


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	SITE INITIATION VISIT		
SOP#: 303	Effective Date: 06/01/2016	Version: 1.0	Page 1 of 3

PURPOSE: The purpose of this SOP is to describe activities that will be accomplished by site staff before, during and after the sponsor's Site Initiation Visit (SIV) using a checklist to outline the critical study requirements and procedures during a clinical trial at the CRC.

SCOPE: This SOP applies to all clinical research studies conducted at the CRC.

RESPONSIBILITY: The Principal Investigator (PI), Study Coordinator, Research Nurse, Research Pharmacist, if applicable, Data Manager, and other designated research personnel are responsible for attending the SIV.

DEFINITIONS:

Case Report Form (CRF): A paper or electronic questionnaire specifically used in clinical 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.

Monitor: An individual who acts on behalf of the sponsor to oversee 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 and often the first document reviewed during audits and inspections. The Regulatory Binder is referred to synonymously as the Study Files, Investigator Binder or Investigator File.

Site Initiation Visit (SIV): A meeting requested by the sponsor of a newly approved/activated trial for the study team at the clinical site to review the specifics (e.g.: the science, design, procedures, CRF completion etc.) of the protocol in preparation to enroll the first subject.

Source Documents: Original documents, data, and records (e.g., hospital records, clinic 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 and initiates a clinical research trial.

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PROCEDURE:

1. The study coordinator will refer to a SIV Checklist (Appendix S) for guidance before, during and after the SIV.
2. Prior to the scheduled SIV, the study coordinator will perform the following activities:
 - 2.1. Establish a suitable date/time/location for the SIV and ensure sponsor, PI and other key personnel availability.
 - 2.2. Request an agenda from the Monitor or create one for the SIV, if needed.
 - 2.3. If needed, provide the Monitor with directions and assistance identifying nearby accommodations.
 - 2.4. Assure personnel are familiar with sponsor-provided study materials (e.g.: protocol, Investigator Brochure, CRFs, etc.) in advance of visit.
 - 2.5. If needed, schedule educational session(s) with involved clinical staff (e.g., nurse, referring physicians)
 - 2.6. Ensure the finalized budget and contract are in process, if not fully executed
 - 2.7. Complete the regulatory binder checklist (Appendix I) to ensure that it contains all of the necessary documents.
 - 2.8. Establish the receipt of adequate test article supplies (if applicable) or ensure the location of test article storage is ready for review and meets the sponsor's requirements.
 - 2.9. Identify any sponsor-provided supplies needed once enrollment begins (e.g., paper-based CRFs, lab draw and shipping supplies).
 - 2.10. Ensure any study-specific initiation visit checklists are completed in advance of the visit.
 - 2.11. Ensure IRB approval has been obtained or review is in process.
3. During the SIV:
 - 3.1. Assure that the PI is present
 - 3.2. Review details of the protocol, including study operations with the Monitor.
 - 3.3. Discuss with Monitor which key personnel are authorized to perform what study-related functions or procedures
 - 3.4. Document operational questions not covered in the protocol and the answers provided by the sponsor.
 - 3.5. Discuss test article administration and accountability (if applicable)
 - 3.6. Review instruction on study-specific activities such as diagnostic tests, lab kits or study-required software and any related recordkeeping requirements (e.g., temperature logs, calibration logs, etc.).
 - 3.7. Review directions for source documentation and/or CRF completion.
 - 3.8. Review required source documents and documentation to be provided at future monitoring visits.

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- 3.9. Discuss applicable study-specific training involving protocol execution (e.g., in-service for physician investigator, research nurse).
- 3.10. Provide the Monitor with an update on any study related issues.
- 3.11. Identify important sponsor and/or monitoring body contacts and corresponding timeframes (e.g., enrollment logs, safety reporting).

4. Following the SIV:

- 4.1. File all training certificates in the regulatory binder. If the sponsor does not provide a record of training, record the timing and details of any training sessions and file in the regulatory binder.
- 4.2. Document SIV in Site Visit Log (Appendix T) if not provided by sponsor and file in regulatory binder
- 4.3. Ensure receipt of sponsor/CRO written documentation summarizing important agreements made during the visit.
- 4.4. Assemble screening/enrollment materials.
- 4.5. Activate recruitment plan once IRB approval is obtained.

REFERENCES:	21CFR 312.50; 21CFR 312.52; 21 CFR 312.60; 21CFR 312.62, 21 CFR 312.66, 21CFR 312.68	
RELATED POLICIES:	SOP 102: Training Clinical Research Staff SOP 104: Clinical Study Conduct SOP 201 Regulatory Documentation SOP 302: Site Qualification Visit SOP 304: Communication Practices	
APPENDICES:	Appendix S: Site Initiation Visit (SIV) Checklist Appendix T: Site Visit Log	
REVISION HISTORY: Keep a running history of all revision dates.		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	06/01/2016	