GUIDELINES FOR SETTING UP A STUDY BINDER AND REGULATORY DOCUMENTS BINDER

Introduction: A study should be organized and well planned BEFORE the initiation of patient accrual. The Research & Education Service recommends the following system for organizing all the documentation for a study. However, this is only a ***guideline***. You may use any system that enables you to present study documents in a well-organized, up-to-date, complete, convenient way that is easily accessible to monitors and auditors. If documents are organized ***and maintained*** in such a systematic way, you should easily bein compliance with regulations and you should do well on any audit.

- It is common practice to set up a study binder/study file. for each subject, which is separate from the subject's medical chart. This study binder contains all information specifically related to a subject's progress through the study. It should be consistent with notes, reports or information in the subject's CPRS record. It should have copies/printouts of pertinent notesand reports. It should contain all the information (source documentation) used to complete the case report forms (CRFs) as well as substantiating documentation for notes and inclusion exclusion I/E criteria and the quality of the informed consent process.
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In contrast, the study binder contains data collection forms (DCFs) and other source documents. It is the repository for data collected by your site on a particular subject or group of subjects.

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Steps in preparing study and regulatory binders:

1. Create a research file for each patient with a hanging folder or a binder. A hanging folder is more convenient for photocopying purposes and requires less space while a binder secures the pages in place.
2. Label the file with protocol number and patient study id number.

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3. As applicable, create the following (or similar) sub-sections for the file using manila folders or dividers. Make sure patient and/or study id number is written on the folders to allow easy replacement within the file:

- Patient entry: registration, signed consent form, HIPAA Authorization
- Eligibility checklists
- Response measurements / DCFs: organize by visit: "Recruitment", "Screening", "Enrollment/Randomization", "Visit 1", Visit 2", …; by type: "Informed Consent", "Notes", "Vital Signs", "Blood Draws", ...; or other logical system)
- Copies of Enrollment and Progress Notes
- Interactions with participants by telephone or in person
- Treatment administration and accountability
- Adverse event reports for this patient
- Other observations or interventions
- Protocol deviations
- Laboratory, Pathology, Radiology reports: be sure to have PI or designate to sign off as "clinically significant" (CS) or "not clinically significant" (NCS).
- Correspondence: email, note-to-file, telephone documentation
- Questionnaires, diaries, etc.

4. There should also be a more global file which should contain the following:

- Master list of subjects and codes/identifiers
- Signature logs of staff, study monitors, etc.
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- An Accounting of Disclosure must be maintained for each and every disclosure of information from the study to a non-VA entity.
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- Other types of documentation that covers the study as a whole as opposed to individual subjects.

5. Take the protocol apart by the above sections and create your own audit review form,

6. Keep a copy of all required elements- (Note: the auditor will check the original as well, so have the originals ready.) This should be done on an ongoing basis so when any auditor comes, including the RCO or external auditors, you may hand out this research file without any extra work or preparation. This will only work if updates are done on an ongoing basis.

Steps in preparing regulatory binders:

1. Keep an organized and updated regulatory binder with the following elements:
   - IRB Submission
   - All IRB-approved versions of the protocol and amendments
   - R&D Committee Submission
   - All correspondence including, but not limited to, that with the funding source or sponsor, and with applicable oversight entities including, but not limited to, IRB, R&D Committee, ORO, etc.
     - IRB approval letters
     - R&D Committee letters/Approval
     - All continuing reviews and IRB/R&D approval letters
     - All amendment applications and IRB/R&D approval letters
   - All versions of IRB-approved consent form.
   - A master list of all subjects for whom informed consent has been obtained in the study
   - All 1571s/1572s and curriculum vitae for all investigators participating in the protocol unless exemption approved
   - Laboratory normal values, licenses and certifications

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- 10-9012s for studies using drugs
- Financial/budget information (can be kept in a separate place)

2. Review the attached guide to major and minor violation assignment during an audit. This is intended as a ***guide*** and is subject to interpretation of the auditor. (Attachment 1)
3. Know the institutional policies. If you are unsure, ask the Research & Education Office or (Officeof Research Compliance) for guidance.

Other Research Documents

- Data analyses
- Reports including, but not limited to, abstracts and other publications