

Procedure Category:	Clinical Management
Procedure CLM-01-05:	Frequency and Purpose of Routine Site Visits

Procedure Overview

To define the frequency and purpose of routine visits to investigative sites.

Responsible Individuals

Qualified MICHHR personnel (including, but not limited to, Project Manager and Clinical Study Monitor); Contracted Clinical Research Associates; Director, MICHHR

Procedure

Routine monitoring visits to investigative sites are made at a frequency agreed upon with the sponsor. The frequency is sufficient to assure that the obligations of both the sponsor and the investigator are fulfilled and patient safety adequately addressed. If the time intervals between visits becomes longer than planned, the CRA will document the reasons for the longer interval. Routine site visits will occur at a minimum of once per site per year.

During the routine visits, the CRA performs inspections and assessments agreed upon between the sponsor and UM MICHHR. The activities typically include, but are not limited to, the following (Federal Register Vol. 60, No. 159, October 97, 1995):

- Confirmation of continued acceptability of the facilities
- Confirmation of adherence to procedures of the protocol or investigational plan
- Verification of compliance with procedures specified by the sponsor and compliance with the applicable regulations of the governing/regulatory agencies having jurisdiction over the clinical trial and investigative site
- Assessment of maintenance of records on subject identification, clinical observations, laboratory tests, and test article receipt and disposition
- Confirmation that reports submitted by the investigator in support of the safety and/or effectiveness of the test article are timely, adequate, and accurate
- Confirmation that the Human Subject Rights Committee (HSRC/IRB/EC) approval of the protocol and laboratory certification are current and that informed consents (ICs) have been signed by all subjects
- Review of subject records and case report forms for accuracy and completeness of information, illegible entries, and missing data. If written case report forms are used, the CRA compares the case report forms with source documents. If remote data entry (RDE) is used, the CRA compares the entered data with the source documents.
- Documentation of subjects who did not complete the study and the reason(s) for early discontinuation

Version Number: 004	Implementation Date: February 11, 2000
Page 1 of 3	Revision Date: June 30, 2004
	Review Date: June 30, 2006
Approval Signature, Date:	

Procedure Category:	Clinical Management
Procedure CLM-01-05:	Frequency and Purpose of Routine Site Visits

- Confirmation that the investigator not only reviews the case report forms but also determines the accuracy of the forms and their consistency with available source documents
- Verification of correct collection, storage and/or transport of specimens (where appropriate)
- Evaluation of the subject recruitment rate
- Review and ensure that the investigator’s regulatory files are complete and properly maintained
- Verification that the investigator is protecting the rights, safety, and welfare of the subjects in the study
- Verification that reportable adverse events are documented and appropriate persons have been notified in accordance with GCP and FDA regulations, and/or applicable regulations of the governing/regulatory agencies with jurisdiction over the clinical trial and the investigative site

Additionally, the CRA acts as the liaison and communication link between the sponsor and the investigator. The CRA is available for consultation at the request of the investigator or sponsor.

Documentation

Routine site monitoring activities are documented on the Routine Monitor Report.

Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

Relevant Definitions

CRA - Clinical Research Associate

Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR, must store documentation of the deviation approval.

Procedure Author

Administrative Core, Michigan Institute for Clinical and Health Research

Version Number: 004	Implementation Date: February 11, 2000
Page 2 of 3	Revision Date: June 30, 2004
	Review Date: June 30, 2006
Approval Signature, Date:	