VCU Research and Innovation

Essential Records Guidance

The purpose of this guidance is to aid study teams in determining what essential records are required to be in the investigator site file (ISF) versus the trial master file (TMF). Every time a study is conducted, it is expected that the study team maintains an ISF that is audit ready. An ISF is required regardless of if it is an investigator-initiated, federally funded or industry-sponsored study. The ISF is composed of the regulatory binder and participant binders. The sponsor of the study will maintain the TMF. The TMF will include all applicable documents for the overall study and for each participating site. If the investigator is also the sponsor (considered the sponsor-investigator) for a multi-site or federally funded study that has other participating sites, it is expected that the sponsor-investigator will maintain both an ISF and TMF. This practice follows ICH GCP guidelines and aids the sponsor and the investigator in fulfilling FDA regulations.

The table within this guidance document lists the expected documents that are expected to be maintained during the course of the study and specifies whether the investigator or the sponsor is responsible for maintaining it.

Table 1: Essential documents

Type of Document	**Purpose**	**Location of Document: ISF (At the investigator site)**	**Location of Document: TMF (With the sponsor)**
Investigator's brochure (IB) and accompanied signature pages (if applicable)/ package insert (initial and all updated versions)	Documents the current scientific information about the product that is being provided for the study. If there are multiple products being used, each product would have its own IB or package insert. The signature page documents the review by the investigator.	X	X

Type of Document	Purpose	Location of Document: ISF (At the investigator site)	Location of Document: TMF (With the sponsor)
Protocol (initial and updated versions) with signature page (if applicable)	Documents the currently approved study protocol and the investigator's agreement to the protocol. This will be resigned when a protocol amendment occurs.	X (Original)	X (Copy)
Sample case report form (CRF)	This is a blank copy of the CRF(s) used for this study and includes what data is expected to be collected at each study visit.	X	X
Any written information given to participants in addition to consent	A sample of any additional written information given to participants (ex: drug diary, participant information sheet). This additional information needs to be IRB approved prior to being given to participants. A sample should be kept of each version if amendment(s) occur(s).	X	X
Subject recruitment advertisement	Samples of any recruitment materials used to enroll participants. Recruitment materials must be approved by the IRB prior to use.	X	
Financial aspects of trial	Documents the financial agreement between the investigator/institution and the sponsor.	X	X
Any signed agreements between sponsor/CRO and institution/investigator	Documents any agreements between the sponsor, their CRO and the institution/investigator.	X	X
Documented approval(s) and submission(s) of IRB for all protocol, amendments, continuing reviews, deviations, safety reports, etc.	Documents that all study materials have been submitted and approved by the IRB of record prior to being used in the study.	X	X

Type of Document	Purpose	Location of Document: ISF (At the investigator site)	Location of Document: TMF (With the sponsor)
IRB composition/roster		X	X
Regulatory authority(ies) initial approval, amendments, and annual report, and withdrawal submissions (Ex: FDA) (if applicable)	If the study has been submitted to the regulatory authority such as the FDA, a copy of the FDA submissions and the associated FDA correspondence (safe to proceed letter, requests for information).	X	X
Relevant documents showing evidence of qualifications of investigators and other study members (CVs, MLs, etc.)	Documents the qualifications and eligibility to conduct the trial and/or provide medical supervision of subjects.	X	X
Trial specific training records and training certificates of all staff on study	Ex: Training logs showing protocol, ICF, IB review, GCP, HSP, dangerous goods (IATA)	X	X
Normal lab ranges	Documents normal ranges of labs used for this study. The sponsor must have a record of all the normal ranges for each participating site.	X	X
Lab accreditations (ex: CAP/CLIA)	Documents lab credentials/accreditations of the lab(s) used for this study. The sponsor must have a record of all lab credentials/accreditations of the lab(s) used for each participating site.	X	X
Sample of label attached to investigational product(s) (IP)	Documents compliance with applicable labeling regulations and instructions provided to participants.	X	X
Manuals/instructions of use for trial-specific systems	Documents instructions needed to ensure compliance, proper usage, etc. (Ex: IRT, EDC systems)	X	X

Type of Document	Purpose	Location of Document: ISF (At the investigator site)	Location of Document: TMF (With the sponsor)
IP manual	Documents instructions needed to ensure proper storage, packaging, dispensing and disposition of IP if not included in protocol or IB.	X	X
Shipping records for IP	Documents shipment dates, batch numbers, method of shipment.	X	X
Certificate(s) of analysis of IP shipped	Documents identity, purity and strength of IP used.		X
Decoding procedures for blinded trials	Documents how in case of an emergency, identity of blinded IP can be revealed without breaking the blind for the remaining participants.	X	X
Monitoring reports	Documents the monitoring of the study conduct. This will occur multiple times throughout the course of the study.	X	X
Study communications	Communication between sponsor and site.	X	X
Completed signed and dated ICFs	Documents that the ICF is obtained in accordance with GCP and the protocol and is dated prior to the participation of each participant.	X	
Source documents	Documents the existence of the participant and acts as the source of truth for where the study data was collected from.	X	

Type of Document	Purpose	Location of Document: ISF (At the investigator site)	Location of Document: TMF (With the sponsor)
Signed, dated and completed CRFs	Documents that the investigator confirms that the data entered in the CRFs is accurate and complete.	X (copy)	X (original)
Documentation of CRF corrections	Documents all changes/additions or corrections made to CRFs after the initial data was recorded.	X (copy)	X (original)
Notification by investigator to sponsor of SAEs	This could include an email or other reporting method that follows the protocol.	X	X
Notification by sponsor and/or investigator to regulatory authority and IRB of unexpected SAEs	This could include a combination of submission documents and responses.	X	X
Notification by sponsor to investigators of safety information		X	X
Completed Screening log	Documentation of the ID of potential participants who are screened	X	X (Copy)
Completed enrollment log (includes completed participant identification code list)	Documents the chronological enrollment of participants by participant ID.	X	X (Copy)
Master randomization list (if applicable)	Documents the assignment of participants to treatment groups	X	X (Copy)
All documentation related to IP accountability at site	Documents shipment, receiving, dispensing of IP and storage conditions	X	X
Signature sheet (if applicable, i.e., DOA is electronic but CRFs are paper)	Documents signatures and initials of all people on study	X	X
Delegation of Authority Log (can be electronic or paper)	Documents delegation of study tasks to those qualified to conduct the study	X	X (Copy)

Type of Document	Purpose	Location of Document: ISF (At the investigator site)	Location of Document: TMF (With the sponsor)
Record of collection, stored and retained body fluids/tissue samples (if applicable)	Documents collection, location (storage conditions), and ID of retained samples	X	X
Documentation of IP destruction (follow institutional policy as applicable)		X	X
Clinical study report(s)	Documents results and interpretation of trials		X

Contact

Please contact for questions regarding this document:

Lauren Wallace, MS, RAC-Drugs
Director of Clinical Research Regulatory Affairs
kanigherl@vcu.edu

Liz Kissell, MPH, CCRP
Clinical Research Monitor/FDA Program Admin
kisselle@vcu.edu

References

A. Good Clinical Practice ICH E6R3
- Appendix C: Essential Records for the Conduct of a Clinical Trial

Document History

Version	Version Date	Brief Description of Change
1.0	12/11/2023	Initial
2.0	3/26/2025	Included other essential records pertinent to clinical trials and updated existing records with additional details. Added a reference section.