

SOP: 405 AMENDMENTS

1. POLICY

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

Specific Policies

1.1 General Provisions

Amendments in approved research during the period for which approval has been given may not be initiated without prior IRB review (convened IRB, expedited review, or exempt, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to participants.

Investigators shall submit requests for amendments to the IRB in writing. Upon receipt of the request, the IRB Chair or designee shall determine if the amendment meets the criteria for minimal risk. If the amendment represents more than a minimal risk to participants, it must be reviewed and approved at a convened meeting of the appropriate IRB. Minor amendments involving no more than minimal risk to the participants shall be reviewed in accordance with the expedited review procedure. (SOP 402, Expedited Review.)

The Investigator must submit amendment requests by completing an IRB Protocol Modification Form. Documentation shall be included with the completed form indicating the requested amendment(s) and must clearly describe them.

In evaluating the IRB Protocol Modification Form and the documentation, the IRB Chair or designee shall consider expedited review or review by the convened IRB. Expedited review shall be utilized only for amendments involving minor or minimal risk. Review by the convened IRB is required for any major, controversial, or questionable amendment(s).

The criteria for approval of amendments to previously approved research is 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. (SOP 203, Duties of IRB Members.)

1.2 Definitions of Minor Amendments

Minor amendments 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 amendments include, but are not limited to:

- Addition of research activities that would be considered exempt or expedited, if considered independent from the main research protocol;
- Minor increases or decreases in the number of participants;
- Amendments in remuneration to participants;
- Amendments to improve the clarity of statements in the informed consent form, research privacy form, or protocol to correct typographical errors, provided that such changes do not alter the content or intent of the statement.

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

These policies and procedures apply to all HRPP and IRB staff, Investigators, research staff, and IRB members.

3. RESPONSIBILITY

The IRB Administrator is responsible for providing the IRB Chair with all the tools and resources needed to complete the initial review of the amendment.

The IRB Chair or 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 designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or designee shall defer the review to another IRB with primary and secondary reviewers with the relevant expertise or obtain consultation for that expertise.

Primary and secondary reviewers are responsible to conduct an in-depth review of all materials.

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

The IRB Chair or designee is responsible for determining expedited review or review by the convened IRB of the amendment.

The IRB Chair or 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 vulnerable populations.

The IRB member (reviewer) is responsible for presenting the amendment at the next convened meeting.

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 402, Expedited Review

SOP 403, Initial Review - Criteria for IRB Approval

SOP 303B, IRB Meeting Administration.

6. ATTACHMENTS

203-D Reviewer Checklist for Research Involving Pregnant Women & Fetuses

203-E Reviewer Checklist for Research Involving Neonates

203-F Reviewer Checklist for Research Involving Prisoners

203-G Reviewer Checklist for research Involving Children

203-I Modification Reviewer Checklist

301-C Protocol Modification Form

301-C-1 Request for Modification of Approved Research

7. PROCESS OVERVIEW

7.1 The IRB Staff makes sure all documents are reviewed for submission, per SOP 301, Research Submission Requirements.

7.2 The IRB Administrator provides to the IRB Chair, designee, or the IRB the item to be reviewed and the tools to conduct the review.

7.3 The IRB Administrator initially reviews the amendment for expedited review or review by the convened IRB. The IRB Administrator forwards the IRB Protocol Modification Form and the documentation to the IRB Chair for expedited review. If the IRB Administrator is not certain if an amendment requires review by the convened IRB, the amendment is forwarded to the IRB Chair to make that determination.

7.4 The IRB Chair or designee reviews the amendment and documents in writing expedited approval of the amendment, request for minor revisions or additional information, or forward for convened IRB review.

If approved, the IRB Administrator prints the approval letter, presents it to the IRB Chair for signature, and sends it to the Investigator. The IRB Administrator also posts the expedited approval to the next appropriate agenda.

If revision or additional information is required, the IRB Administrator forwards this information to the Investigator for a response.

If review by the convened IRB is required, the IRB Administrator places the amendment on the next appropriate agenda for convened IRB review.

7.5 If the amendment is reviewed by the convened IRB, review is conducted in accordance to SOP 303B, IRB Meeting Administration.

7.6 For approved amendments that change personnel, revise enrollment totals, or revise project titles, the IRB Administrator updates the appropriate fields in the IRB database.

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

NEXT ESTABLISHED REVIEW DATE: MAY 2012