

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-7.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/21/2009	REV. B: 8/25/2010	REV. C:
TITLE: Site Termination Visits			Page 1 of 3	

1. PURPOSE

To outline activities required when close-out visits are scheduled at an investigational site involving human Study Participants (SPs).

2. SCOPE

Applies to all site personnel involved in the implementation and coordination of sponsored clinical investigations involving human SPs.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigator(s), Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

4. BACKGROUND

Sponsors conduct close-out visits to ensure that all data has been collected and verified, to perform the final accounting and disposition of test articles, and to verify that the Investigator regulatory files and Case Report Forms (CRFs) are complete and accurate after all patients have completed the study.

Close-out visits are usually scheduled after submission of all clinical data from an investigational site. However, some sponsors elect to conduct the final monitoring at the close-out visit.

5. PROCEDURE

The PI or designee will:

- 5.1. Schedule and arrange a close-out visit as requested by the sponsor. Close-out visits are conducted at the conclusion of the clinical trial and are often dependent upon enrollment. The dates of close-out visits should be scheduled at mutually convenient times, and every attempt should be made to accommodate monitoring deadlines. Participants will include the PI and additional Investigators whenever possible, and the SC and other clinical research personnel and ancillary staff, as appropriate.
- 5.2. Schedule appointments with the PI, Investigators, pharmacists, and other clinical research personnel, as appropriate.
- 5.3. Provide notice to all clinical research personnel that the sponsor will conduct a close-out visit at the site.

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TITLE: Site Termination Visits			Page 2 of 3	

- 5.4. Confirm with the sponsor representative prior to the monitoring visit which cases will be reviewed so that appropriate documentation and files can be obtained.
- 5.5. Ensure that all available requested study subject source documents and CRFs are provided for sponsor representative(s) to review.
- 5.6. Ensure that an appropriate work area is available for the sponsor representative(s) during the close-out visit.
- 5.7. Accompany the sponsor representative(s) to the investigational product (IP) storage area and be available to assist with product accountability review and packaging to return product to the sponsor.
- 5.8. Schedule time to work with the sponsor representative(s) during the close-out visit to review and complete any data clarifications as necessary.
- 5.9. Submit CRFs and study-related documents to the sponsor according to sponsor Standard Operating Procedures (SOPs).

The PI or designee:

- 5.10. Should acknowledge in writing receipt of sponsor reports, if applicable, and document steps taken to correct any deficiencies.
- 5.11. Must submit to the Institutional Review Board (IRB) a [Progress Report for Continuing Review or Project Termination IRB-01 Biomedical Research](#)

6. TERMS & ABBREVIATIONS

CRF	Case Report Form
GCP	Good Clinical Practice
IP	Investigational Product
IRB	Institutional Review Board
PI	Principal Investigator
SC	Study Coordinator
SOP	Standard Operating Procedure
SP	Study Participants

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TITLE: Site Termination Visits			Page 3 of 3	

7. REFERENCES

- 7.1. Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- 7.2. Title 21 CFR 812.140 - Investigator Record Keeping and Record Retention for Device Trials
- 7.3. Guidelines for Monitoring of Clinical Investigations, 1988
- 7.4. ICH GCP Consolidated Guideline - Part 4. Investigator
- 7.5. ICH GCP Consolidated Guideline - Part 5.18 Monitoring
- 7.6. ICH GCP Consolidated Guideline - Part 8.4 Essential Documents - After Completion or Termination of the Trial
- 7.7. Clinical Research Site SOP 200.6.0- CTM Management

8. ATTACHMENTS

None