

	Standard Operating Procedures
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-04:	Managing Investigational Materials Supplies

Procedure Overview

This procedure describes the necessary activities performed by MICHHR personnel to ensure adequate investigational materials supplies.

Responsible Individuals

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

Procedure

1. Prior to study start-up, qualified MICHHR personnel contact the study sponsor or CRO to obtain the necessary information to plan for the investigational materials.
2. Qualified MICHHR personnel determine the expected number of subjects, the amount of storage space available (refer to SOP CLN-03-07), and the necessary shipping time for supplies.
3. Qualified MICHHR personnel should order or confirm plans for initial supplies at least three weeks before the expected first date of patient enrollment. All Study Drug should be shipped directly to the Investigational Drug Service Department (IDS); see university online IDS SOPs for further details. This step should be performed in agreement with the study sponsor or CRO instructions. Keep storage space limitations in mind if applicable. Maintain documentation of all requests for supplies.
4. Upon receiving the initial shipment, review the materials and document the following information:
 - Item(s) received
 - Quantity or amount received for each item
 - Number of damaged items
 - Number of items to be returned
 - Expiration dates of items, if applicable
5. Check for any discrepancies between the supplies order and what was actually received. Contact the study sponsor or CRO to resolve any discrepancies. Supply invoices should be stored in the Study Regulatory Binder.
6. Forward the investigational materials supplies to the designated storage area(s). Storage records should be maintained in accordance with study sponsor or CRO requirements.

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7. At least one week before the expected first date of patient enrollment, qualified MICHHR personnel confirm that all necessary investigational materials are on-hand.
8. A qualified MICHHR personnel assesses the patient visit schedule for upcoming supply requirements unrelated to drug on a weekly basis throughout the study.
9. The IDS Pharmacist assesses:
 - The current investigational materials inventory of supplies
 - The accuracy of the investigational materials inventory. Investigate and correct any deficiencies noted.
 - Expiration dates for investigational materials. Return any expired investigational materials supplies to the study sponsor or CRO in accordance with study policy.
10. MICHHR personnel will follow instruction from the study sponsor or CRO to re-order investigational materials supplies if necessary.
11. At the end of the study, qualified MICHHR personnel and IDS Pharmacist(s) should refer to the Study Close-Out Procedure (SOP CLN-04-09) for guidance on returning unused study supplies to the study sponsor or CRO.
 - In the event a study sponsor authorizes on-site disposal of investigational materials, records must be maintained documenting date, manner of disposal and responsible individual.

Documentation

Documentation for this procedure includes documentation generated using the intra-departmental database, sponsor and/or CRO correspondence and study related order forms.

Deviation Approval

The Director, MICHHR or designee, must approve deviations 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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