

Procedure Category:	Clinical Management
Procedure CLM-01-04:	Routine Site Visit

### Procedure Overview

To define the standard procedures for routine site visits and documentation of such visits.

### Responsible Individuals

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

### Procedure

The following tasks are performed during a routine site visit:

- Maintain personal contact with each investigator and/or study staff by visiting the site regularly
- Frequency of routine visits is sufficient to assure that the obligations of the investigator are fulfilled and patient safety adequately addressed. If the time interval between visits becomes unusually long, the CRA documents the reasons for the longer interval.
- Conduct meetings with the investigator, group of investigators, and/or study staff to ensure that the following obligations of the investigator are being fulfilled:
  - ◇ Continued acceptability of the facilities
  - ◇ Adherence to the protocol or investigational plan
  - ◇ Adherence to applicable GCP, FDA regulations, and/or applicable regulations of the governing/regulatory agencies with jurisdiction over the clinical trial and investigative site regarding the obligations of the investigator
  - ◇ HSRC/IRB/EC approved informed consent documents are signed appropriately
  - ◇ Adequate maintenance of records on subject identification, clinical observations, laboratory tests, and test article receipt and disposition

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- ◇ Reports submitted by the investigator in support of the safety and/or efficacy of the test article are timely, adequate, and accurate
- Review source documents which are relevant and necessary to make the determinations described above. This includes a review of subjects' records and case report forms for accuracy and completeness of information, illegible entries, and missing data. To accomplish this, the CRA compares the case report forms to the investigator's individual subject source records. For studies utilizing remote data entry (RDE) the CRA compares the data entered to the source records. The CRA also verifies the presence of a signed informed consent (IC) document for each patient enrolled in the study.
- Document those subjects who did not complete the study and the reason(s) for early discontinuation
- Ensure that the investigator reviews the case report forms and determines the accuracy of the forms and their consistency with source documents
- Resolve any pending data queries and verify changes to CRF entries
- Review all regulatory documents for accuracy and ensure that all documents are present and current
- Ensure the adequacy of CRFs, test article, and other clinical supplies
- A monitor report (see Appendix 1), with format and content previously approved by the sponsor, is completed at each site visit and includes:
  - ◇ Protocol name and number
  - ◇ Date(s) of the visit
  - ◇ Name and signature of the CRA
  - ◇ Name of the investigator
  - ◇ Description of current patient status
  - ◇ Identification of the source documents checked
  - ◇ Identification of any deficiencies noted during the visit and description of any actions taken by the CRA and/or investigator to remedy such deficiencies

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- ◇ A statement of any pertinent information and any actions taken by the CRA and/or investigator regarding the patients
- ◇ Any additional comments regarding the investigative site, staff, supplies, enrollment, or study conduct that the CRA deems important
- If case report forms are being forwarded to either the sponsor or a third party, completion of a case report form transmittal memo may be required
- The completed monitor report is retained in the UM MICHIR project files and a copy is sent to the sponsor in a timely manner.

### Documentation

The Monitor Report serves as documentation for routine site visits.

### 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

### Appendices

Appendix 1 Routine Monitor Report

### Procedure Author

Administrative Core, Michigan Institute for Clinical and Health Research

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