

	Standard Operating Procedures
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Procedure Category:	Protocol Review
Procedure CLN-01-02:	Assessing Capability to Conduct a Study

Procedure Overview

This procedure describes the steps taken by the MICHHR to determine if a specific study can be conducted by the organization.

Responsible Individuals

Qualified MICHHR personnel; Director, MICHHR

Procedure

When either the MICHHR or an investigator receives a clinical research protocol for review, an assessment must be performed to determine if the organization is capable of conducting the study. Various personnel may assist in this assessment, which is focused on four principal areas:

Investigator and Site Personnel

- Does the investigator have sufficient education, training and experience to conduct and supervise the study?
- Are qualified Clinical Research Associates/Assistants available?
- Is an investigative pharmacist available (if required)?
- Do the relevant site personnel have sufficient time to conduct the study?
- Is there sufficient interest in the organization to support the study?
- Is the budget proposed by the study sponsor sufficient for the conduct of the study?

Facilities and Equipment

- Are there adequate medical facilities for the study?
- Is the site readily accessible to the target study population?
- Is the necessary equipment available to perform all required study procedures?
- Are appropriate secure storage facilities available to store the investigational material?
- Can the investigational material be stored properly with regard to temperature, light and other conditions?
- Is there a secure place for study documents?

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Approval Signature, Date:	

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- Is there adequate space for study monitoring?

Institutional Review Board

- Is there adequate access to the IRB?
- Can the IRB review the study documents in the timeframe required to conduct the study?

Patient Population

- Is there an adequate patient population at the clinical site with the medical indication specified by the protocol? If not, are enough patients available via referral or advertising?
- Are the available patients likely to fulfill all study entrance criteria?
- Can the study population easily obtain transportation to the site?
- Can the organization enroll a sufficient number of patients to meet the needs of the study sponsor?
- If multiple studies are ongoing at the same time, is there a mechanism to ensure patients do not participate in more than one study at any point in time?
- Are there any major competing studies/protocols being conducted concurrently at the UMMC that may limit the availability of eligible subjects?

Documentation

Documentation for this procedure includes:

- The study protocol and supporting documentation
- The Study Capability Checklist (see Appendix 1).

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.

Appendices

Appendix 1 Study Capability Checklist

Procedure Author

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Manager, Research Support Core

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