PURPOSE:

The purpose of this policy is to define the responsibilities of the principle investigator, institutional review board (IRB), and Investigational Drug Services (IDS) related to IDS operations.

POLICY:

The general operations and responsibilities of the IDS shall be in full compliance with regulations and requirements of the FDA, The Joint Commission, Illinois Board of Pharmacy, and other applicable organizations.

PROCEDURES:

1. All investigational drug protocols must be approved by the University of Chicago Medical Center (UCMC) IRB.

2. All Investigational drugs intended for use by inpatients of the UCMC will be distributed through the established inpatient pharmacy drug distribution system.

3. Investigational drugs dispensed to UCMC outpatients will be distributed from one of the following areas:
   a. DCAM Chemotherapy Clinic Pharmacy
   b. IDS
   c. Pharmacy satellite area designated by and under the supervision of IDS

4. Investigational drug use by UCMC outpatients may be exempt from the pharmacy-handling requirement provided that:
   a. The investigator can provide adequate storage and control over the distribution of investigational drug supplies as outlined in the PH 04-306 Investigational Drugs Not Managed by IDS.
   b. The investigator shall assure that dispensing is in accordance with institutional, state, and federal laws and regulations.

5. UCMC IRB responsibility for each study:
   a. The IRB requires that IDS be notified of studies that plan to use investigational drugs.
b. The IDS will be considered notified if the investigator forwards a copy of a the research protocol to the IDS, if an IDS pharmacist is present at study planning, or an IDS pharmacist is present at protocol review sessions other than the IRB.

6. Investigator’s responsibility for each research protocol:
   a. The investigator, or designee, will forward a copy of the complete investigational protocol and investigator’s brochure to the IDS pharmacist.
   b. The investigator, or designee, will contact the IDS pharmacist to arrange for storage, inventory, packaging, labeling, and dispensing of all investigational drugs through the established drug distribution system.
   c. Operational costs associated with the IDS must be planned for in the initial stages of protocol development as defined in the PH 03-305 Investigation Drug Service Fee.

7. Investigator’s responsibility for each patient enrolled in a study:
   a. The investigator, or designee, is responsible for obtaining and documenting informed consent of subject or subject’s legally authorized representatives prior to the subject’s participation in the research, unless these requirements have been waived by the IRB. The Investigator or designee is responsible for notifying IDS that consent has been obtained, either by forwarding a copy of the consent form to the pharmacy or by indicating on the written or electronic order that written informed consent had been obtained.
   b. All Orders must be written in accordance to PC 125A Orders for Investigational Drugs

8. Department of Pharmacy and IDS responsibility:
   a. The Department of Pharmacy has established an IDS whose responsibility is to provide safe and responsible handling of investigational drugs. IDS shall maintain control and accountability of investigational drug use in UCMC to promote maximum benefit and safety for subjects enrolled in studies.
   b. All investigational drugs maintained by IDS will be accounted for in a way that every transaction involving the receipt, dispensing, transfer, final disposition, or other manipulation can be clearly identified as to date, recorder, research subject identifier when applicable, quantity, and balance on hand.
   c. All investigational drugs dispensed by IDS and the inpatient pharmacy will follow all pharmacy policies.
   d. Investigational drug labels will be used to distinguish investigational products from other drugs.
   e. The pharmacist representing the IDS will:
      i. Prepare written dispensing instructions for each protocol to be followed by Pharmacy staff when dispensing investigational drugs. These instructions will provide minimally, subject enrollment, treatment assignment, when applicable, drug dosing and preparation, dispensing, and accountability.
      ii. Returned, unused, or expired investigational drugs will be handled (e.g. destroyed, returned) in accordance with PH 04-308 Destruction of Investigational Medications.
iii. Review investigational drug usage on a routine basis and order new supplies from the sponsor, on behalf of the investigator, when necessary.

iv. Prepare a Protocol Synopsis and Investigational Drug Data Sheet (PSIDDS) for all non-FDA-approved research drugs intended for administration to hospital inpatients. This information is needed to assure proper understanding of the administration and monitoring of the investigational drug by Pharmacy staff.

v. Prepare a Nursing Investigational Drug Data Sheet (NIDDS) for all non-FDA approved research drugs intended for administration to hospital inpatients. This information is needed to assure proper understanding of the administration and monitoring of the investigational drug by nursing staff.

vi. Provide a copy of the NIDDS to the patient-care unit upon dispensing of an investigational drug to a hospital inpatient. This copy will typically be sent with the first dose of each treatment cycle.

9. Storage and Distribution
   a. The storage and distribution of investigational drugs shall adhere to the PH 04-304 Receipt and Control of Investigational Medications.
   b. The destruction of unused, used and partially used containers of study drugs shall adhere to the PH 04-308 Destruction of Investigational Medications.

10. Expanded Access for non-emergency or emergency use
    a. The need may arise to obtain an unapproved drug for non-emergency or emergency use in an individual patient. In these cases, the IDS may assist, but it is the Investigator’s responsibility to obtain the proper authorization from the sponsor, FDA, and IRB.
    b. The following information must be provided to IDS before the investigational drug is received or dispensed:
       i. Investigator’s name
       ii. Subject’s name
       iii. Investigational medication to be used and IND number if applicable
       iv. Sponsor and contact information
       v. Proof of authorization for emergency use

INTERPRETATION, IMPLEMENTATION, AND REVISION:
The Department of Pharmacy Investigational Drug Service, with assistance from the Pharmacy Policy and Procedure Committee, is responsible for the interpretation, implementation, and revision of this policy.

CROSS-REFERENCES:
1. PH 04-304 Receipt and Control of Investigational Medications
2. PH 03-305 Investigation Drug Service Fee
3. PH 04-306 Investigational Drugs Not Managed by IDS
4. PH 04-308 Destruction of Investigational Medications
5. PC 125A Orders for Investigational Drugs

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