

	Standard Operating Procedures
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Procedure Category:	Study Activities
Procedure CLN-04-08:	Patient Completion/Early Termination

Procedure Overview

This procedure describes the necessary activities performed by MICHHR personnel in completing end of study or termination activities for a study subject.

Responsible Individuals

Investigator; Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Quality Improvement Coordinator; Director, MICHHR

Procedure

All study subjects either complete the study or are withdrawn from the study prior to completion. A subject may be withdrawn from a study for a variety of reasons, including voluntary withdrawal, noncompliance with the protocol, or the occurrence of a significant adverse experience that could be related to the investigational material. The following steps define the procedure to follow when a subject completes the study or is withdrawn from the study.

1. A final visit is scheduled by MICHHR personnel (see SOP CLN-04-07). If a final visit is not possible, information regarding the last contact with the subject is recorded on the subject's source documents.
2. The final visit activities are performed according to the study protocol. The corresponding case report form documentation is completed in accordance with the study protocol.
3. MICHHR personnel collect any unused investigational material from the subject. In the event a subject does not return to the study facility every attempt should be made to obtain unused investigational material from the subject. If unable to contact the subject via telephone, a certified letter must be sent in an effort to inform the subject that it is required to return the investigation material.
4. Under certain circumstances it may be necessary for the subject to have follow-up visits after study completion or withdrawal from the study. All such visits must be documented in accordance with the study protocol.
5. For blinded studies, the subject's treatment group assignment is not unblinded except in the case of an emergency (see SOP CLN-04-06). It is essential to preserve the blinding of the treatment group assignment in the absence of an emergency.

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6. Subjects may be asked to complete a voluntarily MICHR Study Subject Assessment Form (see Appendix 2). MICHR personnel, as requested forwards all completed Study Subject Assessment Forms to the Quality Improvement Coordinator or other designed individual for review and as predetermined.
7. As specified in the study close-out procedure (CLN-04-09), all study subjects are sent a Study Follow-Up Letter (see Appendix 1) to thank them for their participation in the study and to provide them with additional study information, if available. For blinded studies this information may include their treatment group assignment.
8. All subjects are provided sponsor contact information for any questions or concerns they may have at a later date regarding the study.
9. Appendix 1 and 2 must be sent to the IRB for approval prior to use in each protocol. Attachment of Appendix 1 and 2 in each New Project Application will serve to solicit IRB approval.

Documentation

Documentation for this procedure includes all final visit/termination documentation including source documents, case report forms, communications provided to the subject and relevant sponsor/CRO correspondence.

Appendices

- Appendix 1 Sample Study Follow-Up Letter
- Appendix 2 Sample Study Subject Assessment Form

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.

Procedure Author

Manager, Research Support Core

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