Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

Regulatory Binder Checklist

The Regulatory Binder serves to demonstrate compliance with Good Clinical Practice (GCP) and all applicable regulatory requirements by organizing study specific essential documents. Keep the binder current and up-to-date. Store the binder in a safe location that is accessible to study staff at all times.

General Guidance
This document is a template. Include only those sections pertinent to your protocol. Omit those unused, and add sections as needed**.**

1. **Binder cover**
    a. Protocol name
    b. Protocol number
    c. IRB/GCO number
    d. PI name
2. **Study contact information**: address, telephone/fax/beeper numbers; 24 hour contact person/numbers
    a. Sponsor
    b. PI
    c. Monitoring person/organization (CRO = Contract Research Organization)
3. **Protocol**
    All versions should contain a version date and/or number
    a. Maintain copies of all versions stored in reverse chronological order with the current approved version on top
    b. Copies of the signature page indicating PI's receipt/approval of the protocol
4. **Investigator Brochure (IB)/Device Manual or FDA approved package insert**
    a. All versions stored in reverse chronological order with the current approved version on top
    b. Copies of signature page indicating PI's receipt the IB/Device manual
5. **Informed Consent Forms/HIPAA Authorizations**
    a. All approved, stamped versions of any consent or assent form used in the study (including translations, short forms, tissue banking, etc.)
    b. Also include in this section any approved study participant recruitment and educational materials including flyers, brochures, etc.
6. **IRB Approvals**
    Copies of all IRB approvals including termination of the study
7. **IRB**
    a. Institutional Review Board Members
    b. FWA and IRB Registration Information
    c. IRB correspondence (all submissions, i.e. requests for initial approval, for protocol/consent amendments, annual continuation, final study report, Reportable new Information Protocol violations/deviations)

8. **Lab documentation***
    a. Normal Lab/reference ranges which are to be current and up-to-date
    b. Laboratory Certifications
       Certificate of Accreditation-Clinical Laboratory Improvement Amendments (CLIA)
       Certificate from the College of American pathologists (CAP)
    c. Laboratory Director CV
    d. Lab correspondence
9. **Study Staff**
   The overall responsibility for study conduct rests with the PI. However, the PI may delegate certain study related tasks to appropriately trained staff. This section provides documentation of qualifications for all study staff.
    a. **CV*** signed and dated in upper right-hand corner of the first page, updated every 2 years to verify that information is accurate and current
    b. **Current medical license*** for all professional study staff (e.g. medical or nursing license)
    c. **Certificates of research training*** (e.g., Human Subjects Protection, HIPAA, Data Security, GCP, Safety and Infection Control training, Shipping Biologicals)
    d. **Sponsor Financial Disclosures**
    e. **Delegation of Authority Log** outlining the responsibilities that the PI may assign to other qualified members of the research team and their dates of involvement in the project
    f. **Training Log** – protocol specific and updated as necessary
    g. **SIV Attendance sheet/SIV power point slides**
    h. **FDA Form 1572**
10. **Other correspondence** as applicable
    a. Sponsor
    b. Clinical Research Unit
    c. Monitor
11. **Data Safety Monitoring Board**
    a. Copy of all DSMB Minutes
    b. Recommendations and correspondence
    c. Copy of all external audit reports
12. **'Notes to File' explaining**
    a. Missing documents
    b. Location of important documents not stored in the Regulatory File
    c. Protocol violations/deviations/exceptions. Include a Corrective Action Plan.

    Notes To File may include site generated and/or sponsor generated notes to file.
13. **Annotated CRFs** (Case Report Forms), if available
14. **Logs**
    a. Site monitoring log – to provide documentation at the site that the study was monitored and the frequency of monitoring
    b. Screening/enrollment log -this may be kept in a separate clinical binder
15. **Adverse Events (AE) and Unanticipated Problems (UP)***
    a. Internal AE and UP tracking log updated in a timely manner
    b. SAE reports submitted to the sponsor/IRB
    c. External IND safety reports provided by the sponsor
    d. IND/IDE tracking log signed and dated by PI and updated in a timely manner
16. **Unmasking procedures** (in blinded trials)
17. **Certificates of Confidentiality**, if applicable

* Another option: a 'Note to File' signed and dated indicating the location of important documents not stored in the Regulatory Binder including documents that are maintained electronically

18. **FDA Requirements for Sponsor Investigated studies***
    a. Signed and dated copies of all Form FDA 1571 submitted to the FDA
    b. Signed copies of all Form 1572 submitted to the FDA
    c. Initial Application, Acknowledgement of Receipt, Comments, and Letter to Proceed
    d. Amendments to the application
    e. Adverse Event Reports
    f. Annual Progress Reports
    g. Form 3674, Certification of Registration to ClinicalTrials.gov
    h. Signed and dated copies of all Form FDA 3454/3455 (Disclosure of Financial Interests)
    i. Closeout/withdrawal application

Make sure patient confidentiality is maintained. Black-out patient names and use subject numbers in reports (e.g. expedited adverse event reports, lab reference ranges, etc.).

Financial/contract paperwork is <u>not</u> kept in this file.

* Another option: a 'Note to File' signed and dated indicating the location of important documents not stored in the Regulatory Binder including documents that are maintained electronically