

	Standard Operating Procedures
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Procedure Category:	General Study Procedures and Activities
Procedure CLN-06-02:	Sponsor Audit Procedures

Procedure Overview

This procedure describes the necessary activities performed by MICHHR personnel for assessing and ensuring preparedness for a partial or complete sponsor audit.

Responsible Individuals

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

Procedure

1. External audits of the MICHHR occur at the request of the sponsor or CRO. Audits are performed to ensure that the obligations of both the MICHHR and the sponsor or CRO are fulfilled in regard to patient safety, appropriate data collection, and confirmation of adherence to the relevant protocol.
2. Upon the receipt of the request from the sponsor or CRO to schedule an audit, MICHHR personnel check to make sure all necessary personnel are available to spend time with the sponsor or CRO representative as required. The necessary personnel are those formally identified on the Form FDA-1572 (see Appendix 1), as well as other staff who are involved in subject and document management for the specific protocol.
3. If the necessary personnel are not available to meet with the sponsor or CRO on the day of the audit, the Study Back-Up must be available to answer all questions and correct any deficiencies that are noted by the sponsor or CRO. The Study Back-Up must be familiar with the study and corresponding documentation prior to the audit. The Study Back-Up must also be familiar with the other personnel who can be consulted in regards to any questions the sponsor or CRO might have during the audit.
4. MICHHR personnel ask the sponsor or CRO if there are specific areas of focus for the audit. If the sponsor or CRO identifies any specific areas, preparation for the audit is completed with this focus in mind.
5. At least two weeks prior to the scheduled audit, MICHHR study personnel informs all study staff of the pending visit.
6. The Study Back-Up or RA reviews all relevant CRFs and completes the Premonitoring Checksheet (see Appendix 2). The Study Back-Up forwards the


Version Number: 002	Implementation Date: November 17, 2000
Page 1 of 1	Revision Date: June 30, 2004
	Review Date: June 30, 2005
Approval Signature, Date:	

Procedure Category:	General Study Procedures and Activities
Procedure CLN-06-02:	Sponsor Audit Procedures

- completed Premonitoring Checksheet to MICHIR study staff and designated Quality Improvement Coordinator or RSC Manager.
7. The Quality Improvement Coordinator (QIC) or PMM designee runs the Study Status Report (see SOP CLN-04-09).
 8. The QIC or PMM designee confirms with the MICHIR study staff that all study related documents have been filed in the ISF; as applicable.
 9. The QIC or designee requisitions the ISF, CRFs and related source documents from Medical Records; as applicable for identified study.
 10. The QIC or designee conducts a Protocol Review (see SOP CLN-04-09).
 11. Following a complete review, the QIC or PMM designee completes the QI Protocol Review Report. Findings are submitted to the designated MICHIR study personnel.
 12. MICHIR study personnel have 72 hours to review and resolve identified issues within the report and Premonitoring Checksheets. Corrections are flagged within the appropriate document for re-review by the QIC or PMM designee as needed. Actions taken are documented in the QI Response Report (see SOP CLN-04-09).
 13. All reports are saved in the QI Protocol Review section of the records.
 14. MICHIR personnel ensure that appropriate space has been reserved for the sponsor or CRO to review all relevant materials.
 15. If possible, MICHIR personnel schedules a time during the visit, preferably at the end of the visit, to meet with the sponsor or CRO representative and review the performance of the MICHIR relative to the sponsor or CRO expectations. This includes a review of any deficiencies noted by the sponsor or CRO representative. If possible, the MICHIR study personnel resolves all deficiencies prior to the completion of the visit.
 16. If there are deficiencies that are not resolved by the end of the visit, the MICHIR study personnel is responsible for the resolution of these issues and communicating the resolution to the sponsor or CRO representative. Data corrections should be made within one week of notification. If a complete listing of deficiencies is not provided following the audit visit, the MICHIR study personnel requests a verbal or written report from the CRA or designee within one week of the audit visit.

Note: Steps 6 – 14 should be completed approximately one week before the visit.

Version Number: 002	Implementation Date: November 17, 2000
Page 2 of 2	Revision Date: June 30, 2004
	Review Date: June 30, 2005


	<p style="text-align: center;">Standard Operating Procedures</p>
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Procedure Category:	General Study Procedures and Activities
Procedure CLN-06-02:	Sponsor Audit Procedures

MICHR study personnel are responsible for ensuring that all required regulatory documents are complete and available for review by the sponsor or CRO including, but not limited to:

- Copy of Investigator's Brochure
- Copy of investigator-signed study protocol, amendments and addenda thereto (signed by investigator)
- Signed Form FDA-1572
 - * Curriculum vitae of investigator(s) who signed the 1572
 - * Training/qualifications of staff identified on the 1572
- All correspondence with Institutional Review Board
 - * IRB approval of protocol
 - * IRB approval of amendments and addenda to protocol requiring approval
 - * IRB approved informed consent statement
 - * IRB membership list(s)
 - * Investigators annual reports to IRB regarding progress of study; if applicable
 - * Reports to IRB of any serious adverse events related to the administration of the test article
- All correspondence between the investigator and the sponsor or CRO generated as the result of the study, e.g.:
 - * Notification of the investigator, by the sponsor, of new findings and/or serious adverse events
 - * Reports from the investigator to the sponsor regarding deviations from and violations of the protocol
 - * Reports from the investigator to the sponsor regarding SAE's
 - * All correspondence between sponsor and investigator relative to conduct of study or results of study.
- Documentation of accountability of study drug
 - * Dates of receipt and quantity received of supplies of Investigational drug
 - * Dispensing log showing date and quantity of drug administered/dispensed to each subject enrolled in the study
 - * Dispensing log showing quantity of drug returns to sponsor, date (or record showing destruction of clinical study drug supplies at the Investigational site)
 - * Documentation of test article storage conditions and monitoring

Version Number: 002	Implementation Date: November 17, 2000
Page 3 of 3	Revision Date: June 30, 2004
	Review Date: June 30, 2005

	Standard Operating Procedures
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Procedure Category:	General Study Procedures and Activities
Procedure CLN-06-02:	Sponsor Audit Procedures

- Signed Informed Consent Form for each subject screened for potential entry into Investigational trial
- Monitor Site Visit Log
- Subject Records, including:
 - * Investigator signed Case Report Forms
 - * Medical Records and Shadow Charts
 - * Clinical laboratory reports
 - * Supporting source documents (EKG, X-Rays, etc...)
- Current Laboratory certification
 - * Normal laboratory values
 - * Documentation of specimen handling
- Master Patient Log

Documentation

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

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

Form FDA-1572 – Statement of Investigator
 IRB – Institutional Review Board
 SAE – Serious Adverse Event

Appendices

Appendix 1 1572
 Appendix 2 Premonitoring Checksheet

Version Number: 002	Implementation Date: November 17, 2000
Page 4 of 4	Revision Date: June 30, 2004
	Review Date: June 30, 2005

	Standard Operating Procedures
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Procedure Category:	General Study Procedures and Activities
Procedure CLN-06-02:	Sponsor Audit Procedures

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Version Number: 002	Implementation Date: November 17, 2000
Page 5 of 5	Revision Date: June 30, 2004
	Review Date: June 30, 2005