Regulatory Binder Instructions

Purpose:

A Regulatory Binder assists sites in obtaining and managing regulatory compliance. The binder also provides:

1. Guidance for organization and record keeping
2. Assistance with proper study documentation and successful study management

The Department of Research Compliance is available to assist investigator-initiated study sites who are creating their own binder.

General Guidance for Using the Regulatory Binder:

- The Regulatory Binder should be established at the beginning of the study, prior to enrollment.
- Keep the Regulatory Binder current and up-to-date.
- Identify individual(s) responsible for maintaining the binder. Ensure that this person is on file with the IRB as a contact person to ensure that all IRB correspondence and documents are received/filed in a timely manner.
- Store binder in a safe and secure location, but accessible to study staff at all times. If sections of the binder are stored in a separate location (centrally filed) **or maintained electronically, write a signed and dated note-to-file indicating the location and who maintains them**. File the note behind the tab to which it applies.
- Subject-specific documentation and information, e.g., signed consent forms, test results, and completed case report forms, should be maintained separately within the subject-specific binder/file.

Customize the binder to meet the needs of your protocol. This Regulatory Binder is a template. Include only sections pertinent to your protocol. Omit unused sections and add sections as needed. See "Applicable sections" below for more information. If unsure of what sections to include/exclude, contact the Department of Research Compliance to clarify.

Applicable Sections:

Depending on the nature of the research, some tabs may not be required. Use the list below to ensure that the applicable sections are maintained. For questions, contact the Research Compliance Department.

All Studies:

1. Delegation of Authority Log
2. Protocol (Amendments, Administrative Letters and Deviations)
3. Study Personnel (CVs, CITI, Licensures)
4. Protocol/Study Training Logs
5. Subject Logs (screening, enrollment)
6. IRB Documents (submissions, continuing review, approval letters, Correspondence and reportable events).
7. Consent Forms
8. Data Collection/CRFs
9. Notes to file

Study Specific:

10. Lab Documents
11. NIH
12. Sponsor (correspondence)
13. Investigational Product
14. Drug/Device Accountability
15. FDA (IND)
16. Financial Disclosure
17. Study Manual
18. Investigator Brochure
19. DSMB
20. Safety Reports
21. Monitoring Visit Log (Monitoring Visit Reports)
22. Advertisements
23. Supply Lists

Contact Information:

For additional questions or comments related to the Regulatory Binder contact the Research Compliance Team: Schauna Gillam, 404-785-8299; Victoria Shay, 404-785-7596; Emily Smotherman, Manager, 404-785-7146.

Please note that the regulatory binder contents are used to ensure compliance with federal regulations, Good Clinical Practice (GCP) guidelines, and CHOA/EMORY Policies. They should be used as a starting point to ensure compliance.