Table of Contents

1. Overview

Purpose

The purpose of this guidance is to describe the process and requirements for closeout of a study, and to ensure that all study closeout activities are conducted in compliance with regulatory requirements, organizational procedures, and sponsor policies. Study closeout relates to the closure of a study site or participating sites once all participants have completed the study and all data queries have been resolved.

Closeout activities are completed by the site Principal Investigator (PI) and designated personnel, and the study sponsor or contract research organization (CRO), if applicable. If the study is an investigator-initiated clinical research project, the lead coordinating site Principal Investigator (PI) is considered the Sponsor-Investigator and is responsible for both sponsor and investigator obligations, including site closeout, under Good Clinical Practice (GCP) Guidelines. If the investigator-initiated clinical research project is a multisite study, the sponsor-investigator is responsible for completing the site closeout for all participating research sites.

2. Definitions

Case Report Form (CRF): an electronic or paper document which is used in clinical research to record the protocol required information about each study participant.

Essential Documents: documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Note-to-File: a document written by a research team member to provide additional information or clarification about a research study. Examples include the explanation of the location of a study document, documentation of a discrepancy or problem and the actions taken to address it, or clarification of unclear protocol instructions.

Regulatory Files: a collection of documents that are essential for a clinical research study to comply with regulations and maintain good practices. These documents are often kept in regulatory binders, also known as study files or investigator binders.

Source Documents: original documents, data, and records that document the existence of a research participant and the integrity of the research data collected.

3. Closeout Preparations

3.1 Confirm that no other study activities are required

Ensure that all participants have completed all required study visits and follow-up procedures, and all study activities are completed. This includes resolution of any/all Serious Adverse Events (SAEs) and Protocol Deviations (PDs). The study team should work with the sponsor to ensure appropriate management, actions, and complete documentation of SAEs and PDs. The complete documentation must be included in the final study records.

3.2 Schedule a study closeout visit with the sponsor/monitor

Ensure all key personnel will be available at the time of the visit and have all records and source documents and essential regulatory files available for review. The closeout visit may be completed via remote or in-person visit.

3.3 Verify data collection and resolve findings

Confirm that all data has been entered in the study database, data queries and previous monitoring findings have been resolved. Data may be entered or corrected on CRFs until the database has been locked and the study terminated with the IRB.

3.4 Review and verify essential documents

Ensure that all essential documents are current, complete, accurate, and filed appropriately. Ensure documents are available for review by the monitor at study closeout. Essential documents include but are not limited to:

- Protocols and amendments
- Approved consent documents
- Recruitment materials
- IRB approvals and correspondence
- Study team CVs/resumes and licenses
- Training records for study personnel
- Financial agreements
- Investigator's Brochures
- Delegation of authority log
- Drug and device shipment, storage, dispensation, and return records
- Participant ID Log
- Signed informed consent forms and HIPAA Authorizations
- Source documents
- Signed and completed CRFs or copy if maintained in the sponsor/CRO's electronic database

Ensure notes-to-file exist for any violations/deviation/occurrences that require additional documentation or explanation.

See Guidance Document ORI-615 Maintenance of Regulatory Files for a full list of essential documents.

3.5 Return or dispose of all study materials and investigational product(s) per protocol

Ensure that any materials or supplies remaining at the conclusion of the study have been returned or destroyed according to protocol, regulations, and sponsor/CRO/institutional requirements. Confirm that all materials are accounted for, any discrepancies have been reconciled, and receipt, storage, dispensing, and disposal of materials has been documented (e.g., shipment receipts, accountability/destruction logs) and properly filed in the regulatory binder.

3.6 Closeout the account with Research Accounting Services (RAS) and Office of Sponsored Programs (OSP)

Review final study budget, if applicable; identify any invoiceable charges and resolve outstanding financial obligations. Work with the department's research administrator(s) to confirm that financial records are reconciled, and all payments have been received by participants, sites, vendors, as applicable.

4. Study Closeout

4.1 Complete and submit Institutional Review Board (IRB) closeout documents

Ensure closure is confirmed by the IRB and that this confirmation is filed. Provide the sponsor/CRO with a copy of the study closeout letter. Please note, that **no** new data may be collected once the study is terminated with the IRB.

4.2 Submit other applicable closure reports

Notify applicable parties/regulatory authorities of the study closure and submit final reports (e.g., the FDA for investigator-initiated, FDA-regulated research).

4.3 Complete study closeout checklist

4.4 File closeout visit report from sponsor/CRO/sponsor-investigator

After the visit, the study monitor will submit a study closeout visit report documenting the visit and noting any items that need additional attention, if applicable. Any identified items will be followed to completion. After completion, copies of the report and follow-up correspondence must be placed in the regulatory binder.

5. After Study Closeout

5.1 Ensure access to systems and files has been terminated

Ensure access to electronic systems, databases, files has been terminated, as applicable.

5.2 Arrange for archiving and/or storage of study materials and study documents

All study-related materials, documents, and records must be stored in accordance with institutional document retention policy and applicable regulatory requirements. Essential documents must be retained for the length of time required by the protocol, current regulations, and institutional requirements. The PI and study team must retain an inventory and location of stored documents. Prior to destruction of any documents, written permission should be obtained from the study sponsor or representative.

5.3 Financial Disclosure Updates

Ensure financial disclosures are updated if any relevant changes occur in the course of the study or for one year following completion of the study, if applicable. Report updated financial disclosures of any investigators or key personnel to the study sponsor/CRO or FDA (for investigator-initiated FDA-regulated research).

6. Responsibilities

6.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, training and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

6.2 Principal Investigator

The PI retains overall responsibility for the study and delegating study tasks as appropriate. The PI is responsible for overall study closeout, including review and final signoff of all CRFs, ensuring appropriate follow-up of participant events and monitoring visit findings, etc. The PI must maintain, review, and retain study documents as specified by the regulatory authorities, GCP, and institutional policies.

6.3 Study Personnel Responsibilities, as delegated by the PI

Study personnel, as delegated by the PI, are responsible for reviewing source documents and CRFs for completeness, resolving monitoring findings and data queries, notifying appropriate parties (e.g., IRB, OSP, RAS) of study closure, and ensuring proper record storage and retention.

7. Resources

- ICH E6 R2 Guidance for Industry Good Clinical Practice

8. Revision and Workgroup Members

8.1 Revision

Version 001/Effective Date 1/24/2025 – Original Document: Study Closeout

8.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

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