Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs

Policy and Procedure

TITLE: IRB Records Retention

PURPOSE:

To describe the policies and procedures regarding creating and organizing records (recordkeeping) of the Institutional Review Board (IRB) which allows the reconstruction of a complete history of all IRB actions related to the review and approval of research.

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) personnel engaged in research, teaching or research administration activities in support of the charitable and educational mission of HPHC.

POLICY:

IRB recordkeeping follows legal and regulatory requirements, sponsor requirements, and organizational policies and procedures. IRB records for a protocol or research plan, including continuing reviews, amendments, and adverse event reports, shall be created and organized to allow a reconstruction of a complete history of all IRB actions related to the review and approval of the protocol or plan.

If a document is signed, a paper or portable document format (PDF) of the signed version should be retained. If a document is an official document, such as a government license or certificate, the original should be maintained and updated as required. If data are stored at an off-site repository, they must remain accessible and the repository must follow HPHC/I policies regarding data retention. When possible, off-site storage must be limited to data from closed studies. For research studies, data retention must be consistent with commitments made to subjects, the IRB and the sponsor. All data must be retained such that it is accessible for investigations and government oversight.

Complete copies of pertinent documents should be maintained in an orderly manner and destroyed in accordance with the *Office of Sponsored Programs Policy and Procedure on Research Records Retention and Destruction.*

PROCEDURE:

1. The Senior Compliance Manager (SCM) is responsible for the creation and maintenance of records pertaining to the activities of the IRB.

2. IRB staff have administrative access to IRBNet, maintain the security of all IRB records, and limit IRBNet access on a need-to-know basis to IRB members, investigators, and administrative staff. IRB staff shall make IRB records accessible for inspection and copying by authorized representatives of regulatory agencies at reasonable times and in a reasonable manner.

3. Paper files for active research studies initiated prior to 09/20/10 are maintained onsite in locked file cabinets accessible to IRB staff.

4. The Principle Investigator (PI) and designee(s) maintain the research study records and limits access to the research team and others on a need-to-know basis. Access shall be full, read, or write only.

5. IRB staff have access to an electronic audit trail in IRBNet of the history of individual access to specific records and the date when this access was granted and/or withdrawn.

6. In order to allow reconstruction of a complete history of IRB actions related to the review and approval of the protocol, IRB records shall include copies of:
   a. a roster of IRB members in the same detail as described in §46.103(b)(3);
   b. all correspondence between the IRB and the investigators;
   c. consent documents;
   d. data and safety monitoring reports, if any;
   e. documentation of non-compliance;
   f. investigator brochures, if any;
   g. justifications for exempt determinations;
   h. justifications for using the expedited procedure, including actions taken by the reviewer;
   i. minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
   j. modifications of previously approved research;
   k. progress reports submitted by investigators;
   l. protocols and research plans;
   m. records of continuing review activities;
   n. recruitment materials;
   o. reports of injuries to subjects;
   p. scientific evaluations, when provided by an entity other than the IRB;
   q. significant new findings;

r. unanticipated problems involving risks to subjects and others;
s. written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

7. IRB records for initial and continuing review of research by the expedited procedure shall also include:
a. the justification for using the expedited procedure;
b. actions taken by the reviewer;
c. any findings required by law, regulations, codes and guidance to be documented.

8. The PI will retain certain study files in instances when the decision-making process behind certain recommendations and actions would be advantageous or necessary to document. There may be occasions when it would be helpful to reference documentation that led to the thought process behind specific recommendations. These instances may include files related to the following:
a. files or documentation related to statistical advice from the biostatisticians;
b. files that reflect suggested changes to the study protocol related to statistical judgments;
c. files that reflect and explain the PI's stance on a subject or that reconstruct discussions that occurred regarding an aspect of the study or a critical decision.

9. The SCM will maintain a master list of all closed IRB records. This list will be reviewed at least annually to identify paper files that are six years old or older and arrangements will be made through HPHCI Manager of Operations to have paper files sent to offsite storage. Study records that exist in IRBNet in electronic format only, can be archived directly in IRBNet. Electronic records remain in the IRBNet platform indefinitely.

10. The SCM, shall maintain a list of files in storage and at least annually will notify the HPHCI Manager of Operations about the files that need to be destroyed and will note the date of purge on the master list.

11. Documents should NOT be destroyed if there is any ongoing or anticipated claim, audit, government or internal investigation, appeal, or litigation. If there are any questions concerning whether any form of a document should be maintained or destroyed, IRB staff shall consult the Research Integrity and Compliance Officer as to whether special circumstances require retaining it beyond indicated time frames.

12. Prior to destroying records, HPHCI employees should check the *Office of Sponsored Programs Policy and Procedure on Research Records Retention and Destruction* to ensure that record retention time periods have not changed. If any HPHCI employee or volunteer, including researchers, research staff, IRB members and IRB staff leaves employment or volunteer service of HPHC or HPHCI, the original study records and documentation remain the property of HPHC.

REVISION HISTORY:

Department: OSP - Research Integrity & Compliance	**Title**: IRB Records Retention
Effective Date: 01/21/19	**Owner:** Senior Compliance Manager, IRB
Replaces P/P Dated: IRB SOP (02/17)	
Related Documents: HPHCI Process for Data Privacy and Security Agreements; Office of Sponsored Programs *Policy and Procedure on Research Records Retention and Destruction*	
References: 45 CFR 46.115(a)-(b); 21 CFR 56.115(a)-(b); ICH-GCP: 3.4, 4.4, 4.9; AAHRPP Element II.5.A.	