**PARTNERS HUMAN RESEARCH COMMITTEE**
**GUIDANCE FOR INVESTIGATORS**

# Recordkeeping and Record Retention Requirements

## GENERAL GUIDANCE

Investigators are required to maintain records of their human research activities. Good recordkeeping is essential for verifying the integrity of study data produced and for demonstrating investigator compliance with applicable regulations, and institutional policies and procedures. The recordkeeping procedures outlined in this guidance document cover the following two types of files:

A. Regulatory document files
B. Individual research subject files

## A. Regulatory Document Files

Regulatory documents that should be maintained on file for a particular research study depend upon the nature of the involvement of human subjects and applicable regulations (e.g., Health and Human Services, Food and Drug Administration, etc.) and the nature of the involvement of human subjects. Human subject research includes obtaining data through:

- Intervention or interaction with subjects;
- Access to identifiable private information in health/medical records; and/or
- Access to human materials/tissue collected for non-research purposes.

Regulatory document files serve as a central location for maintaining study management documents that demonstrate compliance with applicable regulations, and institutional policies and procedures. A separate regulatory document file should be maintained for each study.

Note: The Partners Human Research Quality Improvement (QI) Program provides assistance in developing a print or electronic regulatory document file. For more information regarding an electronic regulatory document file,contact QI at humanresearchqi@partners.org

### All studies involving human subjects

Investigators should maintain the following study-specific documents for every research study that involves human subjects:

1. A complete history of PHRC submissions and correspondence from initial application through study close out, including, when applicable, but not limited to:
    - eIRB application forms
    - Protocol
    - Protocol Summary
    - Consent Form
    - Recruitment materials
    - Any other documents approved by the PHRC
    - PHRC review notification letters
    - Investigator response to review notification letters

- Any other correspondence between investigator and PHRC

Note: Records of all Insight/eIRB submissions and related IRB review notification letters created and submitted after April 6, 2013 are maintained in Insight, with limited exceptions. Exceptions include, among others, records of IRB reviews ceded to another institution or entity, original review notification letters when new letters are reissued and replace the original in Insight, and documents or communications submitted outside Insight. The IRB maintains copies of originals of reissued letters and can provide copies upon request.

2. Sample case report forms (CRFs) and/or data collection forms
3. Completed study management logs or equivalent documentation of the following:
    - Delegation of responsibility / signature log
    - Enrollment/health/medical records/excess human materials (for studies limited to accessing individually private information or samples)
    - Monitoring activities
    - Protocol deviations and unanticipated problems including adverse events
4. Correspondence and/or communications with study sponsor, funding agency, regulatory agencies, research collaborators (e.g., data use agreements, materials transfer agreements, etc.)
5. Financial disclosure forms submitted by study staff responsible for the design, conduct or reporting of the research (of note, the eCOI forms are only available in Insight and only to the individual and the IRB, not to everyone on the study)

**Studies that involve an intervention or interaction with subjects**

In addition to documents 1-5 above, investigators should maintain the following documents for studies that involve an intervention or interaction with subjects:

6. Completed study management logs or equivalent documentation of the following, as applicable:
    - Pre-screening
    - Adverse events
7. Study staff qualifications
    - CVs of all study staff, dated
    - Current licensure and board certifications of professional staff
    - Safety or other training (e.g., infection control, laser safety, CITI, etc.)
    - Study specific training
8. Clinical laboratory certification (e.g., CLIA/CAP certificate) and normal reference ranges, and research laboratory director's CV, when applicable.
9. Correspondence and/or communications with collaborating sites (multi site research)

Note: Study staff CVs, professional study staff licensure and board certifications, safety or other training and laboratory certification and normal reference ranges that support more than one study may be filed centrally for a research group/department.

**Studies that involve FDA regulated drugs/biologics or medical devices**

In addition to documents 1-9 above, investigators should maintain the following documents for studies of FDA-approved or unapproved (investigational) drugs/biologics or FDA-approved/cleared or unapproved (investigational) medical devices:

10. Product information, to include, when applicable:

    10.1 FDA-approved drugs/biologics or approved/cleared medical devices
        - Drug package insert
        - Device manual / Instructions for Use

    10.2 IND drugs/biologics or IDE medical devices
        - Investigator's Brochure (IB)
        - Device information / Report of prior investigations

11. FDA Forms, Submissions and Correspondence

    11.1 IND/IDE Clinical Investigators (IND/IDE held by company, NIH or other entity)
        - Form FDA 1572/Statement of Investigator (IND Investigator)
        - Investigator's Agreement (IDE Investigator)

    11.2 Sponsor-Investigators (IND/IDE held by Investigator)
        - IND/IDE submission
        - IND protocol amendments / IDE supplements
        - IND/IDE safety reports
        - IND/IDE annual reports
        - IDE updated list of investigators
        - Form FDA 1571/IND Application
        - Form FDA 3455/Disclosure: Financial Interests and Arrangements of Clinical Investigators
        - Form FDA 3674/Certification of Compliance, with Requirements of ClinicalTrials.gov

12. Drug/device accountability, to include, when applicable, records of:
    - Shipping and receipt
    - Dispensing to subjects
    - Return of drug/medical device by subjects
    - Return of drug/medical device to sponsor
    - Destruction of drug/medical device, when destroyed at the investigative site

    Note: The research pharmacy maintains these records for most drug studies. When the study does not utilize the research pharmacy, the above must be maintained by the investigator. Areas, such as the operating room or catheterization lab, may maintain records of medical device shipments, receipts and use. When someone other than the investigator maintains information about medical device accountability, document this in a signed and dated note-to-file.

## B. Individual Subject Files

Investigators should maintain the following study-specific documents in a separate file for each subject who signs the consent form or provides oral consent (written documentation of informed consent is waived). Oral consent should be documented in a clinic chart/progress note/other source document. When obtaining written informed consent, investigators should also consider entering a signed and dated note in a clinic chart/progress note/other source document to further document the informed consent process. See Policy on Informed Consent of Research Subjects for more information on documenting informed consent. Individual files are not needed for studies limited to health/medical records, excess human material, secondary use, or a data or tissue repository.

- All original signed and dated consent forms, when applicable
- Documentation of informed consent when written informed consent is waived
- Documentation of subject eligibility and study procedures, as applicable
- All case report forms (CRF) and data forms, signed, dated and complete, as applicable
- All instruments, questionnaires, diaries, or other documents completed by subjects and/or study staff, as applicable
- Correspondence, emails or phone calls to subjects

Note: Research subjects cannot request that study data be "deleted" or "erased" once it has been collected. Contact the Human Research Office for guidance should a subject request that data collected about them be destroyed.

**Record Storage and Retention**

Study documentation may be collected, recorded and stored in physical (paper) or electronic form. Regardless of the form, investigators are responsible for storing study documentation securely to preserve the integrity of the records, protect identifiable health information and maintain the confidentiality of the data. Access to study documentation should be limited to study staff. Study documentation must be available for internal audits, external monitoring, or inspection by regulatory agencies.

Physical (paper) records should be stored in a secure area, such as in a locked file cabinet. Electronic records may be stored on Partners HealthCare and Institutionally compliant computers or mobile devices or other internally hosted services. Investigators should follow Research Information Services & Computing (RISC) recommendations to safeguard electronic protected health information (ePHI) when storing individual subject files electronically.

Research records should be retained for at least seven (7) years from the time the study was completed, or longer as required by the sponsor. For FDA regulated clinical investigations conducted under an IND/IDE, the sponsor of the IND/IDE is responsible for informing investigators when the study records can be destroyed. If the investigator leaves the institution, all such original permanent records must remain in the laboratory or unit, unless alternative arrangements are approved by the principal investigator's Department Chair/Chief or designee.