Study Close Out	CR-206
Clinical Research Standard Practices	**Effective Date:** August 2022

SCOPE AND PURPOSE The document is applicable to the people and processes of the following Penn State College of Medicine and Penn State Health entities specified below engaged in clinical research:

Entities:

[ ]	Penn State Health Shared Services	[X]	Penn State College of Medicine
[X]	Milton S. Hershey Medical Center	[X]	Medical Group – Academic Practice Division
[X]	St. Joseph Medical Center	[X]	Medical Group - Community Practice Division
[X]	Holy Spirit Medical Center	[X]	Penn State Health Life Lion, LLC
[X]	Hampden Medical Center	[X]	Lancaster Medical Center

Roles:

[X]	Principal Investigators	[X]	Regulatory Specialists
[X]	Sub-Investigators	[X]	Key Study Ancillary Personnel
[X]	Study Coordinators/Associates	[X]	Financial Analyst/Research Accountants
[X]	Data Specialists	[X]	Central Research Office Personnel

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor's monitor conducts a study Close Out Visit (COV) to:

- Review all regulatory files for completeness;
- Complete the verification of all data in case report forms (CRFs) with source documentation;
- Meet with the research team to discuss the results of the:
    - final audit of the regulatory files,
    - final source data verification,
    - reconciliation of the study drug shipment and receipt records with drug accountability records,
    - possibility of a quality assurance and/or FDA audit,
    - requirements for data storage.

This SOP applies to the procedures for conducting the study COV for all clinical studies involving human subjects in research during all investigational phases of development. It describes the steps followed by this clinical research site from the time the monitor schedules the COV until all follow-up activities associated with the visit have been completed.

POLICY AND PROCEDURE STATEMENTS

1. Scheduling the study COV
    a. As soon as possible after the last patient has completed all scheduled visits associated with the study, arrange a mutually convenient date and time for the study monitor to conduct the study COV.
    b. For drug study studies, Investigational Drug Services (IDS) needs at least two weeks advance notice to schedule a COV.

2. Preparing for the study COV
    a. Ensure that all regulatory documentation and case report forms not previously monitored are complete and available for review.
    b. Ensure that all data queries received to date have been resolved to the extent possible.
    c. Ensure that the appropriate patient medical records will be available for review at the time of the study COV.
    d. Remind the study pharmacist of the scheduled visit so that study drug can be inventoried and drug accountability records can be completed.

3. Managing the study COV
    a. Ensure that the study monitor has all documents required to complete the COV.
    b. Provide the monitor with an update on any study-related issues.
    c. At the conclusion of the visit, meet with the study monitor to discuss any issues related to:
        i. Final audit of regulatory files
        ii. Final source data verification
        iii. Study drug reconciliation
        iv. The possibility of a quality assurance and/or FDA audit
        v. Requirements for data retention and storage
    d. If data were entered by computer, determine when hard copies of all CRFs will be provided to the site.
    e. Review with the monitor the sponsor's requirements for protecting the integrity of the electronic data.
    f. Discuss with the monitor the sponsor's requirements for patient follow-up for serious adverse events after formal termination from the study.
    g. Discuss the possibility of publication of the data and future studies.
    h. Discuss requirements, pro rata, and timeline for the final payment.

4. Following-up after the study COV
    a. For drug studies,
        i. Ensure that the study drug or device is either prepared for return to Sponsor/CRO or disposed of at the site at the sponsor's written request and per applicable Hershey Medical Center IDS policies
        ii. File copies of study drug packing slips and shipment receipts appropriately.
        OR
        iii. Provide sponsor with documentation of the previously authorized study drug disposal and file site copy appropriately.

b. If the randomization code on any study drug was broken for any reason, ensure that complete documentation is available.
c. Ensure return or destruction of all other study-related materials.
d. Ensure that any equipment on loan is returned.
e. Original copies of the dispensing records are to be maintained in the pharmacy files on site, unless the sponsor provides documentation requesting that the original copies of the pharmacy dispensing records are to be removed from the site at the COV.
f. Inform the IRB that the study is over and submit the final report to Institutional Review Board.
g. Provide sponsor with a copy of the correspondence from the IRB acknowledging closure.
h. After all data queries have been resolved, check study files for completeness.
i. Arrange for transfer of study documents to secure storage, noting storage location at the site.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.50, 56, 59, 60, 62, 64, 66, 68)

International Conference on Harmonization Good Clinical Practice E6(R2)

Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring, Guidance for Industry. *August 2013* (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/oversight-clinical-investigations-risk-based-approach-monitoring)

Penn State University Institutional Review Board Investigator Manual (HRP-103)

APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

May 2023	
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."
Policy and Procedure Statements	Statement *An internal audit may be scheduled by the Human Subject Protection Office Program and/or Research QA after the study monitor has completed the termination visit* has been removed as this a rare, and would be prompted by unique circumstances. Reference to **termination visit** changed to **COV**. Reference to specific IDS policies removed from inline text.