Social Behavioral Study Binder

Table of Contents

Suggested contents for a Social Behavioral Study File:

(Organized chronologically – most recent in the front)

I. IRB Documentation

- Original IRB application and protocol
- All IRB approval letters / acknowledgements
- Copy of current IRB-approved informed consents, assent documents, or information sheets (including translated copies)
- HIPAA Form (if applicable)
- Copies of previous versions of IRB-approved informed consents, assent documents, information sheets and, if applicable, HIPAA form
- Screening checklist and script (as applicable)
- IRB approved advertisements, fliers, postings or educational materials for subjects (including translated copies)
- Amendments, reportable events, protocol deviations
- Continuing Review(s)
- Certificate of Confidentiality (if applicable)

II. Study Personnel Documentation

- Delegation of Study Responsibilities by staff name and job title
- Study Personnel CVs
- Applicable personnel licenses, current professional certification and educational certificates (e.g., CITI, Grants Management)

III. Sponsor or Funding Information

- Correspondence with Sponsor or Funding Agency (i.e., letters, faxes, newsletters)
- Sponsor Protocol, if applicable
- Grant Application, if applicable

Note: financial information or monitoring reports should not be included in the study binder

IV. Logs

- Subject Screening / Enrollment Log (used to capture subject screen /enrollment date, consent date, study completion date, etc.)

V. Miscellaneous

- Other applicable approvals (i.e., USC committees, Site Permission Letter)
- Study-related literature and publications

VI. Subject-Specific Information***

The following should be on file for each subject:

- Original signed informed consent and / or assent form(s)
- Documentation of subject's eligibility to participate in study (inclusion/exclusion criteria)
- Subject-specific notes / observations
- Completed data collection sheet, screening checklist, questionnaires, etc.
- Subject-specific adverse event , unexpected event, protocol violation, or incidental findings
- Correspondence such as e-mails, phone conversations, etc. (as applicable)

*****usually filed separate from Study Binder in individual subject files when subjects will complete more than one of the forms listed above (e.g., consent form and a questionnaire)**