



Procedure Name: Regulatory Documents – the Regulatory Binder
Effective Date: February 26, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: CR-008, Rev 1
Application: Principal Investigators, Research Coordinators, and the Office of Clinical Trials Staff
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OBJECTIVE:

Define the documents required to be maintained in the Regulatory Binder.

SCOPE:

The Regulatory Binder serves as secure storage for a number of essential documents that are required when conducting clinical research. This procedure enumerates many of the documents and describes the procedure for maintaining these documents.

RESPONSIBILITY:

The Principal Investigator (PI) is responsible for creating and maintaining the Regulatory Binder.

Office of Clinical Trials management is responsible for assessing compliance with the requirements established in this procedure.

Sponsor monitors and regulatory investigators will periodically review the contents of the Regulatory Binder.

REFERENCES:

21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator records and reports
21 CFR 812.140	Records
ICH E-6 (RI)	Good Clinical Practice; Section 4.9 “Records and Reports”
ICH E-6 (RI)	Good Clinical Practice; Section 8.0 “Essential Documents”
21 CFR 11	Electronic Records; Electronic Signatures

PROCEDURE:

- 1.0 The Regulatory Binder shall contain the documents listed below (“essential documents”) to permit evaluation of the conduct of the clinical trial and to evaluate the quality of the data produced. These essential documents will be maintained in the “Regulatory Binder”.

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- 2.0 The following items should be present in every Regulatory Binder. Note that the Regulatory Binder is subject to regulatory review. Documents that are not subject to regulatory oversight (budget, contracts, etc.) are not to be kept in the Regulatory Binder. The chronological order of documents in each sub-section will be according to the sponsor's preference; when the sponsor's preference is not specified, the most recent will be on top.
- 2.1 Clinical protocol – current version including the signature page
 - 2.2 Clinical protocol – previous versions including the signature page
Recommendation: Clearly differentiate the current version from previous versions by placing it behind a separate tab
 - 2.3 FDA approval of IDE (device only)
 - 2.4 Investigator Brochure and/or package insert (where applicable)
 - 2.5 FDA Form 1572 (Statement of Investigator) for drug studies or the Investigator statement for device studies (all versions)
 - 2.6 Confidentiality Agreement
 - 2.7 Curricula vita (CV) for the PI and all Key Personnel
 - 2.8 IRB documentation
 - 2.8.1 IRB approval for the protocol and any amendments or revisions
 - 2.8.2 IRB Membership list
 - 2.8.3 All communications with IRB including annual renewal of IRB approval
 - 2.9 Informed Consent forms – all versions in reverse chronological order, including each approved language change
 - 2.9.1 Any written material that may accompany the Informed Consent designed to support the subject's ability to give fully informed consent
 - 2.9.2 IRB-approved advertisements for study recruiting (included if printed or referenced in video, radio, internet, or other format.)
 - 2.10 Lab Certifications (CLIA)
 - 2.11 Lab Normal Ranges for all protocol-mandated analyses – including any updates
 - 2.12 Serious Adverse Event report forms (SAE/UADE)
 - 2.13 Sponsor Correspondence
 - 2.13.1 Any instructions for handling investigational materials not contained in the Investigator's Brochure
 - 2.13.2 All relevant communication (other than site monitoring visits)
 - 2.13.3 Shipping documentation for investigational articles
 - 2.14 Record of monitoring visits including monitoring reports as applicable
 - 2.15 Signature sheets for sponsor visits
- 3.0 Assure that the Regulatory Binder is maintained and stored per the requirements in QA-005 "Record Retention".

REVISION HISTORY

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Rev	DCO	Description of Change	Approved by
1	08-007	Edited for clarity and style	Michael V.W. Bergamini

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