

SOP 102C: IRB & HRPP STAFF EDUCATION/TRAINING

1. POLICY

Training of IRB and Human Research Participant Protection (HRPP) staff involved in research projects is critical if the IRB is to protect the rights and welfare of research participants in a consistent manner throughout the University research community.

IRB and HRPP staff charged with responsibility for reviewing and overseeing human participant research shall receive training by the HRPP Director or designee in the regulations, guidelines, ethics, and policies applicable to human participant research.

Specific Policies

1.1 Education and Training

- 1.1 HRPP and IRB staff who oversee research on 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 ongoing training by the HRPP Director or designee regarding the responsible review and oversight of research and these SOPs.
- 1.2 The NC HRPP Director, in consultation with the Director of Compliance, and the HSC HRPP Director, in consultation with the HSC Vice President for Research shall establish the educational and training requirements for IRB and HRPP staff who review Biomedical and Social Behavioral research involving human participants and who perform related administrative duties. Initial and ongoing training shall be provided and documented by the University through the HRPP Education Coordinator.
- 1.3 HRPP and IRB staff shall receive initial and continuing training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOPs).
- 1.4 HRPP and IRB staff shall attend workshops and other educational opportunities focused on IRB functions. The University shall support such activities to the extent possible and as appropriate to the responsibilities of staff.
- 1.5 The Quality Improvement (QI) Coordinator shall discuss with the HRPP Director and HRPP Education Coordinator implementation of improvements to the HRPP Education Program identified through the QI Program.

1.2 Documentation

The HRPP Education Coordinator shall document such training and continuing education and add it to the records of the IRB as described in these SOPs.

2. SCOPE

This SOP applies to all HRPP and IRB staff.

3. RESPONSIBILITY

- 3.1 The HRPP Director is responsible for guiding the development and curriculum of IRB and HRPP staff training programs.
- 3.2 The HRPP Education Coordinator is responsible for conducting and/or supervising all relevant training programs.
- 3.3 The HRPP Education Coordinator orders and distributes all reference materials, guidebooks, and regulatory texts necessary for new staff training and education.
- 3.4 The HRPP Director prepares and gathers materials for the orientation session. The HRPP Education Coordinator notifies staff of the next scheduled In-House Education Program (HSC only).

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

- 102C-A Training Checklist and Documentation – IRB Staff
- 603B-A Federalwide Assurance- HSC Campus
- 603B-C Federalwide Assurance-Norman Campus

7. PROCESS OVERVIEW

7.1 Initial Education & Training Requirements

7.1.1 Attendance of the IRB and HRPP Staff Orientation Session

The HRPP Director conducts this session promptly, which provides new staff with a general overview of the HRPP program, the organizational structure of the individual units, and their relationship within the University.

Staff are expected to read and become familiar with the information included in the following reference materials:

- OHRP Guidance Document, IRB Guidebook
- *Protecting Study Volunteers in Research, A Manual for Investigative Sites*, Third Edition by Cynthia Dunn, M.D. & Gary Chadwick, Pharm.D., MPH (HSC only)
- *Institutional Review Board Management and Function*, by Robert J. Amdur, MD, and Elizabeth A. Bankert, MA
- OU IRB Standard Operating Procedures (SOP)
- IRB/Clinical Investigator Reference Guide (HSC only)

- CFR & ICH Guidelines Reference Guide (HSC only)
- CFR Medical Device Reference Guide (HSC only)

7.1.2 Successful Completion of the Collaborative IRB Training Initiative (CITI) Basic Web-based Course.

All modules included in the program are required and shall be completed within the first week of employment.

7.1.3 Completion of Individual Instruction Provided by the HRPP Staff

Using the University SOP as a guide, instruction entails day-to-day IRB functions and utilization of the IRB electronic information system and shall be completed within the first two weeks of employment.

7.1.4 Attendance of the Next Scheduled HSC In-House Education Program (HSC Campus Only)

Program covers human research participant protection and includes the following topics:

- 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
- Research Data and Information Security

7.2 Continuing Education Requirements

7.2.1 Read and Review Both the IRB Management & Function Text and the IRB Management and Function Workbook by Amdur & Bankert, in preparation for the IRB Professional Certification (CIP) Exam. Eligibility: After two years of service.

7.2.2 Attendance of PRIM&R Annual Conferences Eligibility: After 2 years of service.

7.2.3 Attendance of IRB Continuing Education Sessions

These sessions will consist of IRB regulatory, University, and/or operational policies and procedures.

7.3 Documentation of Training & Education

The HRPP Education Coordinator or designee documents completion of all education and training requirements by the following:

- IRB & HRPP Staff Orientation: Document attendance with training checklist.

- CITI Web-based Course: A completion report is generated by the program and automatically forwarded to the HRPP Education Coordinator.
- Individual and group training instruction: Progress report of topics covered recorded by the HRPP Education Coordinator.
- HSC In-House Education Program: Sign-in sheet documenting attendance.
- Annual Conference Attendance: Recorded in the personnel file of each attending individual IRB staff member.

APPROVED BY: _____ **DATE:** 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016