

**UNIVERSITY OF UTAH HOSPITALS AND CLINICS POLICY MANUAL
DEPARTMENT OF PHARMACY SERVICES POLICY MANUAL
INVESTIGATIONAL DRUG STUDIES PROGRAM**

Web site: <http://intranet.uuhsc.utah.edu/policy/>

No: 12-10 Review Date 11/29/04 Revision Date: 11/29/04 Chapter: Investigational

10/16/01 10/16/01 Drug Studies

10/26/98 10/26/98

I. PURPOSE

This policy describes the scope and specific procedures for the Investigational Drug Studies Program.

II. DEFINITIONS

III. 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.

IV. 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. Upon receipt of study drug, the following information will be recorded on the appropriate inventory record form:

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 date (if known)

C. Upon dispensing study drug, the following information will be recorded on the appropriate form(s):

1. Date dispensed (month/date/year)
2. Patient number or randomization number (if applicable to the study)
3. Lot number
4. Amount dispensed
5. Inventory balance
6. Initials of the dispensing pharmacist
7. Patient name or initials
8. Name of prescribing physician
9. Prescription number (when necessary)

D. 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

E. 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

F. 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.

G. If a particular study drug has not been dispensed within the last three 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.

H. Inventory records of all pharmacy activities related to drug studies must be maintained for a minimum of 2 years following the date a marketing application for the drug is approved for the drug for the indication which it is being investigated or if no application is to be filed or 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."

I. Notification of expiration dates, extensions, changes in storage requirements, etc. shall be noted on the inventory record and filed in the protocol file.

J Destruction of investigational study drug will be handled as chemotherapy waste.

Investigational study medications will be placed in the chemo waste container. Documentation of destruction will be witnessed by another staff member. Both, the person destroying the study medication and the witness need to initial the drug accountability log in the study notebook.

K. 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 principal investigator, 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.
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.

L. Based upon the information obtained from the PI and study protocol, the IDS pharmacist will prepare pharmacy dispensing guidelines as outlined below.

1. Title of the Study, Name of Principal Investigator, 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. 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
5. Medications
- a. Drug name, Strength, Form (i.e., vial, tablet, etc.)
 - b. Source of the drug (i.e., supplied by the pharmacy or investigator)
 - c. Dosage and schedule (i.e., 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)
6. Concomitant Medication information (if necessary)
7. Unblinding information
8. Information specific to the IDS pharmacist (if necessary)
9. Ordering information including:
- a. Department or individual responsible for ordering additional drug.
 - b. Acceptable inventory levels for the drug.
 - c. Drug manufacturer contact person and telephone number.
10. Date dispensing guidelines are prepared and date of any revisions.
- M. 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.
- N. A study notebook for each protocol will be prepared and include the dispensing guidelines (see section H.), copy of the protocol, IDDF form, and record keeping forms stored in the area where the drug is being dispensed.

O. A copy of the pharmacy dispensing guidelines, study protocol, IDDF form, consent form, study correspondence and other pertinent information will be filed in the IDS files. An additional copy of the pharmacy dispensing guidelines may be given to the Principal Investigator and study coordinator by the IDS pharmacist.

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

Q. Charging: The IDS pharmacist 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. 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 principal investigators 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 Pharmacy Manager, Drug Information, or the Director of Pharmacy will also sign the billing document and retain a copy. The IDS pharmacist will retain a copy of the completed document in the study file. The original copy of the document will be mailed to Research Accounting, 406 Park Building for reimbursement. 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.

APPROVAL BODY: James Jorgenson, Director of Pharmacy

APPROVAL DATE: 10/15/01

POLICY OWNER: Linda Tyler, Pharm.D.

ORIGIN DATE: 3/92

UNIVERSITY OF UTAH HOSPITALS AND CLINICS POLICY MANUAL
DEPARTMENT OF PHARMACY SERVICES POLICY MANUAL
ROLE OF ALL PHARMACISTS IN THE INVESTIGATIONAL DRUG STUDIES PROGRAM

No: 12-12 Review Date 11/29/04 Revision Date: 11/29/04 Chapter: Investigational

10/16/01 10/16/01 Drug Studies

10/26/98 10/26/98

I. PURPOSE

This policy describes the responsibilities all pharmacists have in participating in the Investigational Drug Studies Program.

II. DEFINITIONS

III. POLICY

A. The Investigational Drug Studies (IDS) Pharmacists coordinates the handling of investigational drugs and drugs used as part of a research protocol. The IDS Pharmacists are responsible for ensuring that investigational drugs are handled according to State and Federal laws and regulations, Hospital policy, and sponsor protocol.

B. Departmental pharmacists are responsible for the accurate, efficient, and appropriate pharmaceutical drug distribution services including investigational drugs. Nondepartmental pharmacists (e.g. various clinical and research pharmacists) will be expected to comply with departmental standards. All pharmacists are responsible for maintaining current knowledge concerning State and Federal regulations and statutes for the dispensing of investigational agents and accessing appropriate resource information on investigational drugs.

IV. PROCEDURE

A. 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. Conduct quality improvement activities as assigned.
5. Prepare reports as needed. This includes reports for:
 - a. P&T Committee
 - b. Pharmacy Department
 - c. Financial Purposes

B. The duties of all pharmacists include:

1. Interpreting physician drug orders for investigational drugs and dispensing of investigational drugs. Drugs are dispensed according to Hospital policy and procedures and in accordance with the dispensing guidelines in the study notebook.
 2. 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 IVC, Outpatient Pharmacy, or A-level pharmacies.
 3. Solving problems related to an investigational drug study.
 - a. Consult the notebook of instructions for the study in question.
 - b. If the notebook is not helpful, contact the IDS pharmacist.
 - c. In the absence of the IDS Pharmacist, a member of the Drug Information Service staff will be responsible for covering the IDS beeper. This will usually be the Pharmacy Manager, Drug Information Service.
 - d. If for some reason no one responds to a page on the IDS beeper or for questions after hours, weekends or holidays, contact the following individuals in the order listed:
 - (1) IDS Pharmacists
 - (2) Pharmacy Manager, Drug Information Service
 - (3) Pharmacy Manager or Supervisor, Inpatient Services
 - (4) Director of Pharmacy Services
 3. When the pharmacist has questions or problems concerning investigational drugs, including deviations from the outlined procedures, they shall promptly consult with the investigational drug studies pharmacist or their designee. The pharmacist shall not dispense any investigational drug until all discrepancies have been resolved.
 4. The pharmacist shall maintain accurate drug inventory records when receiving or dispensing investigational drugs.
 6. The pharmacist shall provide drug information about investigational drugs when requested. If the information is not contained in the study notebook, consult the Investigational Drug Studies pharmacist, the Principal Investigator, or study coordinator as outlined in the drug study notebook.
 7. The pharmacist will participate in the quality improvement program for investigational drug studies as directed by the IDS Pharmacist.
 8. If the IDS Pharmacist is absent, the pharmacist will assist in the receipt of drugs, and resolve inventory discrepancies.
- C. Role of Pharmacists in obtaining investigational drugs for Emergency Use

(formerly called 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 drug 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. The appendix, titled "**Procedures For Obtaining Emergency Use Investigational Drugs At University Hospital**" contains an outline of the necessary steps for obtaining drugs for emergency use protocol drugs and includes a request form to be completed by the requesting physician and pharmacist on the patient's unit. The IDS pharmacist should be notified in a timely manner when a physician requests emergency use protocol drug.

APPROVAL BODY: James Jorgenson, Director of Pharmacy

APPROVAL DATE: 10/15/01

POLICY OWNER: Linda Tyler, Pharm.D.

ORIGIN DATE: 3/92

PROCEDURES FOR OBTAINING EMERGENCY USE INVESTIGATIONAL DRUGS AT UNIVERSITY HOSPITAL (formerly termed Compassionate Use)

Definition of emergency use drugs : Use of an investigational drug as last-resort treatment for a specific patient. A physician may also request a drug for emergency use because the drug appears to be the drug of choice based on results of nearly completed clinical trials.

A. The policy and procedures governing the use of investigational drugs also apply to emergency use protocol drugs used in emergency situations.

B. The pharmacist or physician will determine if the hospital has an approved protocol for the drug. This information can be obtained from the Institutional Review Board (IRB) at 1-3655 or the Investigational Drug Studies Pharmacist at 5-2185. If a protocol exists, contact the principal investigator to determine if the patient qualifies for participation in the study.

C. If the hospital does not have an approved protocol for the drug, the physician is responsible for contacting the drug manufacturer and requesting an emergency use protocol and drug supply.

D. The physician should be prepared to discuss the patient's case with the drug manufacturer's study monitor. Specific information required includes:

\$ Patient initials, age and weight

\$ Diagnosis

\$ Current medications - drug, dosage, and schedule

\$ Medications that have been tried and have failed

\$ Laboratory parameters - kidney and liver functions, etc.

If the company elects not to release the medications under their own IND, the physician's other option is to contact the FDA directly for an IND application or authorization in advance of an IND submission.

FDA contacts for obtaining an emergency IND are as follows:

For Drug Products contact: Document Requirements and Services Branch (HFD-53)
(301)827-1501

For Biologic Products, contact: Division of Congressional and Public Affairs (HFM-11)
(800) 835-4709

Nights and weekends: Division of Emergency and Epidemiologic Operations (HFC-160)
(202) 857-8400

E. The physician should ask the company to ship drug directly to the Pharmacy Department to prevent delays in receiving the drug. The drug should be sent to:

University Hospital

Dept. of Pharmacy Services, Room A-100

50 North Medical Drive

Salt Lake City, UT 84132

ATTN: Brett Sower, RPh

(801) 585-2185

The pharmacist must find out about the approximate arrival time of the drug.

F. The physician is responsible for notification of the IRB prior to the patient receiving drug. The only exception is when the situation is deemed a medical emergency and the IRB office is closed. In this situation, the physician is required to contact the IRB within 24 working hours.

The IRB requires the following materials:

1. A copy of the patient consent form.

2. A brief case report indicating why the drug is needed.

3. A protocol and/or any literature references relative to the use, dosage, pharmacology, and toxicity of the drug.

G. The physician must obtain written informed consent from the patient or legal guardian prior to the patient receiving drug. ASHP guidelines dictate the pharmacy is responsible for verifying that the consent form has been signed by the patient before dispensing the initial supply of drug.

H. The physician is also required, by FDA regulations, to complete FDA form 1572, "Statement of Investigator," if the drug is in phase III clinical trials. These forms are supplied by the drug company.

I. An "Emergency Use Investigational Drug Request Form" is provided. It is important to complete all sections of the form as soon as possible and return the checklist to the Investigational Drug Studies Pharmacist.

SUMMARY OF STEPS TO OBTAIN EMERGENCY USE INVESTIGATIONAL DRUGS

A. The physician's responsibilities include:

1. Contact the drug manufacturer to discuss details of the case.
2. Contact IRB
3. Obtain or draft a consent form and secure written consent from the patient.
4. Complete the FDA form 1572 or 1573 supplied by the drug company.

B. The pharmacist's responsibilities include:

1. Complete an "Emergency Use Investigational Drug Request" form with the physician's assistance.
2. Verify that the patient has signed the consent form.

Emergency Use Investigational Drug Request

A. Requesting Physician

Name: Service:

Pager: Phone:

Reason for request:

IRB contacted on Date: Time:

Name of IRB member contacted:

The IRB is located in the University of Utah Medical Center, Room 1C-246 (phone 581-3655).

B. Patient Information

Name: MR#: Location:

Age: Weight:

Other:

C. Investigational Drug Information

Drug Name: Strength:

Dose: Route: Schedule:

Drug company: Date Contacted:

Person Contacted: Phone:

D. Pharmacy

Pharmacist completing form:

Request Date: Time:

Drug expected to arrive: Date: Time:

Patient consent signed (Y/N): verified by: (RPh initials)

Forward this request to the Investigational Drug Studies Pharmacist (phone 585-2185/ pager 339-5746) or the Drug Information Services, Linda Tyler (phone 581-2732).

UNIVERSITY OF UTAH HOSPITALS AND CLINICS POLICY MANUAL
DEPARTMENT OF PHARMACY SERVICES POLICY MANUAL
SOUTHWEST ONCOLOGY GROUP (SWOG) AND NATIONAL INSTITUTES OF
HEALTH (NIH) INVESTIGATIONAL DRUG STUDIES

No: 12-11 Review Date 11/29/04 Revision Date: 11/29/04 Chapter: Investigational

10/16/01 10/16/01 Drug Studies

10/26/98 10/26/98

I. PURPOSE

This policy describes the procedures specific to the SWOG and NIH studies.

II. DEFINITIONS

III. POLICY

A detailed inventory record of receipt, dispensing, and return of all NCI supplied medications will be maintained using the standardized Investigational Drug Accountability Record form in compliance with NCI guidelines. Only authorized investigators may request NCI supplied medications.

IV. PROCEDURE

A. All NCI supplied medications (including SWOG) will be stored in either a Control or Satellite Area. The Control Area is the primary location for drug storage and is currently the Outpatient Pharmacy. A Satellite Area is any storage location outside of the Control Area. Drugs will always be placed at room temperature, in the refrigerator, or in the freezer as appropriate for proper storage.

B. Separate notebooks for SWOG and NCI protocols will be kept in the Control Area.

Each notebook will contain the following:

1. The Investigational Drug Accountability Record for each drug on each protocol.

2. A copy of the current NCI "Investigational Drug Accountability" booklet.

3. The current list of investigators authorized to write for SWOG or NCI drugs.

Hematology/Oncology fellows and Urology residents are included in the list of SWOG investigators. The list of authorized physicians will be updated annually.

4. The most current version of the Department of Pharmacy Services policy 12.11.

5. Other instructions necessary for proper drug handling.

C. The Investigational Drug Accountability Record form will be used to record all transactions involving NCI supplied medications. A separate form will be needed for each NCI drug used on each NCI or SWOG protocol. The form will be designated as either a Control Record or a Satellite Record.

D. Preparation of a **Control Record** for drugs stored in the Control Area.

1. At the top of the form, indicate where drug will be stored (shelf, fridge, freezer).

2. Enter the Page No. and put a check-mark next to Control Record.

3. Enter Name of Institution- write "University of Utah Hospital".
 4. Enter Protocol No. using either the SWOG and/or NCI protocol number.e.g., SWOG-9223, SWOG 9313/ INT-0127, TRC-9103, BTRC-8911, E95-1567
 5. Enter the Drug Name, Dose Form and Strengthe.g., Neupogen (G-CSF) 0.480 mg/1.6 mL vial; Zoladex 3.6 mg/ depot; Casodex 10 mg tablet (100 tablets/ bottle);Tretinoin (trans-Retinoic Acid) 10 mg capsule (120 capsules/bottle)
 6. Enter Protocol Title in an abbreviated manner (e.g., Breast CA, Melanoma, etc.)
 7. Enter Dispensing Area- write "U. of U. Outpatient Pharmacy"
 8. Enter Investigator- Use the investigator named on the Shipment Record of Clinical Drug Request which accompanies all drug shipments from NCI.
 9. Enter the NSC number of the drug below the Dispensing Area
- E. Receipt of drugs from the NCI.
1. Enter the following information on the appropriate **Control Record**:
 - a. Date received
 - b. Patient's Initials, I.D. Number, & Dose- write "Received from NCI"
 - c. Quantity Received
 - d. Balance
 - e. Manufacturer and Lot No.
 - f. Recorder's Initials
 2. File the "Shipment Record of Clinical Drug Request" which accompanies each drug shipment in the SWOG or NCI file cabinet within the Control Area.
- F. NCI drug dispensed from the **Control Area** directly to a patient, including the preparation of a single dose for immediate inpatient or clinic use.
1. A written order or prescription will contain the following information
 - a. SWOG or NCI protocol number
 - b. Patient name
 - c. The six-digit Patient ID Number (NCI registration number)
 - d. Hospital medical record number (inpatient orders only)
 - e. Medication Name, Strength (and Quantity if dispensed directly to the patient)
 - f. Instructions for use
 - g. Date
 - h. Signature of authorized investigator
 2. Record the following on the appropriate **Control Record**
 - a. Date dispensed
 - b. Patient's Initials and Patient's Study I.D. Number (typically a six-digit no.)

- c. Quantity Dispensed
- d. Balance remaining
- e. Manufacturer and Lot No. of the drug being dispensed
- f. Recorder's Initials

3. The label will contain the words "Investigational" or "Study" and the following:

- a. SWOG or NCI protocol number
- b. Patient name
- c. The Patient's Study ID Number
- d. Medication Name and Strength
- e. Instructions for use
- f. Date

And, if dispensed directly to the patient:

- g. Quantity dispensed
- h. Physician's name

G. Dispensing NCI medication to a storage area outside of the **Control Area**

(e.g., IVC, Clinic 3, MD's office, etc.)

1. A **Satellite Record** will be prepared using a new Investigational Drug Accountability Record form. The top portion of the Satellite Record will contain the same information as the Control Record with the following *two exceptions*: Place a check-mark next to Satellite Record (instead of Control Record)

. Dispensing Area- enter the location of the satellite storage area

(e.g., IVC, clinic 3, Dr. Jones's office, etc.)

2. On the **Satellite Record**, enter the following:

- a. Date received
- b. Patient's Initials, I.D. Number, & Dose- write "Received from" and the name of the Control Area i.e., U. of U. Outpatient Pharmacy.
- c. Quantity Received
- d. Balance
- e. Manufacturer and Lot No.
- f. Recorder's Initials

3. On the appropriate **Control Record**, enter the following:

- a. Date dispensed
- b. Patient's Initials and Patient's I.D. Number- enter the location of the satellite storage area (e.g., IVC, clinic 3, Dr. Jones's office, etc.)
- c. Quantity Dispensed

- d. Balance remaining
 - e. Manufacturer and Lot No. of the drug being dispensed
 - f. Recorder's Initials
- H. Dispensing drug from a **Satellite Area**
1. A written order or prescription will contain the following information:
 - a. SWOG or NCI protocol number
 - b. Patient name
 - c. The Patient's Study ID Number
 - d. Hospital medical record number (inpatient orders only)
 - e. Medication Name, Strength (and Quantity if dispensed directly to the patient)
 - f. Instructions for use
 - g. Date
 - h. Signature of authorized investigator
 2. NCI and SWOG prescriptions will be kept with the Satellite Record.
 3. The label will contain the words "Investigational" or "Study" and the following:
 - a. SWOG or NCI protocol number
 - b. Patient name
 - c. The six-digit Patient ID Number (NCI registration number)
 - d. Medication Name and Strength
 - e. Instructions for use
 - f. Date
 - g. And, if dispensed directly to the patient: Quantity dispensed and Physician's name
 3. Record the following information on the appropriate **Satellite Record**:
 - a. Date dispensed
 - b. Patient's Initials and Patient's I.D. Number
 - c. Quantity Dispensed
 - d. Balance remaining
 - e. Manufacturer and Lot No. of the drug being dispensed
 - f. Recorder's Initials
 4. When the Balance on the Satellite Record is zero, the completed Satellite Record will be returned to the Control Area and filed by drug name and protocol.
- I. NCI drug returned from a Satellite Area to the Control Area
1. On the **Satellite Record** enter the following:
 - a. Date returned to the Control Area

- b. For Patient's Initials, I.D. Number, & Dose, write "Returned to" and the name of the Dispensing Area listed on the Control Record.
 - c. Quantity Returned and the Balance (should be 0)
 - d. Manufacturer and Lot No.
 - e. Recorder's Initials
2. The completed Satellite Record will be filed by drug name and protocol number in the Control Area.
3. On the appropriate **Control Record** enter the following:
- a. Date received from the Satellite Area
 - b. For Patient's Initials, I.D. Number, & Dose, write "Received from" and the name of the Dispensing Area listed on the Satellite Record.
 - c. Quantity Received
 - d. Balance
 - e. Manufacturer and Lot No.
 - f. Recorder's Initials
- J. SWOG and NCI drugs returned to NCI
- 1. The IDS pharmacist will return drug to the NCI.
 - 2. Prepare the Return Drug List form by entering:
 - a. Investigator's name, investigator No., and address of hospital
 - b. Protocol Number
 - c. NSC Number
 - d. Drug name, Strength & Dose, and Quantity
 - e. Manufacturer
 - f. Lot Number
 - g. Signature, Date, Title, and Telephone Number
 - h. Type the U. of U. Hospital address in lower right hand corner of the form.
 - 3. On the appropriate **Control Record**, enter the following:
 - a. Date returned to the NCI
 - b. For Patient's Initials, I.D. Number, & Dose, write "Returned to NCI"
 - c. Quantity Returned and the Balance (should be 0)
 - d. Manufacturer and Lot No.
 - e. Recorder's Initials
 - 4. Expired or unused drug will be returned to:
NCI Clinical Repository

C/o McKesson BioServices
627 Lofstrand Lane Rockville, MD 20850

K. Inventory Control

1. Inventory and expiration date checks will be performed monthly by the IDS pharmacist or other designated person in accordance with SWOG/NCI requirements and recorded on the Control Record for each drug on each protocol.
2. The inventory balance of all SWOG/NCI drugs will be recorded on the IDS form titled "SWOG/NCI Inventory and Order Form" and a copy will be given to the University of Utah SWOG office monthly.
3. Outdated drugs will be returned to the NCI as explained in section J.
4. Any inventory discrepancies will be documented on the Control Record by the IDS pharmacist, and will be reported to the SWOG office if the problem cannot be rectified.

L. SWOG Protocol Files

1. Copies of current SWOG protocols are kept in the filing cabinet next to the IDS office in the Central Pharmacy, A-level.
2. Protocols are filed according to SWOG protocol number.
3. Protocols will be updated when revisions/amendments and new protocols are received from the SWOG office. "Permanently closed" protocols will be discarded only after all patients have been discontinued on drug therapy.

M. Transfer of drug between protocols may occur when a protocol is completed and drug is no longer needed or when a protocol has an oversupply of drug. You must contact the Pharmaceutical Management Branch at (301) 496-5725 for prior approval of an oversupply transfer.

1. The IDS pharmacist will transfer drug between protocols.
2. Prepare the "Transfer Investigational Drug Form" by entering:
 - a. Investigator Transferring Drug, NCI Investigator No., Date of Transfer
 - b. Name of Institution- write "University of Utah"
 - c. Street, City, State, Zip Code
 - d. Indicate Completed Protocol, Oversupply Transfer, or Unused Drug Obtained for Special Exception Protocol
 - e. Investigator Receiving Drug and NCI Investigator No.
 - f. Received on Protocol No.
 - g. Transferred to NCI Protocol No.
 - h. NSC Number
 - i. Drug Name, Strength & Formulation, Quantity
 - j. Manufacturer
 - k. Lot Number

I. Signature and Telephone Number

4. On both the transferring and receiving **Control Records**, enter the following:

a. Date

b. On the **transferring** Control Record, write "Completed transfer to" or "Oversupply transfer to" and the name of the receiving protocol.

c. On the **receiving** Control Record, write "Received from" and the name of the transferring protocol.

d. Quantity transferred or received

e. Balance

f. Manufacturer and Lot No.

g. Recorder's Initials

N. Charging of SWOG/NCI drug

1. There is NO charge to the patient for NCI supplied medications.

The patient will be charged for the materials and cost associated with the preparation of a parenteral dose (e.g., IV bag, syringes, diluent, etc.)

5. The IDS pharmacist will determine the total number of prescriptions filled during the quarter and the average number of drugs on inventory for each protocol. The charge for dispensing and drug inventory will be determined annually and an outline of the charges will be sent to the University of Utah SWOG office.

3. The amount of SWOG and NCI dispensing for that quarter will be reported to the Director of Pharmacy Services and the SWOG principal investigator.

4. A campus order form will be completed by the IDS pharmacist and will include the dispensing and inventory charges. The campus order will then be signed by the Director of Pharmacy Services or authorized designee and the SWOG principal investigator or authorized designee.

5. The completed campus order form will be sent to Research Accounting (406 Park Building) for reimbursement.

APPROVAL BODY: James Jorgenson, Director of Pharmacy

APPROVAL DATE: 10/15/01

POLICY OWNER: Linda Tyler, Pharm.D.

ORIGIN DATE: 3/92