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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: Michael Gottesman 2/24/16

Deputy Director for Intramural Research **Date**

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10.1 PURPOSE

This Standard Operating Procedure (SOP) outlines the responsibilities of Principal Investigators (PIs) and Institutional Review Boards (IRBs) regarding amendments to protocols already approved by the IRB.

10.2 POLICY

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, see **References** below and SOP 19 - Investigator Responsibilities).

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 (in the designated IRB system (PTMS or iRIS^{TM}), as applicable).

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. Any new consent/assent document(s).

D. Documentation of other required amendment reviews or approvals, if applicable, e.g., DEC, FDA, Radiation Safety Committee, or IRB approval from another site.

E. Any additional requirements of the IRB.

10.4 PROCEDURES FOR IRB REVIEW AND CLINICAL DIRECTOR (CD) 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 to SOP 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards.

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 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs).

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.

8. Clinical Director signatures/approvals are not required on all amendments. Each CD has authority to decide which IRB actions require CD approval, and they should communicate that information to the IRBs and to the CC Office of Protocol Services (OPS).

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 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: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html