

I. PURPOSE

The purpose of this SOP is to identify the requirements for investigators and the IRB for the conduct of continuing review in accordance with the regulations and CHOP's policies and procedures.

II. POLICY STATEMENT

The IRB conducts continuing review of approved research at intervals appropriate to the degree of risk. FDA regulated research and studies which are greater than minimal risk where activities are not limited to long-term follow-up and data analysis must be reviewed at least annually. The IRB must obtain and review sufficient information to conduct substantive continuing review of research.

III. SCOPE

These policies and procedures apply to all approved research subject to IRB review.

IV. DEFINITIONS

Expiration Date: The date on which the IRB approval of a study will expire. For FDA regulated research and research with greater than minimal risk activities that are not limited to long-term follow-up and data analysis this will be no more than one year after the Meeting Date (or expedited review approval date) at which the research was last approved. For minimal risk research that is not FDA regulated, continuing review is not required unless specifically requested by the IRB.

Final Approval Date: The date at which all required modifications or contingencies have been satisfied. This may be determined at a convened IRB Board meeting or, by the Chair or designee using expedited procedures, as applicable.

Meeting Date: The date of the convened meeting where the research was reviewed.

Continuing Review Application: Required materials in the application for renewal of the research as defined in **SOP 301**.

V. PROCEDURES

A. Requirement for Submission of a Continuing Review

A complete Continuing Review Application should be submitted at least 30 days before the study approval period ends (expiration date) in order to provide sufficient time for review.

B. Approval Period

1. The Continuing Review submission must be reviewed and approved by the IRB prior to the expiration date in order for study-related activities involving human subjects to continue. If final approval is not issued by the expiration date, the following limitations to IRB approval will apply: (1) ongoing study activities (analysis of data, study visits for enrolled subjects) may continue but (2) no new subjects may be enrolled or screened until final approval is issued by the IRB.
2. Extensions of approval cannot be granted; there is no grace period extending the conduct of the research beyond the expiration date of IRB approval.
3. If an investigator fails to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the human subjects research activities must stop, unless the IRB finds that it is in the best interest of individual subjects to continue participating in the research interventions or interactions.
 - (a) Enrollment of new subjects or other human subjects activities cannot occur after the expiration of IRB approval.
 - (b) No research data can be collected until the Continuing Review Submission is reviewed and approved by the IRB, unless determined otherwise by the IRB.
4. Approval period for research approved using expedited review procedures and not subject to FDA regulations:
 - (a) The approval period will be until the time of study closure. If the IRB decides to change the approval period by requiring continuing reviews, the approval period will be based upon the nature of the research and the IRB's experience with the individual investigator.

C. Review Procedures

1. When considering whether or not to renew a study, the IRB reviews the study according to the same criteria used to grant initial approval, as listed in **SOP 402**.
2. IRB office and IRB member pre-review, review, and post-review procedures will be conducted as outlined in **SOP 105**.
3. The reviewer will have access to all of the study materials.

D. Submission Requirements

In order to determine the status of the study, the following will be available for the IRB members to review:

1. Materials maintained within the study workspace in the electronic IRB system including but not limited to:

- (a) Current and previous versions of IRB-approved consent document(s).
 - (b) Current and previous versions of the IRB-approved protocol including any previously-approved amendments to the research.
 - (c) All unanticipated problems related to the research involving risks to subjects or others including SAEs and major protocol deviations that required prompt reporting under **SOP 408**.
 - (d) All amendments to the study.
 - (e) A list of all current study personnel.
2. Continuing Review Submission and supporting documents (e.g. DSMB and monitoring reports).

E. Possible Outcomes of Continuing Review

As an outcome of continuing review, the IRB may take any of actions listed in **SOP 406**. Additionally, the IRB may also take any of the following actions:

1. Require revision of the protocol, consent or other approved materials consistent with the current status of the study and any change in regulatory requirements. (Comment: in eIRB, revisions must be submitted as a separate amendment).
2. Suspend or terminate approval of the research.
3. Impose special conditions or relax conditions previously imposed on the research protocol.

F. Expedited Review for Renewal

1. For a protocol that qualifies for expedited review where continuing review is required, the continuing review may also be conducted using expedited procedures (**SOP 401**).
2. Continuing review of research previously approved by the convened IRB may be reviewed via expedited review under the following situations:
 - (a) Category 8a: the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects;
 - (b) Category 8b): where no subjects have been enrolled and no additional risk to subjects have been identified;
 - (c) Category 8c: the remaining research activities are limited to data analysis;

(d) Category 9: the research is not conducted under an investigational new drug application or investigational device exemption, categories two through eight do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. If the review indicates that there has been a change to either the risks or benefits, the study may be referred for full board review.

G. Duration of Requirement for Continuing Review

1. Continuing IRB review is required as long as the research activity continues to meet the definition of human subject research and is greater than minimal risk or is FDA regulated (see **SOP 405** for requirements for study completion). For studies that are not FDA regulated and are minimal risk, continuing review is not required unless the IRB determines and documents why continuing review is needed for a specific study.
2. When continuing review is not required, CHOP still needs a mechanism to track ongoing human subjects research at the institution. Investigators will be required to use the Progress Update activity in eIRB to confirm that a study is ongoing (or request closure) at intervals of 2 years from the last submission to the IRB. This is a requirement for all studies where continuing review is not required, including exempt submissions. Progress Updates are automatically acknowledged in the eIRB system. Failure to submit a Progress Update may result in administrative closure of a study due to inactivity.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111	21 CFR 56.108, 56.111
Office of Human Subjects Research Protections 2018 Requirements FAQs	

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Processes	SOP 405: Study Closure
SOP 301: Research Submission Requirements	SOP 406: Categories of Action
SOP 401: Expedited Review Procedures	SOP 408: Unanticipated Problems Involving Risks to Subjects
SOP 402: Criteria for Initial IRB Approval	

VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Is responsible for establishing and implementing processes for making research renewal decisions.
Chair, CPHS	The Chair (or designee) is responsible for educating the members to their role in reviewing submissions for continuing review and for conducting or delegating the expedited review of protocols.

IX. ATTACHMENTS

Continuing Review Reviewer Forms are available maintained within eIRB.

X. REVISIONS:

- 07-20-2006 Initial approval
- 03-02-2007 Revised due to changes in IRB office staff responsibilities.
- 05-06-2008 Revised to clarify review procedures and to meet the requirements of AAHRP accreditation and clarified the submission requirements in keeping with information that might already be contained within the electronic IRB management system.
- 06-09-2010 Revised to reflect adoption of the eIRB electronic IRB management system and revisions to other SOPs.
- 07-08-2010 Revised to reflect AAHRPP's recommendations.
- 10-27-2011 Revised to reflect minor updates in the eIRB electronic IRB management system
- 09-25-2012 Revised to reflect changes made as a result of "un-checking the box" for CHOP's FWA.
- 09-25-2018 Revised for minor edits for consistency, and clarification about activities that may be conducted if the research is approved with modifications but the final approval is not issued by the expiration date.
- 01-22-2019 Revised to reflect the changes to the Common Rule. The definitions were updated, the approval period for expedited review and expedited Category 8 were revised. Reference to "Federally funded" was removed from the Policy Statement.
- 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