

HUMAN RESEARCH AFFAIRS

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, also called Regulatory Binder or Essential Documents, must be maintained for all research involving human subjects, which 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 and when complete and appropriately maintained/updated, they demonstrate compliance with applicable regulations, and institutional policies and procedures. A separate regulatory document file should be maintained for each study.

Note: The Mass General Brigham Compliance & Education Office provides tools and resources for assembling and maintaining regulatory document files/Regulatory Binder. For more information, visit the C&E Office website or email humanresearchqi@partners.org.

All studies involving human subjects

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

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

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)
 - Internal and if applicable, external 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 must 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. Investigators are expected to maintain investigational product accountability for each subject as well as for the study overall. Sponsor-Investigators have additional responsibilities related to the management and oversight of the investigational product as outlined in the [Sponsor-Investigator Responsibilities Guidance](#). 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 must 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), as applicable:

- All original signed and dated consent forms
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- Documentation of informed consent when written informed consent is waived
- Documentation of the informed consent process, whether consent was provided with a signature or orally
- Documentation of subject eligibility and study procedures
- All case report forms (CRF) and data forms, signed, dated and complete
- All instruments, questionnaires, diaries, or other documents completed by subjects and/or study staff
- Correspondence, emails or phone calls to subjects
- Adequate and accurate source documents and trial records. Source data should be attributable, legible, contemporaneous, original, accurate and complete.

For studies limited to health/medical records, excess human material, secondary use, or a data or tissue repository, subject files may be more limited in nature, depending on the protocol.

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 Mass General Brigham 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.