# SOP: 101
# STANDARD OPERATING POLICIES AND PROCEDURES MAINTENANCE

## 1. POLICY

The IRB shall follow regulations and guidance of DHHS, FDA, and institutional policies to facilitate the protection of the rights and welfare of human participants. The IRB shall oversee and review research and maintain it in a uniform manner, regardless of changes in personnel. Written standard operating policies and procedures (SOPs) foster the highest quality and integrity of the review and oversight of research involving human participants and for the adequate documentation of such oversight.

SOPs provide the framework for the ethical and scientifically sound conduct of human research. The policies are general statements of principles within the SOPs and provide overall ethical guidance. The standard operating procedures are specific, detailed directives for implementation of the policies.

### Specific Policies

### 1.1 Review, Revision, and Approval of SOPs

A. Changes to regulations, federal guidelines, research practice, and University policies may require a new SOP or a revision to an existing SOP.

B. The HRPP Director of the applicable campus shall review all SOPs.

C. Appropriate institutional officials shall review SOPs at intervals established by the Director of Compliance.

D. The Director of Compliance or designee must approve new or revised SOPs.

E. Documentation of review and approval shall be by signature of the responsible and authorized individuals.

### 1.2 SOP Dissemination and Training

A. When new or revised SOPs are approved, the IRB office shall disseminate them to the institution via campus-wide email distributions, if possible; IRB website postings; and educational sessions.

B. All members of the IRB, IRB staff, and HRPP staff shall receive training on any new or revised SOPs. The IRB Education Coordinator and/or HRPP Director shall document and file such training.

C. Each new IRB member shall be advised by the Education Coordinator and the HRPP Director of all applicable SOPs prior to undertaking any responsibilities at the IRB. Each new IRB member shall sign a form acknowledging receipt of the SOPs, and this form shall be maintained in the HRPP office.

D. Each new IRB staff member shall be advised by the Education Coordinator and the HRPP Director of all applicable SOPs prior to

undertaking any responsibilities at the IRB. Each IRB staff member shall sign a form acknowledging receipt of the SOPs, and this form shall be maintained in the HRPP office.

E. The HRPP office shall maintain all documentation of IRB member and staff training.

### 1.3 Revision Logs

The IRB shall use the SOP Revision Log to document the review, track the date, and describe the purpose for the revision or new SOP.

## 2. SCOPE

This SOP applies to all HRPP staff, IRB staff, and IRB members.

## 3. RESPONSIBILITY

The Director of Compliance is responsible for granting final approval of new and revised SOPs for both campuses and maintaining standardized policies across campuses, to the extent appropriate.

The HRPP Director is responsible for establishing and periodically reviewing and modifying SOPs, subject to approval of the Director of Compliance.

The IRB Chair or designee is responsible for periodically reviewing and suggesting modifications to the SOPs, to the HRPP Director.

## 4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.113
45 CFR 46.108

## 5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other policies and SOPs.

## 6. ATTACHMENTS

101-A SOP Revision Log

101-B Forms Revision Log

101-C SOP Template

101-D HRPP SOP Acknowledgment Form

## 7. PROCESS OVERVIEW

7.1 The IRB shall maintain written procedures for quality of review and integrity of research.

7.1.1 Revisions to an existing SOP or a new SOP may be required when changes to regulations, federal guidelines, or research practices occur.

7.1.2 Policies are reviewed by the HRPP Director and IRB Chair at intervals established by the Director of Compliance.

7.1.3 Proposals for SOP changes are reviewed by the IRB Executive Committee for each campus.
7.1.4 Final review and approval is granted by the Director of Compliance or designee.

7.2 The HRPP Director monitors and notes the need for revisions or new policies as needed.
7.2.1 The HRPP Director and IRB Chairs meet regarding changes.
7.2.2 The HRPP staff and IRB staff discuss changes and determine if additional procedures are required.
7.2.3 The HRPP Director revises or creates new SOPs along with any forms that need to be created or revised.
7.2.4 The Director of Compliance or designee reviews and signs new or revised policies that are approved.
7.2.5 The HRPP Director updates SOPs, archives copies of the previous SOPs, and delegates changes of the electronic system.
7.2.6 The new or revised SOPs will include an effective date. Old versions of the SOPs are archived.
7.2.7 SOPs are integrated into the daily operations of the IRB.
7.2.8 The HRPP Director notifies the research community of revised SOPs via campus-wide email distributions, if possible; website postings; and educational sessions.

7.3 Approved revised or new SOPs are distributed to appropriate individuals.
7.3.1 Training is provided to all IRB members and staff for revised or new SOPs.
7.3.2 New IRB staff review and receive training by the Education Coordinator or HRPP Director on SOPs prior to undertaking IRB responsibilities.
7.3.3 New IRB members review and receive training by the Education Coordinator or HRPP Director on the SOPs prior to beginning their work as an IRB member.
7.3.4 A member of the HRPP office documents evidence of training.

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

**NEXT ESTABLISHED REVIEW DATE: MAY 2012**