

<b>OFFICE FOR EDUCATION &amp; QUALITY IN CLINICAL RESEARCH</b>	<b>CATEGORY</b>	<b>Clinical Research: Project Activities</b>
	<b>SUBJECT</b>	<b>Investigational Drug Accountability</b>
	<b>SOP #</b>	<b>4.4</b>
	<b>EFFECTIVE DATE</b>	<b>August 6, 2008</b>
	<b>REVISION DATE</b>	<b>January 3, 2018</b>

#### **OBJECTIVE**

Describe accounting procedures for investigational drug products during the span of time they are on-site. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

#### **APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 312                      Investigational New Drug Application

21 CFR 812                     Investigational Device Exemptions

HCMC Investigational Drug Policy:

[http://infooncall/Policies/MedicationManagement/HCMC\\_P\\_005361?dDocName=HCMC\\_P\\_005361&parentID=16731&isSearch=1](http://infooncall/Policies/MedicationManagement/HCMC_P_005361?dDocName=HCMC_P_005361&parentID=16731&isSearch=1)

#### **REFERENCES TO RELATED SOPs**

SOP 2.2

SOP 2.11

SOP 2.12

#### **ATTACHMENTS**

Sample Investigational Drug Accountability Form

- 1) **Inpatient** drug research studies.
  - a) Complete and submit an Investigational Drug Data Form to the Hennepin County Medical Center (HCMC) Investigational Pharmacist.
  - b) Contact the pharmacy to enter investigational drug orders into EPIC. Provide the protocol title to differentiate it from other medication orders.
  - c) Develop an inpatient drug accountability form if one is not supplied by the sponsor.
  - d) Investigational drug will be stored in the Inpatient Pharmacy.
  - e) The Investigational Pharmacist will be responsible for maintaining Drug Accountability Records for all investigational drug products delivered to the pharmacy, including perpetual inventory, dispensing of drugs to research subjects, and the return to the sponsor or alternative disposition of unused product.
  - f) Study drug will be dispensed by an HCMC dispensing pharmacist.
  - g) Study drug is to be administered only by an individual licensed within the state of Minnesota and so authorized by their professional scope of practice.
    - i) Study drug is to be administered in accordance with the research protocol.
    - ii) Study drug is to be administered in accordance with any other hospital policies pertaining to medication administration.
    - iii) Administration of all doses of an investigational drug must be documented on the MAR.
  - h) Ensure that the blinds (if applicable) are enclosed or that access to unblinding is defined.
- 2) **Outpatient** drug research studies.

- a) Complete and submit an Investigational Drug Data Form to the Hennepin County Medical Center (HCMC) Investigational Pharmacist.
  - b) Study drugs for research performed in an HCMC Clinic should preferably be housed in the HCMC Investigational Pharmacy. If not:
    - i) Ensure that the information on the packing slip corresponds exactly with what has been shipped to the site, report any discrepancies, breakage, or evidence of tampering to the sponsor. Retain all packing/delivery slips.
    - ii) Ensure that the blinds (if applicable) are enclosed or that access to unblinding is defined.
    - iii) Investigational drug should be stored as specified by the sponsor and in accordance with regulatory requirements. Ensure that study drug is:
      - (1) In a storage area that has been identified to the investigational pharmacist
      - (2) In a storage area that is large enough for the supply of study drug
      - (3) In a storage area that must be locked
      - (4) Stored with access that is limited to study staff identified to the investigational pharmacist
      - (5) Stored separately from other drugs
      - (6) Non-dispensed drug is stored separately from returned drug
      - (7) Inventory control procedures are used
      - (8) In a storage where environmental controls are maintained (maintain a storage area temperature log if applicable)
      - (9) Controlled substances must be stored in a locked location
  - c) Develop an outpatient drug accountability form if one is not supplied by the sponsor.
- 3) There must be an order entered into EPIC in order to dispense study drug.
- 4) Drug labels must comply with federal and state regulations.
- a) Federal
    - i) The immediate package must have a label with the statement “Investigational Use Only”.
  - b) State
    - i) Investigational drugs, not dispensed in unit dose, must comply to Minnesota Rules on labeling for any drug dispensed to or for a patient and will include:
      - (1) Name, address, and telephone number of the principal investigator
      - (2) Subjects name
      - (3) Name of prescribing practitioner
      - (4) Title of study
      - (5) Directions for use
      - (6) Unique prescription number
      - (7) Name of the manufacturer or distributor of the finished dosage form of the drug
      - (8) Auxiliary labels as needed
      - (9) Date of original issue or renewal
      - (10) Generic or trade name of drug and strength, or study name to identify drug, except when specified by prescriber to the contrary
  - c) Fill out the drug accountability form each time study drug is dispensed or returned. Documentation should include, but not be limited to:
    - i) Protocol number
    - ii) Lot number dispensed
    - iii) Name of individual returning study drug
    - iv) Date and time of returning drug
    - v) Amount dispensed
    - vi) Expiration date
    - vii) Name of individual dispensing study drug

- viii) Subject's study ID number
- ix) Date and time of dispensing drug
- x) Lot number returned
- xi) Amount returned

- 5) Study drug is to be dispensed by an individual licensed within the state of Minnesota and so authorized by their professional scope of practice.
- 6) Study drug is to be administered in accordance with the research protocol.
  - a) Study drug administered in an HCMC clinic must be documented in the subject's MAR or study file.
  - b) Study drug is to be administered in accordance with any hospital or clinic policy pertaining to the administration of medications.
  - c) Retrieve and store used drug containers (if required by sponsor). Document the reason and amount if drug container is missing or not returned.
- 7) Monitor subject compliance by noting any discrepancies between amount of drug used and the amounts expected to be returned.
- 8) The % compliance may be calculated with the following formula:
 
$$\frac{(\# \text{ of pills or vials returned})}{(\# \text{ of pills or vials dispensed})}$$
- 9) Notify the sponsor when additional study drug is needed.
- 10) Unused product is to be returned to the Sponsor or disposed of per Sponsor's requirements.
- 11) Retain the shipping slip when the monitor returns study drug to the sponsor during the study termination visit.
- 12) If unused product it to be disposed it may be done by the Investigational Drug Pharmacist or Principal Investigator in accordance with the Sponsor's investigational protocol or HCMC Pharmaceutical Waste Policy #001832.
- 13) Ensure that a copy of all study drug delivery slips, return receipts, dispensing documents, or destruction records are placed in the regulatory binder.

### Sample Investigational Drug Accountability Form (per subject)

Date Received \_\_\_\_\_ Received By \_\_\_\_\_

Protocol Title \_\_\_\_\_ Site ID \_\_\_\_\_

Protocol ID \_\_\_\_\_ Principal Investigator Name \_\_\_\_\_

Subject ID: \_\_\_\_\_ Randomization Number: \_\_\_\_\_

Container ID	Dose per Unit	Units per Container	Dispensed to Subject		Returned by Subject		Counted by (Initials)	Shipped for Destruction or Returned to Sponsor Shipment Number	Comments (Expired, study termination, returned by subject)
			Date (dd/mm/yyyy)	Dispensed by: (Initials)	Date (dd/mm/yyyy)	Number of Units			

Return Drug/Containers to:	Shipment Date	Signature
Name:	#1 Date	
Address:	#2 Date	
	#3 Date	
Telephone #:	#4 Date	