

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Activities
Procedure CLN-04-09:	Study Close-Out Procedures

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in preparing for a study close-out visit with the sponsor and/or CRO.

**Responsible Individuals**

Qualified MICHHR personnel (including, but not limited to, Study Coordinator, Research Assistant, Quality Improvement Coordinator and supervisory personnel); Investigational Drug Manager; Laboratory Manager (if in-house lab utilized); Director, MICHHR

**Procedure**

The study close-out visit is conducted after one of the following events occurs: an investigator completes the study, the sponsor decides to discontinue the study or the individual study site, or the investigator decides to discontinue participation in the study.

The final visit normally occurs after all subjects have completed or discontinued the study. All CRFs should have been completed and forwarded to the sponsor/CRO. It is not necessary for all queries to have been generated before the study close-out visit.

1. Upon receipt of a request from the sponsor or CRO to schedule a study close-out visit, MICHHR personnel checks to make sure all necessary personnel are available to spend time with the sponsor or CRO representative as required.
2. Every effort is made to select a day and time for the post-study visit that is acceptable to all the necessary study personnel. If the necessary study personnel are not available to meet with the sponsor or CRO on the pre-selected day, if acceptable with the sponsor or CRO, a study back-up can be identified to attend the required visit meetings. The responsible individual must be familiar with the targeted protocol prior to the visit. This is accomplished by a review of the Investigator Brochure, the final protocol, and the case report forms, as applicable.
3. MICHHR personnel ask the sponsor or CRO for the visit agenda, Statement of Study Discontinuance Form and, if available, a Study Close-Out Checklist.


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4. At least two weeks prior to the scheduled visit, necessary MICHHR personnel are informed of the visit. An internal pre-close-out meeting is scheduled as needed with all relevant MICHHR study personnel, Investigator, and any other relevant personnel to discuss study performance issues, concerns, problems, study material archiving processes, etc.) prior to the sponsor/CRO visit.
5. MICHHR personnel complete the processes identified in the following list in preparation for the study close-out visit: (refer to the Appendices and documents from the sponsor/CRO for additional processes).
  - a) Ensure that all required regulatory documents are filed and current in the Investigator Study File (ISF).
  - b) Ensure that all adverse events have been reported and appropriately documented.
  - c) Ensure that documentation of notifications of IRB Safety Updates have been reported and filed in the ISF.
  - d) Ensure that all case report forms have been completed and submitted with resolution of any outstanding data queries.
  - e) Ensure that test article inventory and dispensing records are current, accurate and ready for retrieval by the sponsor/CRO.
  - f) Ensure all used and unused test article(s) are prepared for return and or destruction in accordance with IDS, sponsor and/or CRO requirements.
  - g) Ensure randomization code card documents are present for submission to the sponsor/CRO. Ensure all code breaks are appropriately documented.
  - h) Ensure that after the study close-out visit, the IRB, GCRC and IDS has been notified in writing of the Study Discontinuation and that this notification letter is placed in the ISF and submitted to the sponsor/CRO.
  - i) Ensure that all equipment borrowed from the sponsor/CRO is prepared for return, if applicable.
  - j) Ensure shipments of any remaining laboratory samples are submitted in accordance with sponsor and/or CRO requirements. Ensure also that assay results, methodologies, and validation documentation are maintained in the ISF and/or designated Laboratory Notebook for the targeted protocol.
  - k) Review the sponsor/CRO, GCP and Institutional policies for record retention. Be prepared to verbalize plan with the sponsor/CRO.
  - l) Ensure that the Master Patient Logs (paper and computer versions) are current. Print a complete and final copy for filing in the ISF.

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- m) Ensure that the PI has reviewed and signed off on the Statement of Clinical Study Discontinuance. Submit the original document to the sponsor/CRO during the study close-out visit and file the copy in the ISF.
  - n) Destroy potential patient list or phone records.
  - o) Disposal of unused form will be at the sponsor's discretion.
7. After MICHIR personnel have reviewed and prepared all study documents for the visit, the QIC or SCC designee is notified and asked to schedule a secondary review. This review is to occur at least one week prior to the sponsor/CRO visit.
  8. The QIC or SCC designee generates the QI Protocol Review report (see Appendix 1). Documented findings are submitted to the appropriate MICHIR personnel. MICHIR personnel resolve any outstanding items noted in the report within two days of the scheduled visit and documents any actions in the QI Response Report (see Appendix 2).
  9. MICHIR personnel confirm the schedule for the visit one or two days in advance of the visit, either by phone, fax, or email.
  10. MICHIR personnel ensure that appropriate space has been reserved for the sponsor or CRO to review all relevant materials.

NOTE: If no subjects have been enrolled in the study, MICHIR personnel return the study documents to the sponsor/CRO (e.g. Investigator's Brochure).

Post-visit follow-up activities are described in the following list.

1. If there are deficiencies that are not resolved by the end of the visit, MICHIR personnel are responsible for the resolution of these issues and for communicating the resolution to the sponsor or CRO representative. Any data corrections should be made within one week of receipt.
2. Supervisory MICHIR personnel ensure all sponsor/CRO commitments to the MICHIR and the investigator have been fulfilled (e.g. payments, research reports, site evaluations)
3. MICHIR personnel request a copy of the research report summary for filing in the ISF. Note: The investigator may need to review and possibly sign this report.
4. MICHIR personnel should receive copies of all completed Data Clarification Forms for review and retention with subject CRFs, accompanied by the Investigator Authorization of Clarification letter (signed by the investigator). The investigator must forward the signed letter to the sponsor/CRO and retain a copy in the ISF. The investigator is assisted as needed.

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5. Supervisory MICHHR personnel discuss the possibility of a study audit by the sponsor, CRO and/or regulatory authority. See SOP CLN-06-02 regarding sponsor audit procedures.
6. Supervisory MICHHR personnel closes out the study budget once all funding has been reconciled.
7. MICHHR personnel archive the study documents per institution and MICHHR SOP (see SOP CLN-03-07).

### Documentation

Documentation for this procedure includes documentation generated during the scheduling of the visit, during the visit, and resulting from follow-up activities related to the visit.

### Appendices

- Appendix 1 QI Protocol Review Report Sample
- Appendix 2 QI Response Report Sample

### Deviation Approval

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

### Procedure Author

Manager, Research Support Core

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