Comprehensive Study Documents List

(Biomedical Studies)

Investigators conducting human subjects research must maintain study documents in adherence to federal and state regulations, USC policies, and good clinical practices. The Comprehensive Study Documents List is a tool that provides a model and one-stop-resource to successfully organize and maintain clinical trial documentation. An overview and general instructions are included regarding the Regulatory/Study Binder, Source Documents, Case Report Forms, and Additional Study Documents.

I. Regulatory/Study Binder

A Regulatory Binder (also known as a Study Binder) is a standard tool used to organize Essential Documents for a clinical research study. If a study is industry-sponsored, the sponsor typically provides all participating sites the Regulatory Binder(s). This template is available to assist investigators involved in investigator-initiated and/or sponsor-investigator studies. Regulatory Binders are study-specific.

For best practice, organize items in reverse chronological order with the most recent entry at the front of each section.

A. Contact Information

- Study Team Contact List (e.g., research team, sponsor, monitor, pharmacist)

B. Logs (tracking ledger)

- Monitoring Log (can be used to track internal monitoring such as study self-assessments or external monitoring, or both)
- Subject Screening Log
- Subject Enrollment Log

C. Plastic Sleeve Content

(for easy access to frequently used documents)

- Copy of the most recent IRB approved informed consent
- Copy of the most recent HIPAA Authorization form

D. Regulatory Documentation (tabs 1-17)

1. IRB CORRESPONDENCE

- Original IRB application
- Amendment submissions and corresponding IRB approval letters
- All versions of informed consent forms and/or information sheets submitted to the IRB and corresponding IRB approval letters
- IRB approved advertisements, fliers, postings or educational materials for subjects (including translated copies)
- Continuing Review submissions and corresponding IRB approval letters
- Reportable Event submissions and corresponding IRB acknowledgements
- Certificate of Confidentiality (if applicable)
- IRB Membership List
- Other correspondence with IRB (e.g., emails, documentation of telephone discussions)
- Optional: IRB Submissions Log (list items submitted to IRB with dates of submission and response/approval dates)

2. SPONSOR/CLINICAL RESEARCH ORGANIZATION (CRO) CORRESPONDENCE

- Correspondence from and to sponsor or CRO (e.g., letters, emails, newsletters)
- Site visit reports

3. GENERAL CORRESPONDENCE

- Correspondence from and to FDA and federal sponsor*
- Correspondence and/or approvals from and to other committees or entities as applicable (e.g., Clinical Trials Unit)
- Other general correspondence (e.g., emails, documentation of telephone conversations)

4. CONSENT AND HIPAA FORMS

- IRB stamped approved informed consents, assent forms, information sheets and Significant New Information/Findings (SNIFs) including translated copies
- HIPAA authorization forms or documentation of waiver

5. PROTOCOL

- Original protocol (sponsor's or PI's) including signed signature pages

- Amendments to the protocol including signed signature pages

6. DEVIATIONS / VIOLATIONS / EXCEPTIONS

- Ongoing log of all deviations, violations and exceptions that occurred during the study
- Copies of all deviations, violations and exceptions that were reported to the IRB (or file under item IV)

7. **INVESTIGATOR'S BROCHURE(S) (IB) & PACKAGE INSERT****

- *For drug studies*: Investigator's Brochure including signed signature page and/or package insert
- *For device studies*: Device Manual or equivalent information including signed signature page

8. SERIOUS ADVERSE EVENTS (SAE)

- SAE communications: Include all AE and SAE reports (internal and external) reported (include all paperwork that shows the event was reported to the sponsor, IRB and FDA when appropriate)
- IND Communications and Safety Reports (e.g., CIOMS, MEDWATCH, Medical Alert Letters)

9. FDA FORMS

- FDA Form 1572
- FDA Form 1571 (sponsor-investigator studies only)
- IDE Statement of Investigator's Commitment*

10. STUDY PERSONNEL

- Delegation of Responsibilities Log
- Current Curriculum Vitae and professional licensure for all research personnel
- Financial Disclosure Forms
- Confidentiality Statements
- Required Education: All personnel involved in research with human subjects must complete the required education courses. Include copies of educational completion certificates for:

- Human Subjects, Good Clinical Practice, Responsible Conduct of Research training*
- HIPAA training
- Certification of IATA Compliance* (for transportation of Dangerous Goods)

- Study Specific Training*
  - Documentation of study-related training

11. LABORATORY*

- Current Curriculum Vitae of Laboratory Director
- For studies that use laboratories for specimen testing, current laboratory certificate(s) (CLIA or CAP)
- Current Normal Range Values for laboratories used in study
- Shipping Logs (if central laboratory is used)
- Specimen Tracking Log* (e.g., if samples are kept on site for batch shipping)

12. LABORATORY SUPPLIES*

- Contact/Ordering information
- Shipment and Receipt Records

13. REGISTRATION OF CLINICAL TRIALS*

The International Committee of Medical Journal Editors (ICMJE) has established a requirement that all clinical trials be entered in a public registry before onset of subject enrollment as a condition of consideration for publication

- Application for www.clinicaltrials.gov
- Response notification

14. DRUG/DEVICE*

a. Drug/Device Dispensing Log (or note to file if kept separately)

b. Drug/Device Inventory (or note to file if kept separately)

c. Drug/Device Shipment and Receipt Records

d. Contact/Ordering information

e. Decoding procedure for blind studies*

f. Drug/Device Storage Temperature Log

g. Drug/Device Disposal Records

15. INTERACTIVE VOICE RESPONSE SYSTEM (IVRS)*

- IVRS Documentation
- Contact information

16. CASE REPORT FORM

a. Blank set of case report form

17. MISCELLANEOUS

- Other documentation that does not belong to previous sections

**as applicable to the study*

II. Source Documents

Source documents are original records or certified copies used to capture subject information. Anything used to initially capture subject information is a source document. For best practice, organize items in reverse chronological order with the most recent entry at the front of each section.

Each subject should have the following on file:

- Subject contact information
- Original signed informed consent(s), assent form(s) or information sheet(s)
- HIPAA form(s): signed HIPAA Authorization form, if applicable
- Copies of all notes/observations including physician notes, nurse notes or other types of forms used to document medical information such as vital signs, medications taken, diagnosis date, demographic information, etc.
- Copies of all laboratory results, radiology reports, physical exams including tests conducted to determine study eligibility (i.e., blood test results, CT scan reports, etc.)
- Inclusion/exclusion worksheet
- Subject-specific study calendar
- Protocol deviations

- Adverse Event Log and/or toxicity worksheets
- Compensation documentation
- Miscellaneous forms (e.g., subject diaries, questionnaires, telephone log)

III. Case Report Forms (CRFs)

Case Report Forms (CRFs) are subject-specific forms used to record/transcribe required study information for each subject collected in original source documents. CRFs are usually supplied by the study sponsor. A blank copy of a CRF should be kept in the Regulatory Binder.

IV. Additional Study Documents

The following are additional documents that are often filed separately from the Regulatory Binder:

- Schedule of Events (e.g., Study flow sheet or Calendar)
- Study medication prescription information/dose calculation/administration instructions
- Blank subject cards, diaries, calendars and appointment reminders
- Research Order Form
- Study Contract and Budget
- Subject Compensation Forms (to process)
- Data Entry Instructions (if study uses electronic CRFs)