

	Standard Operating Procedures
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-07:	Study Supply Storage

Procedure Overview

This procedure describes the supporting documentation and basic activities related to the storage of investigational materials, laboratory supplies, regulatory documents and case report forms (CRFs).

Responsible Individuals

Investigators; Qualified MICHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Director, MICHR

Procedure

The storage procedures and supporting documentation vary depending on the material to be stored.

Investigational Materials (Drug and/or Device) Storage

There are three major sources of information regarding the storage of investigational materials:

1. Refer to the study sponsor and/or CRO documentation regarding acceptable storage for investigational materials. This documentation should also cover investigational material return and/or destruction after study completion.
2. Refer to the Food and Drug Administration’s (FDA) “Code of Federal Regulations (CFR)”, Part 312 and “International Conference on Harmonisation” (ICH), Parts 4.6,5.13 and 5.14.
3. Refer to internal policies and procedures for guidelines on the storage of investigational materials; General Clinical Research Center (GCRC) and Investigational Drug Service (IDS) Department.

Laboratory Supplies Storage

There are three major sources of information regarding the storage of laboratory supplies:

1. Refer to study sponsor or CRO documentation regarding the storage of laboratory supplies. If a centralized laboratory is utilized, there should be specific documentation from the laboratory regarding the storage of supplies. The study protocol may also provide information regarding the storage of laboratory supplies.

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2. Refer to internal policies and procedures for guidelines on the storage, handling and shipping of laboratory supplies; General Clinical Research Center, local lab department.
3. Occupational Safety and Health Administration (OSHA) guidelines.

Regulatory Documents Storage:

1. The Investigator Brochure, Investigator Study File and all CRF notebooks must be filed in a secure, readily accessible location for active studies. The Clinical Research Associate or designee normally organizes the files by study sponsor, protocol number and patient number, as applicable.
2. MICHIR personnel files all study-related materials on a daily basis in the appropriate location for reference by study personnel.
3. Shadow chart documents, signed informed consent documents and other related study source documents for active protocols are filed in accordance with the SOP CLN-03-09, unless otherwise specified by the Sponsor or CRO.
4. All MICHIR staff must closely monitor access to study-related documents by outside parties.
5. Any extra CRF notebooks or duplicate Investigator Brochures are filed by study sponsor and protocol number in a designated area, readily accessible to study personnel.
6. After a study has been closed-out by the study sponsor or CRO, all study documents are to remain in their designated location until the study sponsor or CRO indicates that all data corrections have been resolved and all correspondence is complete.
7. Refer to study sponsor or CRO documentation for instructions regarding disposing or returning of extra study documents (i.e., blank CRFs, extra notebooks, etc.).
8. After the study sponsor or CRO completes the Notification of Study Completion, MICHIR personnel ensure that all study documents have been appropriately filed.
9. After verification that all study documentation is filed, MICHIR personnel transfer all study documentation to the designated archive area, identified in the MICHIR / Client Contract.
10. Remind the PI and Department Administrator that study documentation must be retained for a minimum of two years following the New Drug Application (NDA) approval date. If the application is not approved, or no NDA is submitted, documents must be retained for at least 2 years after the FDA has been notified that all clinical investigations for this indication have been discontinued. The

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study sponsor may request longer retention periods (see ICH guidelines, part 5.5).

11. At the completion of the retention period, it is the responsibility of the Principal Investigator or MICHHR Contract Designee to contact the study sponsor or CRO for written authorization for the record destruction. Once the requested scope of services are complete and queries are resolved, MICHHR personnel may send study related documents back to the PI for retention (see Attachment I).
12. If MICHHR study files are returned to the Principal Investigator, the document return letter (see Appendix I) is attached to the documents and shipment is documented in the return document log (see Appendix II).

Documentation

Documentation for this procedure includes internal, study sponsor or CRO policies and procedures, as well as, related correspondence with the study sponsor or CRO.

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.

Relevant Definitions

CRF - Case Report Form
 CRO - Contract Research Organization
 NDA - New Drug Application
 FDA - Food and Drug Administration
 CFR- Code of Federal Regulations
 ICH - International Conference on Harmonisation
 GCRC - General Clinical Research Center
 IDS - Investigational Drug Service
 OSAHA - Occupational Safety and Health Administration

Appendices

Appendix I Study Document Return Letter
 Appendix II Study Document Return Log

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