

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Activities
Procedure CLN-04-05:	Preparing for Sponsor or CRO Routine Monitoring Visits

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in preparing for and assisting in routine monitoring visits carried out by a sponsor or clinical research organization (CRO). This procedure covers tasks necessary to ensure all relevant documentation, information, data, equipment, and supplies are current, accurate and compliant with all federal and local regulations, sponsor or CRO requirements, and policies related to the targeted protocol.

**Responsible Individuals**

Qualified MICHHR personnel (including, but not limited to, Study Coordinator, Research Assistant and Manager, RSC); Project Manager; Director, MICHHR

**Procedure**

**Pre-Visit Preparation**

1. Routine monitoring visits by a sponsor or CRO are to occur at the frequency agreed to by the sponsor and the MICHHR. This frequency is determined so that the visits are adequate to ensure that the obligations of both the MICHHR and the sponsor or CRO are fulfilled in regards to patient safety, appropriate data collection, and confirmation of adherence to the relevant protocol.
2. Upon the receipt of the request from the sponsor or CRO to schedule a routine monitoring visit, MICHHR personnel check to make sure all necessary personnel are available to spend time with the sponsor or CRO representative as required. The necessary personnel are those formally identified on the Form 1572 as well as staff who attended the investigator's meeting or were involved in either the pre-study or study initiation visit. Personnel likely to be involved include laboratory staff, IDS, study coordinators, investigators, etc.
4. Every effort is made to select a day and time for the pre-study visit that is acceptable to all the necessary study personnel. If the necessary study personnel are not available to meet with the sponsor or CRO on the pre-selected day, if acceptable with the sponsor or CRO, a study back-up can be identified to attend the required visit meetings. The responsible individual must be familiar with the targeted protocol prior to the visit. This is accomplished by a review of

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the Investigator Brochure, the final protocol, and the case report forms, as applicable. MICHHR personnel ask the sponsor or CRO if there are specific areas of focus for the visit. If the sponsor or CRO identifies any specific areas, preparation for the visit is completed with this focus in mind.

5. MICHHR personnel will schedule the visit and notify all necessary study personnel of the scheduled visit, at least two weeks in advance (if possible).
6. MICHHR personnel confirm the schedule for the routine monitoring visit one or two days in advance of the visit, either by phone, fax, or email.
7. MICHHR personnel ensure that appropriate space has been reserved for the sponsor or CRO to review all relevant materials.

### **Necessary Documentation**

1. MICHHR personnel are responsible for ensuring that all required regulatory documents are available for review by the sponsor or CRO including, but not limited to:
  - Accurate and original Form 1572
  - Original signed protocol and amendments
  - Curriculum vitae for all appropriate personnel
  - All IRB approval letters for the specific protocol and an updated list of the IRB members
  - Notification to the IRB of all Serious Adverse Events reported by the MICHHR and a copy of the Serious Adverse Event Reports
  - Copies of all sponsor-reported Serious Adverse Events (Dear Dr. Letters) and the associated IRB notification letters
  - Complete and current Master Patient Log
  - All correspondence related to the protocol
  - Clinical pharmacy records, if applicable
  - Central/local laboratory certification/and or quality control documents along with laboratory reference ranges
2. MICHHR personnel ensure that all informed consent forms are available for review and include all appropriate signatures and dates.
3. MICHHR personnel ensure that all patient case report forms (CRFs) are complete, up-to-date, accurately reflect the information on the corresponding source documents, and are properly stored. Source documents must also be available for review.

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4. MICHHR personnel ensure that all appropriate laboratory results have been reviewed by the appropriate individual and are available for review along with the associated patient charts.
5. MICHHR personnel ensure that all other study/protocol specific requirements/documentation are up-to-date including, but not limited to:
  - Accurate drug accountability/dispensing records
  - Current and accurate freezer/refrigerator calibration/temperature log
  - Current and accurate maintenance and calibration of all protocol specific equipment.
  - Inspection of all laboratory-associated supplies to ensure expiration dates and/or calibrations are current

If these responsibilities are designated to other personnel, inform the involved staff of the pending visit.
6. MICHHR personnel ensure that all study supplies, including study medication, are appropriately stored and available for inspection by the sponsor or CRO. If these responsibilities are designated to other personnel, inform the involved staff of the pending visit.
7. MICHHR personnel ensure that all study materials or supplies not associated with this specific sponsor or CRO are stored appropriately to ensure the confidentiality of other sponsors or CROs.
8. If possible, MICHHR personnel schedule a time during the visit, preferably at the end of the visit, to meet with the sponsor or CRO representative and review the performance of the MICHHR relative to the sponsor or CRO expectations. This includes a review of any deficiencies noted by the sponsor or CRO representative. If possible, the Clinical Research Associate/Assistant resolves all deficiencies prior to the completion of the visit.

**Post-Visit Follow-Up**

1. If there are deficiencies that are not resolved by the end of the visit, MICHHR personnel are responsible for the resolution of these issues and communicating the resolution to the sponsor or CRO representative. Data corrections should be made within one week of the visit.
2. If possible, MICHHR personnel establish a specific date with the sponsor or CRO representative for the next routine monitoring visit at the MICHHR.

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**Documentation**

Documentation for this procedure includes documentation generated during the scheduling of the visit, documentation generated during the visit, and documentation resulting from follow-up activities related to the visit.

**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**

IRB - Investigational Review Board

**Procedure Author**

Manager, Research Support Core

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