
SWOG
CLINICAL RESEARCH ASSOCIATE (CRA) MANUAL
VOLUME I

DRUG ORDERING AND MAINTENANCE	CHAPTER 6	REVISED: October 2012
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DRUG ORDERING AND MAINTENANCE

Disclaimer: Please note that the instructions provided in this chapter only apply to agents provided by the Pharmaceutical Management Branch (PMB), of Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI). For investigational or study drugs supplied by pharmaceutical sponsors, follow instructions provided in the designated study protocol.

Procurement of Investigational Agents

Who Can Order The Agents?

Investigational agents may only be ordered from the National Cancer Institute (NCI) by a CTEP-approved investigator or someone he or she designates. Investigational agents may be ordered only for protocols on which their institution or group participates. The NCI requires that the investigator's NCI investigator number be supplied with each order. If the investigator's NCI number is unknown, it can be obtained from the NCI by calling (301) 496-5725. Any investigator who receives and administers an investigational agent supplied by the NCI must be registered with the NCI by submitting a curriculum vitae, filing the FDA-1572 form and the Supplement Investigator Data Form (SIDF), and a Financial Disclosure Form (FDF). (<http://ctep.cancer.gov/forms/>). The registration of the investigator must be renewed annually. Investigational agents provided by the NCI to a registered investigator are the direct responsibility of the investigator. Secondary distribution to other registered investigators does not relieve the primary investigator to whom the original shipment was made from his/her responsibility.

Who Supplies Investigational Agents?

Investigational agents are supplied by the Division of Cancer Treatment and Diagnosis (DCTD) of NCI through the Pharmaceutical Management Branch (PMB). Investigational agent shipment will be sent to the address designated on the SIDF. Direct shipment of investigational agents to the preparation site is preferred because it simplifies mail and drug handling tracking for investigators and PMB, minimizes delays in correspondence in emergencies, assures drug shipment integrity, reduces administrative workload (maintenance of additional accountability records, drug transfer forms, and correspondence) and eliminates secondary shipping expenses. Investigational agents from the NCI must not be re-distributed or transferred to another institution or site, with the exception of satellite distribution. Satellite distribution would be to a preparation site in close proximity to the shipping address in which a direct courier service is provided. However, the central or control pharmacy service is ultimately responsible for all investigational agents received and must provide copies of all accountability records during any Cancer Treatment Evaluation Program (CTEP) directed audit.

How To Order The Agents

The DCTD of NCI supplies most of the investigational agents for SWOG trials. In some cases, investigational agents are supplied from other sources. Always refer to the drug information section of the protocol to identify the supplier of the investigation agents. For investigational agents that are available through the NCI, the investigators or designees MUST submit agent

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requests through the PMB Online Agent Order Processing (OAOP) application (<https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp>). Access to OAOP requires the establishment of a CTEP Identity and Access Management (IAM) account (<https://eapps-ctep.nci.nih.gov/iam/>) and the maintenance of an “active” account status and a “current” password. Submitters will receive a confirmation email of each successful order submission. Order status may be viewed at any time through the OAOP application. Only for pre-approved exceptions, the drug ordering can be completed using the investigators or designees can submit agent requests through the PMB Online Agent Order Processing (OAOP) application (<https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp>). Access to OAOP requires the establishment of a CTEP Identity and Access Management (IAM) account <https://eapps-ctep.nci.nih.gov/iam/> and the maintenance of an “active” account status and a “current” password. Submitters will receive a confirmation email of each successful order submission. Order status may be viewed at any time through the OAOP application. The drug ordering can also be completed using the **NCI Clinical Drug Request** (<http://ctep.cancer.gov/forms/>) with the following information:

Investigator name = (the principal investigator or the designated investigator at the institution for this protocol).

NCI Investigator Number

Designee/Requester Name

Title (physician, pharmacist, nurse, or data manager).

Telephone Number (contact telephone number of the requester).

Fax Number (facsimile number of the requester).

Investigator Signature (investigator or designee may sign the form).

Date (date order sent).

NCI Protocol Number (use the NCI designated protocol number; do not use institutional assigned protocol number).

Number of Patients Currently Being Treated (number of patients enrolled and active on protocol).

Patient or Special Code (only if applicable patient initials or ID number for certain protocols are required for drug ordering; for protocols in which the investigational agents are sent patient specific/blinded).

Your Current Inventory (amount of drugs on hand).

NSC Number (6-digit number assigned to a particular drug that can be located either on the cover page or in the “Drug Information” section of the protocol).

Drug Name (use the same name as indicated on the protocol).

Strength and Dosage Form (xx mg vials, ampoules, tablets etc.).

Quantity Ordered (recommend to order 6 to 8 weeks supply).

Date Needed (usually expect approximately 1 week for delivery; see instructions below for urgent request).

Routine Orders Normal PMB processing time is two (2) working days. Orders are shipped by U.S. Postal Service Priority Mail or other ground service. Agents having special

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storage conditions [e.g., thermo labile agents that require refrigerated or frozen (-20 or -70 degree C) storage conditions] or shipping requirements (e.g., dangerous goods, infectious substances) are shipped Monday through Thursday for next day delivery.

Shipping Address (located at the lower left hand corner; recommend using the address where drugs will be stored, e.g. central or control pharmacy; this address must match with the shipping address that the investigator provided on the SIDF).

In accordance with the FDA guidelines on Good Clinical Practice and the Joint Commission on Accreditation of Healthcare Organization (JCAHO), whenever possible, the pharmacy department should be responsible for drug receipt, storage, accountability, and preparation. Fax* original Clinical Drug Request Form to:

Pharmaceutical Management Branch
Drug Management and Authorization Section
Division of Cancer Treatment, NCI
Fax number: (310) 480-4612

For online ordering submissions, a confirmation email will be sent upon shipment to include the order details and tracking information.

For Emergency Supply (Overnight) Of Study Drugs

PMB provides next day delivery to meet "emergency" or urgent needs. Fax the Clinical Drug Request form directly to PMB of NCI at (301) 480-4612 prior to noon eastern time or email request by 2:00 PM Eastern Time for next day delivery. Make sure to complete the form with all the information listed above including the requirement for "next day delivery", and include an express courier name and account number. Submitters will receive a confirmation email for successful order submission. For faxed order request, a follow-up telephone call to NCI at (301) 496-5725 is highly recommended. Rush drug orders are made only in emergency situations, such as starter supplies or if the supply is unexpectedly low. Because of the additional checks with blinded agents supplied by NCI, blinded agents cannot be shipped overnight, but they can be expedited (2 day delivery)

Initial Drug Orders For Blinded Studies

Initial drug orders are made automatically by the SWOG Statistical Center for some blinded studies (see the particular protocol for details). For questions about drug orders for blinded studies, call the Statistical Center. For questions about other drug orders, call the Operations Office.

Denial of Starter Supplies

In some protocols where the drug supply is limited or slow patient accrual is expected, a starter supply of the drug may not be available. Upon enrollment of a patient, use the procedure for emergency supply of drugs to order drugs or refer to the drug transfer procedures if the circumstance does not allowed for timely delivery of the drugs via the emergency ordering procedure.

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For Drugs Supplied By A Pharmaceutical Company

Most studies require ordering by phone. Always refer to the protocol under the “Drug Information” section for specific instructions.

Drug Accountability and Compliance Check Receipt of Investigational Agents

What To Do With The Shipping Receipt

Investigational agent shipments are accompanied by a shipment document (receipt). This document should be reviewed to identify the drug with the appropriate protocol. The shipment should be verified with the receipt for correctness and appropriate shipping conditions. Contact the supplier by phone if the shipment is incorrect or damaged and arrange for more shipment as necessary. Always file the Drug Shipment Receipt so they will be readily accessible for future site audits.

There are studies where the drug supplier will require a copy of the shipment receipt be faxed or mailed to the supplier to indicate acknowledgement of receipt, be sure to refer to the protocol and shipping material for appropriate handling.

How To Complete The Drug Accountability Record Form (DARF)

For each drug supplied for a study, a NCI Drug Accountability Record Form (DARF) or equivalent form provided by the study sponsor must be maintained. This DARF is contained in the publication entitled Investigational Drug Accountability (<http://ctep.cancer.gov/forms/>) and is available on the Cancer Therapy Evaluation Program (CTEP) website <http://ctep.cancer.gov>. The DARF is also available from the SWOG Operations Office. This form has been designed to account for drug inventories and usage on clinical trials. A separate DARF must be used for each protocol and each research drug. If there is more than one strength or dosage form of a drug for the same protocol, a separate DARF is required for each drug product. Electronic DARFs are allowed as long as a print version of the log process is identical to the current NCI DARF.

When completing the DARF, keep the following in mind:

1. All drug supplies received must be logged in on the drug log, i.e., drug received from the NCI or another protocol.
2. If the supply is patient specific/blinded, a DARF is required for each patient on the study (see protocol for details).
3. Central or Control Pharmacy records must reflect returns from satellite locations.
4. All shipping, return, and transfer receipts must be maintained for audit purposes

To start a new DARF, complete the upper portion of the form:

1. **Page Number** (record the page number consecutively on the forms for each drug used on the protocol).

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2. **Control Record** (check if the record is being used to account for research drug stored at the central or control pharmacy).
3. **Satellite Record** (check if the record is being used to account for research drug at a satellite pharmacy).
4. **Name of Institution** (the name of the location to which the drug is shipped from NCI).
5. **Protocol Number** (NCI; may add the institutional protocol number if necessary).
6. **Drug Name, Dose Form and Strength.**
7. **Protocol Title** (may use abbreviations if necessary.)
8. **Dispensing Area** (the location where the drug is dispensed, e.g. infusion center pharmacy, satellite location, central pharmacy).
9. **Investigator** (name of the investigator in whose name the drug is ordered from NCI).
10. **Investigator NCI number.**
11. **Balance Forward** (enter zero if the current page is the first page or bring the balance forward from the previous page).

To Make An Entry On An Existing Drug Accountability Record Form

Upon receiving a drug shipment, enter the following information in the appropriate columns:

1. **Date** (Date the drug is received including year).
2. **Patient's Initials and Patient's ID Number** (Enter "Rec'd from [name of the study sponsor]").
3. **Dose** (leave blank).
4. **Quantity Dispensed or Received** (" + " and # of vials, ampoules, tablets, or kits received).
5. **Balance** (Enter new total obtained by adding the new quantity received).
6. **Manufacturer and Lot Number** (Lot # and expiration/preparation date; if the drug shipment contains more than one lot number, make separate entry for each lot # for optimal record keeping).
7. **Recorder's Initials.**

What To Do With The Investigational Agents?

Investigational agents are to be stored separately by protocol and have separate DARFs. Since many protocols use the same agent, consider labeling the agent container with the drug name, dosage form, and protocol number. The investigational agents must be kept in a secure, have a limited access storage area, and stored under the recommended storage conditions. Investigational agents should be stored separately from any commercial supplies of medications. If more than one study uses the same drug, each study should have its own DARF form.

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Dispensing of Investigational Agents

How To Dispense The Drugs At The Central Or Control Pharmacy

For drugs that are being prepared or dispensed at the control pharmacy, enter in the DARF:

1. **Date** (the date of dispensing/preparation including year).
2. **Patient's Initials** (use the same initials as for the protocol registration).
3. **Patient's I.D. Number** (patient's study number).
4. **Dose** (actual dose administered).
5. **Quantity Dispensed** ("-" and # of vials, ampoules, tablets, or kits dispensed).
6. **Balance** (enter new total obtained when subtracting the # dispensed).
7. **Manufacturer and Lot Number** (lot number(s) and the expiration date(s) of the drugs; if there are more than one lot number being used, make separate entries for optimal record keeping).
8. **Recorder's Initials.**

All drugs dispensed must be labeled per federal law requirements. Identification of the investigational drug/agent by the statement "Caution: New Drug—Limited by Federal (or United States) law to investigational use" on the medication label is required.

When Can The Central Or Control Pharmacy Send Drugs To A Satellite Pharmacy?

For institutions that are located on the same campus or in close proximity to the central or control pharmacy service where transportation of the drugs can be conducted by an institution employee, transfer of the investigational agents is permitted. The DCTD supplied agents must NOT be repackaged and forwarded by mail or overnight delivery services to another institution or site. The institutions should be tied through affiliation agreements and the professional staff should be shared or have joint appointments.

Satellite pharmacies should follow the same procedures for drug preparation and dispensing, as the Central or Control pharmacy. This includes using the DARF to document investigational agent use.

How To Transfer Drugs From The Central Or Control Pharmacy To The Satellite Pharmacy

If the investigational agent is to be prepared at a satellite location, the research study drug needs to be dispensed to the satellite location. Enter in the DARF of the central or control pharmacy the following information:

1. **Date** (the date including year).
2. **Patient's Initials and Patient's I.D. Number** ("dispensed to [name of satellite location]").
3. **Dose** (leave blank).
4. **Quantity Dispensed and Received** ("-" and # of vials, ampoules, tablets or kits dispensed).

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5. **Balance** (enter new total obtained when subtracting # dispensed).
6. **Manufacturer and Lot Number** (lot number(s) and the expiration dates(s) of the drugs; if there are more than one lot number being used, make separate entries for optimal record keeping).
7. **Recorder's Initials.**

Label the package with the drug name, protocol number, patient's name (optional) and storage condition.

What To Do When The Drugs Are Received At The Satellite Location Or Pharmacy

Upon receiving the drugs, the satellite should enter in the DARF:

1. **Date** (the date including year).
2. **Patient's Initials and Patient's I.D. Number** ("Received from [name of Central or Control Pharmacy]").
3. **Dose** (leave blank).
4. **Quantity Received** ("+" and # received).
5. **Balance** (new balance obtained when adding # received).
6. **Manufacturer and Lot Number** (lot number(s) and the expiration date(s) of the drugs; if there are more than one lot number being used, make separate entries for optimal record keeping).
7. **Recorder's Initials.**

Affiliates/Components At Greater Distances

Institutions that are separated geographically by greater distances (e.g. different cities or states) are not considered satellites. The drug supplier should ship investigational agents directly to these sites.

The affiliate should follow the same procedures for drug preparation and dispensing, as well as the documentation required for the central or control pharmacy.

Documentation Of Returned Drugs By Patients

For protocols that required accountability of drugs returned by patients (especially for oral medications where adherence checks are required), a separate DARF should be maintained. Drug returned from a patient should not be logged on the original DARF except for some double-blinded studies where protocol specific DARFs are provided to capture this information.

Returning and Transferring of Investigational Agents

When Can Drugs Be Returned To The Supplier?

For NCI approved investigational agents, investigators are required to return unused drugs if:

1. The study is completed or discontinued and the agent cannot be transferred to another DCTD sponsored protocol.
2. The drug is outdated

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3. The drug is damaged (e.g. loss of refrigeration). Do NOT return broken vials. They should be destroyed at the clinic site according to institutional standard operation procedures following proper documentation.

Drugs should be returned within 90 days of study closure and/or last patient activity although outdated or damaged drug should be removed from inventory immediately.

How To Return and Dispose of Drugs To The Supplier

To return drugs to NCI, complete the Return Drug List Form (Appendix IV) and make an entry on the DARF subtracting the amount returned from the balance. A copy of the Return Drug List Form should be kept on file with the DARF for a future audit. Send the drugs and the Return Drug List Form to the NCI Clinical Drug Repository at the address indicated on the Return Drug List Form. Package the drugs securely to prevent breakage and return via mail. All drugs can be returned to NCI at room temperature using standard delivery because they will be disposed thereafter. Do NOT use "Collect" or C.O.D. shipments.

Agents that have been dispensed to a patient, opened, or partially used vials/bottles should not be returned. Partials including drug returned from patients should be destroyed according to institutional policies.

In general, if the research drug is a cytotoxic drug, the method of disposal should follow the recommended guidelines provided by the Occupational Safety and Health Administration (OSHA). The institution or its source for drug destruction services should have written policies and procedures for research drug destruction on site.

When investigational (and sometimes commercial) agents are provided for a study by a supplier other than NCI, study drug may usually be disposed of on site but sometimes may be requested to be returned to that supplier. Return of research study drug to these suppliers may require the use of a separate Return Drug Form. Please refer to the specific protocol or contact the responsible Protocol Coordinator at the SWOG Operations Office for directions to return or dispose of the drugs. Document the disposal or return on the DARF.

Transfer

Investigational agents may be transferred from one active protocol to another DCTD approved protocol within an institution.

Who Can Transfer Agents?

The "transferring" investigator must be the investigator who originally ordered the agent or the investigator to whom the agent was previously transferred (i.e. double transfer). The "receiving" investigator must be a participant on the trial to which the agent is being transferred. Transfer of NCI supplied agents shall only be made between registered active NCI investigators.

When Can Drug Transfer Occur?

Transfer of investigational agents should be restricted to the following situations:

1. When the protocol is closed and there is another protocol at the institution that utilizes the same agent and formulation. However, transfer of DCTD-supplied agents

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- to non-DCTD approved protocols is NOT permitted under DCTD, NCI, and FDA policies and regulations.
2. When there is excessive inventory for a protocol and the transfer will minimize drug wastage due to outdate.
 3. The study drug has short dating.
 4. In case of medical emergency. (e.g. an urgent approval of a protocol and a very sick patient who needed to begin therapy immediately).
 5. When a drug ordered for an individual patient on Special Exception (compassionate) protocol is no longer required for the patient and there is a DCTD approved protocol at the institution using the same study drug.

When You Should NEVER Transfer Drugs

1. Transfer of NCI supplied agents for commercial use is both prohibited and illegal.
2. Replacement of NCI supplied agents with commercial agents is also prohibited and illegal.
3. Agents for blinded studies should NEVER be transferred between protocols.
4. Borrowing of a study drug is prohibited. Study drugs should not be ordered for one protocol to replace what was "borrowed" from another protocol.

What To Do When A Drug Needs To Be Transferred

Transfer of DCTD supplied agents from an active protocol requires prior PMB approval by phone at (301) 496-5725. PMB should be notified by phone within the next working day if emergency transfers are required during weekends or holidays, or after hours. An NCI Agent Transfer Record (<http://ctep.cancer.gov/forms/>) must be completed and submitted by fax (301) 402-4612 to the PMB for each agent transferred. Transfer forms should be submitted within 72 hours of the actual transfer. A copy must be retained for accountability and future audits.

Storage of Investigational Agents

Who Should Handle And Store The Drugs?

In accordance with the FDA guidelines on Good Clinical Practice and the Joint Commission on Accreditation of Healthcare Organization (JC), whenever possible, the pharmacy department should be responsible for drug receipt, storage, accountability, and preparation.

How To Store The Drugs

All investigational agents should be stored in a locked, secure cabinet or area with limited access. The drugs should be stored separately from the commercially available drugs, preferable in a separate cabinet, area, or location. The drugs should be placed in separate containers according to protocol and dosage form. If an agent is used for more than one protocol, there must be separate physical storage and accountability for each protocol. The containers should be labeled with the drug name, strength, and protocol number.

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What Documentation Of Storage Do I Need For Audits?

A daily temperature log should be kept for the refrigerator and the freezer used for storing research drugs and should be readily available for audit inspection. Room temperature storage control should be maintained at all time to avoid excessive heating of the drugs. Light sensitive products should be kept in the original container prior to administration or an amber light protection bag should be used to provide the protection required.

Compassionate Use, Special Exemptions, or Emergency Use of an Investigational Agent for a Patient

Who Is Eligible?

Patients who are refractory to standard measures, who are not eligible for an ongoing research protocol, and who have a cancer diagnosis for which an investigational agent has demonstrated activity are potential candidates to receive this category of drugs.

How To Enroll The Patient

The physician of the patient is required to call the sponsor, NCI at (301) 496-5725 or the pharmaceutical manufacturer of the drug, to obtain approval to use the drug on a patient. The following information will be required by the sponsor:

1. Patient's age, sex, diagnosis and date of diagnosis.
2. Justification for requesting the study drug.
3. Previous cancer therapy.
4. Current clinical status.
5. Intended dose and schedule of the requested drug.
6. Any proposed concomitant cancer drugs or other therapies.

Upon approval, the sponsor will provide verbal or written instructions on other information needed to complete the application. Institutional Review Board (IRB) must be obtained prior to the initiation of the treatment. IRB approval varies between institutions. Please contact your IRB for their policies.

Ordering Of The Drugs

The initial shipment of the drug will be mailed upon approval of the application. Reordering of the drug will be handled like other NCI or pharmaceutical company sponsored studies.

Handling And Documentation

Follow the same policy and procedures as the other NCI or pharmaceutical company sponsored study drugs. Group C drugs can be transferred to other NCI sponsored study when the Group C protocol for that drug is no longer active at the institution.

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SWOG Database Pharmacy Data

Every SWOG investigator who registers patients must be linked to an assigned pharmacy in the SWOG database. The initial pharmacy assignment is done by completing the Investigator Pharmacy Form (located on the SWOG website under Administrative Forms – example on next page) included in the new investigator membership packet. It is preferable to use an actual pharmacy under the direct supervision of a qualified pharmacist, although it is recognized that in some cases this may not be feasible. It is also preferable to have as many investigators as possible at an institution use the same drug shipment location, although there can be exceptions to this, too, when the situation requires it.

The Operations Office sends an annual review of pharmacy information to the Head CRA of every Member, CCOP, UCOP, and Special Member institution by email on a rotating schedule throughout the year. This review consists of a listing of all the investigators at the institution and its affiliates/ components, showing the pharmacy to which each is linked, and a report showing the contact information for these pharmacies. It is the responsibility of the Head CRA at the main institution to further distribute these to subordinate institutions as needed. Each of these documents should be reviewed, missing information added and incorrect information changed, and returned to the Operations Office by email, fax, or mail by the deadline specified.

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SOUTHWEST ONCOLOGY GROUP
New Investigator Pharmacy Information

Shipment of investigational drugs must be made to a designated pharmacy location. The pharmacy location designated by each investigator is entered into the SWOG database to expedite drug shipment when a patient is placed on a protocol using investigational drugs. Annually you will receive a report showing pharmacy information for review and updating as necessary. Please provide initial pharmacy information below:

Investigator Name: _____

Institution Name: _____ Institution number: _____

Pharmacy Contact Name:

_____, RPh PharmD RN CRA _____

Pharmacy Name and Shipping Address:

Pharmacy Phone number: _____

Pharmacy FAX number: _____

Pharmacy Email address: _____

Signature _____ Date _____

(For Operations Office Use Only)

Investigator number: _____

Pharmacy Number: _____

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