

**SOP: 102A**  
**IRB MEMBER EDUCATION**

**1. POLICY**

Education of IRB members 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 members charged with responsibility for reviewing, approving, and overseeing human participant research shall receive education in the regulations, guidelines, ethics, and policies applicable to human participant research.

All IRB members shall be apprised of University organizational structure with emphasis on the independent nature of the relationship between the IRB and the University. The actions of the Board members relating to their responsibilities to protect human participants of research shall not be measured or evaluated in terms of institutional or financial goals.

**Specific Policies**

**1.1 Training**

- A. IRB members who are overseeing research on human participants, as defined in the glossary, 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 education by the HRPP Director or designee regarding the responsible review and oversight of research and these policies and accompanying procedures.
- B. The HRPP Director, under the direction of the Director of Compliance, shall establish the educational requirements for IRB members who review biomedical and behavioral research involving human participants. The HRPP Education Coordinator shall provide and document initial and continuing education.
- C. Members of the IRB shall participate in initial and continuing education in areas germane to their responsibilities.
- D. IRB Chairs and Vice Chairs shall receive additional education in areas germane to their additional responsibilities.
- E. IRB members shall attend workshops and other educational opportunities focused on IRB functions. The University shall support such activities to the extent possible based on budget considerations and as appropriate to the responsibilities of IRB members and staff.

**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 this SOP.

**2. SCOPE**

These policies and procedures apply to all IRB members.

**3. RESPONSIBILITY**

The HRPP Education Coordinator, under the direction of the HRPP Director, is responsible for establishing, conducting, and/or supervising all relevant education programs for all campuses.

The HRPP Education Coordinator is responsible for guiding the development of IRB member education programs, in collaboration with the HRPP Director.

The HRPP Education Coordinator documents new IRB member training.

#### 4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107

45 CFR 46.107

OHRP 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

102A-A Bibliography & Resource List

102A-A-1 Bibliography & Resource List-NC

102A-B Training Checklist and Documentation – IRB members

603B-A Federalwide Assurance- HSC Campus

603B-C Federalwide Assurance-Norman Campus

#### 7. PROCESS OVERVIEW

##### 7.1 Initial Education Requirements

###### 7.1.1 Attendance of the New IRB member Orientation Session

The HRPP Director and/or IRB Education Coordinator will conduct this education session, which provides new IRB members with a general overview of the HRPP program, policies, and procedures pertinent to IRB meeting functions and Board member expectations.

Timeframe for completion is prior to appointment to the IRB.

The HRPP Education Coordinator will provide IRB members with a new IRB Member Packet that includes the items listed below. IRB members are expected to read and become familiar with the information included in the following reference materials:

- OHRP IRB Guidebook containing federal regulations, Belmont Report, OHRP and FDA guidance documents
- IRB Member Handbook by Robert Amdur, M.D.
- IRB Primary Reviewer Checklists
- Orientation Power Point Presentation Handout

###### 7.1.2 Health Sciences Center Campus IRB members:

###### Attendance of the next scheduled HSC In-House Education Program

This 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

- Overview of Federal Regulations and Agencies Governing Research
- Institutional Review Board
- HIPAA & Human Participant Research
- Informed Consent – Document & Process
- 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 Successful Completion of the CITI Basic Web-based Course

On the HSC Campus, the timeframe for completion is within three months of attendance of the in-house program.

On the Norman campus, new members shall complete the CITI Basic Social/Behavioral training within the first three months of their tenure.

## 7.2 Continuing Education Requirements

7.2.1 Successful Completion of the (CITI) Refresher Web-based Course.

Timeframe for completion: Required every other year for HSC IRB members. Norman campus members take the CITI refresher course in social/behavioral research every year, subsequent to the basic training.

7.2.2 Board Member Education Series:

On the HSC campus, information regarding new or revised IRB policies and federal regulations/guidance is posted via Blackboard (campus web-based course management system). Board members review this information, which is posted periodically.

On the Norman campus, the HRPP Director periodically distributes updated information regarding new or revised IRB policies and federal regulations/guidance as well as informative articles on current events in human research participant protections.

7.2.3 Attendance of PRIM&R and ARENA Annual Conferences

IRB Chairs, Vice Chairs, and members are encouraged to attend as funds allow.

7.2.4 Attendance of Regional or National Conferences

As conferences on current regulatory issues or issues pertaining to human participant research protection become available, IRB members (including Chairs & Vice Chairs) are encouraged to attend based on their role and area of expertise in relation to topics covered at available conferences. Frequency of conference attendance is based on availability of funding.

## 7.3 Documentation of Training & Education

The HRPP Education Coordinator documents the completion of the education requirements.

- New IRB Member Orientation Session: Sign-in sheet documenting attendance.
- HSC In-House Core Education Program: Sign-in sheet documenting attendance.
- CITI Web-based Courses: Completion reports are generated by the CITI program, automatically forwarded to the Education Coordinator at HSC and to the HRPP Director at OU-NC.
- HSC review of Educational Information on Blackboard: Log-in recorded by system.
- Norman Campus: Sign-in sheet documenting receipt of educational materials.
- PRIM&R and ARENA Annual Conference: Recorded in the file of each attending IRB member on both campuses.
- Attendance of additional regional or national conferences: Attendance recorded in the file of each attending IRB member on both campuses.

The HRPP Education Coordinator keeps documentation of requirements in a file for each IRB member. IRB tracks completion of IRB member requirements electronically.

**APPROVED BY:** \_\_\_\_\_

**DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012