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VIRGINIA COMMONWEALTH UNIVERSITY

VCU Make it real.

Regulatory Binder Checklist for FDA-Regulated Sponsor/Sponsor-Investigator Studies

DIRECTIONS:

1. The purpose of a regulatory binder is to assure that all essential elements are maintained in an organized fashion throughout the lifecycle of a study. These documents are essential to quality conduct of the study.

2. As a sponsor of an IND/IDE you must keep a regulatory binder. If you are also the investigator you will need to keep those essential documents also. If you are not the investigator you will need to assure as part of your monitoring program that the investigator does maintain an investigators regulatory binder.

3. The following checklist will outline the essential documents to be maintained by both the sponsor and the investigator.

4. This checklist can also be utilized for investigator intiated non FDA regulated research by following only the investigator required documents.

5. The Regulatory Binder should be monitored throughout the study and is subject to Audit.

6. Use a separate 3-ring binder for the regulatory documents for each study. Use labeled dividers to organize documents by topic and file documents in chronological order.

7. As appropriate for the study, some documents may be stored electronically. Please include an explanation in the binder indicating where electronic documents can be located.

8. The storage location needs to be secure, whether study documents are stored in a binder or electronically.

Regulatory Binder Checklist for FDA-Regulated Sponsor/Sponsor-Investigator Studies

Study title _____

PI name _____

IRB number _____

IND/IDE Number: _____

Checklist completed by _____ **Date:** _____

PI initials indicating that checklist is complete _____ **Date:** _____

Regulatory Binder Checklist

- ✓ Use a separate 3-ring binder(s) for each IND/IDE. If you have multiple studies under an IND/IDE then also keep a separate binder for each study..
- ✓ Use labeled dividers to organize documents by topic and file documents in chronological order.

A. FDA Documents		**✓ Check one**	
Tab Label	**Documents to include in binder**	**Yes**	**N/A***
1. Form 1571 (IND only)	Maintain all versions		
2. IND or IDE Application	Copy of full application		
3. FDA Annual Reports	Copy of all reports sent to the FDA		
4. FDA Correspondence	Include communication with FDA, such as letters, facsimiles, telephone discussions, emails, etc.		
5. FDA Form 1572 (drug study only)	Include all versions		
6. All amendments to the IND/IDE	This includes, submissions for changes to protocol, new protocols, new investigators.		
7. Statement of Investigator or Investigator Agreement (device study only)	Note: This is a brief agreement provided by the sponsor. It is <u>not</u> the Sponsored Research Agreement negotiated by Legal Contracts Administration.		
8. FDA Final Report			
9. FDA Safety Reports	Include all reports and related correspondence, FDA Forms 3500 and 3500A		
10. Form 3674	Certification of Clinicaltrials.gov registration. Keep all versions		
11. Investigational Product Information (device study only)	Summary document describing the investigational product under study.		

12. Transfer of Obligations	If any sponsor or investigator responsibilities are transferred to another organization (ex CRO) this formal agreement and any related correspondence must be maintained.		
13. Laboratory Documents	1. Normal ranges 2. CAP certification 3. CLIA certification		
14. Financial Disclosure(s)	1. Certification of Financial Interest and as applicable Disclosure of Financial Interest by investigator 2. Form 3454 and as applicable Form 3455		
15. Sample Case Report Form (CRF)	Include a blank CRF if available		
16. Data Safety Monitoring Board (DSMB)	Include membership, charter, copy of reports and correspondence, if applicable		
17. Study-specific SOPs	Include SOPs from sponsor and those developed by the study team/work unit.		

B. IRB Documentation		**✓ Check one**	
Tab Label	**Documents to include in binder**	**Yes**	**N/A***
IRB Correspondence	Include copies of the following: 1. IRB submission forms 2. All documents submitted to the IRB (e.g. initial protocol submission with attachments, continuing reviews, protocol amendments, unanticipated problems involving risks to subjects or others reporting, etc.) 3. All IRB approval minutes/letters 4. IRB membership/roster (include roster from initial approval of study and annual updates).		

C. Study Tracking Logs		**✓ Check one**	
Tab Label	**Documents to include in binder**	**Yes**	**N/A***
1. Subject Logs	Depending on your study, this could include: 1. Master subject log: Include name, study number, date enrolled and completed, medical record number, contact information 2. Screening log (include screened failures and reason for failure) 3. OnCore usage for participant management is adequate		
2. Adverse Event Reporting	Include all reports (or logs) of adverse events and serious adverse events ***Note**: It is recommended that you keep all reports in one		

Note: Unanticipated problems involving risks to subjects or others reporting are filed under the IRB Correspondence tab.	binder OR that you keep all reports in the individual subject files. Be consistent and describe the method used for your study.		
4. Investigational Product Accountability **Note:** If this information is kept on file with the Pharmacy or another department, then include an explanation stating where the information is located.	1. Drugs: Include logs showing receipt of drug (lot #, expiration date), dispense date and quantity, return/disposal, temperature log (if applicable). 2. Devices: Include logs showing date the device was received, date device was implanted or given to participant, and date of disposition.		
4. Monitoring Log*	This includes any documents related to monitoring of the study (by the sponsor). For example, these may include sign-in logs, monitoring reports, confirmation letters, pre-site selection visit, site initiation visit.		
5. Delegation of Responsibility Log	Include tasks delegated to specific study team members. This can serve as the signature log.		
6.. Training Log (as applicable)	Include documentation of special training completed for the study (e.g. training on a study-specific device). Document who received training, date, name of instructor.		

D. General Correspondence		✓ **Check one**	
Tab Label	**Documents to include in binder**	**Yes**	**N/A***
General Correspondence	Include communication on study-specific issues with clinical personnel, pharmacy, etc. This may include letters, facsimiles, telephone discussions, emails, etc.		

E. Study Personnel		✓ **Check one**	
Tab Label	**Documents to include in binder**	**Yes**	**N/A***
1. CVs and Licensure	Include copies for all individuals as appropriate for the study. *Note*: These documents may be retained in a separate binder, stored electronically, or shared among multiple studies (as appropriate). If kept separately, please include an explanation in the binder stating where the information is located.		

Subject Files Checklist for FDA-Regulated Studies

Study title _____

PI name _____

IRB number _____

IND/IDE Number: _____

Checklist completed by _____ **Date:** _____

PI initials indicating that checklist is complete _____ **Date:** _____

Subject Files Checklist **(complete only one checklist per study)**

- ✓ Use a separate file (or binder with dividers) for each subject enrolled in the study.
- ✓ Review subject files to ensure that the following documents are included (as applicable for study).

Documents to include in file	Comments	✓ Check one	
		Yes	N/A*
1. Informed consent documents for all subjects	Verify the correct version of informed consent was signed. If a subject was required to sign more than one consent, verify that all applicable versions are signed and retained.		
2. Completed Case Report Forms (CRF)	Depending on your study, this may include the clinical history, inclusion/exclusion criteria, concomitant medications, etc.		
3. Source documents	Include source documents such as: lab reports, x-rays, diagnostic tests, scans, etc. **Certify copies of emr**		
4. Study drug or device administration	Include any files/records that are maintained separately from the Research Pharmacy or distribution area.		
5. Adverse Event Reporting For example: Adverse Events, Serious Adverse Events, Unanticipated problems involving risk to subjects or others reporting **(*See Note)**	Include adverse events, serious adverse events and unanticipated problems involving risks to subjects or others reporting that have been reported for a subject. ***Note**: It is recommended that you keep all reports in one binder OR that you keep all reports in the individual subject files. Be consistent and describe the method used for your study.		
6. Receipts for subject reimbursement	Reimbursement means you are repaying a study subject for actual cost he/she incurred while participation in the study. For example: mileage, lodging, food, parking fees, etc.		