


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	SITE MONITORING VISIT		
SOP#: 310	Effective Date: 06/01/2016	Version: 1.0	Page 1 of 3

PURPOSE: The purpose of this SOP is to describe the procedures followed by key research personnel engaged in clinical research at the CRC during a periodic monitoring visit from the sponsor representative.

SCOPE: This SOP applies to all human subjects clinical research studies conducted at the CRC. The PI will designate appropriate research team members to facilitate monitoring visits to ensure high standards of data collection and source data verification are maintained at all times.

RESPONSIBILITY: The Principal Investigator (PI) and key research personnel are responsible for arranging, managing, participating in, and/or resolving any outstanding items resulting from the monitoring visit.

DEFINITIONS:

Case Report Form (CRF): A paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

Monitoring: The act of overseeing the progress of a clinical trial, and of ensuring that is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Monitoring Report: A written report from the Monitor to the sponsor after each site visit and/or other trial- related communication according to the sponsor's SOP.


Regulatory Binder: Method used to organize/store essential study documents. The regulatory binder is often the first document reviewed during audits and inspections.

Sponsor: An individual, company, institution, or organization that takes responsibility for and initiates a clinical research trial.

Test Article: The object of an investigation for human subject use to FDA regulations to include a drug, biologic, medical or investigational device or the study control used in a clinical trial. Also referred to as an investigational product (IP)

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 different way from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. Also referred to as a test article.

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	SITE MONITORING VISIT		
SOP#: 310	Effective Date: 06/01/2016	Version: 1.0	Page 2 of 3

PROCEDURE:

The primary key research personnel assigned to the study will do the following activities before, during, and after a monitoring site visit:

1. Preparing for the Site Monitoring Visit:

- 1.1 Refer to Site Monitoring Visit Checklist (Appendix V).
- 1.2 Schedule all monitor visits, including the first visit following initial enrollment or periodic visits throughout the study. When possible, the next monitor visit should be scheduled at the conclusion of the current visit.
- 1.3 Request the monitor's agenda, if not already provided in a monitor visit letter, to ensure appropriate key research personnel will be available as needed (e.g., PI, research nurse, pharmacist).
- 1.4 Ensure all regulatory documentation and case report forms (CRFs) are complete and available for review.
- 1.5 Ensure all unanticipated problems, adverse events (as defined in the protocol) and protocol deviations have been reported to the sponsor and the IRB.
- 1.6 Ensure all data queries received to date have been resolved to the extent possible.
- 1.7 Assure the test article is securely stored according to the instructions in the protocol (e.g., temperature or light specifications) and all accountability records are updated.
- 1.8 Ensure the appropriate study participant medical records will be available for review at the time of the monitoring visit. The monitor or any other sponsor representative(s) should not be granted direct access to the EMR). The research employee will request the applicable source data from medical records at least 7 days in advance of visit. The monitor should never be allowed to navigate through EPIC using an employee's login information.
- 1.9 Be prepared to ask questions or discuss any concerns you may have about communications or operations of the study.

2. During the Monitoring Visit:

- 2.1 Ensure the monitor signs the monitoring visit log (See Appendix T of SOP# 303: Site Initiation Visit).
- 2.2 Assure the study monitor has all documents required to complete the monitoring visit.
- 2.3 Provide the monitor with an update on any study-related issues.
- 2.4 Throughout the visit, check periodically with the monitor and provide information or documents as needed.
- 2.5 At visit conclusion, the monitor will identify any outstanding items requiring attention (e.g., protocol adherence, source document verification, etc.).
- 2.6 Key study personnel managing the monitor visit will address any outstanding items.

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC**SITE MONITORING VISIT****SOP#: 310****Effective Date: 06/01/2016****Version: 1.0****Page 3 of 3****PROCEDURE (cont.):**

- 2.7 The monitor may request to speak with the PI, who should be available during the visit.
3. Follow-up after the Monitoring Visit:
- 3.1 Ensure any outstanding items are addressed in a timely manner and the necessary information is provided to the sponsor and/or monitor.
 - 3.2 Provide outstanding item resolution to the sponsor and/or monitor and document resolution in the study files (e.g., fax additional source documentation for an adverse event to the sponsor and/or monitor and file the fax with confirmation in the AE section of the regulatory binder(s)).
 - 3.3 Forward the PI a copy of the monitor visit report, if not already done so by the monitor, and inform them of the plans to address any outstanding issues identified during the visit.
 - 3.4 File the monitor visit letter in the regulatory binder.

REFERENCES:	21 CFR 312.50; 21 CFR 312.56; 21CFR 312.59; 21CFR 312.60; 21CFR 312.62; 21CFR 312.64; 21CFR 312.66; 21CFR 312.68; January 1988 Guidelines for the Monitoring of Clinical Investigations; May 1997 International Conference on Harmonization (ICH) Good Clinical Practices;	
RELATED POLICIES:	SOP 201: Regulatory Documentation; SOP 204: Adverse Event Reporting; SOP 302 Site Qualification Visit; SOP 303 Site Initiation Visit; SOP 304 Communication Practices; SOP 305: Investigational Product Accountability; SOP 311: Study Close-Out Visit; SOP 501: Case Report Completion; SOP 502: Source Documentation	
APPENDICES:	Appendix V: Site Monitoring Visit Checklist	
REVISION HISTORY: Keep a running history of all revision dates.		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/01/2016