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of human research participants.

Specific Policies

1.1 Scholarly Misconduct

If an incident of scholarly misconduct is reported to the HRPP Director, the HRPP Director shall notify the Director of Compliance or HSC Vice President for Research, as appropriate, and the Senior Vice President and Provost or designee, in accordance with the University’s Ethics in Research Policy.

1.2 Non-Compliance

Non-compliance is defined as a proven failure to follow the regulations or the requirements and determinations of the IRB.

1.2.1 Technical non-compliance is defined as non-compliance that is neither serious nor continuing non-compliance. To the extent that technical non-compliance is addressed by other University policies, the corrective actions in this policy shall be in addition to and not in lieu of any actions or sanctions provided under such other policies.

Examples of technical non-compliance:
• late submission of a continuing review, although within the required timeframe for review and approval prior to the expiration date
• failure to complete IRB education requirements in a timely fashion
• failure to submit a Modification/Notification Form regarding minor changes to a human research project that do not involve risks to participants

1.2.2 Serious non-compliance is defined as disregarding or failing to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB.

Examples of serious non-compliance:
• failure to provide a Continuing Review Report
• failure to report serious adverse events
• failure to obtain IRB approval prior to implementation of a change in the human research protocol (unless the change is to prevent imminent harm to current participants)
• conducting human research without IRB approval
• failure to provide IRB requested information
• failure to obtain informed consent from a participant

For purposes of VA research projects, serious non-compliance is defined as a failure to follow requirements for conducting human research that may:
• Present a genuine risk of substantive harm to the safety, rights, or welfare of human research participants, research staff, or others.
• Substantively compromise the effectiveness of the VA facility’s HRPP.

1.2.3 Continuing non-compliance is defined as a pattern or repeated incidents of failure to comply with applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, or determinations of the IRB governing human participant research.

Examples of continuing noncompliance are patterns of or repeated failure to:
• provide Continuing Review
• report serious adverse events
• obtain IRB approval prior to implementation of a change in the human research protocol (unless the change is to prevent imminent harm to current participants)
• conduct human research without obtaining prior IRB approval
• provide IRB requested information
• obtain informed consent from a participant

For purposes of VA research projects, continuing non-compliance is defined as a persistent failure to adhere to the laws, regulations, or policies governing human research. The determination that non-compliance is “continuing” rests with the IRB.
1.3 Evaluation of Non-Compliance

1.3.1 When the IRB receives an allegation of non-compliance involving human participant research, the HRPP Director, QI Coordinator, and/or the IRB Chair will conduct an initial evaluation to determine if the allegation of non-compliance can be substantiated and whether the non-compliance is technical, serious non-compliance, and/or continuing non-compliance.

1.3.2 If the issues raised in the allegation cannot be completely resolved during the initial evaluation, or if the IRB determines the non-compliance might be serious or continuing, a For-Cause Evaluation will be conducted in accordance with SOP 901: Quality Improvement Program. The scope of the evaluation will initially be limited to the allegation but could expand as indicated by the evaluation findings.

Evaluation findings will be presented to the convened IRB and either the Director of Compliance or HSC Vice President for Research, as appropriate.

1.3.3 If the IRB makes the determination that the allegation meets any of the definitions of serious or continuing non-compliance, the HRPP Director shall report in writing the serious or continuing non-compliance to the appropriate Senior Vice President and Provost or designee and the matter is placed on the agenda of the next IRB meeting for review by the convened IRB.

1.3.4 The IRB shall consider how serious each event is in relation to the protection of participants or others, and whether the allegations of non-compliance are serious and/or continuing incidents.

1.4 Convened IRB’s Review of Serious or Continuing Non-Compliance

1.4.1 Documentation of the serious or continuing non-compliance shall be reviewed at the next convened IRB meeting. Documents will be provided to all members and may include evaluation reports and communications between the investigator and the IRB as well as any supplemental information such as relevant applicable laws and/or regulations, the ethical principles of the Belmont Report, IRB policies and procedures, and determinations of the IRB.

1.4.2 Corrective actions are based upon the nature and degree of the non-compliance. In the evaluation of non-compliance, the convened IRB may consider one or more of the following actions as appropriate:

- Modifying the protocol.
- Modifying the information disclosed during the consent process.
- Providing additional information disclosed during the consent process.
- Providing additional information to past participants.
- Notifying current participants when such information may relate to participants’ willingness to continue to take part in the research.
- Requiring current participants to re-consent to participation.
- Modifying the continuing review schedule.
- Monitoring the research.
- Monitoring the consent process.
- Suspending the research.
• Terminating the research.
• Referring non-compliance to other University offices.
• Requiring education for one or more members of the research team.
• Requiring increased reporting to the IRB.
• Restricting use of the research data for publication.
• Restricting or terminating the investigator’s research privileges.

1.4.3 Following the convened IRB review of the serious or continuing noncompliance, more than minor modifications to the approved protocol or research documentation shall be submitted as described in SOP 405: Modification/Notification, for review by the convened IRB.

2. SCOPE
This SOP applies to actions associated with allegations of non-compliance or scholarly misconduct in human research.

3. RESPONSIBILITY
3.1 All researchers, staff, students, other employees, and/or members or consultants of the IRB from the University as well as from other sites operating under the auspices of the IRB are responsible for reporting any allegations of violations of applicable laws and regulations, requirements or determinations of the IRB, and/or scholarly misconduct to the IRB and/or the appropriate University officials.

3.2 The Director of Compliance provides guidance and recommendations to the HRPP Director and the IRBs regarding non-compliance issues.

3.3 The HRPP Director is responsible for reporting in writing to the Director of Compliance and the appropriate Senior Vice President and Provost or designee any suspected or apparent or reported allegations of scholarly misconduct as well as any suspected or apparent or reported allegations of serious or continuing non-compliance.

3.4 The HRPP Director and IRB Chair are responsible for the initial review of allegations of non-compliance and for determining the appropriate course of action after the initial review of allegations.

3.5 The HRPP Director is responsible for reporting in writing serious and continuing non-compliance and suspension or termination of research to OHRP, FDA, sponsor, and/or VA Central Office per SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

4. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46.113
21 CFR 56.113
OU Faculty Handbook, Ethics in Research Policy
VHA Directive 1200.5

5. REFERENCES TO OTHER APPLICABLE SOPS
SOP 303C: Meeting Minutes
SOP 308: Reporting to Regulatory Agencies and Institutional Officials.
SOP 405: Modification/Notification
6. ATTACHMENTS

   901-A HSC Quality Improvement Evaluation Checklist
   901-A-1 NC Quality Improvement Evaluation Checklist

7. PROCESS OVERVIEW

7.1 Reports of Non-Compliance/Scholarly Misconduct

The IRB may receive reports of non-compliance or scholarly misconduct from a number of sources. Each report must be immediately forwarded to the HRPP Director for further evaluation and reporting.

Concerns of non-compliance may be identified at a convened IRB meeting or during the expedited review process for IRB submissions related to Continuing Review, Protocol Modifications, Protocol Deviations, Unanticipated Problems, and/or during a QI/Evaluation.

7.2 Review and Determination

7.2.1 Initial reports of allegations of non-compliance or scholarly misconduct can be made in person or by telephone, email, or letter. The HRPP Director will discuss and review the allegation with the IRB Chair and determine the appropriate course of action.

7.2.2 The HRPP Director reports all allegations of scholarly misconduct in human research in writing to the Senior Vice President and Provost or designee, who may report in writing allegations of scholarly misconduct to the federal Office of Research Integrity (ORI) if applicable.

7.2.3 Incidents of serious or continuing non-compliance are referred to the Director of Compliance.

7.2.4 If the IRB substantiates non-compliance, the HRPP Director or IRB Chair or IRB designee may direct the IRB Administrator to add the issue as a discussion item to the next available IRB meeting, the minutes of which are documented in accordance with SOP 303C: Meeting Minutes.

7.3 Evaluations of Non-compliance

7.3.1 If the IRB determines that non-compliance is serious or continuing, the non-compliance is reported to federal and University officials in accordance with SOP 308, Reporting to Regulatory Agencies and Institutional Officials.

7.3.2 Either the IRB Chair or IRB designee or the QI Coordinator or HRPP Education Coordinator continues to monitor and/or follow up on corrective measures instituted by the IRB and/or the investigator.

7.3.3 The HRPP Director provides follow-up reports to federal and/or Institutional Officials in accordance with SOP 308: Reporting to Regulatory Agencies and Institutional Officials.

APPROVED BY: __________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
1. POLICY

The HRPP/IRB/Privacy Board reviews requests for waivers or alterations of Authorizations with the goal of ensuring participant protected health information (PHI) that is accessed, created, acquired, disclosed, or maintained during the conduct of human participant research is protected in accordance with the Privacy Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), applicable state and federal laws, and the University HIPAA Privacy and Security Policies.

Under HIPAA, a covered entity must establish a Privacy Board or delegate authority to the IRB to serve as a Privacy Board to review uses and disclosures of PHI in research. The University has designated the IRB to serve as the Privacy Board for research.

The Privacy Board shall consist of at least two members with varying backgrounds and appropriate professional competency necessary to review the effect of research protocol on the research participant’s privacy rights. At least one member must not be affiliated with the University or any University research sponsor (or related to such individuals). No Privacy Board member shall review a project if the member has a conflict of interest (see IRB SOP 104B: Conflict of Members – IRB Members).

The University has designated a University Privacy Official and a HIPAA Security Officer who work to assure compliance with HIPAA regulations. The University Privacy Official and HIPAA Security Officer shall provide guidance on research-related HIPAA issues at the request of the Privacy Board or HRPP Director.

Specific Policies

1.1 Role of the Privacy Board

The Privacy Board shall review each research project submitted to the IRB and, if it determines that PHI is involved, ensure that appropriate HIPAA Authorizations/waivers are utilized.

Either the IRB or IRB Chair or IRB designee shall conduct the human research project review. The University’s HIPAA Privacy Official and/or HIPAA Security Officer shall be consulted as needed.

1.2 HIPAA Determinations

The Privacy Board shall make the following determinations:

1.2.1 Whether the written Authorization appropriately documents permission from the research participants for the University to collect, use, and disclose their PHI (Privacy Forms 1-4).

1.2.2 Whether a Waiver of Authorization is appropriate when direct permission from the research participant is either not necessary or not possible, and, based on documentation provided by an investigator on a Waiver of Authorization document (Privacy Form 5), whether the use or disclosure of PHI involves no more than a minimal risk to the research participant’s privacy, consistent with the elements identified on
Privacy Form 5 (45 CFR 164.512(i)(2)(ii)). Clinical research will generally not qualify for a waiver if the research participant will be asked to sign an informed consent form.

1.2.3 Whether a limited data set is being used. When a research project involves health information that is identifiable only by certain identifiers specified under HIPAA, the data are considered a limited data set, as documented by an investigator on Privacy Form 9. If the investigator plans to share the limited data set with another entity, a written agreement (a Data Use Agreement), described in Privacy Form 10, must be utilized.

1.2.4 Whether proposed access to PHI qualifies as access preparatory to research. When the investigator is seeking to review PHI preparatory to research, such as to prepare a research protocol, prior to accessing PHI the investigator must submit verification of such activity on Privacy Form 6. PHI may not be removed from the custodian of the PHI for such activity.

The Privacy Board shall comply with the following:

1.2.5 An Authorization is not required for research that involves only the PHI of decedents, as documented by an investigator on Privacy Form 7.

1.2.6 An Authorization is not required for research that involves health information that is non-identifiable to a participant, as documented by an investigator on Privacy Form 8.

2. SCOPE

This SOP applies to all human research that involves the access to or creation, acquisition, disclosure, or maintenance of protected health information.

3. RESPONSIBILITY

3.1 The IRB, acting as the Privacy Board, has the authority and the responsibility to review human research projects for privacy issues, consistent with the University’s HIPAA “Research” policy and applicable law, as well as for security issues, consistent with the University’s HIPAA Security policies.

3.2 The investigator is responsible for submitting verification via the appropriate Research Privacy form or other documentation of the manner in which PHI is accessed, collected, used, maintained, and/or disclosed for research purposes.

3.3 The University Privacy Official and HIPAA Security Officer are responsible for providing current guidance to the Privacy Board and HRPP Director regarding HIPAA regulations. The University Privacy Official is also responsible for updating HIPAA Privacy forms and policies.

3.4 The HRPP Director or designee is responsible for bringing HIPAA issues for clarification to the University Privacy Official or HIPAA Security Officer.

4. APPLICABLE REGULATIONS AND GUIDELINES

Health Insurance Portability and Accountability Act, 45, CFR parts 160 and 164, August 2003, as amended, including by HITECH.
5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

1001-A  Research Privacy Form 1: Use or Disclose PHI for Research
1001-AA Research Privacy Form 1: Use or Disclose of PHI for Research - Spanish
1001-A-1 Research Privacy Form 1: Use or Disclose PHI – Norman Campus
1001-B  Research Privacy Form 2: Psychotherapy Notes for Research
1001-C  Research Privacy Form 3: Use or Disclose PHI for Repository
1001-D  Research Privacy Form 4: Use or Disclose PHI and Repository
1001-E  Research Privacy Form 5: Waiver of Authorization
1001-F  Research Privacy Form 6: Review Preparatory to Research
1001-G  Research Privacy Form 7: Decedent Information
1001-H  Research Privacy Form 8: De-Identified Information
1001-I  Research Privacy Form 9: Limited Data Sets
1001-J  Research Privacy Form 10: Use Agreement on Limited Data Sets
1001-K  University of Oklahoma Notice of Privacy Practices
1001-L  Authorization for Use/Disclosure of Individual Protected Health Information for Research Purposes – Saint Francis Hospital

HIPAA Policy - Research

7. PROCESS OVERVIEW

7.1 The IRB Administrator conducts a preliminary review of all new research, continuing review, and modification submissions to determine that those studies involving the collection of PHI include the appropriate HIPAA documentation and comply with relevant HIPAA policies.

7.2 The IRB Chair or IRB designee or the convened IRB reviews the acquisition, creation, use, maintenance, and/or disclosure of PHI for each submission to determine if an Authorization, waiver, Data Use Agreement, or other Research Privacy form or documentation is needed.

7.3 The IRB Chair or IRB designee or the convened IRB alerts the IRB Administrator if a particular or different HIPAA form is indicated based on the review of PHI usage.

7.4 The IRB Administrator contacts the investigator to request an alternate or additional HIPAA form if indicated upon either preliminary review or IRB or IRB Chair request.

7.5 The IRB Administrator directs HIPAA-related issues requiring additional guidance to the HRPP Director or designee, who confers with the University Privacy Official and/or HIPAA Security Officer, as appropriate.

7.6 Requests for revisions to the University’s HIPAA forms are forwarded to the University Privacy Official, who documents any indicated instructions or revisions to documentation and returns to the HRPP Director or designee, who forwards to the appropriate IRB Administrator.
7.7 The HRPP Director or designee serves as a liaison between IRB Chairs and the University Privacy Official and HIPAA Security Officer.

7.8 Projects determined by the IRB to be non-research but requiring review regarding HIPAA issues shall be forwarded to the University Privacy Official for a determination. These projects do not generally require further involvement by the IRB.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 1002: PRIVACY & CONFIDENTIALITY

1. POLICY

In accordance with federal law and regulations, the IRB shall determine that where appropriate, adequate provisions are in place to protect the privacy of participants and maintain the confidentiality of data when reviewing human subjects research. There must be an adequate plan in place to preserve the participant’s right to choose how and when his or her private information will be used, withheld, and or disclosed. Potential risks of a breach to privacy and confidentiality must be disclosed. The IRB may determine additional methods as needed to minimize risks to participants.

Specific Policies

1.1 Protecting Privacy

The IRB may only approve research that does not unreasonably invade the privacy of research participants. Privacy is a person’s right to control the extent, timing, and circumstances of sharing access to oneself (physically, behaviorally, or intellectually) and to their information with others.

1.1.1 Human participant research must be designed to gather only the minimum necessary information to accomplish the intended purpose of the use, disclosure, or request without the participants’ knowledge or consent in any phase of the research, including recruitment and screening.

1.2 Maintaining Confidentiality

The IRB will approve research that adequately protects the confidentiality of research data commensurate with risks associated with disclosure, legal obligations, and the confidentiality commitment made to research participants.

Confidentiality pertains to non-disclosure of personal information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

1.2.1. Methods for keeping information confidential range from using routine precautions, such as substituting codes for participant identifiers and storing data in locked cabinets, to more elaborate procedures involving statistical methods (e.g., error inoculation) or data encryption. The method(s) selected are determined by the nature of the information collected and potential risk to participants from a breach of confidentiality.

1.3 NIH Certificate of Confidentiality

Some research projects may require that the investigator obtain a Certificate of Confidentiality to protect the privacy and confidentiality of research participants. Investigators generally may not be compelled to release data covered by a Certificate of Confidentiality in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

OHRP does not issue Certificates of Confidentiality. The NIH and other federal agencies issue these to protect identifiable information from forced or compelled disclosures. See https://humansubjects.nih.gov/coc/index for Info from NIH about CoC.
Other federal agencies may evaluate IRB research projects for Certificates of Confidentiality using different criteria.

1.3.1 Restrictions on Disclosure:

a. When research is covered by a Certificate of Confidentiality, investigators may not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding:
   - the name of research participant
   - any information, document, or biospecimen that contains identifiable, sensitive information about the research participant and that was created or compiled for purposes of the research,

In addition to the above restrictions, investigators may not disclose or provide this information to any other person not connected with the research.

b. Exceptions to the above restrictions include when:
   - Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
   - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
   - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
   - Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

1.3.2 Federally-Funded Research: Effective October 1, 2017, all research that commenced or was ongoing on or after December 13, 2016, that collects or uses identifiable sensitive information is automatically issued a CoC for applicable NIH awards as part of the award terms and conditions.

“Identifiable sensitive information” is information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research where the following may occur:
   - An individual is identified; or
   - For which there is at least a very small risk that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

The IRB website provides additional information on how Investigators can obtain a Certificate of Confidentiality. In the IRB submission, the investigator will indicate that a Certificate of Confidentiality is needed. The IRB will hold the official approval letter but will issue a contingent approval letter for the research project in order for the investigator to
obtain the Certificate of Confidentiality. However, no research activities can begin until the Certificate of Confidentiality is received by the IRB. At that time, the IRB will release the research project approval letter and stamped consent documents to the investigator.

If a CoC is automatically issued, such as for an NIH-funded study, the IRB will not require a separate CoC document. However, the consent form must include the appropriate CoC language, located in the consent template.

Non-Federally-Funded Research: The IRB may determine that investigators obtain a Certificate of Confidentiality if the research will collect or use information that is of a sensitive nature and protection is necessary to perform the research. Research that collects information related to the following types of information may be considered sensitive:

- Information related to sexual attitudes, preferences, or practices
- Information related to the use of alcohol, drugs, or other addictive substances
- Information pertaining to illegal conduct
- Information that if released, could reasonably be damaging to an individual’s financial standing, employability, or reputation in the community
- Information that would normally be recorded in the patient’s medical record, but disclosure could reasonably lead to social stigmatization or discrimination
- Information pertaining to psychological well-being or mental health
- Genetic information

1.3.3 Sharing Identifiable, Sensitive Information with Other Researchers and Organizations: Investigators conducting research covered by a Certificate of Confidentiality, regardless of the funding source, must ensure that if identifiable, sensitive information is provided to other investigators or organizations, the other investigator or organization must comply with applicable requirements of the Certificate.

1.3.4 Required Disclosure Under Oklahoma Law: Even though a Certificate of Confidentiality has been issued by a federal agency, Oklahoma law requires disclosure of certain information, such as child abuse or intent to harm self or others. In these situations, the consent documents must notify research participants of the investigator’s legal reporting obligations.

1.3.5 VA Research Requirements for Notes in the Medical Record:
   a. For studies that do not involve a medical intervention, no annotation may be made in the medical record.
   b. For studies involving a medical intervention, a progress note in the medical record should be made indicating the following:
      - the individual has enrolled in a research study,
      - any details that will or may impact clinical care, and
      - the name and contact information of the Principal Investigator.

1.4 Web-Based Survey, Data Collection, and Data Storage Tools
Investigators may use a variety of web-based programs to administer surveys and collect and store research data. Collecting data using web-based programs can increase potential risks to confidentiality. To aid in minimizing such risks, investigators should use University IT-approved programs or submit the programs to IT for a risk assessment and work with the appropriate University office to enter into a contract with the vendor that includes sufficient protection of the research data before using any web-based software for data collection.

1.4.1 REDCap is the recommended software for survey administration, data collection, and data storage. REDCap satisfies all data security requirements for the University, state law, and regulatory requirements such as HIPAA and FERPA.

1.4.2 SurveyMonkey and Qualtrics may only be used if the survey or other tools will collect and store de-identified or anonymous information. Personally Identifiable Information (PII) and Protected Health Information (PHI) cannot be stored or transmitted in either program.

Refer to SOP 502L: Internet/Social Media-Based Research for more information regarding technology-assisted survey administration and data security.

Investigators should also contact their respective campus’ IT Office for additional information regarding the process to use web-based programs in human research, including risk assessments and obtaining agreements with vendors.

1.5 Other University Requirements That Impact Human Research

1.5.1 Portable Computing Device Encryption Policy: The University requires encryption of portable computing devices that are used for University business. This applies to all University personnel, including affiliates and volunteers, who use portable computing devices, regardless of ownership. Portable devices include laptops, tablets, flash drives, and smartphones.

The privacy protections in this policy apply to all investigators engaged in human participant research at the University and all device types listed above that are used to collect data for research purposes. Refer to the Senior Vice President and Provost’s Encryption memo and to University IT Security Policy for more information.

1.5.2 Information Security Risk Assessment Policy: In accordance with this University IT Security Policy, investigators’ technology, software, devices, and the like that are acquired for or used in University research must undergo a product review or risk assessment through IT Security.

Refer to the IT Security website and policy for more information regarding this process.

1.5.3 Investigators must comply with the University’s HIPAA policies (including those of the HRPP) when applicable to their research. Refer also to SOP 1001: Health Insurance Portability and Accountability Act (HIPAA Privacy Rule).

2. SCOPE

This SOP applies to all human research that involves the access to or creation, acquisition, disclosure, or maintenance of identifiable participant information.

3. RESPONSIBILITY
3.1 The IRB is responsible for reviewing all human subjects research protocols to ensure that adequate protections for privacy and confidentiality are in place, according to applicable federal law and regulations, applicable local and state requirements, and applicable policies.

3.2 Investigators are responsible for including adequate provisions to protect the privacy of participants and confidentiality of participant information and research data. These provisions must be described in the IRB application and research protocol.

3.3 Investigators are responsible for ensuring they comply with all HRPP, IT, and other University policies related to securing and protecting the privacy and confidentiality of individuals enrolled or included in human subjects research.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111
21 CFR 56.111
Health Insurance Portability and Accountability Act (HIPAA)
Family Educational Rights and Privacy Act (FERPA)
10 O.S. § 7103

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other HRPP/IRB SOPs.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The IRB Chair or IRB Designee or the convened IRB will review human subjects research applications and determine whether adequate provisions are in place to protect the privacy of participants and the confidentiality of their information, according to applicable federal law and regulations, applicable local and state requirements, and applicable policies.

7.2 The IRB may require verification of information submitted by an investigator or the IRB may require additional provisions to minimize potential risks to participants. The IRB will document such requests in the IRB’s electronic information system.

7.3 The IRB Administrator contacts the investigator to request verification or additional provisions if indicated during IRB review.

7.4 The QI Coordinator will verify compliance with this policy during random and for-cause evaluation procedures as described in SOP 901: Quality Improvement Program.

APPROVED BY: __________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020
SOP 1101: OKLAHOMA STATE LAWS PERTAINING TO RESEARCH

1. POLICY

Federal regulations require the IRB to conduct research in compliance with applicable state law. The IRB and investigators must comply with Oklahoma State laws as they pertain to human participant research. This policy outlines Oklahoma State laws pertaining to research activities.

Specific Policies

1.1 Research Involving Protected Populations

1.1.1 Emancipated Minors

Under 63 O.S. §2601, any minor who is married, has a dependent child, or is emancipated (released from parental or guardian control and is not supported by the parents or guardian) may consent to certain health services. Health services do not include research or experimentation except when the research or experiment is an attempt to preserve the life of that minor or research as approved by an appropriate review board involved in the management of reportable diseases.

1.1.2 Cognitively Impaired Individuals

Under 63 O.S. §3201A, under certain conditions consent of a cognitively impaired individual to participate in a research project may be obtained from a legal guardian, attorney-in-fact with health care decision authority, or a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage). However, if cognitively impaired individuals were legally competent to express permission or prohibition prior to becoming cognitively impaired, the legal guardian or family member cannot override the individual's previously expressed permission or prohibition.

1.1.3 Fetal Materials

Under 63 O.S. §1-735, research on fetal tissue resulting from an abortion is prohibited. An abortion is defined as the purposeful termination of a pregnancy with intent other than to produce a live birth or remove a dead unborn child.

The use of fetal tissue resulting from a spontaneous miscarriage for research purposes is not specifically prohibited.

1.2 Other Applicable State Law

There are other state laws that could extend to the research being conducted. For example, state law requires that any person having reason to believe that a child under the age of 18 is a victim of abuse or neglect shall report the matter to the Department of Human Services. This state law is not specific to or even related to research; however, during the conduct of research, personnel could become aware of child abuse or neglect and would be required to report the abuse under state law.
2. SCOPE
   This SOP applies to all other SOPs.

3. RESPONSIBILITY
   It is the responsibility of the investigator to conduct research according to applicable Oklahoma State laws.
   It is the responsibility of the IRB Chairs to approve only research that is in compliance with applicable Oklahoma State laws.

4. APPLICABLE REGULATIONS AND GUIDELINES
   Oklahoma Statutes, 63 O.S. §2601
   Oklahoma Statutes, 63 O.S. §3201
   Oklahoma Statutes, 63 O.S. §1-735

5. REFERENCES TO OTHER APPLICABLE SOPS
   This SOP affects all other SOPs.

6. ATTACHMENTS
   None

7. PROCESS OVERVIEW
   7.1 Legal Counsel provides guidance on Oklahoma law to HRPP Director and/or IRB Chairs.
   7.2 The HRPP Director and/or IRB Chair or designee contacts with Legal Counsel as needed for guidance on the application of Oklahoma State law pertaining to human research.
   7.3 The HRPP Director acts upon or disseminates the guidance of Legal Counsel to the IRB Chair and/or IRB staff and documents advice for reference as needed.

APPROVED BY:______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020