I. PURPOSE

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

II. POLICY STATEMENT

The IRB conducts continuing review of approved research at intervals appropriate to the degree of risk. Federally funded and FDA regulated research must be reviewed at least annually. The IRB must obtain and review sufficient information to conduct substantive continuing review of the research.

III. SCOPE

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

IV. DEFINITIONS

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

eIRB: The electronic IRB management system.

Expiration Date: The date on which IRB approval of a study will expire. For federally-funded and FDA-regulated research, this will be no more than one year after the convened IRB Board Meeting Date (or expedited review approval date) at which the research was last approved.

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, for changes that are not substantive, by the Chair or designee using expedited procedures.

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

V. PROCEDURES

A. Requirement for Submission of a Continuing Review

A complete Continuing Review Application should be submitted at least 30 days before the 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 (charts reviewed, etc.) 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 submit a complete continuing review application to the IRB or the IRB has not reviewed and approved a research study by the expiration date, 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 either FDA regulations or federally-funded:

   (a) The initial approval period will be for 1 year. Thereafter, the reviewer of the continuing review submission may extend the approval period based upon the nature of the research and the IRB's experience with the individual investigator.

   (b) The maximum approval period will be 3 years.

C. Review Procedures

1. When considering whether 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, but not limited to, 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 the 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 review using expedited review, the continuing review may also be reviewed using expedited review (**SOP 401).**

2. Expedited review procedures may be used for continuing review of research not conducted under a FDA-issued investigational new drug application or investigational device exemption, where expedited review Categories two (2) through eight (8) do not apply but the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified (expedited review Category 9).

3. Continuing review of research previously approved by the convened IRB may be reviewed via expedited review as follows (expedited review Categories 8

(a)(b) or (c)):

(a) 8(a) where the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects;

(b) 8(b) where no subjects have been enrolled and no additional risk to subjects have been identified;

(c) 8(c) where the protocol remains open for data management (query resolution) or analysis.

4. When conducting research under an expedited review procedure, the IRB conducts the review using the same criteria used to grant initial approval, as listed in **SOP 402**.

(a) If the review indicates that there has been a change to either the risks or benefits, the study may be referred for convened 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 non-exempt human subjects research (see **SOP 405** for requirements for study completion).

2. Continuing IRB Review is required when CHOP's IRB oversight includes at least one Relying Institution until human subjects research activities are complete at all of the Relying Institutions.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111	21CFR56.108, 56.111
OHRP Reports 95-01	

VII. REFERENCES TO OTHER APPLICABLE SOPS

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

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:

3/2/07 Revised due to changes in IRB office staff responsibilities.

5/6/08 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.

6/9/10 Revised to reflect adoption of the eIRB electronic IRB management system and revisions to other SOPs.

7-8-10: Revised to reflect AAHRPP's recommendations.

10-27-11: Revised to reflect minor updates in the eIRB electronic IRB management system

09-25-12: Revised to reflect changes made as a result of "un-checking the box" for CHOP's FWA.

9-25-2018 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.

XI. APPROVAL:

Director, Human Subjects Research	Date
Chair, Committees for the Protection of Human Subjects	Date