Children's Hospital of Chicago
Medical Center

Standard Operating Procedure



## I. Purpose

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

## II. Policy Statements

A. The Investigational Drug Service (IDS) Pharmacy will store medications for all Investigational Review Board (IRB) approved Clinical Research Studies conducted at the Lurie Children's Hospital of Chicago. 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 or courier service, 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 or courier service 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 the necessary study documentation will be filled out appropriately. This may include, but are 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).
   6. Any discrepancies, temperature excursions, damaged items will be reported

immediately upon discovery.

B. Storage of Study Specific Investigational Medications
   1. All study medication 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 satellite 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, excluding holidays.
   4. IDS Pharmacy personnel will be responsible for the maintenance of the 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 medication will remain quarantined as directed.

C. Dispensing of Study Specific Investigational Medications
   1. All study medications will be dispensed 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 a signed prescription by the Principal 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 dispenses will be documented manually or electronically on the appropriate forms.
   5. Study medication may be delivered by a member of the IDS Pharmacy staff directly to an authorized study designee or the study subject. Study medication may also be picked-up from the IDS Pharmacy by an authorized study designee or study subject.
   6. When appropriate, IDS Pharmacy staff will dispense study medication with IRB approved study documents and will provide patient education and/or counseling.
   7. Study medication will be double checked by a second person before dispensing. If IDS Pharmacy staff is not available, the second check can be a person from the Oncology Pharmacy area.

D. Accepting Study Specific Investigational Returned Medications
   1. IDS Pharmacy staff may 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 either manually or electronically on study documents.

3. All returned items will be disposed of on-site under "Accountability and Destruction of Investigational Drugs" policy.
4. IDS Pharmacy will not accept any returns from used IV bags, IV tubing, or IV syringes.
5. Contaminated medications that need to be disposed of from an isolation room will not be returned to the IDS Pharmacy. These medications will be disposed of as infectious medical/pharmaceutical waste in the patient care area as appropriate (i.e. red sharps disposal container in the patient room for all medication syringes/needles and the pharmaceutical waste containers in Soiled Utility Rooms for all other medication waste from the isolation room).

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

1. Administrative Policy, "Investigational Drugs"
2. Investigational Drug Services (IDS) Medication Storage Temperature Monitoring Procedure for Freezer (-15C and -70C) Temperature Monitoring
3. Investigational Drug Services (IDS) Medication Storage Temperature Monitoring Procedure for Room Temperature and Refrigerator Temperature Monitoring
4. Accountability and Destruction of Investigational Drugs

Date Written: 4/1/2016
Date Reviewed/Revised: 4/1/2016, 12/15/2017, 02/11/2021
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