SOP 405: MODIFICATIONS

1. POLICY

Any modifications to a previously approved research project, such as modifications to the inclusion/exclusion criteria, research project population, research project procedures, or consent process, requested by the Investigator or sponsor must be approved by the IRB before the modifications are implemented. Such modifications are also known as amendments, protocol modifications, revisions, or changes.

Specific Policies

1.1 General Provisions

Modifications in approved research during the period for which approval has been given may not be initiated without prior IRB approval, except where necessary to eliminate apparent immediate hazards to participants.

Modifications to approved research that are initiated without IRB approval in order to eliminate apparent immediate hazards to the participant must be promptly reported to the IRB. The IRB shall review said modifications to determine whether each change was consistent with ensuring the participants’ continue welfare.

Investigators shall submit requests for modifications to the IRB. Upon receipt of the submission, the IRB Chair or IRB designee shall determine if the modification meets the criteria for minimal risk. If the modification represents more than a minimal risk to participants, it must be reviewed at a convened meeting of the appropriate IRB. Minor modifications involving no more than minimal risk to the participants may be reviewed in accordance with the expedited review process (SOP 402: Expedited Review).

The Investigator must submit modification requests by completing an IRB Modification/Notification Form with a clear description of the requested changes. The Investigator shall include documentation with the completed form indicating the requested modification(s) or for any minor modifications that involve more than minimal risk.

In evaluating the IRB Modification/Notification Form and the documentation, the IRB Chair or IRB designee shall consider expedited review or review by the convened IRB. Expedited review shall be utilized only for minor modifications involving minimal risk. Review by the convened IRB is required for any major, controversial, or questionable modification(s) or for any minor modifications that involve more than minimal risk.

The criteria for approval of modifications to previously approved research are the same as those for initial review (SOP 403: Initial Review - Criteria for IRB Approval).

The Primary and Secondary reviewer model is used for review of modifications to currently approved research projects that require convened IRB review (SOP 203: Duties of IRB Members).
The IRB may require that any significant new findings that arise from the modification and that might relate to participants’ willingness to continue participation will be provided to participants.

1.2 Definitions of Minor Modifications

Minor modifications to previously approved research are those that meet all of the following criteria:

- Involve the addition of no more than minimal risk to participants.
- All added procedures are eligible for initial review using the expedited procedure, if considered independently of the research.

Examples of minor modifications include, but are not limited to:

- Addition of research activities that would be considered exempt or expedited, if considered independently from the main research protocol;
- Minor increases or decreases in the number of participants;
- Changes in the compensation to participants;
- Revisions to improve the clarity of statements in the informed consent documents, research privacy forms, or protocol to correct typographical errors, provided that such changes do not alter the content or intent of the statement;
- Changes in Key Study Personnel.

1.3 Other Criteria

The IRB may require verification of information submitted by an Investigator to provide necessary protection to participants, when deemed appropriate by the IRB.

2. SCOPE

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

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for initial identification of submissions that may qualify for review by the convened IRB. The IRB Administrator coordinates with the IRB Chair or IRB designee to assign Primary and Secondary reviewers and forward these assignments to those reviewers providing or obtaining the tools and resources the IRB members need to complete its research reviews.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer
the review to another IRB with Primary and Secondary Reviewers with the relevant expertise or obtain consultation for that expertise.

3.3 The IRB Chair or IRB designee and the IRB Administrator are responsible to check each item on the agenda to determine whether a consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context, or knowledge or experience in working with special populations.

3.4 Primary and Secondary reviewers are responsible to conduct an in-depth review of all materials and present their findings at the convened IRB.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

3.6 The HRPP Education Coordinator is responsible for the initial and continuing education of the IRB members.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109
21 CFR 56.109

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 203: Duties of IRB Members
SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 403: Initial Review - Criteria for IRB Approval

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
301-C Modification/Notification Form

7. PROCESS OVERVIEW

7.1 The IRB Staff verifies all necessary documents are received per SOP 301: Research Submission Requirements.

7.2 The IRB staff conducts pre-review of the submission, assigns the appropriate Board, and forwards the item to the IRB Administrator for processing. The IRB Administrator checks the modification/notification form for accuracy of information and to verify that all required documents are submitted. An initial assessment of the modification request or notification is conducted to determine if it requires review by expedited procedures or a convened IRB. The submission is either assigned to the next appropriate IRB agenda or assigned to the IRB Chair or IRB designee for review.
7.3 The IRB Chair or IRB designee reviews the content with respect to the risk/benefit analysis, research project design, selection of participants, and the inclusion of required elements in the informed consent document according to applicable federal law and regulations, the Belmont Report, and applicable local and state requirements. If the submission requires convened IRB review, the IRB Chair or IRB designee returns the submission to the IRB Administrator, who assigns the submission to the next appropriate IRB agenda.

7.4 The IRB Chair or IRB designee may require verification of information submitted by an investigator. This information may be obtained from third parties such as the sponsor, other institutions participating in the research, and other IRBs reviewing the research. The IRB Chair or IRB designee will document this verification in the IRB’s electronic information system.

7.5 Prior to the meeting, the IRB Chair designates the Primary and Secondary reviewers for each submission on the agenda. The IRB Administrator assigns the Primary and Secondary reviewers who are reflected in the agenda.

7.6 The IRB Administrator provides to IRB members the agenda and previous IRB meeting minutes prior to each convened IRB meeting.

7.7 The IRB Primary and Secondary reviewers summarize their findings on the reviewer checklists provided in the electronic information system. All IRB members are encouraged to provide information from their review of agenda items using the IRB’s electronic information system. The IRB reviewers determine whether special considerations exist that may influence the review of the submission and whether evidence exists or is needed for third party verification of submitted information. The IRB reviewers present a summary of findings and recommendations at the convened IRB meeting. The IRB Administrator records the conclusions in the IRB meeting minutes.

7.8 All submissions eligible for expedited review shall follow the expedited review process outlined in SOP 402: Expedited Review.