

Procedure Category:	Clinical Management
Procedure CLM-01-03:	Site Initiation Visit

Procedure Overview

This procedure describes the process of preparing for and conducting the site initiation visit.

Responsible Individuals

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

Procedure

The following procedures are performed during site initiation visits:

- Ensure that all required regulatory documents have been filed with the sponsor and a copy has been filed in the Investigator Regulatory File, including:
 - ◇ Signed Statement of Investigator (FDA Form 1572 for drugs) for an Investigational New Drug Study
 - ◇ Current curricula vitae for personnel listed on the Statement of Investigator (CVs should reflect current addresses, institutional and/or clinical affiliations. If possible, CVs for primary investigators should not be more than two years old).
 - ◇ Signed final protocol and amendments/addenda (may require signed signature pages)
 - ◇ Human Subject Review Committee (IRB/EC) approval documentation for the protocol, amendments/addenda, and informed consent form
 - ◇ Copy of approved informed consent form
 - ◇ Laboratory certification and normal ranges
 - ◇ Human Subject Review Committee (IRB/EC) membership list or MPA number
 - ◇ Clinical study agreement (CSA, filed separately from the regulatory file)
 - ◇ Investigators brochure and/or package insert
 - ◇ IRB-approved advertisements and patient education materials, if any
 - ◇ Master Patient Log (see Appendix 1)
 - ◇ Randomization code, if applicable
 - ◇ Test article disclosure envelopes, if applicable
 - ◇ Monitor Visit Log (see Appendix 2)
 - ◇ Site Personnel Signature Log

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- Ensure that the investigator and staff are fully aware of their obligations and responsibilities with regard to the conduct of the trial including compliance with the study protocol and specified procedures, timelines, number of subjects required, GCP guidelines, applicable governing agency regulations, informed consent requirements, and adverse event reporting requirements.
- Review the case report forms and the case report completion requirements
- Check the security and proper storage of the test article and review dispensing and accounting procedures and records
- Confirm that the site facilities and study personnel continue to be adequate
- Review source document requirements
- Complete a Site Initiation Visit Report (see Appendix 3). The completed form is retained in the MICHIR project files, and a copy is sent to the sponsor on a timely basis.

Documentation

Study initiation visits are documented on the Site Initiation Visit Report.

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

- CSA - Clinical study agreement
- HSRC - Human Subjects Review Committee
- IRB - Institutional Review Board
- IEC - Institutional Ethics Committee
- GCP - Good Clinical Practice

Appendices

- Appendix 1 Master Patient Log Template
- Appendix 2 Monitor Visit Log Template
- Appendix 3 Site Initiation Visit Report Template

Procedure Author

Administrative Core, Michigan Institute for Clinical research

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