Harvard Pilgrim Health Care Institute

Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs and Office of Research Integrity and Compliance

Policy and Procedure

TITLE: Research Records Retention and Destruction

PURPOSE:

To set forth how long records created or used in the conduct of research, teaching or research administration activities in support of the charitable and educational mission of HPHC must be maintained and provide disposal guidelines for how such records should be destroyed

PERSONS AFFECTED:

This policy & procedure (P/P) applies to all Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim 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, Inc.

POLICY:

Complete copies of pertinent documents should be maintained in an orderly manner for the duration indicated in Table 1, in a location and manner appropriate to the nature of the material. Unless otherwise specified, retention does not require retaining both paper and electronic forms. 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. If data are stored at an off-site repository, it must remain accessible, and the repository must follow HPHC/I policies regarding data retention. As far as 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, IRB, and the sponsor. All data must be retained such that it is accessible for investigations and government oversight.

DEFINITIONS:

Destroy - To destroy documents in a manner appropriate to their nature, such as deletion of e-mails and archived e-mails; shredding of documents containing protected information; locked-box recycling of confidential information; and erasure of electronic information on computer equipment consistent with applicable information security policies.

Records - A record is information that has been recorded or captured, regardless of physical form or characteristics. Paper or electronic records, as described in Table 1, include study protocols, reports, memoranda, notes, files, correspondence, medical records, patient charts, manuals of operation, case report forms, meeting minutes, e-mails, and other writings, including, but not limited to documentation of:

(a) Association for the Accreditation of Human Research Protection Programs, Inc. ("AAHRPP") accreditation;

(b) Export Controls;

(c) Financial Conflicts of Interest ("FCOI");

(d) Institutional Review Board ("IRB");

(e) Research Misconduct Proceedings;

(f) Sponsored Programs funding;

Retain - To maintain a written or electronic form of a document or information in a manner that is appropriately secure given its nature, in an organized manner that allows later users to access the documents without extensive search. Retention may include archival, such as storage at Iron Mountain, computer data ("CD") storage, shared drives, or microfiche.

Retention Period - The Retention Period is the length of time required for the storage of records. This period is based upon, among other factors, statutory or regulatory requirements, agency custom, and retention schedules. Records must be maintained in an accessible format for the duration of the retention period.

Study Close-out - Study close-out activities occur at the completion of the study or in early termination of the study. Early termination of the study can occur in the following instances:

(a) serious adverse events;

(b) decline in subject enrollment;

(c) failure to comply with regulatory requirements;

(d) funding is stopped; and

(e) significant findings or discoveries associated with the study

PROCEDURE:

A. Retention of Study Specific Documents by OSP

OSP will retain electronic administrative files of awarded grants and contracts. These files will contain the Sponsored Programs Application ("SPA"), stored either on the j:drive or in Cayuse; institutional approvals; Notice of Award ("NOA") and other sponsored research agreements and amendments such as contracts and subcontracts; budget and expenditure files including invoices; correspondence, etc.

The DOSP will maintain a list of files in storage and periodically will identify the files that can be purged and inform the Institute Manager of Operations who will notify offsite storage of the need to purge and will note the date of purge on the master list.

B. Retention of Study Specific Documents by IRB Committee:

The Research Integrity and Compliance Officer (RICO), or designee, will be responsible for maintaining records pertaining to the activities of the IRB.

The Research Integrity and Compliance Officer (RICO), or designee, will maintain a master list of all closed IRB paper records for studies initiated prior to IRBNet. This list will be reviewed annually to identify the paper files that are six years old or older and arrangements will be made through Institute Manager of Operations to have these files sent to offsite storage.

The Research Integrity and Compliance Officer (RICO), or designee, will maintain a list of paper files in storage and annually will identify the files that can be purged and inform the Institute Manager of Operations who will notify offsite storage of the need to purge and will note the date of purge on the master list.

C. Retention of Study Specific Documents by PI

The PI will retain certain study specific files in instances when the decision-making process behind such recommendations would be advantageous to document. There may be occasions when it would be helpful to reference documentation that allows the thought process behind specific recommendations to be referenced. 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; and

(c) Files that reflect and explain the PI's stance on a particular subject or that reconstruct discussions that occurred regarding a particular aspect of the study or a critical decision.

D. Exceptions

Documents should NOT be destroyed if there is any ongoing or anticipated claim, audit, government or internal investigation, appeal, or litigation. Consult with the Party Responsible for Compliance if you have questions concerning whether any form of document should be maintained or destroyed, whether special circumstances require retaining it beyond indicated time frames, or any other question or concern you have.

E. Training on this Policy and Training Records

The Compliance Specialist will be responsible for educating HPHCI employees regarding this policy. All records pertaining to training that are maintained by the Compliance Specialist shall be maintained as set forth in the Research Record Retention Schedules, Table 1, below.

F. Research Records Retention Schedules

Table 1, below, sets forth the retention schedules for research records. Direct questions to the DOSP or the RICO

Table 1: Research Record Retention Schedules

Record Type	Record Description	Party Responsible for Compliance	Retention Period	HPHCI Retention Period
AAHRPP Accreditation Records	Applications, reports, and other documents from site visits resulting in accreditation and all documents following and relating to that accreditation.	Research Integrity & Compliance Officer	At least 10 years from the date of the most recent accreditation.	At least 10 years from the date of the most recent accreditation.
Export Controls	Export Controls records include results from restricted persons screening, the latest date of export or reexport activities including: the date of any known reexport, transshipment, or diversion of such export, the date of any termination of the transaction, whether formally in writing or by other means y in the case of records pertaining to transactions involving restrictive trade practices or boycotts, the date the regulated person receives the boycott-related request or requirement. See below page for a list of the records the EAR requires to be kept: http://www.bis.doc.gov/ind	Administrative Coordinator in OSP, Research Integrity & Compliance Officer as applicable.	In Section 762.6 of the EAR, parties are required to keep export records for at least five years from the latest date of export or reexport activity from the U.S.	At least five years from the latest date of export or reexport activity from the U.S.
FCOI Records	FCOI records of all financial disclosures and all actions taken by the Institute with respect FCOI.	COI Administrator and Grants Managers	At least 3 years from the date of submission of the final expenditures report or final payment, or where the Institution has identified a FCOI and to all investigator Significant Financial Interests (SFI) disclosures, whether or not such disclosure generated a response by HPHC 42 CFR § 50.604 (i).	At least 3 years from the date of submission of the final expenditures report or final payment, or where the Institution has identified a FCOI and to all investigator Significant Financial Interests (SFI) disclosures, whether or not such disclosure generated a response by HPHC 42 CFR § 50.604 (i).
Financial Records	Financial records include programmatic records, supporting documents, statistical records, and all other records that are required by the	Grants Managers	If federally funded: at least 3 years after the submission of the	At least 6 years after final report then sent offsite;

	terms of a grant or may reasonably be considered pertinent to a grant, including, but not limited to administrative files; sponsored programs application (SPA); institutional approvals; notice of award (NOA); and other sponsored research agreement and amendments; budget and expenditure files; correspondence, etc.		final annual Federal Financial Report (FFR). NIH Grants Policy Statement, § 8.4.2 Record Retention and Access.	Purged periodically if stored for 6+ years
IRB Records	IRB Records include: 1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects; 2. Minutes of IRB meetings; 3. Records of continuing review activities; 4. Copies of all correspondence between the IRB and the investigators; 5. A list of IRB members; 6. Written procedures for the IRB; and 7. Statements of significant new findings. 45 CFR § 46.115.	IRB Staff	For at least 3 years and records related to the conduct of research shall be retained for at least 3 years after completion of the research.	At least six (6) years after the closure research study then sent offsite; Purged 6 years after sent offsite
Investigator Records	Investigator records, as required by the HHS regulations, including but not limited to application, protocol, study data/analyses, and amendments.	Investigator	If federally funded: for at least 3 years after completion of the study (45 CFR 46.115(b)).	At least 6 years after final report then sent offsite; Purged 6 years after sent offsite
Invention Disclosures and Research Participation Agreements	Invention disclosures – Note: all intellectual property developed with the support of federal or commercial funding is owned in accordance with the terms of the NOA or the clinical trial agreement. Any clinical records created during the course of a study are owned by the entity under whose control the clinical care is provided. Notwithstanding the foregoing, if patented, duration of patent and all continuation applications.	Invention disclosures and documents relevant to inventorship	(1) Patent license duration plus 6 years; (2) Sponsored research agreement plus 6 years; (3) All research-related records retained for at least 2 years after study completion; (4) Investigational new drug (IND) study records must be retained for at least 2 years after approval of drug marketing	At least 20 years.

			application or withdrawal of IND, or as indicated by sponsor; (5) No NIH records may be destroyed unless consistent with NIH policies governing record maintenance and retention and applicable regulations; (6) Research Participation Agreements for at least 3 years following employment.	
Research Misconduct Proceedings	Research misconduct proceedings records includes: 1. The records the Institute secures for the proceeding pursuant to §§93.305, 93.307(b) and 93.310(d), except to the extent the Institute subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained; 2. The documentation of the determination of irrelevant or duplicate records; 3. The inquiry report and final documents (no drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by § 93.309(d); 4. The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to §93.310(g); and 5. The complete record of any institutional appeal covered by § 93.314.	Research Integrity & Compliance Officer	At least 7 years after the termination of the inquiry if no investigation (42 CFR § 93.309(c) or at least 7 years following the proceedings, unless the records have been transferred to HHS in accordance with the regulations or the DHHS Office of Research Integrity ORI) has advised the Institute in writing that it no longer needs to retain the records (42 CFR § 93.317(b).	At least 7 years after the termination of the inquiry if no investigation (42 CFR § 93.309(c) or at least 7 years following the proceedings, unless the records have been transferred to HHS in accordance with the regulations or the DHHS Office of Research Integrity ORI) has advised the Institute in writing that it no longer needs to retain the records (42 CFR § 93.317(b).

Training Records	Training Records include any records, in paper or electronic form, created and maintained to track compliance with OSP training requirements.	Compliance Specialist	For at least 3 years and records related to the conduct of research shall be retained for at least 3 years after completion of the research or termination of employment, whichever is later.	At least 6 years after the closure research study or termination of employment then sent offsite. Purged 6 years after sent offsite.

DEPARTMENT: OSP & ORIC	**TITLE:** Research Records Retention and Destruction
EFFECTIVE DATE: 10/22/24	**OWNER:** Director Office of Sponsored Programs, Research Compliance QA/QI Specialist
REPLACES P/P DATED: "Records Retention and Destruction" 6/2016, 5/17/17; P/P (10/26/20, 10/10/2023)	
REFERENCES: HPHC Investigator Handbook Section VIII.H. - Record Retention Guidelines; HPHC IRB Policy 'IRB Records Retention'; Uniform Guidance §200.333; Harvard Pilgrim's Record Management Program; Retention and access requirements for records - 45 CFR 74.53; *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*) applicable to grants and cooperative agreements (2011 Revised Regulations) - 42 CFR 50.604; Public Health Service (PHS) Policies on Research Misconduct – 42 CFR Part 93	