

SOP 801: Investigator Qualifications and Responsibilities

1. POLICY

The purpose of this policy is to outline the qualifications and responsibilities of the principal investigator and key personnel 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 review by the IRB.

Graduate students on the Norman Campus may serve as a Principal Investigator. In order for a graduate student to serve as a Principal Investigator, the following criteria must be 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. Must be fully admitted and degree seeking in an academic program.
- c. Must be in good academic standing, and 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 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 have been 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).

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 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 includes information to the IRB regarding the communication process between sites and the management of information obtained during the course of the research project such as:

- Unanticipated problems involving risks to participants or others
- Protocol deviations
- Interim results reporting
- Protocol modifications

The IRB will evaluate this 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 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.
- 1.10.2 The principal investigator must promptly report protocol deviations to the IRB and, when applicable, to the sponsor as described in SOP 407: Protocol Deviations and Unanticipated Problems. Protocol deviations may or may not place participants at risk.
- 1.10.3 The principal investigator must promptly report any allegations of noncompliance and/or scholarly misconduct to the IRB as described in SOP 903: Non-Compliance/Scholarly Misconduct.
- 1.10.4 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.
- 1.10.5 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

1.12 Conflict of Interest

The principal investigator is responsible for disclosing all potential conflicts of interest to the IRB for any member of the research team at the time the research project is submitted for review, in compliance with SOP 104A: Conflict of Interest-Investigators.

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 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 to conduct research. The IRB will not accept new research project submissions that include KSP 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. These issues must be resolved prior to assigning the submission to an IRB reviewer.
- 7.2 The IRB Administrator provides assistance to investigators on 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 on curriculum development for training investigators and research team members.
- 7.4 The HRPP provides investigators and research team members with appropriate training on the responsibilities and conduct of human participant research.

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- 7.5 The IRB Staff and IRB Chair 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 part of the auditing 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:** 09/09/2016

NEXT ESTABLISHED REVIEW DATE: AUGUST 2018