I. PURPOSE

The purpose of this SOP is to describe the IRB's procedures for documentation and document management.

II. POLICY STATEMENT

The IRB's records will contain the complete history of all IRB actions related to review and approval of a research proposal, including continuing reviews, amendments, changes in personnel and other required reports (e.g., SAEs, protocol deviations, and unanticipated problems related to research) reports. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and institutional policy.

Records must be accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, regulatory agencies, accrediting agencies and institutional auditors at reasonable times and in a reasonable manner.

Required documents must be provided to the appropriate funding entity as required.

III. SCOPE

These policies and procedures apply to all protocol documents submitted to the IRB.

IV. DEFINITIONS

eIRB: The electronic IRB management system.

Serious Adverse Event (SAE): Any adverse event that meets any of the following conditions:

- results in death;
- is life-threatening (places the subject at immediate risk of death from the event as it occurred);
- requires inpatient hospitalization or prolongation of existing hospitalization; (hospitalization for a protocol-specified activity or for an elective, pre-planned procedure is not considered an SAE.)
- results in persistent or significant disability/incapacity;
- results in a congenital anomaly or a birth defect; or
- based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated Problems Involving Risks to Subjects or Others: Any incident, experience,

or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol, Investigator's Brochure, and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to a subject's participation in the research; and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

V. PROCEDURES

A. Protocol-Specific Document Retention

1. The IRB Office retains records regarding an application (regardless of whether it is approved) for at least three (3) years; for approved research applications, records are retained for at least three (3) years after completion of the research or longer if required by the CHOP Policy A-3-9: Retention and Destruction of Records.
2. Access to IRB records shall be restricted to authorized individuals who have a role or institutional responsibility related to the study. The eIRB login establishes an individual's possible role(s) and access.
3. Retained documents include but are not limited to:

   (a) Copies of all research protocols reviewed, scientific reviews (if applicable) that accompany the protocol, approved consent documents, amendments, continuing reviews and progress reports submitted by investigators, and reports of injuries to subjects (including serious adverse events), other unanticipated problems related to research and reports of deviations from the protocol.

   (b) Minutes of all convened IRB meetings.

   (c) Copies of all submitted audit/monitoring reports and site visit reports.

   (d) Copies of relevant correspondence between the IRB and the investigators.

   (e) Statements of significant new findings provided to subjects.

   (f) Documentation of all determinations required by federal or state laws, regulations, guidance or CHOP policies.

   (g) For research reviewed via expedited review procedures, the action

taken by the reviewer and, if applicable, the justification for requiring continuing review.

(h) For research determined to be exempt, the justification for making the exempt determination.

(i) The version of Common Rule regulations applied, and the date of transition to the 2018 Common Rule requirements if applicable.

(j) Executed IRB Authorization Agreements or other reliance documentation between CHOP and external institutions.

B. Administrative Documents

1. The IRB Office maintains and retains all records regarding IRB administrative activities that affect review activities for least three (3) years, or three (3) years after completion of the research (or longer if required by the CHOP Policy A-3-9: Retention and Destruction of Records), including:

   (a) Current rosters of regular and alternate members of each IRB.

   (b) Rosters include the following information:

      (1) Member name;

      (2) Earned degrees;

      (3) Representative capacity;

      (4) Indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations;

      (5) Affiliation status;

      (6) Alternate members, with an indication of the regular members for whom the alternate may substitute;

      (7) Scientific/non-scientific status.

   (c) An updated roster of IRB members will be submitted to OHRP and the FDA within 90 days after the changes are made by the Director, Human Subjects Research.

   (d) Obsolete membership rosters.

   (e) Current and obsolete copies of the Standard Operating Policies and Procedures.

   (f) Signed IRB Confidentiality Agreements for IRB members and guests who have attended IRB meetings. **Note**: Members of the Office of General Counsel attend IRB meetings as counsel to the committee; a signed IRB Confidentiality

Agreements is not required for their attendance.

C. Maintenance of IRB Records

1. All IRB files, including studies withdrawn or terminated, cancelled without subject enrollment, will be kept for a minimum of 3 years after study completion, withdrawal or termination in compliance with CHOP policy and regulatory requirements (or longer if required by the CHOP Policy A-3-9: Retention and Destruction of Records).
2. Actions related to HIPAA determinations will be retained for at least 6 years after study completion, withdrawal or termination (or longer if required by the CHOP Policy A-3-9: Retention and Destruction of Records).

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 45 CFR 46.115	21 CFR 56.115
45 CFR 164	

VII. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs	

VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for ensuring that IRB staff adhere to all applicable regulatory compliance requirements and establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
IRB Analyst	Responsible for maintaining complete files on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements

IX. ATTACHMENTS

CHOP policy A-3-9 is available on the CHOP intranet at:
https://at.chop.edu/communities/policyprocedure/administrative/Active/a-3-9.pdf

X. REVISIONS:

06-19-2006	Initial approval
02-14-2007	Revised to incorporate changes in IRB office staff responsibilities.
11-10-2008	Revised to incorporate AAHRPP recommendations and to include the use of an electronic IRB management system
06-09-2010	Revised to reflect mandatory use of the eIRB electronic IRB management system
07-08-2010	Revised to clarify the timeline for storing IRB records.
02-13-2013	Editorial changes
09-25-2018	Revised to include CHOP logo, include IRB Authorization Agreements and editorial changes.
01-22-2019	Revised for the 2018 Common Rule requirement for justification for continuing review for research qualifying for expedited review.
06-09-2022	Revised to make administrative edits
04-25-2023	Revised to reflect current processes regarding IRB Confidentiality Agreements

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 04/25/2023
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS