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&D 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