Guidance: The Participant Binder

Background

An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation (21 CFR 312.62).

The participant file is separate from their medical chart and the study's regulatory file.

Introduction

Study participant records should be kept separate for each individual participant. For most studies, the records for each participant should be kept in separate 3-ring binders. The binder spines should be labeled with the protocol number, participant initials, and the participant's study ID number, at minimum. It may also be helpful to include the PI, IRB number, and sponsor.

For studies that require minimal visits and documentation, it may be more appropriate to keep all participant records in the same binder, separated by tabs that clearly distinguish the end of one participant's records from the beginning of another.

Elements of the Participant Binder

The participant binder should contain all the information (source documentation) used to complete the case report forms (CRFs) as well as substantiating documentation for notes, inclusion/exclusion criteria, and consent documents.

Labeled dividers should be included between each section and study visit to easily find information. Consistency among the organization of individual participant files is recommended to facilitate review by a study monitor or auditor and for instances where another coordinator may be required to conduct future study visits.

The binder should read like a story - visits should be added in the order in which they occur.

It is helpful to keep "living logs" such as Adverse Events and ConMed Logs toward the front of the binder. These should be referenced at each visit and updated as needed.

Information to include in the participant source binder:

- Participant Demographics Sheet
    - Patient identifying information should be kept at the front so that participants can be quickly reached in case of an emergency, back-up coordinators can more easily cover study visits, and there is less likelihood of mistaking one participant's files for another. This identifying information can be a printout demographics page from the medical record or can be a stand-alone document created by the coordinator. Information should include, at minimum: Participant name, birthdate, medical record number, phone number
- Signed Informed Consent Document / Consent note
    - Original signed and dated consent form
    - Consent note can be on a pre-structured source document or free text, but should include at minimum: name of person conducting the consent process, date of consent, statement that the participant was provided the opportunity to ask questions and all questions were answered, statement that the participant was provided a copy of their signed ICF, statement that consent was obtained prior to any study activities
    - Any re-consents and re-consent notes should be kept alongside the original consent
- Medical Records Release form
- Medical History Log - when required
- Con Med Log
- AE Log
- Inclusion/Exclusion checklist (signed by PI) and supporting documentation
- Randomization report
- Prescription with PI/Sub-I signature
- Visit Notes/Coordinator Notes - Separate by "Screening," "V1," "V2"... or however visits are labeled in the protocol
- Laboratory, Pathology, Radiology reports - These should be signed by the PI or Sub-I who is responsible for the participant's care
- Correspondence
    - Print any email correspondence with participant
    - Print all relevant email correspondence with the sponsor/CRO pertaining to the participant's participation in the study
    - Write documentation of any phone calls (completed or attempted)
- Participant diaries
    - All returned paper diaries or printouts of electronic diaries used to make trial-related decisions or to assessment of participant compliance
- Questionnaires - Can be kept all together, but it is helpful to keep with the corresponding visit; Tip: Questionnaires should be signed and dated by the person completing
- Shipping records, including copies of lab requisition forms - Can be kept all together, but it is helpful to keep with the corresponding visit