

Standard Operating Procedure

Receipt, Storage and Dispensing of Product
Scope: Investigational Drug Services, Pharmacy

Effective Date: April 1, 2016
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I. Purpose

To provide guidance on the procedures to be followed for receiving, storing, and dispensing study specific investigational medications in the Investigational Drug Services Pharmacy at Ann and Robert H. Lurie Children's Hospital of Chicago.

II. Policy Statements

- A. The Investigational Drugs Services (IDS) Pharmacy will store medications for all Investigational Review Board (IRB) approved Clinical Research Studies conducted at the Main Hospital facility. Additional supportive medications may be stored and dispensed pursuant to the requirements of each study protocol and assessed on an individual basis.
- B. IDS pharmacy staff will be responsible for receiving study medications delivered by the shipping and receiving staff, unpacking the product in a timely fashion and following all instructions provided with the shipping documents.
- C. Once the study medication has been unpacked, each item will be stored under the appropriate conditions, as described in the study protocol and/or the study pharmacy manual.

III. Procedures

- A. Receipt of Study Specific Investigational Medications
 1. Pharmacy staff will accept all shipments from hospital shipping and receiving staff and sign any forms, paper or electronic, to document the delivery.
 2. Pharmacy staff will remove all study medication from its respective shipping boxes, taking special precautions to make sure that all packages have been emptied.
 3. Pharmacy staff will reconcile all study medication received against accompanying shipping documents and then sign, date and, if required, time the shipping document.
 4. For refrigerated items that are shipped with a temperature tracking device, instructions accompanying the product will be followed to stop/inactivate the tracker. Further instructions regarding downloading the temperature tracking device data, etc. will be followed and completed.
 5. All of the necessary study documentation will be filled out appropriately. This may include, but is not limited to, returning copies of shipping documents (paper and/or electronic) to the study sponsor, confirming receipt of shipments via phone or computer drug management systems, and recording as appropriate, on all site accountability logs (master/subject specific).

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6. Any discrepancies, temperature excursions, damaged items will be reported immediately upon discovery.
- B. Storage of Study Specific Investigational Medications
1. All study supplies will be kept in the IDS Pharmacy which serves as a secure, locked, limited access area unless arrangements have been made for storage in the Inpatient Pharmacy or other location.
 2. All study medication for a specific study will be stored as defined by each study protocol.
 3. Room, refrigerator, and freezer temperatures will be recorded daily, Monday through Friday.
 4. IDS pharmacy personnel will be responsible for the maintenance of thermometer and ensure timely calibration of devices and their replacement once expired.
 5. Temperature excursions will be documented by IDS pharmacy personnel and reported to study sponsors as required per study protocols.
 6. All excursion data and correspondence will be documented and study drug will remain quarantined as directed.
- C. Dispensing of Study Specific Investigational Medications
1. All study medications will be dispensed in accordance with labeling required for the proper use and identification of a prescription item and in accordance with applicable law.
 2. Study medications will be dispensed only upon the prescription of the Principle Investigator or authorized designee. The IDS pharmacy is not responsible for checking consent and/or assent prior to dispensing medication.
 3. Study medication will be prepared according to study protocol and/or pharmacy manual instructions and dispensed as appropriate for each individual medication.
 4. All dispensed will be documented per stud protocol requirements, either manually or electronically, on the appropriate forms.
 5. All study medication will be delivered by a member of the IDS pharmacy staff directly to an authorized study designee or directly to the study subject.
 6. When appropriate, IDS pharmacy staff will dispense study medication with required study documents and obtain necessary signatures and will provide patient education and/or counseling.
 7. Study medication will be double checked by a second person before dispensing. If research staff is not available the second check can be a person from the Oncology Pharmacy area.

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D. Accepting of Study Specific Investigational Returned Medications

1. IDS pharmacy staff will accept patient study medication returns as instructed by each individual study protocol
2. IDS pharmacy staff will document all study medication returned by study subjects and document appropriately, either manually or electronically on study documents.
3. All returned items will be disposed of on-site or retained for monitor verification per each individual study protocol.

NOTE: These are general guidelines that apply to most of the Clinical Research studies conducted at Lurie Children's Hospital. For such situations that are not part of the daily routine, specific guidelines will be outlined by the pharmacist to suit the individual needs of that study. Updates or changes may be made as the pharmacy's work circumstances require.

IV. Cross References / Related Policies

Administrative Policy, "Investigational Drugs"

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Approved by: Jenny Elhadary, Senior Director, Pharmacy Services