

Procedure Category:	Clinical Management
Procedure CLM-01-07:	Study Close-Out Visits

Procedure Overview

To define the standard procedure for conducting a study close-out visit.

Responsible Individuals

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

Procedure

The study close-out visit is conducted whenever an investigator completes the study, the sponsor decides to discontinue the study or close a site, or the investigator decides to discontinue participation in the study. The following tasks are completed during a study close-out visit:

- Ensure that all required regulatory documents are on file and are current
- Ensure that all adverse events have been reported and appropriately documented
- Ensure that documentation of notification to HSRC/IRB/EC of all IND Safety Updates (if applicable) is on file
- Ensure that all case report forms have been completed and collected with adequate resolution of all data queries
- Ensure that investigational material inventory and dispensing records have been retrieved and returned to the appropriate location
- Ensure that all unused investigational material has been returned or destroyed in accordance with sponsor requirements
- Ensure randomization code documents are retrieved and returned to the sponsor if applicable. Ensure all code breaks are appropriately documented.
- Remind the investigator to inform the HSRC/IRB/EC of study discontinuation (see Appendix 1) and to ensure that the Operational Regulatory File documentation of this notification is placed in the Investigator Regulatory File and is sent to the sponsor
- Ensure that all equipment loaned to the investigator has been returned
- Review the record retention policy and publication policy with the investigator
- Retrieve a copy of the Monitor Visit Log for the sponsor's file
- Complete a Study Close-Out Visit Report (see Appendix 2). The completed report is filed in the UM MICHHR/RSC files and a copy is sent to the sponsor in a timely manner.

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Approval Signature, Date:	

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Documentation

The following serve as documentation for this procedure:

- Notice of Study Discontinuation (see Appendix 1)
- Study Close-Out Visit Report (see Appendix 2)

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
 HSRC - Human Subjects Review Committee
 IRB - Institutional Review Board
 EC - Ethics Committee

Appendices

Appendix 1 Notice of Study Discontinuation Template
 Appendix 2 Study Close-Out Visit Report Template

Procedure Author

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