	Center for Clinical and Translational Research Standard Operating Procedure	

Section: **Clinical Research Center**	Date Created: **November 1, 2010**
Title: **Closeout (Termination) Visit**	Version Date: **January 1, 2023**
SOP Number: **SM51**	

PURPOSE: This standard operating procedure (SOP) describes the processes followed to facilitate a closeout visit. This visit is the final visit performed to ensure that all data has been collected and verified, the final accounting has been completed, investigational product has been destroyed or returned to sponsor, and to verify that the investigator's files are complete and accurate after all subjects have completed the study. The visit is usually scheduled after submission of all clinical data from a site.

SCOPE: The SOP applies to all sponsored clinical trials at the University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM).

PERSONNEL RESPONSIBLE: All members of the clinical research team, as delegated by the Principal Investigator (PI) may be involved in arranging, managing, participating in, or following up after the study closeout/termination visit.

DEFINITIONS:
- **Case Report Form (CRF):** A printed, optical, or electronic document to record all of the protocol required information to be reported to the sponsor on each study subject.
- **Institutional Review Board (IRB):** An independent group made up of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by reviewing and approving the clinical protocol, informed consent forms, and the methods and materials used in the trial.
- **Investigational Product (IP):** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
- **Monitoring:** The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s).
- **Source Documents:** Original documents, data, and records (e.g., hospital records, clinical and office charges, laboratory results, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records) that contain the first recording of pertinent information.

PROCEDURES:
- The PI or his/her designee will schedule and arrange the closeout visit as requested by the sponsor representative. Attendees will include all pertinent staff (if available).

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- Closeout visit will be scheduled at a mutually convenient time and every attempt will be made to accommodate the monitoring deadline.
- Prior to the visit, the PI designee will confirm with the sponsor representative what materials will be reviewed so that appropriate documentation and files will be made readily available. These materials may include:
    - Subject source documents and corresponding CRFs
    - Regulatory binder
    - Safety reports and/or adverse event documentation
    - Access to investigational product storage and accountability documentation
- The PI designee will make sure that an appropriate work area is available for the monitoring visit.
- The PI designee will schedule time to work with the monitor during the visit to review and complete any data clarifications as necessary.
- The PI designee will complete the appropriate paperwork to obtain a user ID and password assigned to the monitor to gain access to the electronic medical record.
- The PI designee will arrange for IP review of accountability, reconciliation, and final disposition.
- CRFs and study related documents will be submitted to the sponsor according to sponsor SOPs. All documents will only include the subjects study number for identification.
- Any final issues of record retention, publication policies, and final payments will be discussed at this meeting.
- All research records will be maintained on site until all sponsor queries are resolved. The research records will be prepared for storage. Study documents will be placed in boxes with contents labeled on the outside of the box. A study document box storage list will be prepared with one copy saved electronically in a designated file in each department.
- After sponsor approval, the clinical trial will be closed with the IRB of record. No further study procedures may occur. However, if financial reconciliation is ongoing, the trial may remain open with the UNMC Office of Regulatory Affairs until contract financials are fully executed and final payment is received.

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ASSOCIATED FORMS:

Box storage list

RESOURCES:

- UNMC IRB #3.5 Retention of Research Records
- Title 21 CFR 312.62- Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- Title 21 CFR 812.140-Investigator Record Keeping and Record Retention for Device Trials
- Title 21 CFR 54 Proposed Obligations of Clinical Investigators.
- NM Policy and Procedure: ADM019 – Destruction of Investigational Products
- IDS SOP-3: Investigational Product Returns and Destruction

Department Approval

Signed *Katie Penas*

Clinical Research Manager   Signed: 2/21/2023

Signed *Serena Gaines*

Research Nurse Manager   Signed: 2/21/2023

Signed _____

Assistant Vice Chancellor for Research   Signed: 4/3/2023

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Box Storage List

Study Pet name – PI – *add name*
Sponsor –*add sponsor name*
IRB #*add IRB number*

Long Term storage of Study Documents:

Study Closed with IRB on *add date*
Study boxed up into XX boxes

Box 1:

Box 2:

Box 3:

Box 4:

Box 5: