

PARTNERS HUMAN RESEARCH COMMITTEE GUIDANCE FOR INVESTIGATORS

Recordkeeping and Record Retention Requirements

GENERAL GUIDANCE

Investigators are required to maintain records of their human-subjects research activities. Good records are essential for verifying the quality of study data produced and demonstrating investigator compliance with good clinical practice guidelines and applicable regulatory requirements. In general, investigators should establish three sets of files for each study:

1. Regulatory documents
2. HRC correspondence
3. Individual subject files

1. **Regulatory Documents.** Regulatory documents should be maintained for all studies, regardless of sponsor/funding source. These documents are typically organized within a regulatory binder, which can be obtained from the Partners Human Research Quality Improvement (QI) Program, either online or as a hard copy.

As outlined in Section 8 of E6 Good Clinical Practice: Consolidated Guidelines, the Regulatory binder should contain the essential documents listed below. Some documents that may be common to more than one study, such as CVs and professional licenses, may be filed centrally; others may be stored electronically. In such cases, place a signed/dated note-to-file in the binder to indicate their location.

Basic regulatory documents required for all studies. The following documents should be maintained in the regulatory binder:

- a. Protocol: original version and all amended versions; all versions should be numbered and dated.
- b. CVs for all study staff: CVs document qualifications and eligibility to conduct a study and provide supervision of subjects. CVs should be signed and dated. It is recommended that CVs be updated every two years to verify that the information is accurate and current.
- c. Valid licenses and certifications for all professional study staff.
- d. Study logs to assist with organization and record keeping (templates can be found in the Tools section of the QI Program website).
 - Screening log: captures all potential subjects who have been pre- screened for the study.
 - Enrollment log: captures all subjects who have signed a Partners Human Research Committee (PHRC)-approved consent form or, with IRB approval, have given verbal consent or had informed consent waived.
 - Staff Signature/Delegation of Responsibility log: documents the signature and initials of all staff that collect and record study data, and lists the

study-related procedures each has been delegated by the Principal Investigator.

- Monitoring log: documents any study-related activity performed to monitor study progress or the accuracy and completeness of study records.
 - Adverse Event log: documents all adverse events that may be reported to the PHRC, sponsor, and/or regulatory groups, indicating their seriousness, expectedness, and relationship to the study.
- e. Copy of all IRB-approved versions of the consent form.
 - f. Laboratory documents (if applicable): Updated copies of Lab certification, the Lab Director's CV, and normal lab/reference values. These materials document the competency of all lab facilities being used in the study and support the reliability of test results.
 - g. Blank copies of all CRFs, data collection forms, and/or questionnaires.
 - h. NIH grant applications and progress reports (if applicable).
 - i. Correspondence with study sponsor/funding agency (if applicable).
 - j. Data/Safety Monitoring Board reports (if applicable).

Additional regulatory documents required for investigational drug or device studies.

The following additional documents should be maintained in the regulatory binder:

- k. Copies of all Form FDA 1572s (Statement of Investigator) and Form FDA 1571s (Investigational New Drug Application), if applicable.
- l. Drug/device shipment and receipt records (may be maintained by the Research Pharmacy or Investigational Drug Service (IDS)).
- m. Drug/device accountability log (drug accountability log may be maintained by the Research Pharmacy or IDS).
- n. Signed/dated copies of financial disclosure for all investigators listed on Form FDA 1572.

Tools to assist with regulatory documents. The following tools are available in the Tools section of the QI Program website:

- Self assessment checklist (applicable to all studies).
- FDA Sponsor and Investigator checklist (applicable to IND or IDE holders).
- Data and Safety Monitoring Plan checklist (applicable to all studies).
- Drug/device accountability log (applicable to studies with investigational drugs or devices).
- Coordination Center Regulatory Documentation Tracking log (applicable to coordinating centers for multi-site studies).
- Temperature log (applicable to studies storing refrigerated or frozen drugs, biologics, or blood/tissue samples).

2. **PHRC Correspondence.** All study-related correspondence with the PHRC should be maintained in a separate file for each study. These documents include copies of all:

- a. Signed and dated submissions.
- b. Approval letters or notifications of IRB decisions.
- c. Investigator responses to IRB notifications (if applicable).
- d. Approved recruitment materials.

- e. Approved educational materials or other study information distributed to subjects.
- f. Any additional PHRC correspondence relating to the study.

Tools to assist with PHRC correspondence. The following logs are available in the Tools section of the QI Program website:

- Protocol Amendments/Version tracking log.
- Protocol Deviation/Exception tracking log.
- Protocol Violation tracking log.

3. **Individual Subject Files.** There should be a separate file for each subject enrolled in or screened for a study. The following documents are placed in each file:
 - a. An eligibility checklist, signed and dated by the person determining eligibility, lists specific inclusion/exclusion criteria. Source documentation to support medical criteria should be available in the subject's medical record.
 - b. Original signed and dated consent form.
 - c. Individual case report forms (CRF), data collection forms, questionnaires, and/or subject diaries are used to capture all data required by protocol for each subject. All primary data should be promptly recorded in clear, adequate, original and permanent form.
 - d. Copies of source documents, if applicable, should be retained to corroborate entries on the CRF or data collection sheets.

Tools to assist with individual subject files. The following logs are available in the Tools section of the QI Program website:

- Subject Eligibility Checklist.
- Informed Consent Compliance checklist.
- Source Documentation: Investigator Responsibilities (lists requirements for recording data on source documents).
- Subject Information Sheet (documents contact information as well as race/gender/ethnicity data required at Continuing Review).

RECORD RETENTION

Research records should be retained for at least seven (7) years from the time the study has been completed or longer as required by the sponsor. All such permanent records must remain in the laboratory or unit upon departure of the investigator from the institution. Consideration of alternative arrangements for copies to be kept at the institution, instead of original records, must be done with the chairs/chiefs or their designee.