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, review human 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 participant research. The policies are general statements of principles within the SOPs and provide overall ethical guidance that includes specific detailed directives for their implementation.

Specific Policies

1.1 Review, Revision, and Approval of SOPs

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

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

1.1.3 Appropriate Institutional Officials or their designees shall review SOPs at intervals established by the Director of Compliance.

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

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

1.2 SOP Dissemination and Training

1.2.1 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.

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

1.2.3 Each new IRB member shall be advised by the Education Coordinator and the HRPP Director of all SOPs prior to undertaking any responsibilities at the IRB. Each new IRB member shall sign a form acknowledging receipt of the SOPs.

1.2.4 Each new IRB staff member shall be advised by the Education Coordinator and the HRPP Director of all SOPs prior to undertaking any responsibilities at the IRB. Each IRB staff member shall sign a form acknowledging receipt of the SOPs.

1.2.5 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

3.1 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.

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

3.3 The IRB Chair or IRB 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

None.

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, University policies, or research practices occur.

7.1.2 SOPs 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. If lack of consensus regarding an issue or SOP change occurs, the issue or change is brought to the Joint IRB Executive Committee meeting for further discussion and resolution.

7.1.4 Final approval is granted by the Director of Compliance or designee.

7.2 The HRPP Director monitors and notes the need for revisions or new SOPs 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 SOPs that are approved.

7.2.5 The HRPP Director updates SOPs, archives copies of the previous SOPs, and delegates that these changes be made to the electronic information system.

7.2.6 The new or revised SOPs will include an effective date. Old versions of the SOPs will be 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; IRB 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 receives training by the Education Coordinator or HRPP Director on SOPs prior to undertaking IRB responsibilities.

7.3.3 New IRB members receive training by the Education Coordinator or HRPP Director on SOPs prior to beginning their work as IRB members.

7.3.4 A member of the Office of HRPP documents evidence of training.

APPROVED BY: __________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020