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 or temporary full- or part-time paid faculty or staff appointment. Students, fellows, or residents may serve as a co-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.

Graduate students on the Norman Campus may serve as a Principal Investigator, but the research project must include a faculty member as a Faculty Sponsor. Student applications to the IRB must include an Appendix A.

Employees of the affiliated institutions under the University's FederalWide Assurance may also serve as principal investigators.

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 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 IRB Review of Research.

The principal investigator must obtain prior IRB review and approval before engaging in research involving human participants, except in the case of an emergency exemption from IRB review.

1.5 Responsible Conduct of Research.

Principal investigators engaged in research involving human participants are responsible for:

1.5.1 Designing protocols that minimize risks to participants and maximize benefit.

1.5.2 Providing for the safety and welfare of the participants enrolled.

1.5.3 Conducting the research in compliance with the IRB-approved research protocol, the applicable regulations, and in accordance with the principles of the Belmont Report.

1.5.4. Control of FDA test articles under investigation.

1.5.5 Personally conducting the research and supervising all sub-investigators and key research personnel involved in the research.

1.5.6 Complying with the Belmont Report, IRB policies, institutional policies, and federal and state law and regulations.

1.5.7 Not enrolling participants prior to IRB approval or on or after expiration of IRB approval.

1.5.8 When the investigator is the lead investigator of a multi-site study, the principal investigator must submit information to the IRB regarding the communication process between sites and the management of information obtained during the course of the study such as:

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

The IRB will evaluate the management plan as it relates to the protection of participants to assess that it is adequate.

1.5.9 If the principal investigator determines that the participant is to be removed from the study for non-compliance, the investigator should notify the participant in writing of this action if the participant can be reached.

Investigators are subject to QI evaluations to determine knowledge and compliance with 21 CFR 312 or 812 and Good Manufacturing Practice.

1.6 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 only the informed consent document approved and stamped by the IRB.

1.7 Amendments/Modifications

The principal investigator must submit in writing any proposed amendments/modifications in the research project or informed consent form for IRB review and approval before initiating the change, except when necessary to eliminate apparent immediate hazards to human participants.

The principal investigator may not enroll more participants than approved by the IRB without obtaining IRB approval for increased numbers.

1.8 Continuing Review

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 an application for continuing review prior to the expiration of the research project.

1.9 Reporting Responsibilities

1.9.1 The principal investigator must promptly report to the IRB any unanticipated problems involving risks to participants or others as described in SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations.

1.9.2 The principal investigator must promptly report protocol deviations to the IRB and, when applicable, to the sponsor. Protocol deviations are events that are departures from the specific protocol procedures approved by the IRB. Protocol deviations may or may not place participants at risk.

1.9.3 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.

1.9.4 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.

1.10 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 forms
- 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 co-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 study

1.11 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.

2. SCOPE

These policies and procedures apply to all investigators involved in human participant research activities.

3. RESPONSIBILITY

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.

IRB Chair or 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.

The investigator is responsible for conducting research that is in compliance with the Belmont Report, IRB policies, federal law/regulations, state law/regulations, institutional policy, and IRB policy.

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, institutional policy, and IRB policy.

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 104A, Conflict of Interest-Investigators

SOP 403, Initial Review – Criteria for IRB Approval

SOP 404, Continuing Review

SOP 405, Amendments

SOP 406, Determination of Human Research

SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations

SOP 502A, Categories of Research Drugs

SOP 701, Consent Process and Documentation.

SOP 802, Sponsor Responsibilities

SOP 901, Quality Improvement Program

6. ATTACHMENTS

801-A Investigator's Manual
102B-A Written Attestation

7. PROCESS OVERVIEW

7.1 Upon receipt of a new study application, IRB Staff confirms employment status of the principal and co-principal investigators. The IRB will not accept new project applications that include key personnel who have not completed the required IRB education. Residents, fellows, and graduate students are not allowed to serve as principal or co-principal investigators at the HSC campus. The HSC IRB Staff is also responsible for obtaining the new Registration Form. These issues must be resolved prior to entering the new study into the database.

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.

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: 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012