General Guidance

Investigators are required to maintain records of their human-subject research activities. Good record keeping is essential for verifying the quality of the study and the data produced, and demonstrating compliance with applicable regulation and requirements. In general, investigators should establish the following types of documents in a file for each research study:

1. Regulatory documents
2. IRB correspondence and
3. Study Subject documents

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 SEQuR office or supplied by a sponsor.

A Regulatory binder should contain essential elements. Some documents that are common to more than one type of study (such as CV's and professional licenses) may be centrally filed or filed electronically. If a hard copy is not included in a regulatory binder a signed/ dated Memo-to-File in the Regulatory binder should indicate their location.

Basic Regulatory Documents required for all studies. The following is a list of documents that should be maintained in the regulatory binder:

Protocol: original version and all amended versions: all versions should be numbered and dated. It is recommended that the Principal Investigator sign and date the original protocol and all amendments (this may be a sponsor requirement).

CV's for all study staff: CV's document qualifications and eligibility to conduct a study and provide appropriate supervision of study subjects. CV's should be signed and dated and it is recommended that CV's be updated every two years.

Valid licenses and certifications: for all professional research staff

Study Logs: assist in organizing and tracking study processes. The following Templates of study logs may be found at the SEQuR web site.

- Screening / Enrollment log: captures all potential subjects who have been pre-screened for enrollment into a study and those who have signed an MMC IRB approved Informed Consent Form
- Staff Signature log: documents the signature, initials, date beginning and ending for study responsibilities for all staff that collect and record study data.
- Roles and Responsibility log: lists the study related procedures each member of the research team has been delegated by the Principal Investigator.
- Staff Training log: Document the protocol specific research training provided to and received by members of the research staff.
- Monitoring log: documents study related visits and activity preformed to monitor study accuracy, completeness and progress of study records.
- Recruitment log: tracks recruitment activities.
- Deviation log: document and explains protocol deviations.

- Drug/Device Accountability log: documents and tracks drug/device dispensation and accountability.

Copy of all IRB approved versions of the Informed Consent documents
Laboratory documents (if applicable): Up to date copy of all applicable Laboratory Certifications including the Lab director's CV, a copy of the lab's normal reference values

A blank copy of all CRF's: and data collection forms and or questionnaires including any instructions for their completion

NIH grant application and progress reports (if applicable)

Correspondence with the study sponsor/funding agency (if applicable)

Data safety Monitoring Board reports (if applicable)

Additional regulatory documents to be maintained in a Regulatory binder and required for investigational drug or device studies Include:

- Copy of the Form FDA 1572, 1571 (if applicable)
- Drug/Device shipment and receipt records (these records may be maintained in the research pharmacy and placed in the regulatory binder at the close of a research study)
- Signed and dated copies of the "Financial Disclosure form" or Conflict of Interest form for all investigators listed on the 1572, 1571.
- IRB correspondence regarding all study related issues: these documents include; the signed and dated original IRB submission, approval letter or notifications of IRB decisions and the responses, approved recruitment materials, educational materials and other materials distributed to study subjects

Study Subject Files: There should be a separate file for each subject enrolled in or screened for a study. The following documents may be components of this file.

- Eligibility Checklist, signed and dated by the person determining eligibility, this checklist includes specific inclusion and exclusion criteria. The source documentation to support all medical or documented criteria should be available in the subject's medical record.
- Original signed and dated ICF
- Individual case report form (CRF), data collection forms, questionnaires, and or subject diaries that are used to capture all data required by the protocol for each subject.
- Copies of source documents if applicable should be retained to corroborate entries on the CRF or data collection forms.

Record Retention: Research records should be retained according to the outlined requirements on the "Research Record Keeping and Retention- Administrative Records Relating to Research" (Attachment A) or longer as required by a study sponsor. Maintaining all such permanent records is the responsibility of the department where the research has occurred. Study records must be maintained per MMC record retention policy . Each department/Investigator is responsible for ensuring that all study records are stored securely on site or offsite arrangements have been made.