801-A

The University of Oklahoma

Investigator's Manual
For
Research Involving Human Participants

Human Research Participant Protection Program
February 2, 2015

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Introduction

This manual is designed to provide information, direction, and assistance to University of Oklahoma (OU) faculty, staff, students or other personnel who are conducting human participant research at The University of Oklahoma- Norman Campus (NC) and/or The University of Oklahoma Health Sciences Center (HSC).

The OU Office of Human Research Protection Program (HRPP) and the Institutional Review Board (IRB) have developed policies and procedures that describe and explain the various aspects of the review process and the regulatory requirements governing human participants research. All Investigators are expected to be familiar with all applicable policies, procedures, and regulations and laws that govern the human research process before submitting applications or other documents to the IRB and before beginning their proposed research. This manual is aimed at providing a guide and overview of the policies, procedures and laws, as well as important topics, related to human participant research. It is intended to assist you in understanding the basic requirements for IRB review and approval and guide you in preparing your research submission to the IRB.

The links referenced in this document are located on the IRB's website at www.irb.ou.edu or www.ouhsc.edu/irb/ where additional information is available

Contact the HRPP Office for further assistance at 405-271-2045 (HSC) or 405-325-8110 (NC).

1. Overview of the OU Human Participants Protection Program

Function of the HRPP/IRB

OU's Human Research Participant Protection Program (HRPP Program) is a comprehensive university-wide program that ensures the safe and ethical conduct of human participant research by all faculty, staff, and students of OU and its affiliates. This program includes review of proposed research by relevant oversight committees; continuing oversight for compliance with applicable regulations and policy; education and training for investigators, staff, and board members; quality assurance; and continuing process improvement. The realization of the University's commitment to the highest ethical standards in the protection of human participants in research requires the dedication of all members of the OU research community and University administration. While the IRB forms the core of the HRPP Program, other regulatory committees play an important role, including: the Institutional Biosafety Committee (IBC), the Radiation Safety Review Committee, and the Office of Research Administration/Office of Research Services.

The mission of the HRPP Program is to ensure the protection of rights, privacy and welfare of all

human participants in research projects conducted by OU faculty, professional staff, and students. The IRB is a unit within the HRPP Program, the HRPP Program is unit within of the Office of Compliance for the NC and the Vice President for Research for HSC. The HRPP Program operates under the auspices of the Organizational Official, the Vice President of the University and General Counsel, who has the authority to oversee the HRPP Program and responsibility to ensure its effectiveness in protecting research participants.

Authority of the IRB

OU's IRBs must review and approve all research involving human participants, both biomedical and social science/behavioral, before research commences. The IRB has the authority to approve, require modification in (to secure approval), or disapprove human research activities at OU and its affiliate institutions; to suspend or terminate approval of research not being conducted in accordance with pertinent laws, IRB requirements or University policy; and to observe, or have a third party observe the consent.

NC has established a Federal Wide Assurance (FWA00003191) through the Office for Human Research Protections (OHRP) to conduct human participant research. NC's FWA covers faculty, employees of OU and its affiliated institutions, students, trainees, and anyone conducting such research under the auspices of NC or its affiliates, regardless of the funding source. Investigators who wish to use an outside IRB as the IRB of record for a particular research study must apply to the IRB for authorization to do so.

HSC has established a Federal Wide Assurance (FWA00007961) through the Office for Human Research Protections (OHRP) to conduct human participant research. HSC's FWA covers faculty, employees of OU and its affiliated institutions, students, trainees, and anyone conducting such research under the auspices of HSC or its affiliates, regardless of the funding source. Investigators who wish to use an outside IRB as the IRB of record for a particular research study must apply to the IRB for authorization to do so.

Responsibilities of the IRB

The IRBs have the responsibility to approve, require modifications to, or disapprove all human subject research before it is initiated in order to comply with ethical principles and federal, state and local regulations and institutional policy. The IRBs provide continuing oversight of all human participant research, at least yearly. The IRBs have the authority to assure, on an ongoing basis, that the risks of proposed research are justified by the potential benefits to the participants and to society, that the risks do not fall disproportionately on one group and that risks are minimized to the extent possible consistent with sound research design. The IRBs are authorized to oversee the consenting process to ensure that agreement by an individual to participate in research is voluntary and knowing. Individuals who are particularly vulnerable (pregnant women, fetuses, children, prisoners, students, employees, or those whose capacity to consent may be in doubt) may require additional protection during the consent process.

2. Composition of the IRB

The IRB is tasked with safeguarding the rights and welfare of human participants. All IRBs at OU consist of at least five members with at least one member representing the local community. The IRB members review proposed research to ensure it complies with institutional policies and procedures, applicable regulations and laws, and standards of professional conduct and practice. Qualified persons from multiple professions with a diversity of expertise on human subjects research and of both sexes are considered for membership on the IRBs.

See SOP 201: Composition of the IRB for additional information.

NC- IRB

NC-IRB consists of two boards that meet once a month and only review social-behavioral research for the OU-Norman campus, OU-Tulsa campus, and Cameron University. Bio-medical research that is conducted by a Norman-program based researcher may be referred to the HSC-IRB for review.

HSC- IRB

HSC-IRB consists of five boards that meet once a month and review human research performed at the HSC campus and at OU-Tulsa, as well as at the various affiliates in and around campus (e.g. VA Medical Center, Dean McGee Eye Institute, OFDR and OMRF). Each board has a focus for protocol review, as follows:

- Board 1 – medical/behavioral
- Board 2 – oncology/medical/surgical/radiotherapy
- Board 3 – medical/pediatrics
- Board 4 – primarily adult medical/behavioral
- Board 5 – meets on an ad-hoc basis

For additional information regarding the NC and HSC IRBs, see the rosters and meeting schedules.

Research Collaboration Between NC and HSC Investigators

When a research project involves or engages both the NC and the HSC (joint faculty collaboration, use of one campus' facilities or resources by the other, recruitment on one campus by the other campus' investigator etc.), a mutual determination is made by the IRBs for NC and HSC as to which campus will have sole IRB oversight of the research project to ensure protection of human participants. This determination is based on several factors, including: where participants are recruited, where participation occurs, and the type of research involved.

See the SOP 602G: IRB of Record Reciprocal Review Policy (Norman – OKC) for additional information.

3. Governing Principles for Human Subjects Research

All human participant research at OU is conducted in compliance with the principles of the Belmont Report and other ethical codes of the conduct for research, such as the Declaration of Helsinki and the Nuremberg Code. The passage of the National Research Act in 1974 established the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*. The Commission published a report entitled, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," otherwise known as the *Belmont Report.* This report articulates the basic ethical principles that guide the conduct of research with human participants. The University, the IRB, and investigators share the collective responsibility for the ethical conduct of all research involving human participants. We must be guided by the ethical principles as set forth in the *Belmont Report.* Three principles are defined as basic to the protection of human participants:

1. **Beneficence**

   The principle of beneficence requires that researchers maximize the potential benefits to the participants and minimize the potential risks of harm. Benefits to the participants, or generalized knowledge gained from the research, should always outweigh the risks. If there are any risks resulting from participation in the research, there must be benefits that are accrued to either the participant or humanity in general.

2. **Autonomy/Respect**

   Investigators are required to seek voluntary, written informed consent from potential participants, unless the requirements for waiver of informed consent are met. Voluntary informed consent requires that participants be provided explicit assurances of the voluntary nature of their participation in the study in language that is easy to understand, free of coercion, and presented when the participant is not under duress. Respect for vulnerable populations requires taking extra precautions to protect these individuals. The extent of protection depends on the risks and benefits of the research to the participants. This principle also pertains to maintaining the privacy and confidentiality of participants.

3. **Justice**

   The principle of justice mandates that participants be selected fairly, and that the risks and benefits of the research study be distributed equitably among participants. Investigators should base inclusion criteria on those factors that most effectively and soundly address the specific research problem. Investigators should take precautions to prevent biased selection of participants.

IRBs are responsible for ensuring that all approved human-participant research complies with the letter and spirit of the human-participant protection regulations., as well as the three Belmont principles previously defined.

4. When is IRB Review of Research Required?

All research involving human subjects conducted by any faculty, staff member, or student at OU and its affiliate institutions must be submitted to either the NC or HSC IRB for review and approval prior to beginning any research activities. In order for you to determine if your work involves research and more specifically, research involving human subjects, please refer to the following step-by-step guide that is provided by the Office of Human Research Protections at the U.S. Department of Health and Human Services:

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1 .

There are some activities that involve humans that are not defined as research and these types of activities may not require IRB approval.

See SOP 401: Research Exempt from IRB Review for additional information.

Any investigators who are unsure if their activity meets the definition of human subjects research should submit a request for a Determination of Human Research that is available in iRIS (Integrated Research Information System), the IRB online submission system, before beginning research activities. After the IRB makes a determination, you will receive instruction on the next steps for beginning your research project.

See SOP 406 Determination of Human Research/Protocol Development for additional information.

Investigators are advised that the IRB is the final authority on whether a research project is or is not human participants research. If a project is determined to be human participant research and research activities have begun prior to the granting of IRB approval, the investigator will be subject to University policy regarding research misconduct.

See SOP 903: Non-compliance/Scholarly Misconduct for additional information

Also, see definitions for human participants and research in the Glossary

See the IRB's Statement of Authority and Purpose for additional information.

5. Responsibilities of Investigators and Sponsors

Responsibilities of Investigators

All investigators at OU should understand that conducting research at OU is not a right, but rather, it is a privilege granted by society as a whole and by the Board of Regents of the University of Oklahoma in particular.

As such, it is your responsibility to design and conduct research involving human participants in accordance with Institutional policies and procedures and applicable government laws and regulations. You should consider the design of the research project as it pertains to minimizing risks to participants as outlined in these regulatory documents as well as the ethical principles associated with the responsible conduct of research and strictly adhere to the requirements of the research protocol.

Also, investigators should understand and fulfill their responsibility to maintain appropriate oversight of each research project and appropriately delegate research responsibilities and functions to research staff and trainees.

All investigators are responsible for adhering to all Institutional policies and procedures and to the requirements and/or determinations of the IRB.

Investigators 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. GCP applies only for clinical research and it is not applicable to non-clinical research.

The Board of Regents' policy entitled, "Ethics in Research" is located in section 3.5.4 of the Regents' Policy Manual for the University of Oklahoma.

SOP 801:Investigator Qualifications and Responsibilities for additional information.

Investigator's Responsibility to Disclose Conflicts of Interest

All Investigators and key study personnel must identify in the IRB application, whether they or any other person responsible for the design, conduct, or reporting of the research, under University policy, has an actual or potential conflict of interest with the sponsor or any outside entity whose interests would reasonably appear to be affected by the research. Investigators who have a potential conflict of interest shall indicate the conflict on the initial IRB application for research involving human subjects and complete and submit the HRPP Conflict of Interest Disclosure Form to the IRB for review. If the conflict has been disclosed to the Vice President for Research (VPR) and a management plan is available, the Investigator shall also include this information with the IRB submission.Under University policy, you are required to update your disclosure annually and disclose any conflicts that arise during the year.

See SOP 104A: Conflicts of Interest In Human Participant Research for additional information.

Education Requirements for Investigators

The education of faculty, staff, and students who conduct research involving human participants is a critical to protecting the rights and welfare of these participants. OU requires investigators and associated research staff to complete the human participant

research training prior to IRB approval. NC and HSC have distinct education requirements which are expressly outlined in the SOPs.

See SOP 102B: Key Study Personnel Education for additional information.

Responsibilities of Sponsors

Apart from investigators being held responsible for performing their research in accordance with GCP if it is both sponsor-initiated and sponsor-funded, the IRB expects the sponsors of trials to adhere to established ethical principals and monitor the conduct of the research in accordance with federal regulations as well. Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) 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 ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.

See SOP 802: Sponsor Responsibilities for additional information.

6. IRB Submission Requirements

Research Submission Requirements

IRB members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets the federal regulatory criteria for approval. Initially, IRB staff review each submission confirm that the appropriate documentation is included in the online submission materials before the research project is assigned for review by the IRB.

See SOP 301: Research Submission Requirements for additional information.

IRB Submission Forms

Most IRB forms can be accessed in iRIS (Integrated Research Information System). iRIS is the IRB's electronic submission system and serves both the HSC and NC campuses. The forms used by NC an HSC are different, so you should make sure to use site-appropriate forms to avoid delays in processing your submission. Training for the online submission system is offered on a regular basis and is also available upon request.

IRB forms can also be accessed on the HSC IRB or NC IRB web sites, respectively. Each time you begin a new research project, remember to download the current forms within iRIS or the appropriate web site since the forms are periodically updated. The IRB forms must not be altered since they have been developed to include federally required elements.

Submission Requirements for VA Research

The VA Research & Development Committee (R&DC) oversees all VA research activity conducted at the VAMC and the process for review and approval is separate from the IRB. The IRB is considered a subcommittee of VA R&DC for VA research. Research cannot be initiated at the VA until the Investigator obtains approval from the IRB and from the R&DC. Investigators may contact the VA Research Administration Office at (405) 456-3100 for more information regarding the addition of the VAMC as a site for research.

Investigators are required to complete the VA R&DC application and submit the consent document utilizing the VA Form 10-1086, if applicable, and the VA HIPAA Authorization utilizing VA Form 10-0493, if applicable.

The Principal Investigator, Local Site Investigator, and/or Investigators must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including the local VA facility's SOPs, regarding the conduct of research and the protection of human subjects.

> For additional information see SOP 603A: Veterans Affairs Medical Center and VHA Handbook 1200.05 § 9 for more detailed information regarding investigator responsibilities when conducting VA Research.

7. Levels of IRB Review

There are two levels of IRB review for research projects: Expedited and Full Board. Only the IRB will make a determination regarding the level of review that is required for each particular study. Expedited reviews are conducted continuously by an IRB Chair or IRB designee. Full board reviews occur only at the monthly convened meeting and are assigned to a specific board.

Expedited Review

Research may be reviewed by the IRB Chair or IRB designee through an Expedited review procedure if the research activities: (1) present no more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the categories listed in the OHRP regulations at Federal Register Volume 63, No 216.

> See SOP 402: Expedited Review for additional information.
>
> A list of Exempt and Expedited categories is available on the HSC and NC IRB websites.

Full Board Review

Research projects that may present greater than minimal risk for participants require Full Board review. Additionally, the following may also be included for full board review:

- Initial submission of FDA-regulated research
- Submissions involving prisoners as a population.
- Submissions involving deception
- Significant changes in the risk/benefit ratio, changes to inclusion/exclusion criteria or protocol changes which specifically note Full Board review
- Major revisions to the Informed Consent Document
- Submissions forwarded from expedited review

You should submit your IRB application as early as possible to assure that IRB approval is granted in time to begin your research, especially if travel is required to collect data. If your research project is deferred and/or if satisfactory responses are not received by the IRB in the time specified, the protocol may be administratively withdrawn by the IRB.

See SOP 403: Initial Review - Criteria for IRB Approval for additional information.

8. IRB Initial Review and Criteria for Approval

All research projects that intend to enroll human participants must meet certain criteria before study-related procedures can be initiated. These criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and explained herein. In addition, certain other criteria that are unique to The University of Oklahoma may apply and must be met as well.

As previously stated, no investigator has a right to conduct research within this institution. 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 evaluates each protocol on an individual basis in order to assess whether the investigator is providing all of the necessary services in an effort to protect the participant. This 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 assessment will be ascertained using the initial IRB application which includes the protocol, outside IRB approval letters, letters of support, advertisements, and all other supporting documents. The IRB will consult the investigator for additional information regarding necessary services.

During the course of review by the IRB, the research project will be evaluated to determine whether it provides adequate resources to protect the rights and welfare of participants.

See SOP 403: Initial Review - Criteria for IRB Approval for additional information.

IRB Communication & Notification

It is vital that open and frequent communication be maintained between you and the IRB. General inquiries to the IRB will be answered as promptly as possible by the appropriate IRB staff. Once your research project has been assigned to a board, the IRB administrator for that board will be your point of contact. Concerns and/or suggestions that cannot be satisfactorily addressed by HRPP or IRB staff may be addressed in a meeting with the appropriate administrative individuals. The IRB notifies investigators and designated research contacts of all decisions made by the IRB in writing using iris.ou.edu or iris.ouhsc.edu. When correspondence is available in the online submission system, you will receive email notification.

See SOP 601: IRB Communication and Notification for additional information.

IRB Categories of Action

As a result of its review, the IRB may decide to approve, defer, or disapprove the proposed research project. The IRB may also contingently approve the application when additional documentation or modifications to the research documents you have submitted are required to secure IRB approval of the research activity. For studies reviewed by the full board, the decision will be made based on a vote of a majority of the members present. For research projects with Expedited review, the IRB Chair or designee can take any of these actions except to disapprove a research project.

See SOP 409: Categories of Action for additional information.

9. Additional (Non-IRB) Reviews That May Be Required

Protocols that include any of the following will require an additional review/approval by another administrative unit affiliated with OU. As a result of the additional level of review, it will take longer to process your IRB application. To avoid lengthy delays, you should review the related IRB policies to find out what specific supplemental information may be required.

Stephenson Cancer Center (OUHSC) Scientific Review Committee

See SOP 602H: Stephenson Cancer Center Scientific Review Committee .

Institutional Biosafety Committee (IBC)

See SOP 602F: Institutional Biosafety Committee .

Office of Research Administration (OUHSC) or Office of Research Services (NC)

Protocols for which there is a grant or for which funding (cash, equipment, or other remuneration) is provided by an outside entity. See SOP 602D: Office of Research Services (ORS) – Norman Campus or SOP 602C: Office of Research Administration (ORA) - Oklahoma City Campus for additional information.

Radiation Safety Committee

See SOP 602I: Radiation Safety Office .

Veterans Affairs Medical Center (VAMC), Oklahoma City

See SOP 603A: Veterans Affairs Medical Center and VA Links on HSC website.

10. Advertising and Recruitment of Research Participants

Recruitment is the dialogue that takes place between the you and a potential participant prior to the initiation of the consent process. Respect for potential participants begins with recruitment procedures that ensure that participation is voluntary, and preserve privacy and confidentiality. The IRB must approve the methods and language used to recruit participants to ensure that the methods are not coercive and that the confidentiality and privacy of participants are protected.

See SOP 410: Research Project Recruitment for additional information.

11. Special Populations

The IRB approves research that involves special populations that is of minimal risk or that will benefit these populations directly. The extent of protection considered by the IRB depends upon the risk of harm and the likelihood of benefit. The IRB gives special consideration to recruitment methods, oversight of the consent process, and the participant's capacity to consent. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

The IRB may invite members or consultants with special expertise and related competency to participate in the review.

The inclusion of participants from vulnerable populations does not, in and of itself, necessitate review by the convened IRB. The level of risk involved must be considered in making this

determination. For example, research involving children that poses minimal risk may be expedited under 45 CFR 46.404

Special populations may include:

- Pregnant women, fetuses, and neonates
- Children
- Cognitively impaired persons
- Prisoners
- Traumatized and comatose patients
- Terminally ill patients
- Elderly/aged persons
- Minorities (e.g. Native Americans)
- Students, employees, and health volunteers
- Economically or educationally disadvantaged persons

See SOP 501: Special Populations for additional information.

12. Reviews Requiring Special Consideration

The categories of research defined in the following policies involve either methodologies that might require additional considerations, or for which there are federally mandated determinations that IRBs are required to make and document. Please refer to the applicable policy by selecting the referenced link:

Banking of Biological Specimens, Genetic Testing, & Gene Therapy

See SOP 502H: Categories of Research - Banking of Biological Specimens, Genetic Testing, and Gene Transfer for information.

Cell Lines and Cloned DNA/RNA

See SOP 502H: Human Cell Lines and Cloned DNA/RNA for information.

Clinical Research Involving Biologics

See SOP 502B: Categories of Research - Biologics for information.

Clinical Research Involving Devices

See SOP 502C: Categories of Research - Devices for information.

Clinical Research Involving Drugs

See SOP 502A: Categories of Research - Drug for information.

Collaboration with Non-OU Researchers

See SOP 602G: IRB of Record

Emergency Use of FDA-Regulated Products

See SOP 502G: Emergency Use of FDA-Regulated Products for information.

Humanitarian Use of Devices Protocols

See SOP 502F: Humanitarian Use Devices for information.

International Research

See SOP 502K: International Research for information.

Internet/Social Media-Based Research

See SOP 502L: Internet/Social Media-Based Research

Medical Records, Chart Reviews, & Case Studies

See SOP 502D: Categories of Research - Medical Records, Chart Reviews, and Case Reports for information.

Federal Agencies (DOD, EPA, Energy, Education)

See SOP 603F: Department of Defense
See SOP 603G: Other Federal Agencies

Request to Defer IRB Review to another IRB

See SOP 602G: IRB of Record

Social/Behavioral

See SOP 502J: Categories of Research - Social/Behavioral for information.

Treatment Use Protocols

See SOP 502E: Treatment Use of Investigational New Drugs/Devices for information.

13. Informed Consent

Informed consent is the process by which the research study is explained to the potential participant and the participant voluntarily agrees to participate in the research. The IRB assures that provisions are made to obtain legally effective informed consent prospectively from each research participant or from his/her legally authorized representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with the Federal Regulations.

See the SOP 701: Consent Process and Documentation policy for additional information.

A template for consent forms is provided on the IRB websites. These templates incorporate the applicable elements of federally defined legally effective informed consent.

14. HIPAA

Protected Health Information (PHI) that is created, acquired, and maintained during the conduct of human participant research must be protected and safeguarded in accordance with the Privacy Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), applicable state laws, and the University of Oklahoma HIPAA Privacy Policies.

See the and the IRB's SOP 1001 Health Insurance Portability & Accountability Act (HIPAA Privacy Rule) – Privacy Board and the University HIPAA website for additional information.

Templates for HIPAA forms are available in iRIS for each campus

15. Other Types of Submissions

Continuing Review

The IRB conducts continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research involving human participants must be reviewed no less than once per year.

See the SOP 404: Continuing Review for additional information.

Protocol Modifications

Any modifications or changes to the previously approved research project such as changes to the inclusion/exclusion criteria, study population, study procedures or consent process,

requested by the investigator or sponsor, must be approved by the IRB before the revisions are implemented.

See the SOP 405: Modifications for additional information.

Unanticipated Problems Involving Risks to Participants and Others and Protocol Deviations

Investigators are required to promptly report any unanticipated problem that involves risks to participants or others. Unanticipated problems involving risks to participants or others is any problem that (1) was unforeseen at the time of occurrence, is (2) related or possibly related and (3) indicates that participants are at increased risk of harm.

Investigators are also required to report protocol deviations. Protocol deviations are events that are a departure from the specific protocol procedures approved by the IRB. Protocol deviations may or may not place participants at risk.

The IRB has the authority to suspend or terminate approval of research or require changes to research that has been associated with unexpected serious harm to participants.

See SOP 407: Protocol Deviations and Unanticipated Problems for additional information and reporting instructions. See SOP 603A: VAMC for specific VA reporting requirements.

Study Completion

The completion or termination of a study is a change in activity; and therefore, must be reported to the IRB. Completion or termination of a study may be reported to the IRB.

See the SOP 408: Research Project Completion policy for additional information.

16. Quality Improvement Program

The Quality Improvement Program monitors and measures the effectiveness of the Human Research Participant Protection Program. This is accomplished through Routine and For-Cause Evaluations and Self-Assessment Evaluations against institutional policies and procedures, applicable federal regulations and Oklahoma state law.

The Board of Regents' policy, "University Compliance and Quality Improvement Program" is located in section 3.5.1 of the Regents' Policy Manual for the University of Oklahoma.

See the Office of Compliance policy, "Compliance and Quality Improvement Program" and the IRB's SOP 901: Quality Improvement Program for additional information.

17. Non-Compliance

Investigators and research staff are required to promptly report non-compliance to the IRB. The HRPP will report any serious or continuing noncompliance with applicable regulations or the requirements or determinations of the IRB to the appropriate institutional official(s), regulatory authorities, and sponsors.

The IRB has the authority to suspend or terminate approval of the research that is not being conducted in accordance with the IRB policies and/or is not in compliance with federal, state, and local laws.

See the SOP 903: Non-Compliance/Scholarly Misconduct for additional information.

Suspension or Termination of IRB Approval

Approved research projects that are not conducted in accordance with IRB policies/procedures, government laws or regulations, or that have been associated with unexpected harm or serious adverse events to participants may be suspended or terminated by the IRB.

See SOP 411: Suspension or Termination of IRB Approval for additional information.

18. IRB Office Locations and Contact Information

Norman Campus

Office for Human Research Participant Protection
One Partners Place
350 David L. Boren Blvd., Suite 1750
Norman, OK 73019
Telephone number: 405-325-8110
Email address: irb@ou.edu

HSC Campus

Office for Human Research Participant Protection
1000 Stanton L. Young Blvd., LIB 176
Oklahoma City, OK 73117-1213
(or) P.O. Box 26901
Oklahoma City, OK 73190-1046
Campus Mail: Library 176
Telephone number: (405)271-2045
Email address: IRB@ouhsc.edu