Oklahoma State University Institutional Review Board Standard Operating Procedures		
IRB Member/URC Staff Training	SOP #	GA 102
	Effective Date	1/1/2012
	Revision Date	08/11/2015
	Revision #	1
	Approval: IRB	10/14/2015

1. POLICY

Training of Institutional Review Board (IRB) members and Office of University Research Compliance (URC) staff assigned to support the IRB is critical if the IRB is to fulfill its mandate to safeguard the rights and welfare of human subjects in a consistent manner for the Oklahoma State University (OSU) research community.

IRB members, URC staff, and others charged with responsibility for reviewing, approving, and overseeing human subject research should receive comprehensive training in the regulations, guidelines, ethics, policies, and procedures applicable to research involving human subjects conducted by agents of OSU.

All IRB members and appropriate URC staff will be apprised of OSU's organizational structure with emphasis on the independent nature of the relationship between the IRB and the University. The actions of the IRB and the administrative staff relating to their responsibilities to safeguard the rights and welfare of human subjects of research conducted by agents of OSU will not be measured or evaluated in terms of institutional or financial goals.

Specific Procedures

1.1 Training

1.1.1 The Institutional Official (IO), the Alternate Institutional Official (AIO), the IRB Chair, and the IRB Manager establish the educational and training requirements for IRB members and URC staff who review research involving human subjects that is conducted by agents of OSU , as well as those who perform related administrative duties on behalf of the IRB. Initial and ongoing training is provided and documented by OSU through the Collaborative Institutional Training Initiative (CITI) and overseen by the IRB Manager or designee.

1.1.2 IRB members and URC staff who oversee research conducted by agents of OSU that involves human subjects, as defined in 45 CFR 46.102 (f), will receive initial and ongoing training regarding the responsible review and oversight of research involving human subjects. This requirement must be met by successfully completing the appropriate course or courses within the Collaborative Institutional Training Initiative (CITI) online human subjects research training program. A list of pertinent courses follows.

- IRB Committee Member/Alternate
- IRB Chair
- IRB Staff
- University Research Compliance Officer (Asst. VP)
- Institutional Official (VPRTT)

In addition, educational materials and/or training will be provided to IRB members at convened meetings.

1.1.3 New IRB members, including alternate members, will receive the following educational materials upon their appointment to the Board:

- OSU Policy 4-0115 - Policy for the Protection of Human Subjects in Research
- Website link to the IRB's standard operating procedures (SOPs)
- Website link to the OSU IRB webpages
- Institutional Review Board Member Handbook
- 45 CFR 46 Federal Policy for Protection of Human Subjects
- Belmont Report
- Declaration of Helsinki
- Nuremburg Code

1.1.4 The IRB Chair and Vice Chair will receive additional training in areas germane to their responsibilities.

1.1.5 New URC staff assigned to support the IRB will receive the following educational materials:

- OSU Policy 4-0115 - Policy for the Protection of Human Subjects in Research
- The IRB's SOPs
- Institutional Review Board Member Handbook
- 45 CFR 46 Federal Policy for Protection of Human Subjects
- Belmont Report
- OSU IRB website

1.1.6 URC staff assigned to support the IRB will receive initial and continuing training in the areas germane to their responsibilities, including all IRB policies, IRB SOPs, and IRB and URC procedures.

1.1.7 IRB members, including alternate members, and URC staff assigned to support the IRB will be encouraged to attend workshops, webinars, and other educational opportunities focused on IRB functions and human subject protection. OSU, through URC, will support such activities to the extent possible and as appropriate to the responsibilities of particular IRB members and URC staff.

1.2 Documentation

Training and continuing education shall be documented in the members' file and staff personnel records.

2. SCOPE

This standard operating policy and procedure applies to all IRB members and URC staff with IRB responsibilities.

3. RESPONSIBILITY

Under the direction of the IO, the IRB Manager, in collaboration with the IRB Chair and the AIO(the Assistant Vice President for Research Compliance), is responsible for establishing, monitoring, and/or conducting all relevant training programs for IRB members and URC staff. In addition, the IRB Manager (or designee) is responsible for guiding the development of IRB member training programs, in collaboration with the IRB Chair and the AIO.

4. APPLICABLE REGULATIONS AND GUIDELINES

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

This SOP affects all other SOPs.

6. ATTACHMENTS

7. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
IO IRB Manager IRB Chair Assistant V.P. -URC	Establish training and educational requirements and content for IRB members and administrative staff. Set annual budget.	
	Based on requirements and budget, determine training & education schedule. Acquire outside publications, schedule attendance at PRIM&R and seminars as budget allows. Coordinate CITI training program.	
IRB Manager	Notify IRB Coordinator regarding contacting IRB members about training/education requirements & timeframe. Send reminders as needed.	CITI database
IRB Manager (or designee)	Maintain documentation of all training and education completed.	CITI database & IRB member files