

I. PURPOSE

The purpose of this SOP is to establish procedures for review and acknowledgment of modifications or changes to approved research.

II. POLICY STATEMENT

Investigators may not make any changes in the research activity, except when necessary to eliminate apparent immediate hazards to the subject. Reports of significant information received by the investigator or IRB during the course of the approval period may constitute a change in the research and require modification of the research.

III. SCOPE

These policies and procedures apply to all research approved by the IRB.

IV. DEFINITIONS

Amendment: Any change in the research activity from what was approved by the IRB, including, but not limited to, modifications to the protocol, consent document, recruitment material, or information included in the Investigator's Brochure.

Material Change: A modification to the research-related documentation that alters the conduct of the research at sites overseen by CHOP or the assessment of the risks and benefits of the study. Non-material changes (e.g., staff changes) do not require IRB review or approval.

Minor Amendment: A proposed change in the research-related activities that does not materially affect assessment of the risks and benefits of the study and does not substantially change the specific aims, objectives, or design of the study. A modification may not be considered "minor" if the changes involve the addition of a procedure that is more than minimal risk or a procedure that cannot be reviewed under Expedited Categories 1-7 (Representative minor modifications are included in the **SOP 401** Appendix 2).

Full Board Review: Review of proposed research at a convened Full IRB meeting at which a majority of the membership of the IRB is in attendance, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members attending the meeting.

Review Using Expedited Procedures: Review of proposed research by the Chair, CPHS or their designee. The designee must be an experienced IRB member/alternate.

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V. PROCEDURES

A. Amendments

1. Changes in approved research may not be initiated without prior IRB review (full board or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects.
 - (a) When an immediate hazard is present, investigators may take any action necessary to mitigate risk to study participants.
 - (b) The investigators must promptly report to the IRB all actions taken and changes made in approved research without IRB approval.
 - (c) The IRB will review the change to determine whether or not the action was consistent with ensuring the subject's continued welfare.
2. Changes in the research activity which are anticipated, must be approved by the IRB prior to implementation; sponsor approval may also be necessary but in the absence of IRB approval is not sufficient.
3. Investigators must submit the materials listed in **SOP 301** for IRB review of the proposed protocol amendment(s).
4. Upon receipt of the submission containing material changes, the Chair or designee will determine if the revision requires simple acknowledgment, meets the criteria for expedited review procedure, or requires full board review. **SOP 401: Expedited Review Procedures** enumerates those amendments eligible for review using expedited procedures.
5. All modifications to previously approved research will be available to all members in the eIRB system.

B. Reports of New Information During the Approval Period

The IRB Office may receive additional materials from the investigative team that constitute a change in the research activity. These materials will be reviewed in order to determine if the materials impact the risk - benefit assessment or conduct of the research at CHOP. These additional materials may include, but are not limited to:

1. Reports generated from a Data and Safety Monitoring Board (DSMB) or study Steering Committees;
2. Reports in the current literature;
3. Updates to the Investigator's Brochure/Package Insert or investigational device manual; and

4. Complaints from research participants (or parents).

Complaints from participants may be reported to the investigator, research staff, other CHOP personnel or directly to the IRB.

- (a) When reported to the investigator, a description of the complaint, an assessment of the merits of the complaint and a summary of the actions taken by the investigator to address the issues raised, including any modifications to the research, will be submitted via the electronic IRB management system.
- (b) When the IRB receives a complaint, the following actions will take place:
 - (1) The individual receiving the complaint will inform the Director, HSR, Assistant Director, IRB Operations, IRB Operations Manager, IRB Chair or one of the IRB Vice Chairs.
 - (2) The subject/family will be contacted promptly for follow up.
 - (3) The Director/Assistant Director or the Chair/Vice Chair will discuss the events leading to the complaint with the subject/family and will provide follow up contact as necessary.
 - (4) A comment will be logged in the eIRB system to document the contact and the complaint, as applicable.
 - (5) The Director, HSR or the IRB Chair/Vice Chair will discuss the complaint with the principal investigator or other representatives of the investigative team to determine the appropriate course of action.

C. IRB Actions in Response to Reports of New Information

- 1. Reports of new information submitted during the approval period will be reviewed using expedited procedures, as applicable. Based on the initial review, the IRB Chair or designee may determine that the report should be forwarded to a convened IRB for review. The IRB will determine whether the new information should be communicated to research participants and the method of communication (e.g., revised consent form, letter to the subject, conversation between the investigator and subject).
- 2. If the event might meet the definition of an unanticipated problem involving risks to subject or others, the study team will be required to report the event in the eIRB system in accordance with **SOP 408**.
- 3. If the event represents non-compliance with the research plan, the event will be managed in accordance with **SOP 901**.

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VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103(b)(4), 110(b)	21CFR56.108(a), 110(b)
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VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements	SOP 408: Unanticipated Problems Involving Risks to Subjects or Others
SOP 401: Expedited Review Procedures	SOP 901: Non-Compliance with Human Subjects Research Policies

VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	The Director is responsible for establishing the processes for conducting ongoing reviews of research.
Chair, CPHS	The IRB Chair (or designee) is responsible for conducting expedited reviews of amendments and new information during the approval period or assigning review to the full Board.

IX. ATTACHMENTS

The eIRB system contains all forms required to report amendments, interim study reports and subject complaints.

X. REVISIONS:

- 07-07-2006 Initial Approval
- 05-29-2009: Correction of minor typographic errors, deletion of Section IV: Principles to harmonize with the current SOP template, editing of the Unanticipated Problems section and addition of reference to SOP 408; updating the title of the Director for Human Subjects Research; addition of reference to the electronic IRB management system and the IRB website.
- 06-15-2010: Revised to correct minor typographic errors, eliminate overlap between this and other SOPs and to clarify the procedures for review of protocol amendments and subject complaints.

- 07-07-2010: Revised to reflect AAHRPP's recommendations.
- 09-04-2012: Revised to reflect clarifications regarding acknowledgement of non-material changes.
- 09-25-2018: Revised with editorial changes and updated definitions.
- 06-09-2022: Revised to reflect current processes

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 06/09/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS