UNIVERSITY OF UTAH HEALTHCARE
HOSPITALS AND CLINICS

DEPARTMENT OF PHARMACY SERVICES

POLICIES AND PROCEDURES

INVESTIGATIONAL DRUG STUDIES PROGRAM

No: 12-10 Review Date: 02/01/2010 Revision Date: 02/01/2010
Chapter: Investigational Drug Studies

I. PURPOSE

This policy describes the scope and specific procedures for the Investigational Drug Service (IDS) Program.

II. POLICY

The IDS pharmacist prepares study-specific information to facilitate handling of a study drug by other pharmacists in the Department and coordinates the inventory and drug control procedures. All protocol information and IDS instruction material containing protocol information is confidential. While principal investigators are expected to pay for pharmacy services related to their study, the IDS pharmacist will provide service to all investigators regardless of ability to pay. The IDS pharmacists are responsible for ensuring that investigational drugs are handled according to state and federal laws and regulations, hospital policy, institutional review board (IRB) policy, and sponsor protocol.

III. PROCEDURE

A. Documentation of receipts, dispensing and returns for each study drug maintained by the Department of Pharmacy Services will be recorded on forms provided by the study sponsor or on forms created by the IDS pharmacist and approved by the sponsor. The completed forms, or a copy, must remain in the possession of the IDS program. Invoices for study drugs will be filed according to protocol by the IDS pharmacist.
B. The IDS pharmacist coordinates the handling of drug studies by the Department of Pharmacy Services. This includes:
    1. Meeting with investigators to set-up drug studies
    2. Meeting with pharmacy personnel to discuss dispensing procedures, potential problems and protocol requirements.
    3. Initiating a study by setting up a drug study notebook that describes the dispensing procedures, and contains the study protocol and drug inventory record. The study notebook will outline who is an approved investigator for the study, and all special instructions for the study.
    4. Conducting quality improvement activities as assigned.
    5. Preparing reports as needed. This includes reports for:
        a. P&T Committee
        b. Pharmacy Department
        c. Financial Purposes
C. To set up a drug study, the IDS pharmacist will review the IRB paperwork, protocol, available drug information, and discuss the study with the study sponsor (monitor), principal investigator (PI), or study coordinator to establish the following information:

1. Name(s) and telephone number(s) of the PI, co-investigator(s), and study coordinator involved. Name of any company monitors (if applicable).
2. Name and telephone number of emergency contact person.
3. The start date and expected conclusion date for the study, if known.
4. The number of patients expected to participate in the study and the duration of therapy.
5. Name, strength, dosage form and route of administration of the study drug(s). Packaging of the drug (ie, patient specific, open label, blinded) will also be included.
6. The source of the drug (i.e., supplied by pharmacy or investigator).
7. Location and proper storage of the drug.
8. Proper preparation and labeling of the study drug.
9. Delivery of the drug to the patient care area.
10. Disposition of empty study drug materials (i.e., save or discard).
11. Type of inventory log to be kept.
12. Discuss study budget and determine the proper method of charging for the study drug, supplies, and preparation costs. (i.e., patient expense or investigator).
13. Person responsible for and method of ordering additional drug.
14. Acceptable inventory levels of the study drug.
15. Randomization and blinding procedures if applicable.

D. Based upon the information obtained from the PI and study protocol, the IDS pharmacist will prepare short instructions and/or pharmacy dispensing guidelines as outlined below.
    1. Title of the study, name of PI, and IRB #
    2. Dispensing/labeling/record keeping instructions will include:
        a. Location of study notebook(s)
        b. Location and proper storage of study drug(s)
        c. Information necessary on the prescription/order
        d. Randomization of patients
        e. Dose calculations and preparation
        f. Proper labeling including computer codes
        g. Record keeping forms to be completed when dispensing
        h. Dispensing
        i. Charging information (i.e., patient or investigator)
        j. Handling drug returned by patients and returning drug to sponsors
    3. Investigators and study coordinators: Name, telephone number and department of the principal investigator, co-investigators and study coordinators. This will also include the emergency contact person(s) and telephone number(s).
    4. Medications
        a. Drug name, Strength, Form (eg, vial, tablet, etc.)
        b. Source of the drug (eg, supplied by the pharmacy or investigator)
        c. Dosage and schedule (eg, mg/kg BID, etc.)
        d. Reconstitution instructions and precautions (if applicable)
        e. Stability information (if applicable)
        f. Administration instructions and precautions (if applicable)
        g. Drug Incompatibility information (if applicable and available)
    5. Concomitant medication information (if necessary)
    6. Unblinding information
    7. Information specific to the IDS pharmacist (if necessary)
    8. Ordering information including:
        a. Department or individual responsible for ordering additional drug.
        b. Acceptable inventory levels for the drug, if applicable.
    9. Date dispensing guidelines are prepared and date of any revisions.

10. Drug company contacts
    a. Study monitor or contact person (if applicable)
    b. Individual to contact for emergency drug information (name and phone number
    c. Individual to contact in emergency situations
    d. Individual to contact for drug ordering

E. Upon receipt of study drug, the following information will be recorded on the appropriate inventory record form and filed with the appropriate protocol file:
    1. Study name and protocol number (if appropriate)
    2. Drug name, strength, and dosage form
    3. Manufacturer or Supplier
    4. Principal Investigator
    5. Department and telephone number of principal investigator
    6. Date received (month/date/year)
    7. Lot number
    8. Amount received
    9. Receiver's initials
    10. Expiration or retest date (if known)
    11. Confirm drug shipment receipt via facsimile, e-mail, telephone, etc (if applicable)

F. Dispensing study medication
    1. Informed consent: On receipt of an initial order for an investigational drug, the pharmacist shall check that an **informed consent has been signed by the patient and that the physician ordering the drug is an investigator approved for the study.** The drug shall not be dispensed until these two conditions have been met.
        a. Consent may be verified by viewing the signed consent form **or** by receiving written or verbal confirmation from an approved investigator or study coordinator.
        b. Approved investigators and study coordinators are listed in the drug study notebook. Each study has a separate notebook of instructions. Notebooks are located in the University of Utah Hospital in-pharmacy and the IDS cabinet near the back of the Huntsman Cancer Hospital (HCH) pharmacy.
    2. Upon dispensing study drug, the following information will be recorded on the appropriate form(s):
        a. Date dispensed (month/date/year)
        b. Patient name or initials
        c. Patient number or randomization number (if applicable to the study)
        d. Lot number
        e. Amount dispensed
        f. Inventory balance
        g. Initials of dispensing pharmacist
        h. Name of prescribing physician (typically located at the top of form)
        i. Prescription number (when necessary)

G. When study drug is returned to the manufacturer because of expired drug, completion of study, drug recall, or when deemed appropriate, the following information will be recorded on the appropriate inventory control record:
    1. Date (month/day/year)
    2. Lot number
    3. Quantity returned
    4. Ending balance
    5. Initials of pharmacy personnel returning drug
    6. Name of person or manufacturer to whom drug was returned

7. Return form shall be filed in the appropriate protocol file

H. Monthly inventories will be completed and recorded on the appropriate record for each study drug maintained by the Department of Pharmacy Services. Additional inventory checks will be done when deemed appropriate by the IDS pharmacist. The date of inventory, lot #, quantity and person conducting inventory will be recorded.

I. Any discrepancies between actual count and number recorded on the inventory control record will be rectified if possible. The principal investigator will be notified of any discrepancies which can not be rectified.

J. If a particular study drug has not been dispensed within the last six months, the principal investigator will be contacted to determine the current status of the study. If the study is closed, the IDS pharmacist will follow the study closure procedure.

K. Inventory records of all pharmacy activities related to drug studies must be maintained for a minimum of 2 years following: 1) the date a marketing application for the drug is approved for the drug for the indication which it is being investigated or 2) if no application is to be filed or 3) if the application is not approved for such indication until 2 years after the investigation is discontinued and the FDA is notified (21CFR312.62). Functionally, once a study is closed the records will be sent to Records Management or other suitable storage facility and labeled "Store indefinitely."

L. Notification of expiration dates, extensions, changes in storage requirements, etc. shall be noted on the inventory record and filed in the protocol file. Upon receipt, study medication should be labeled with the expiration or retest date, if known.

M. Destruction of investigational study drug will be handled as biohazard or chemotherapy waste. Investigational study medications will be placed in the appropriate waste container. Documentation of destruction will be witnessed by another staff member. The person destroying the study medication and the witness need to initial the drug accountability log in the study notebook.

N. The PI is responsible for completing the Investigational Drug Data Form (IDDF) for studies involving investigational drugs. However, the IDS pharmacist will assist when requested.

O. A study notebook for each protocol will be prepared and include the short instructions and/or dispensing guidelines (see section D), copy of the protocol (if applicable), and record keeping forms stored in the area where the drug is being dispensed. A copy of the protocol will be stored in the study notebook or protocol file. Study correspondence and other pertinent information will be filed in the protocol file.

P. The IDS pharmacist will be responsible for providing information to the pharmacists involved in dispensing the drug. In-services are available on request.

Q. Charging: The IDS pharmacist or designee will bill separately for each investigational drug study and submit it to the principal investigator or designee, on at least a quarterly basis. The total number of prescriptions or doses dispensed for a particular study will be determined at least quarterly by the IDS pharmacist or designee. The dispensing fee per prescription or dose and study maintenance costs will be determined during the study set-up. This will then be assessed to each dose or prescription filled during that quarter. Miscellaneous charges will be included (i.e. mailing costs, prepackaging, and compounding fees). The following information will be completed on a campus order form or other acceptable billing document:

1. Date
2. Name and address of buying department
3. Name and address of pharmacy department (ie: selling department)
4. Account number of investigational study grant
5. Account number of pharmacy investigational drug studies account
6. Any additional pharmacy account number for supplies\services
7. Abbreviated name of the study and principal investigator
8. Quantity of prescriptions or doses dispensed

9. Dispensing fee per prescription or doses dispensed.
10. Quarterly study maintenance
11. Miscellaneous charges
12. Total amount to be charged

R. Billing documents are sent to PI for their signature or the signature of a designee and then returned to the IDS office. A copy of the billing document will be retained by the principal investigator or their department. The IDS pharmacist or designee may also sign the billing document and retain a copy. The IDS pharmacist will retain a copy of the completed document in a designated billing or receiving notebook. The IDS at HCH will e-mail Research Accounting a spreadsheet indicating transfer of funds between accounts. The IDS at the University of Utah Hospital will automatically transfer funds 2 weeks after sending out invoices to each PI. Billing documents may be prepared monthly on studies with a high volume of doses or prescriptions per month at the discretion of the IDS pharmacist. Exceptions to the above outlined charging procedure are as follows:
    1. If it is predetermined that the patient will be charged directly for the dispensing, compounding, or prepackaging fees, supplies or other miscellaneous charges. Any charges incurred by the patient must be outlined in the informed consent.
    2. If the drug is being dispensed for an emergency use protocol, the IDS pharmacist will compile charges for reporting purposes, however the investigator will not be billed.
    3. If the principal investigator is outside of the University Hospital system. A special invoice will be submitted to the principal investigator for reimbursement.
    4. The Director of Pharmacy will be notified of all investigators who are unwilling or unable to pay. When appropriate, the Associate Administrator for Pharmacy or Finance shall also be contacted.

S. Solving problems related to an investigational drug study
    1. If for some reason no one responds to a page on the IDS pager or for questions after hours, weekends, or holidays, contact the following individuals in the order listed:
        a. IDS pharmacist
        b. IDS pharmacy manager
        c. Pharmacist in the central pharmacy
        d. Director of pharmacy

T. Role of pharmacists in obtaining investigational drugs for Emergency Use (formerly Compassionate Use)
    1. Emergency use protocol studies generally involve drugs that are not FDA approved but offer therapeutic options or potentially life saving therapy for a particular disease state. An investigator may have both a treatment protocol and an emergency use protocol study for the same drug. These are separate studies with separate drug inventories and must not be used interchangeably.
    2. Attending physicians may request emergency use protocol drugs directly from the potential supplier (usually a pharmaceutical company). The requesting physician must notify the IRB of emergency use protocol prior to drug use if possible or within 24 hours. As with all investigational drugs, the patient must give signed informed consent prior to administration of the drug.

APPROVAL BODY: Administrative Director of Pharmacy or designee
APPROVAL DATE: 02/01/10
POLICY OWNER: Manager of the Investigational Drug Service(s)

HISTORICAL INFORMATION

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