PM-304 REVISION HISTORY

Date of Revision	Page(s)/Section(s) Revised	Revision Explanation
01AUG2011		
04APR2017		
31OCT2017	All	Cosmetic Only
26MAR2019	All	Minor corrections and updates.

PM-304 STANDARD OPERATING PROCEDURE FOR SPONSOR/CRO MONITORING VISITS

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor's monitor conducts a monitoring visit to:

- Assess adherence to the protocol;
- Review regulatory files for completeness;
- Ensure appropriate study drug storage, dispensing, and accountability;
- Verify data in case report forms (CRFs) with source documentation;
- Meet with the research nurse/coordinator and investigator to discuss progress of the study and any concerns raised as a result of the visit.

2. SCOPE

This SOP applies to the procedures for conducting the monitoring 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 a monitoring visit 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
SS-203	Investigator and Site Initiation Meetings
PM-301	Site-Sponsor/CRO Communications
PM-303	Regulatory Files and Subject Records
PM-305	Study Termination Visit
PM-306	Investigational Drug Accountability, Storage, Dispensing and Return

DM-501	Data Management

5. RESPONSIBILITY

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

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

6. DEFINITIONS

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

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

Compliance (in relation to trials): Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

Contract: A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

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

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

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).

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

Protocol Amendment: A written description of a change(s) to or formal clarification of a protocol.

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).

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

7. PROCESS OVERVIEW

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

8. PROCEDURES

A. SCHEDULING THE MONITORING VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator Support staff	Work with the study monitor to schedule a mutually convenient date and time to conduct the monitoring visit.

B. PREPARING FOR THE MONITORING VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Ensure that all regulatory documentation and that case report forms are complete and available for review. Ensure that all data queries received to date have been resolved to the extent possible.
Research Director/Manager Research coordinator	Ensure that the appropriate patient medical records will be available for review at the time of the monitoring visit.

Support staff	

C. MANAGING THE MONITORING VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Ensure that the monitor signs the visit monitoring log. Ensure that the study monitor has all documents required to complete the monitoring 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: Adherence to the protocol, Review of the regulatory files, Verification of data in the CRFs with the source documentation, Study drug storage, dispensing and accountability requirements for data storage.
Research Director/Manager	Discuss any payment issues.

D. FOLLOWING-UP AFTER THE MONITORING VISIT

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Ensure that all issues identified for resolution or follow-up at the monitoring visit are addressed.

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01AUG2011		
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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