CTO – SOP 3.3

New Mexico Cancer Care Alliance

MONITORING VISITS

INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at New Mexico Cancer Care Alliance sites, including UNM CC when a monitor conducts a site 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 team members to discuss progress of the study and any concerns raised as a result of the visit.
- Fees for cancelled visits with less than a 24 hour notice, (weather dependent), and/or a change in monitor.

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 or investigational device evaluation (IDE) regulations for devices 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. It ensures that quality data are generated and that patient rights and safety are maximized.

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 312.62	Investigator recordkeeping and record retention
21 CFR 312.66	Assurance of HRRC review
21 CFR 312.68	Inspection of investigator's records and reports
September 1993	FDA Compliance Program Guidance Manual 7348.811: Clinical Investigators
September 1994	FDA Compliance Program Guidance Manual 7348.810: Sponsors, Contract Research Organizations and Monitors
January 1988	FDA Guidelines for the Monitoring of Clinical Investigations
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline

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 (but not limited to) the following:

- Principal investigator
- Sub-investigator
- Research Nurse
- Research Manager
- Research Coordinator
- Regulatory Coordinator
- Study Pharmacist
- Data Coordinator
- Program Manager

PROCEDURES

Scheduling the monitoring visit

- Research Nurse
- Research Coordinator
- Data Coordinator

Data coordinator will work with the study monitor and PI to schedule a mutually convenient date and time to conduct the monitoring visit.

Data coordinator will only allow one monitor per day for each PI.

Monitoring visits are scheduled from 8-5pm only and cannot exceed two days unless permission is given by research supervisor.

Reserve room to conduct monitoring activity.

Schedule the monitor date in the general calendar.

If the site has a master agreement or active study with sponsor, sponsor will often combine site qualification and study initiation visits; if new sponsor- the new study must have approval from the disease specific Clinical Working Group (CWG) before site qualification visit can occur.

Preparing for the monitoring visit

- Research Nurse
- Research Coordinator
- Data Coordinator

Determine IT needs of the monitor and provide information to CRDM Information Technology Section at least 1 week prior to visit.

- What operating system is used?
- What virus check system is used and last update
- Does the monitor need cabling?
- Does the monitor need power?
- Does the monitor need electronic access to a printer?
- Does the monitor need any specialized software?

Ensure 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.

Ensure that the appropriate patient medical records are printed from EMR systems or requested and received from outside medical practices and placed in research chart. CRFs will be available for review at the time of the monitoring visit.

• Regulatory Coordinator	Ensure that the regulatory binder is up to date. Address all regulatory queries and questions
• Research Nurse • Research Coordinator • Data Coordinator	Inform the study pharmacist of the scheduled visit so that study drug storage and drug accountability records can be prepared for review. Complete a Clinical Trial Monitoring Visit Scheduling Record form (Attachment A) and email it to the assigned Regulatory Coordinator and Pharmacy at least 48 to 72 hours in advance.

Managing the monitoring visit

• Research Nurse • Research Coordinator • Data Coordinator	Monitors must sign in on arrival and be accompanied to the monitor room by monitor visit the administrative assistant or data coordinator.
• Regulatory Coordinator	Monitor must send within two weeks of a visit, a written summary of all findings must be provided to PI, Data Coordinator and Research Supervisor. Ensure that the study monitor has all documents required to complete the monitoring visit. Provide the monitor with an update on any regulatory or study-related issues. Monitor will review source documents and submit questions and queries via method of their choice and these will be addressed prior to the next monitoring visit. Only for immediate data lock situations or protocol issues requiring attention will the data coordinator address items at the time of the monitor visit.
• PI or sub-investigator • Research Nurse • Regulatory Coordinator • Research Coordinator • Data Coordinator • Pharmacist • Regulatory Manager • Program Manager	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. • Request copies of all monitoring visit follow up letters • Option to Bill Sponsor/or CRO for cancelled monitor visits with less than 24 hour notice, (weather dependent). • Bill Sponsor/or CRO per monitor change. •

Responding to the monitoring visit

• Research Nurse • Regulatory Coordinator • Research Coordinator • Data Coordinator • Pharmacist	Ensure all queries are resolved prior to the next monitoring visit or provide an explanation as to why items have not been resolved.
• PI	PI will meet with monitors as required per Sponsor agreement or as needed to address monitoring findings.

David C. Aron 2/17/12

CPDMI Medical Director Date:

Clinical Trial Monitoring Visit (Appendix A)
Scheduling Record

Scheduled by:_____ **Date:** _____

Sponsor name:	
Study Number:	
Type of visit:	☐ **Routine monitoring** ☐ **Close-out** ☐ **Other: (specify)**
CRO, if any:	
Monitor Name:	
Monitor e-mail:	
Date(s) of next visit(s):	
Primary Regulatory Coordinator:	
Date sent to Primary Regulatory Coordinator:	
Date Received: (by Primary Regulatory Coordinator)	
Cancelled/Reason	
Monitor Change Date	