Biomedical Regulatory Binder

Table of Contents

(Organized chronologically – most recent in the front)

I. Logs (tracking ledger)

- Monitoring Log (can be used to track internal monitoring (study self assessment), external monitoring (study assessment by others), or both)
- Subject Screening Log
- Subject Enrollment Log
- Optional: IRB Submissions Log (list items submitted to IRB with dates of submission and response/approval dates)

II. Plastic Sleeve Content

(easy access to frequently used documents)

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

III. Regulatory Documentation (tabs 1-11)

1. IRB CORRESPONDENCE

- Original IRB application/protocol
- IRB protocol approval letters
- IRB stamped, approved informed consents, assent forms or information sheets (including translated copies)
- IRB approved advertisements, fliers, postings or educational materials for subjects (including translated copies)
- Amendments and corresponding IRB approval letters, consent and assent forms
- Continuing Reviews
- Certificate of Confidentiality (if applicable)
- IRB Membership List

2. PROTOCOL

- Protocol (sponsor's or PI's)

- Correspondence from Sponsor (i.e., letters, faxes, newsletters)

3. HIPAA

- HIPAA authorization forms or documentation of waiver

4. 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
- IRB response letter to each report

5. INVESTIGATOR'S BROCHURE(S) (IB) & PACKAGE INSERT

(for drug / device study only)

6. SERIOUS ADVERSE EVENTS (SAE)

- Include all AE, SAE, and IND safety reports (internal and external) reported (include all paperwork that shows the event was reported to the sponsor, IRB and FDA when appropriate).
- IRB SAE/IND communications

7. FDA FORMS

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

8. STUDY PERSONNEL

- Study personnel contact sheet
- Delegation of Responsibilities Log
- Current Curriculum Vitae, bio-sketches and professional licensure for all research personnel
- 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, Responsible Conduct of Research or GCP training as applicable
    - HIPAA training

9. GENERAL CORRESPONDENCE

- Correspondence from FDA, NIH, Sponsor, etc.
- Other Correspondence (i.e., literature and publications)
- If using the CTU, application, correspondence and approval letter
- All other general correspondence (i.e., e-mails, phone conversations, etc.)

10. LABORATORY

- Curriculum Vitae of Laboratory Director (if required)
- For studies that use laboratories for specimen testing, current laboratory certificate(s) (CLIA or CAP)
- Current Normal Range Values for laboratory(-ies) used in study

11. 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

12. MISCELLANEOUS

- Other documentation that does not belong to previous sections