

NIH HRPP SOP 10 v1

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &  
IMPLEMENTATION**

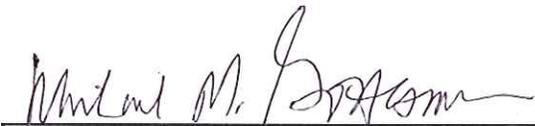
**OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS**

**SOP Number: 10**

**SOP Title: AMENDMENTS TO IRB-APPROVED RESEARCH**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB  
Chairs, IRB Administrators, Protocol Navigators**

**Approval:**

  
Deputy Director for Intramural Research

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Date

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## SOP 10 AMENDMENTS TO IRB-APPROVED RESEARCH

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## **SOP 10 AMENDMENTS TO IRB-APPROVED RESEARCH**

### **10.1 PURPOSE**

This SOP outlines the responsibilities of PIs and IRBs regarding amendments to protocols already approved by the IRB.

### **10.2 POLICY**

Principal Investigators (PIs) are responsible for obtaining IRB approval of proposed amendments to an IRB-approved protocol before implementing them. The only exception to this requirement is when a change is necessary to eliminate apparent immediate hazards to subjects (see 45.CFR 46(b)(4) and SOP 19, "Investigator Responsibilities") or when the amendments are only administrative in nature and not changes to the research.

### **10.3 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR (PI)**

The PI is responsible for submitting the following materials for IRB review of amendment requests:

- A. An NIH Intramural Clinical Protocol Amendment Application (Appendix 1).
- B. Updated drafts of any documents that would be changed by the amendment, such as the current approved protocol and consent/assent document with the proposed changes highlighted showing deletions, additions and version dates.
- C. Documentation of other required amendment reviews or approvals, if applicable, e.g., DEC, FDA, Radiation Safety Committee, or IRB approval from another site.
- D. Any additional requirements of the IRB.

### **10.4 PROCEDURES FOR IRB REVIEW OF PROTOCOL AMENDMENTS**

- A. Administrative Pre-review of Protocol Amendments: The IRB administrative staff may pre-review amendment requests to assist the IRB chair to determine if the investigator submitted all necessary information. Pre-review may also be used to

determine whether the amendment would be a minor change to the research and may be eligible for expedited review (See SOP 7A “Requirements for Expedited Review of Research by NIH IRBs”).

- B. Expedited Review of Amendments: If the Chair or designee decides that the amendment is eligible for expedited review, it is reviewed according SOP 7A.8 (Procedures and Criteria for Expedited Review of Amendments that Constitute a Minor Change).
- C. Review of Amendments by the Convened IRB:
1. All IRB members receive all the submitted amendment materials and will have access to the complete IRB protocol.
  2. IRB members must review the provided materials in order discuss them and vote at the meeting.
  3. The IRB Chair may assign an IRB member to perform a primary review of the amendment and lead the discussion at the IRB meeting.
  4. In reviewing the proposed amendment, the IRB should consider how it will affect the conduct of the study; whether it meets the regulatory criteria for approval (45 CFR 46.111); and whether or not it can be approved as written based on the IRB’s risk/benefit assessment.
  5. The IRB can take the following actions on amendments: unconditional approval, approval with stipulations, deferred approval, tabled or disapproved, as described in SOP 7B (“Requirements for the Conduct of Research Review at a Convened NIH IRB Meeting”).
  6. The IRB will document in the minutes its discussion about and vote on the amendment and its determination whether current or past subjects must be informed of the amendment, and, if so, how they will be informed (verbally and/or in writing). Current and past subjects must be notified if the study amendment affects their safety and welfare and current subjects re-consented if the amendment changes future clinical study procedures. Correspondence or other communications with subjects shall be submitted to and approved by the IRB.

7. The IRB votes separately on new amendments that accompany continuing reviews.

### **10.5 NOTIFICATION OF THE IRB'S DECISION TO INVESTIGATORS**

- A. Investigators are notified in writing of the decision of the IRB and of any stipulations required. Amendments are not approved by the IRB until all stipulations have been satisfied.
- B. The written amendment approval notification must state that further changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.
- C. The PI may implement the changes provided in the amendment after IRB approval. If changes are required in the consent document, they are implemented after IRB approval and posting of the consent document by the Office of Protocol Services (OPS).
- D. The continuing review date is not affected by the approval of amendments.

### **10.6 CHANGES IMPLEMENTED IN A RESEARCH STUDY WITHOUT PRIOR IRB APPROVAL**

- A. Changes to research without prospective review and approval may only occur when they are necessary to eliminate immediate hazards to subjects and must be reported to the IRB as soon as possible. Changes to research without prospective IRB review and approval are protocol deviations and must be reported according to the requirements of SOP 16, "Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations."
- B. Such changes to research may or may not lead to an amendment to the protocol but, if they do, the procedures of this SOP apply.

## **REFERENCES**

- A. 45 CFR 46.103
- B. 45 CFR 46.110
- C. 45 CFR 46.111
- D. 21 CFR 50.25
- E. 21 CFR 56.111

## **LIST OF APPENDICES**

APPENDIX A: NIH Intramural Clinical Protocol Application

APPENDIX B: NIH Application Supplements