



I. Policy

A. Introduction

Principal Investigators are required to maintain complete and accurate regulatory documentation for clinical studies.

B. Guidance

This policy provides guidance to meet FDA federal regulations, and good clinical practice for appropriate documentation for human research studies.

In general, investigators should establish three sets of files for each study.

1. Regulatory documents
2. IRB Records and Correspondence
3. Individual subject files

C. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

II. Procedures

The Principal Investigator's site file (regulatory binder) contains all required documentation to meet GCP compliance and regulations. The Principal Investigator is required to obtain and maintain these documents in a safe and secure place during the study and for the required retention period.

A. Regulatory Documents

The study regulatory binder must contain specific documents as noted 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, and the location noted

1. Protocol: original version and all amended versions; all versions should be numbered and dated.
2. Signed and dated CVs for co-investigators documenting qualifications and eligibility to conduct the study and provide clinical management of research subjects.
3. Current licensure/certification for all professional study staff.
4. Study logs.
 - a) Screening log: captures all potential subjects who have been pre- screened for the study.
 - b) Enrollment log: captures all subjects who have signed an MUSC IRB approved consent form or, with IRB approval, have given verbal consent or had informed consent waived and whether the subject meets inclusion/exclusion criteria for the study.
 - c) Staff Signature/Delegation of Responsibility log: documents the signature and initials of all staff that collects and record study data, and lists the study-related procedures each has been delegated by the Principal Investigator.
 - d) Monitoring log: documents any study-related activity performed to monitor study progress or the accuracy and completeness of study records.
 - e) Adverse Event log: documents all adverse events that may be reported to the IRB, sponsor, and/or regulatory groups, indicating their seriousness, expectedness, and relationship to the study.
5. Copy of all IRB-approved versions of the consent form.
6. Laboratory documents (if applicable): Updated copies of Lab certification 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.
7. CRFs (or other data collection forms)
8. NIH grant applications and progress reports (if applicable).

9. Correspondence with study sponsor/funding agency (if applicable).
10. Data/Safety Monitoring Board reports (if applicable).

The Principal Investigator must maintain an accurate and complete accounting of all clinical study materials (investigational drug/device records) received, dispensed, and returned to the Sponsor. These records must be maintained in the study site regulatory binder for the same retention time.

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

B. IRB Records and Correspondence

IRB records must include the following:

1. Scientific evaluations.
2. Progress reports submitted by investigators.
3. Records of continuing review activities.
4. Statements of significant new findings provided to participants.
5. For initial and continuing review of research by the expedited procedure:
 - a) The specific permissible category.
 - b) Description of action taken by the reviewer.
 - c) Any findings required under the regulations.
6. For exemption determinations, the specific category of exemption.
7. Unless documented in the IRB minutes, determinations required by the regulation and protocol-specific findings supporting those determinations for:

- a) Waiver or alteration of the consent process.
 - b) Research involving pregnant women, fetuses, and neonates.
 - c) Research involving prisoners.
 - d) Research involving children.
- 8. For each protocol's initial and continuing review, the frequency for the next continuing review.
- 9. Copies of IRB Approved Documents.
- 10. For VA research – in addition to any other requirements noted in this policy
 - a) Correspondence between the IRB and the VA Research and Development Committee.
 - b) Correspondence between the IRB and researchers.
 - c) Internal serious adverse events.
 - d) Documentation of Protocol violations..
 - e) A resume for each IRB member.
 - f) All previous membership rosters.
- 11. All study-related correspondence with the IRB should be maintained in a separate file for each study. These documents include copies of all
 - a) Submissions, signed and dated.
 - b) Approval letters or notifications of IRB decisions.
 - c) Investigator responses to IRB notifications (if applicable).
 - d) Approved recruitment materials

C. Individual Subject Files

Regulations and GCP guidelines require the PI to maintain adequate and accurate records of each study subject in a study. These records include the following documents but are not limited to

- 1. CRFs (or other data collection forms)

2. Appropriate source documents where applicable, such as:
 - a) Medical history records
 - b) Physical exam results
 - c) Laboratory results
 - d) Documentation of the informed consent process
 - e) Progress notes including study subject clinical management and documenting study visits.

D. Retention of Records

1. HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years. At the end of three years, records are boxed, labeled and sent to central storage for another 3 years.
2. Research records should be retained for a sufficient minimum period to allow evaluation and repetition by others of the results and to investigate an allegation of research misconduct. Usually [unless granted an exception by the Department of Health and Human Services (HHS) or the Office of Research Integrity (ORI)], this minimum period is six years.
3. For VAMC studies,
 - a) all records, including the investigator's research records and codes/keys linking subject data to identifiers, must be retained in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors. If a VA protocol is cancelled without participant enrollment, IRB records will be maintained in accordance with VHA's Records Control Schedule (RCS 10-1). The local VA Research and Development Committee will have access to all IRB records related to VA Research.
4. All records must be accessible for inspection and copying by authorized representatives of HHS and FDA at reasonable times and in a reasonable manner. A log of stored records is maintained in the IRB office for retrieval if files are needed for audit purposes.

III. References

- A. [45 CFR 46.115](#)