

Procedure Category:	Clinical Management
Procedure CLM-01-02:	Investigator/Site Qualification Visit

Procedure Overview

To define the standard procedures for preparation and conduct of the Investigator/Site Qualification Visit.

Responsible Individuals

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

Procedure

Qualified MICHR personnel and/or sponsor representatives personally visit each potential investigative site to evaluate the potential investigator's resources and capabilities. The Investigator/Site Qualification Visit is conducted prior to final selection of investigators and the following procedures are performed during the visit:

- Ensure that the investigator understands the investigational status of the test article, the nature of the protocol or investigational plan, the corresponding investigational controls, and the obligations as set forth in the regulatory guidelines.
- Ensure that the investigator and staff have sufficient time and access to an adequate number of subjects to conduct the clinical investigation and to fulfill their obligation as an investigator and investigational site.
- Ensure that the investigator has sufficient access to a Human Subjects Review Committee (Institutional Review Board or Ethics Committee) and that the investigator understands his or her obligations to comply with the procedures and policies as set forth by this committee.
- Ensure that the necessary technical equipment and adequate treatment facilities are available and that there is a secure place for medication storage.
- Assess adequacy of other facilities, such as laboratory and pharmacy facilities and if applicable, ascertain laboratory certification information.
- Ascertain the magnitude and nature of other studies being conducted concurrently by the investigator and confirm that the investigator is not participating in competing studies and can devote an appropriate amount of attention to the proposed clinical investigation.

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- Review the roles and responsibilities of the monitor, study manager, UM MICHHR personnel, and the study sponsor.
- Review the policy on retention of study records.
- Review the documents required prior to study initiation.
- Ensure that if competing studies are being conducted at an investigative site, there is a reasonable mechanism in place to determine which patient is enrolled in which study.
- Review the need for source documentation and request that source documents be made available as required.
- Complete an Investigator/Site Qualification Visit Report (see Appendix 1). The completed form is retained in the UM MICHHR project files, and a copy is sent to the sponsor on a timely basis.

Documentation

Investigator/Site Qualification Visits are documented on the Investigator/Site Qualification Visit Report.

Deviation Approval

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

Relevant Definitions

CRA - Clinical Research Associate

Appendices

Appendix 1 Investigator/Site Qualification Visit Report

Procedure Author

Administrative Core, Michigan Institute for Clinical and Health Research

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