Regulatory Binder

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Regulatory Binder

Goals

- To learn about regulatory binders.
- To learn about Essential documents for the regulatory binder
- Put together a regulatory binder

Purpose

The purpose of the Regulatory Binder is to provide an organizational framework for filing paper versions of essential study documents (or referencing location of an electronically stored file).

Who Creates and Maintains

Study coordinators or individuals responsible for establishing the Essential Document Binder (synonyms: Investigator Binder , Regulatory Binder, Investigational Site File (ISF), or Study Binder).

It is the responsibility of the Investigator to ensure compliance with Good Clinical Practice (GCP), institutional review board (IRB), and applicable regulatory requirements.

Instructions

Create tabs for each section listed below and place the appropriate documents in each corresponding section in a binder. Be sure to label the outside of the binder (cover and spine) with the protocol number, PI name, and study site. Use multiple binders or master binders to maintain documentation if needed.

Store items in reverse chronological order, with the newest items within a section placed at the front of the section.

Multi-site studies: the lead site may choose to customize the checklist for the study and provide to all participating sites.

Anytime information is kept in a master binder, place a note to file (in the section of the Binder) referencing the location of the separate binder.

Things to Know about Essential Documents

According to GCP guidelines Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory requirements. Filing essential documents in a timely manner can greatly assist in the successful management of a clinical trial or research study.

The Regulatory Binder is often the first document reviewed during audits and inspections. Not all the essential documents are available at the start of the study and may never be depending on the type of study you are conducting. Documents can be grouped into those that are generated before study initiation, those that are generated during trial conduct and those that are generated after study completion.

Not all documents have to be filed in one single binder. The Regulatory Binder may sometimes consist of several binders that are stored in the same or different locations. It is important to know where all these documents are located to be able to pull them out when needed in a timely manner.

Study Team

Study Team Contact List
Study Team Signature and Delegation Log
CVs, Licenses, Financial Disclosures, Applicable Certifications of Key Study Personnel
Training log

Protocol

Study Protocol & Amendments
IRB Stamped Consent Document and Translations
IRB Stamped Advertisements
Investigator Brochure (IB)
Safety Update letter for inclusion in IB
Sample of Questionnaires / Survey forms
Sample of Diary cards
Sample of Memory aids for study procedures
Any other written information given to the patient
Sample of CRF

Regulatory

Committee for Protection of Human Subjects (IRB)
IRB Submission Forms (Initial, amendments, renewals, etc.…)
IRB Outcome Letters (approvals, acknowledgments, etc.…)
IRB Correspondence (or location)

Food and Drug Administration

Form FDA 1572 for all Key Study Personnel
Copy of IND / IDE submission
FDA Correspondence
Annual Reports

Patient Logs

Screening Log
Enrollment Log
Subject Visit Schedule Log
Signed Informed Consent Forms (or Location)

Unanticipated Problems

Copies of AE reports if not included in CRF
AE log for events in non-site subjects
AE log for events in site subjects
Adverse Event Reports
Protocol Deviation logs

Drug / Device Accountability

Package Insert / Prescribing Information
Drug / Device Receipt (Shipping Records)
Drug / Device Accountability Log
Drug Disposal Records
Sealed Unbinding envelopes (or location)
Individual treatment codes (or location)
Temperature logs

Laboratory

Laboratory name and contact address
Logistic arrangements with lab (if local lab is used)
Lab certifications and normal ranges
Biological specimen sampling, labeling, storing and shipping procedure
Biological specimen log
Shipping records (if central lab is used)
Temperature logs

Monitoring

Monitoring Log
Monitoring reports
Initiation meeting information (sign in sheet, agenda, minutes etc…)
Correspondence

Financial Documents

Clinical Trial Agreement
Budget
Financial expenditure records
Billing statements
(all these documents may be stored in a separate location)

Other documents

Completed CRF's (location)
Study closure documentation
Publications, presentations, manuscripts, etc…

This and any other information can be found in our UT Health CPHS web site which I have included in this slide:

https://www.uth.edu/cphs/

https://www.uth.edu/ctrc/regulatory/gcp-policies.htm

https://www.uth.edu/cphs/for-researchers/reg-iris-training.htm

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Questions or Comments

Thank You!
Gracias!