PM-305 STANDARD OPERATING PROCEDURE FOR STUDY TERMINATION VISIT

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor's monitor conducts a study termination visit study termination visit 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,
  - the final source data verification,
  - the reconciliation of the study drug shipment and receipt records with drug accountability records,
  - the possibility of a quality assurance and/or FDA audit,
  - the requirements for data storage.

2. SCOPE

This SOP applies to the procedures for conducting the study termination visit for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics during all investigational phases of development. It describes the steps followed by this clinical research site from the time the monitor schedules the STV until all follow-up activities associated with the visit have been completed.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.56	Review of ongoing investigations
21 CFR 312.59	Disposition of unused supply of investigational drug
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.66	Assurance of IRB review
21 CFR 312.68	Inspection of investigator's records and reports

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team

PM-301	Site-Sponsor/CRO Communications
PM-303	Regulatory Files and Subject Records
PM-306	Investigational Drug Accountability, Storage, Dispensing and Return
DM-501	Data Management
QA-601	Audits

5. ATTACHMENTS

A. Study Termination Visit Checklist

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in arranging, managing, participating in or following up after the study termination visit. This includes the following:

- Principal investigator
- Sub-investigator
- Research Director/Manager
- Research coordinator
- Support staff

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline, apply to this SOP.

Audit: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

Clinical Trial/Study Report: A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report.

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, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s).

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and

complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

8. PROCESS OVERVIEW

A. Scheduling the study termination visit
B. Preparing for the study termination visit
C. Managing the study termination visit
D. Following up after the study termination visit

9. PROCEDURES

A. SCHEDULING THE STUDY TERMINATION VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator Support staff	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 termination visit. (See Attachment A, Study Termination Visit Checklist.)

B. PREPARING FOR THE STUDY TERMINATION VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Ensure that all regulatory documentation and that case report forms not previously monitored are complete and available for review. Ensure that all data queries received to date have been resolved to the extent possible.
Research coordinator Support staff	Ensure that the appropriate patient medical records will be available for review at the time of the study termination visit. Inform the study pharmacist of the scheduled visit so that study drug can be inventoried and drug accountability records can be completed.

C. MANAGING THE STUDY TERMINATION VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Ensure that the study monitor has all documents required to complete the termination visit. Provide the monitor with an update on any study-related issues.

PI Research coordinator	At the conclusion of the visit, meet with the study monitor to discuss any issues related to: Final audit of regulatory files, Final source data verification, Study drug reconciliation, The possibility of a quality assurance and/or FDA audit, Requirements for data retention and storage.
PI Research coordinator	If data were entered by computer, determine when hard copies of all CRFs will be provided to the site. Review with the monitor the sponsor's requirements for protecting the integrity of the electronic data.
PI Research coordinator	Discuss with the monitor the sponsor's requirements for patient follow-up for serious adverse events after formal termination from the study.
PI Research coordinator Research Director/Manager	Discuss the possibility of: Publication of the data, Future studies. Discuss requirements, pro rata, and timeline for the final payment.

D. FOLLOWING-UP AFTER THE STUDY TERMINATION VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Ensure that the study drug is either prepared for return to sponsor/CRO or disposed of at the site at the sponsor's written request. File copies of study drug packing slips and shipment receipts appropriately. OR Provide sponsor with documentation of the previously authorized study drug disposal and file site copy appropriately. If the randomization code on any study drug 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.
Research coordinator	Inform the IRB that the study is over and submit the final report. Provide sponsor with a copy of the correspondence.
Research coordinator	After all data queries have been resolved, check study files for completeness. Arrange for transfer of study documents to secure storage, noting storage location at the site.

Attachment A

Study Termination Visit Checklist

DATE	DONE BY (initials)	
_____	_____	All data queries resolved or designated unresolvable
_____	_____	Regulatory files reviewed for completeness
_____	_____	Study drug returned to sponsor/CRO or destroyed
_____	_____	Any instances of emergency breaking of the blind appropriately documented
_____	_____	IRB notified that study has terminated
_____	_____	Report submitted to IRB
_____	_____	Sponsor copied on IRB correspondence
_____	_____	All study-related supplies that are no longer need either returned or destroyed
_____	_____	Final payment received
_____	_____	Any equipment on loan returned
_____	_____	Study files prepared for long-term storage