

	Standard Operating Procedures
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Procedure Category:	Clinical Management
Procedure CLM-01-01:	Study Site/Investigator Selection

Procedure Overview

This procedure describes the process of identifying potential study sites and investigators.

Responsible Individuals

Qualified MICHIR personnel; Contracted Clinical Research Organizations; Director, MICHIR

Procedure

Study site and primary investigator selection is performed by the study sponsor or CRO responsible for implementing and conducting the clinical trial. The following steps are taken to identify potential study sites and primary investigators:

- The study sponsor/CRO determines the desired number of sites and patients per site.
- Investigator specifications are developed, including:
 - ◆ Medical specialty
 - ◆ Patient population
 - ◆ Experience required
 - ◆ Facilities required [including accessibility to a HSRC / IRB / IEC (local IRB versus central IRB), laboratories, treatment administration units, etc.]
 - ◆ Staff required
 - ◆ Geographic location
 - ◆ Recruitment requirements
 - ◆ Study start date

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- Potential investigators are identified from the following sources:
 - ◆ In-house database
 - ◆ Previous investigators/investigative sites
 - ◆ Personal contacts
 - ◆ Commercial databases
 - ◆ Directories of medical specialists
 - ◆ Literature review
 - ◆ Other investigators
 - ◆ Consultants/investigator placement firms
 - ◆ Quality Assurance department recommendations
 - ◆ Internet sources (e.g., www.clinicalinvestigators.com, www.clinmark.com)

- For U.S. IND studies, the FDA’s “Disqualified/Restricted/Assurances List for Clinical Investigators” (www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm) is reviewed, and any investigator rated as D is eliminated from consideration. Investigators who are rated as R or A may be considered if approved by the study sponsor. For non-IND studies, to the extent possible, it is confirmed that the investigator is not banned from conducting clinical trials by any regulatory authority with jurisdiction over the current clinical study or by authorities in any country where study results are planned to be presented or reported.

- An overview of the study is presented to potential investigators. Items to be discussed include:
 - ◆ Background information regarding the investigational material
 - ◆ Study type description (including phase, number of patients, length of follow-up, etc.)
 - ◆ Investigator specification list
 - ◆ HSRC / IRB / IEC submission requirements and frequency of meeting dates
 - ◆ Proposed budget

- If the investigator is interested and appears to meet initial criteria, a tentative investigator/site qualification visit is scheduled.

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- All communication between the site, the study sponsor and/or the CRO is documented.
- With the study sponsor’s consent, the following information may be sent to selected potential investigators:
 - ◆ Confidentiality statement
 - ◆ Current draft of the protocol
 - ◆ “Information for Investigators” section of the Investigator’s Brochure
 - ◆ Proposed budget
 - ◆ Investigator/site qualification visit agenda
- Notify investigators who were not selected and thank them for their interest.

Documentation

Documentation for this procedure includes:

- Site, study sponsor or CRO telephone contact reports
- Correspondence to selected potential investigators
- Correspondence to potential investigators who were not selected

Deviation Approval

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

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Relevant Definitions

FDA Misconduct List Types:

D – Disqualified investigators ineligible to receive investigational products.

R – Investigators agreeing to some restriction in the use of investigational products.

A – Investigators whose assurances for performance of future studies with investigational products were accepted after regulatory hearing or through consent agreement. These are investigators whose work was found to be in violation of regulations but on whom no sanctions were imposed because of assurances given for future compliance.

HSRC - Human Subjects Review Committee

IRB - Institutional Review Board

IEC - Institutional Ethics Committee

Procedure Author

Administrative Core, Michigan Institute for Clinical and Health Research

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