

SOP: 102B
Key Personnel Education

1. POLICY

Education of key personnel 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.

Key personnel are individuals who provide study-related services or assistance and who have knowledge of the study protocol and the identity of study participants or their protected health information. Key personnel include principal investigators, co-principal investigators, sub-investigators, research coordinators, and individuals from an affiliated institution.

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

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

The IRB will not accept new project applications that include key personnel who have not completed the required IRB education.

The IRB shall provide key personnel who are engaged in research involving human participants 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 read and agree to comply with the standards.

IRB Standard Operating Procedures and the Investigator's Manual are available to key personnel involved in research.

Specific Policies

1.1 Education

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

- C. Key personnel shall participate in initial and continuing education in areas germane to their responsibilities.

1.2 Documentation

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

2. SCOPE

These policies and procedures apply to all key personnel engaged in human participant research.

3. RESPONSIBILITY

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

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

The HRPP Director or IRB Education Coordinator maintains and updates the CITI 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

102B-B Memorandum dated 08/01/05 from Dr. Joseph Ferretti, OUHSC Senior Vice President & Provost

102B-B-1 Email correspondence dated 3/07/05 from Director of Compliance/University Privacy Official

603B-A Federalwide Assurance-HSC Campus

603B-C Federalwide Assurance-Norman Campus

7. PROCESS OVERVIEW

The education status of all key personnel designated on the application is verified by the HRPP Director or designee. The IRB does not accept new project applications that include individuals who have not completed the required IRB education.

Individuals from non-affiliated institutions (those not designated under the OU 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 IRB Education Coordinator will discuss with the HRPP Directors and the QI Coordinator, implementation of improvements to the Education Program identified through the QI Program.

7.1 Initial Education Requirements

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. Power Point presentations and program materials are available on the IRB website for attendees to download prior to 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
 - Tissue Banking and Genetics Research
 - Special Issues for Behavioral & Psychiatric Research
 - Research Data and Information Security
- 7.1.3 Written Attestation signed by key personnel to follow applicable federal regulations governing research involving human participants.
- 7.1.4 Timeframe for Completion of Initial Requirements.

Key personnel 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 project application to the IRB.

Norman Campus

- 7.1.5 Faculty, staff, and students must successfully complete the Collaborative IRB Training Initiative (CITI) Basic Social Behavioral Web-based Course before they can submit research projects to the IRB.

7.2 Continuing Education Requirements

Health Sciences Center Campus

- 7.2.1 Key personnel 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. Key personnel are encouraged to attend.

Norman Campus

- 7.2.3 Key personnel are required to successfully complete the CITI Refresher Social Behavioral Web-based Course every 2 years subsequent to the completion of the Basic Social Behavioral course.
- 7.2.4 The HRPP Director and Education Coordinator routinely educate students and key personnel in classroom settings via an IRB PowerPoint presentation.

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 their own completion report.

In-House Core Education Program:

Certificate of completion will be generated and distributed at the program.

Written Attestation:

Key personnel will obtain a Written Attestation document from the IRB website. Upon completion of the initial requirements, they will sign, date, and forward their 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 off a copy of their own completion report.

IRB Workshops:

A certificate of completion is generated by the IRB Education Coordinator and forwarded to attendees. A copy is retained by the 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.

The HRPP Director or IRB Education Coordinator will maintain files to house documentation regarding education status. The education status of all key personnel is also tracked electronically. Research study submissions will not be accepted by the IRB without confirmation that all key personnel have completed the required education.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012