**PURPOSE:** This describes the steps followed by this clinical research site from the time the Study Termination Visit is scheduled until all follow-up activities associated with the visit have been completed.

A Study Termination Visit is a final monitoring visit conducted after all subjects have completed the study and all data are recorded in case report forms (CRFs). The purposes of the visit are:

* to ensure that all investigational product has been administered according to the protocol, accounted for, and the remaining product returned to the Sponsor or destroyed;
* to ensure that all documents regarding investigational product accountability are accurate, complete, and legible;
* to complete monitoring at the study site and return all completed CRFs to the Sponsor;
* to confirm the return (or final disposition) of all study-related materials (including forms, blank CRFs, etc);
* to ensure that all regulatory documents are on file at the investigational site;
* to review with the Investigator his/her responsibilities after termination activities have been completed

**SCOPE:** This applies to all clinical research staff involved in the study termination visit.

**PERSONNEL RESPONSIBLE:**  Principal Investigator and when delegated by the Principal Investigator---- Sub-Investigators, Study Coordinator and/or other pertinent staff.

**PROCEDURES:**

The research coordinator and/or designated individual(s) from the research team will perform the following:

**Preparing for the Study Termination Visit**

* After the last subject has completed all visits associated with the study, schedule a mutually agreeable date/time for Investigator, Study Research Pharmacist, Regulatory Coordinator, CRC, and monitor to accommodate the study closeout visit.
* Ensure that the appropriate patient medical records will be available for review at the time of the study termination visit. If applicable, inform the study pharmacist of the scheduled visit so that study drug can be inventoried and drug accountability records can be completed.
* Confirm visit date/time with Investigator and Study Pharmacist if applicable. Notify Regulatory Coordinator if applicable.
* Ensure that all regulatory documentation and case report forms not previously monitored are completed and available for review.
* Ensure that all data queries received to date have been resolved.

**Conducting the Study Termination Visit**

* Provide the monitor with all documents required to conduct the visit. Ensure that the monitor signs the visit monitoring log. Provide the monitor with an update on any study-related issues.
* Be available periodically throughout the visit to answer the monitor’s questions.
* Maintain confidentiality of other clinical studies.
* If data was entered by computer, determine when hard copies of CRFs will be provided to the site and review Sponsor’s requirements for protecting the integrity of the electronic data.
* At the conclusion of the visit, meet with the monitor to discuss issues related to:
* Final audit of regulatory files
* Final source data verification
* Study drug/device reconciliation
* Possibility of a QA and/or FDA audit
* Requirements for data retention and storage
* Sponsor’s requirements for subject follow-up of serious adverse events after formal termination from the study

**Follow-up after the Study Termination Visit**

* Ensure that study drug/device is prepared for return to Sponsor/CRO or disposed of on site at the Sponsor’s written request and according to SOPs for study article destruction.
* File copies of study drug packing slips, shipment receipts, accountability records, and disposal instructions appropriately or provide Sponsor with documentation of the previously authorized study drug/device disposal and file site copy appropriately.
* If the randomization code on any study drug/device was broken for any reason, ensure that complete documentation is available. Ensure return or destruction of all other study-related materials. Ensure that any equipment on loan is returned.
* Inform the IRB that the study is completed and submit the final report. Provide sponsor with a copy of this correspondence.
* Once all data queries have been resolved, check study files for completeness. Store all documents and archive records appropriately.