

Procedure Category:	Clinical Management
Procedure CLM-01-11:	Maintenance of the Investigator's Regulatory File

### Procedure Overview

To define the standard procedures for monitoring and maintaining the Investigator's Regulatory File.

### Responsible Individuals

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

### Procedure

The CRA performs the following tasks:

- Ensure that the investigator understands the regulations regarding records retention:
  - ◊ Study files must be retained for a minimum of two years after the Investigational New Drug (IND) application is withdrawn or until two years after the New Drug Application (NDA) is either approved or withdrawn
  - ◊ An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of two years after the latter of the two dates; the date on which the investigation is terminated or completed or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
- Ensure that the investigator understands the Master Patient Log requirements:
  - ◊ Maintained for 15 years after the study has ended
- Ensure that the Statement of Investigator (FDA Form 1572 for drugs) form is updated and forwarded to sponsor following any change in study personnel
- Ensure that the study-related financial information is not kept in the Investigator's Regulatory File
- Ensure that the following documents are present and current (sponsor may require additional documents):
  - ◊ Signed protocol and amendments/addenda
  - ◊ Signed Statement of Investigator (FDA Form 1572 for drugs)
  - ◊ CVs for all personnel on Statement of Investigator (CVs should reflect current addresses, institutional and/or clinical affiliations, etc. If possible, CVs for Principal Investigators should not be more than two years old)
  - ◊ HSRC/IRB/EC approval letters (protocol and amendments/addenda; informed consent document; reapprovals) and list of applicable Human Subject Review Committee members or MPA number
  - ◊ Documentation of notification of Serious Adverse Events to HSRC/IRB/EC
  - ◊ Informed consent document(s) approved by the HSRC/IRB/EC
  - ◊ Laboratory certification and normals

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- ◇ Test article shipment and return documentation
- ◇ Test article inventory documents
- ◇ Randomization code, if applicable
- ◇ Test article disclosure envelopes, if applicable
- ◇ Substantive site communication reports and correspondence
- ◇ Statement of Study Discontinuance
- ◇ Investigator Brochure (and updates) and investigator's meeting minutes (where applicable)
- ◇ Monitor Visit Log
- ◇ Clinical Study Agreement (filed separately from the Regulatory File)
- ◇ IRB-Approved advertisements and patient education materials, if any
- ◇ Master Patient Log
- ◇ Site Personnel Signature Log

### Documentation

Documentation of the file inspection is recorded on the appropriate report at the time of the study site visit. The reports utilized include the:

- Investigator/Site Qualification Visit Report
- Study Initiation Visit Report
- Monitor Report
- Statement of Study Discontinuance
- Study Close-Out 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

CRA - Clinical Research Associate  
 IND - Investigational New Drug  
 NDA - New Drug Application  
 HSRC - Human Subjects Review Committee  
 IRB - Institutional Review Board  
 EC - Ethics Committee

### Procedure Author

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