Oklahoma State University Institutional Review Board Standard Operating Procedures		
Maintenance of Standard Operating Procedures	SOP #	GA 101
	Effective Date	1/1/2012
	Revision Date	1/10/2014
	Revision #	1
	Approval: IRB	05/14/14

1. POLICY

Following federal regulations and guidance, which is supported by Oklahoma State University (OSU) policies, ensures that the rights and welfare of human subjects of research will be overseen and protected in a uniform manner, regardless of changes in personnel. Written standard operating procedures (SOPs) must be in place to ensure the highest quality and integrity of IRB review and oversight of human subject research and the appropriate documentation of such oversight.

Specific Procedures

1.1 Review, Revision, Approval of Standard Operating Procedures

1.1.1 Changes to regulations, federal guidelines, or research practice as well as the policies and procedures of OSU may require a new SOP or revision of a previously issued SOP.

1.1.2 SOPs will be reviewed by the appropriate OSU official(s) at regular intervals established by the Assistant Vice President for Research Compliance who manages the Office of University Research Compliance (URC). At a minimum, review of SOPs shall take place at least once every four (4) years. New or revised SOPs will be reviewed initially by the IRB Manager, the IRB Chair, and the Assistant Vice President for Research Compliance. A final draft will be distributed to the IRB for comment and acceptance.

1.1.3 Final approval of new or revised SOPs is required by the Institutional Official (IO). Documentation of review and approval is accomplished by signature of the IO on the new/revised SOP.

1.2 SOP Dissemination and Training

1.2.1 When new or revised SOPs are approved, they will be disseminated to the appropriate individuals and departments via email or mail and will be available on the Office of University Research Compliance website.

1.2.2 Training will be provided to all members of the IRB and IRB staff on new and revised SOPs. Evidence of training will be documented and filed by the IRB Manager.

1.2.3 Each new IRB member or IRB office staff employee must review all applicable SOPs prior to undertaking any responsibilities with the IRB. Evidence of training will be documented and filed by the IRB Manager.

1.3 Forms

Forms are used to 1) ensure that policies are integrated into the daily operations of research and review throughout OSU, and 2) enable IRB office staff to manage, review, track, and handle notification functions consistently. Forms are either controlled or non-controlled.

1.3.1 Controlled forms are regulatory documents that become part of the permanent record of IRB review and determination. Therefore, they must be reviewed and approved as described in sections 1.1 and 1.2.

1.3.2 Non-controlled forms are management tools that are not subject to the standards of control cited in sections 1.1 and 1.2.

2. SCOPE

These SOPs apply to all IRB personnel and appropriate URC office staff.

3. RESPONSIBILITY

The OSU Institutional Official (IO) is responsible for granting final approval (as appropriate) to new and revised SOPs for the IRB.

The OSU Assistant Vice President for Research Compliance is responsible for establishing intervals for the timely review of SOPs and for periodically reviewing and modifying (as appropriate) OSU policies pertaining to research involving human subjects.

The IRB Manager and IRB Chair (or his/her designee) are responsible for periodically reviewing and suggesting modifications as appropriate to the IRB's SOPs.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108
21 CFR 56.108, 56.109, 56.113

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

GA 101-A SOP Revision Worksheet
GA 101-B SOP Review Meeting Template
GA 101-C SOP Revision Log
GA 101-D Forms Revision Log
GA 101-E SOP Template

7. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
Assistant VP for Research Compliance	Monitor appropriate sources and contacts for procedure updates, note procedures that may need revisions and indicate priority.	SOP Revision Worksheet
IRB Manager IRB Chair	On pre-determined schedule, meet regarding changes to SOPs.	SOP Review Meeting Template

IRB Manager IRB Staff	Discuss changes and determine if additional procedures are required or if forms need to be revised.	
IRB Manager	Revise standard operating procedures. Revise forms as needed. Track changes.	SOP Template SOP Revision Log Forms Revision Log
Institution Official	Sign new and revised SOPs.	
IRB Manager	Update SOPs and archive hard copies of previous SOPs.	
IRB Manager	Notify appropriate staff to make changes on electronic system and to archive previous versions of SOPs.	
	Replace & destroy paper copies of obsolete SOPs.	
	Notify research community & distribute new SOPs & forms as needed.	Notification of SOP Change