SOP 102B: KEY STUDY PERSONNEL EDUCATION

1. POLICY

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

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

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

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

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

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

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

Specific Policies

1.1 Education

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

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

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

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

2. SCOPE

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

3. RESPONSIBILITY

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

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

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

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Guidance Document, IRB Guidebook
NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

5. REFERENCES TO OTHER APPLICABLE SOPS

None.

6. ATTACHMENTS

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

7. PROCESS OVERVIEW

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

Individuals from non-affiliated institutions (those not designated under the University FWAs) must provide documentation that they completed a course in human research participant protection. In lieu of such a course, these individuals must fulfill the requirement as stated under either 7.1.1 or 7.1.5 of this SOP.
The HRPP Education Coordinator will discuss with the HRPP Director and the Quality Improvement (QI) Coordinator implementation of improvements to the Education Program identified through the QI Program.

7.1 Initial Education Requirements
The IRB will not accept new research project submissions that include KSP who have not completed the required IRB education.

Health Sciences Center Campus
7.1.1 Completion of the Collaborative IRB Training Initiative (CITI) Basic Web-based Course. The CITI Basic Course consists of modules covering the protection of human participants in both biomedical and social/behavioral research.

7.1.2 Attendance of the HSC In-House Education program on human research participant protection. Human research education materials are available on the IRB website for attendees to download prior to the program. Important points are reinforced with a quiz distributed at the conclusion of the program. The program will include the following core topics:

- Introduction
- Historical Review of Research with Human Participants
- Ethical Principles Underlying Research with Human Participants
- Conflict of Interest
- Overview of Federal Regulations and Agencies Governing Research
- Institutional Review Board
- HIPAA & Human Participant Research
- Informed Consent – Document & Process
- Recruitment & Advertising
- Clinical Research with Drugs, Biologics, Devices & Good Clinical Practice
- Special Issues for Behavioral & Psychiatric Research
- Research Data and Information Security

7.1.3 Written Attestation signed by KSP to follow applicable federal regulations governing research involving human participants.

7.1.4 Timeframe for Completion of Initial Requirements.

KSP requiring IRB education must register for and attend a scheduled HSC In-House Education Program during which they can sign the Written Attestation. They must complete the CITI Basic Web-based Course prior to submission of a new research project to the IRB.

Norman Campus
7.1.5 KSP must complete the Collaborative IRB Training Initiative (CITI) Basic Social Behavioral Web-based Course before their IRB research project
can be approved. For Graduate Student research, this includes the Faculty Sponsor.

7.2 Continuing Education Requirements

**Health Sciences Center Campus**

7.2.1 KSP are required to successfully complete the CITI Refresher Web-based Course every other year in areas germane to their responsibilities.

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

**Norman Campus**

7.2.3 KSP are required to successfully complete the CITI Refresher Social Behavioral Web-based Course every other year subsequent to the completion of the Basic Social Behavioral course.

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

7.3 Documentation of Education

**Health Sciences Center Campus**

7.3.1 Education Requirements

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

**In-House Education Program:**
Certificate of completion will be generated and distributed at the program.

**Written Attestation:**
KSP will obtain a Written Attestation document from the IRB. Upon completion of the initial education requirements, KSP will sign, date, and forward the Written Attestation to the IRB office.

7.3.2 Continuing Education Requirements

**CITI Refresher Web-based Course:**
A completion report is generated by the program and automatically forwarded to the IRB. Once the user completes the course, the program allows the user to print a copy of the completion report.

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

CITI Basic Web-based Course:
A completion report is generated by the program and automatically forwarded to the IRB and to the faculty, staff, or students.

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

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

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

APPROVED BY: ________________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016