Welcome to this video tutorial on Agent Dispensing in the PMB Investigational Drug Accountability series.

This video will review recording procedures for agent dispensing on both the Oral DARF and the original NCI DARF.
Upon receiving a prescription for study agent for use in an NCI approved protocol, first verify that the ordering investigator has an active CTEP registration.
PHARMACEUTICAL MANAGEMENT BRANCH (PMB)

The Pharmaceutical Management Branch (PMB) is charged with providing pharmaceutical support for clinical trials sponsored by the National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP). This support includes:

- Provision of pharmaceutical information about CTEP IND agents
  - Agent Management
  - Investigators Brochure (IB) List
  - Material Safety Data Sheet (MSDS) List
  - Cytochrome P450 Drug Interaction Table
  - Patient/Caregiver Ad Hoc Education Template
- Registration of all investigators and associates participating in CTEP clinical trials and the maintenance of all registration records
  - Investigator Registration
  - Investigator Registration Expiration Date
  - Associate Registration (CTEP-IAM)

You can check investigator registration status and expiration date here on the CTEP website.

http://ctep.cancer.gov/branches/pmb/default.htm
Upon entering both the CTEP Investigator ID and Investigator Last Name, the results will display the investigator registration status and expiration date.

If the CTEP Investigator ID is unknown, you can look it up in OAOP or check with your research coordinator. The CTSU website can also be used if you have access to it. The Regulatory tab provides a list of all investigators at a site with their registration status and CTEP Investigator ID.
This is an example of an investigator with an active CTEP registration status. Note that this investigator does not have any current affiliations. Investigator affiliations indicate eligibility to participate on rostered participant protocols.
The next step requires a copy of the current version of the protocol, in addition to the investigator registration status search results, in order to verify that the ordering investigator is study-eligible to participate on the trial. Let’s review a couple examples.
For non-rostered single or multicenter studies, each study eligible institution and ordering investigator must be listed on the protocol title page. In this example of a multi-center study we’ve verified the investigator name, institution, and CTEP site code on the title page with the investigator registration status search results. This investigator has an active CTEP registration and is eligible to participate.
To check study eligibility of an ordering investigator for a rostered participant protocol, utilize the investigator affiliations in the investigator registration status search results when referring to the protocol title page. In this example, the investigator has affiliations with ALLIANCE, a Lead Academic Organization or LAO, and a Phase 2 Consortium or P2C.
Now refer to the participating organizations on the title page. For rostered studies each study-eligible investigator is NOT listed on the title page. The P2C that this investigator is affiliated with appears on the title page so the investigator is study-eligible for this rostered participant protocol. Investigators without affiliations to the rostered participants need to be listed on the title page as non-member collaborators in order to participate.
The agent dispensing checklist must be complete prior to dispensing study agent. We’ve verified that the ordering investigator has an active CTEP registration, is study-eligible, and checked that the study prescription is signed or co-signed by the registered study eligible investigator. Ensure the prescription is written for a registered study participant at either a control or satellite dispensing area, that it is written appropriately per protocol, and that the patient meets all protocol-defined criteria for treatment.
Now let’s review agent dispensing accountability examples. On the Oral DARF or the original NCI DARF, each dispensing entry must be complete, with the Date, Patient’s Initials and ID Number, Dose, Quantity, Balance, Lot Number, and Recorder’s Initials. The Oral DARF is formatted for the dispensing and return information to appear in the same row. Please see PMB’s Oral DARF video tutorial for additional information on recording patient returns.
Record the date that the agent is prepared for dispensing. It may differ from the date it is provided to the patient or the date the patient begins treatment. Record the patient’s initials and patient’s ID number. In the dose field, record the prescribed dose. There can be different approaches to recording in the dose field given the space limitations. Keep in mind that this field is intended to support the quantity dispensed. Do not record the total dose dispensed per cycle for oral agents. For example, 2800 mg for an agent that is dosed at 100 mg daily for 28 days.
The quantity dispensed should be recorded in units supported by information in the protocol. The protocol may state that the agent must be dispensed in its original bottle or the protocol may permit repackaging for dispensing. When recording the balance, verify the quantity of the agent inventory after dispensing. Complete the dispensing line item by recording the lot identifier and recorder’s initials. If unsure which lot identifier to record on the DARF, refer to PMB’s Agent Receipt video tutorial.
Let's review an example of agent dispensing at a satellite location. The satellite received 12 bottles from the control and recorded the quantity as 408 tablets because this agent can be dispensed in the original container or in a pharmacy bottle for dispensing an exact quantity. The Control Dispensing Area is managing inventory by bottle and the Satellite is managing inventory by tablet. It is not necessary for the Control and Satellite Dispensing areas to use the same accountability method. The inventory should be received and maintained consistent with the unit most appropriate for dispensing at the control or satellite location.
Multiple Lots or Multiple Strengths

If multiple lots were used in the same dispensing, record the quantity of each lot used on separate lines of the DARF. If multiple strengths were used in the same dispensing, record on each appropriate DARF. In this example, note that the dose field is consistent between the two DARFs of different strengths. We’ve finished reviewing examples on the Oral DARF. Next we’ll review examples specific to injectable agent accountability on the original NCI DARF. Keep in mind all applicable agent dispensing procedures from the Oral DARF examples.
When dispensing injectable agents on the original NCI DARF, often the dose dispensed is intended for a single administration. If the dose requires calculations, for example mg/m², record it as the total dose dispensed. Verify the calculations and any dose rounding procedures by referring to the protocol. Dispense the quantity required for dose preparation in vials. If the product is manufactured as a liquid formulation, overfill can be used and documented as such on the DARF. Do not document destruction of agent remaining in single-use vials following dose preparation.
If dispensing from a multi-dose vial, PMB recommends tracking inventory either by milligram or by vial. Tracking by milligram involves more calculations whereas the term partial can be used when tracking by vial. Record either the number of vials plus the word partial when using the vial method, or the number of vials plus the milligram amount remaining in the partial vial. You must document destruction of partial multi-dose vials on the DARF when they are no longer suitable for use.
We’ve reviewed the agent dispensing checklist and examples of accountability procedures. Another helpful resource is Section 5.3 Agent Accountability and Pharmacy Operations of the NCI Guidelines for Auditing Clinical Trials for the NCTN found on the Clinical Trials Monitoring Branch website. Institution specific policies and procedures should also be in place for dispensing investigational medications.
Dispensing areas should have procedures in place for ensuring the agent is suitable for clinical use. Once an expiration date is known, PMB will issue notification to each ordering investigator and all shipping and ordering designees at each institution. Access PMB stock notification letters through OAOP or contact PMB with any questions prior to dispensing.
Dispensing areas should not mail investigational medications to study subjects.
Lastly if any dispensing errors within a DCTD approved protocol are identified, contact PMB and provide details of the event. Institutional policies and procedures should be in line with institution specific systems to minimize errors. Refer to the FAQ available here on the PMB website for additional information.
Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist.
Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.
Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone Monday through Friday from 8:30am to 4:30pm Eastern Time or by email any time.
U.S. Department of Health and Human Services
National Institutes of Health | National Cancer Institute

http://ctep.cancer.gov/
1-800-4-CANCER

Produced June 2015