Organizing the Regulatory Binder

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Regulatory Binder: Objectives

- *Understand the purpose of maintaining organized regulatory files*
- *Understand what documents should be maintained in the regulatory file*
- *Understand how to organize the contents of the regulatory file*

Is a regulatory binder necessary?

- Not required but is good clinical practice
- Keeps documents organized and available
- Compiles all study related documentation in one place
- Quick and easy access to most current documentation
- Assists in the management of the trial
- A tool for monitoring regulations and standards set by federal departments (FDA, HHS, OHRP), your sponsor, and local regulatory bodies (IRB)

What should be included?

- ICH E6 Good Clinical Practice Guidelines
  - Chapter 8
    - Essential documents
    - Describes the purpose for each document
    - http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf
- Files should be customized to the demands of the study

Organizing the Binder

- Setting up the binder or file
  - Use dividers with tabs
  - Most frequently accessed documents should be in the front
  - If necessary use more than one binder
  - If documents maintained electronically, write a note indicating location and who maintains them. File this note in the regulatory binder

Binder cover and contents

- Cover and Binding Label
  - IRB Docket number
  - Study title
  - PI
  - Sponsor
  - Institution
  - Binder number (if multiple binders)
- Title Page
  - IRB number and study title
  - Binder number (if multiple binders)
- Table of Contents

Contents

- Protocol and Investigator Study Plan
  - All final IRB approved versions of the study protocol with most recent on top
  - Should include IRB approval letters
- Investigator Brochure (if applicable)
  - Use a separate binder for multiple, or thick brochures

Contents (cont'd)

- IRB Submissions/Continuing Review
  - Initial Submission
    - IRB application, Protocol, Consent, study documents, FDA applications, etc.
    - IRB Approval Letter
  - Continuing review applications
    - IRB continuing review approval letter
- IRB Correspondence
  - All informal correspondence with the IRB (emails, faxes, phone log)

Contents (cont'd)

- Amendments
  - Most recent IRB approval letters on top
  - Copies of submitted documents
- Consent
  - Most current approved stamped consent on top(recommend plastic cover if using this to make copies)
  - Previous expired consents
  - HIPAA

Contents (cont'd)

- Adverse Events
- Protocol Deviations
- Key Study Personnel
  - Delegation and signature log
    - Notates all study personnel and their dates of involvement in the project
  - CVs of all current key study personnel (if federally regulated)
  - Documentation of trainings, formal and informal (CITI< eCRF, CLIA, protocol training)
  - 1572 (if FDA regulated)
  - Financial Disclosures (if FDA regulated)

Contents (cont'd)

- Laboratory
  - Certificate of accreditation
  - CV of laboratory director
  - Copy of normal ranges
- Advertising / Recruitment
  - Screening log with de-identified information
  - Enrollment log
  - Approved IRB ads or language

Contents (cont'd)

- Drug/Device accountability logs (if not using IDS)
  - Temperature logs
- Case Report Form (CRF)
  - A blank CRF template is filed in the binder
  - CRF Appendix
    - All questionnaires or forms the participant actually completes (Demographic, financial, etc.)

Contents (cont'd)

- Sponsor
  - All correspondence with the sponsor (formal and informal)
  - Monitoring log
  - Monitoring reports
  - Other sponsor related documents
- Standard Operating Procedures (if your department has them)
- Misc
  - Catch-all section for things you are not quite sure what to do with

Conclusion

- Regulatory binder is a tool that should fit the demands of the study and expectations set by regulating bodies
- Organized in a logical fashion with most frequently accessed items in the front
- Should be in a central location where all approved personnel may access the documents
- Updated on a regular basis