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

This video will review common reasons for returning investigational agents, the return process, how to document returns, and strategies to reduce the need for returns.
During the course of a clinical trial, it may become necessary to return PMB supplied agents. Common reasons for returning investigational agents when instructed by PMB are:

- The study is closed to accrual and all patients have completed therapy.
- The study using the agent has closed.
- The investigational agent was involved in a temperature excursion during shipping or storage.
- The investigational agent has been recalled or is expired.
If the excess supply is due to study closure or all patients being off therapy, it may be possible to transfer the supply to another CTEP sponsored IND trial. Refer to the Agent Transfers video for a detailed explanation of the transfer process.
Agent Return Checklist

- Confirm the agent was supplied by PMB and may be returned to the NCI Clinical Repository.
- Complete the Return Drug List Form.
- Subtract the return quantity from the inventory balance of the DARF.
- Package the returns.
- Ship the returns to the NCI Clinical Repository.

If the excess supply cannot be transferred, it must be returned to the NCI Clinical Repository using the following steps:

- Confirm the agent was supplied by PMB and may be returned to the NCI Clinical Repository.
- Complete the Return Drug List Form.
- Subtract the return quantity from the inventory balance of the DARF.
- Package the returns.
- Ship the returns to the NCI Clinical Repository.

Now let’s review each step.
Only un-dispensed PMB supplied agents should be returned to the NCI Clinical Repository. Keep in mind any supplies returned by a patient must be documented and destroyed per your institution’s SOPs. Please view the Oral DARF video for specifics.
“DG”= Dangerous Goods

A Dangerous Good or DG is a compound requiring special labelling and packaging for shipping. If the agent is a DG, it will be noted on the Shipment Record and stock recovery notices. If your institution does not have the capability for shipping DGs, approval is required from the PMB for local destruction. This approval must be received prior to destruction. International sites should request local destruction of all agents. Refer to the Local Destruction video for more information.
Only those clinical supplies distributed by the PMB are returned to the NCI Clinical Repository. For all other items, refer to the protocol, study sponsor, or supplier for final disposition instructions.
Once you confirm the investigational agent can be returned to the NCI Clinical Repository, complete the Return Drug List Form.
Shown here.
This form is located on the CTEP website and can be completed electronically prior to printing. Let’s review the form.
For this example, we will return 4 bottles of 200 mg pazopanib tablets. The CTEP investigator is Dr. John Smith, at State University Hospital. The protocol number is 1234, and the 200 mg pazopanib tablets come in 34 count bottles.
Start by entering the investigator name and CTEP Investigator ID. This will be the investigator noted on the shipping record, unless the agent was transferred. The investigator listed on the DARF will be the same as on the Return Drug List Form.
Next, insert the mailing address, including institution name. Enter an email address in the box at the bottom right of the form to receive a copy of the completed receipt from the NCI Clinical Repository.
Now, complete row 1: NSC Number, agent name, NCI Protocol Number, strength & formulation, lot number (or patient ID for patient-specific supplies), manufacturer, quantity including whole or partial containers.

Opened containers with un-dispensed study agent must be returned to the NCI Clinical Repository. Do not return partial injectable vials.

Indicate the reason for the return by checking the appropriate box.

If multiple lots or agents are recorded on the same form, record only 1 lot per row.
All agents on the form must have been ordered by or transferred to the investigator listed at the top of the form.
Finally, print, sign and date the form. Include a telephone number in case you need to be contacted.
The agent return can then be completed with appropriate inventory documentation, packaging, and shipping.
Document returns on the appropriate DARF. The 4 bottles being returned in our example are recorded on line 15 of this Oral DARF.

Agents stored at a satellite location must be returned to the control location, which returns them to the NCI Repository.
Package agents securely to prevent breakage. We recommend double bagging to minimize the risk to couriers and the NCI Clinical Repository staff. Enclose the Return Drug List Form, keeping a copy for your records.

Returns from multiple investigators can be shipped together. However, there must be a separate Return Drug List Form for each investigator. If multiple investigator returns are included in one shipment, please bag returns separately by investigator.

Do not place the Return Drug List form inside of the bag with the returning agent.
Ship agent returns to the address on the PMB Return Drug List Form. Room temperature is acceptable for all returns. Express delivery is not necessary. The investigator or designee is responsible for the cost of shipment.
The NCI Clinical Repository will return the completed Return Drug List Form via email to the address placed in the box in the bottom right-hand corner of the form. Review the form and reconcile any discrepancies noted by the Repository. File the form with your records.
Reducing the need for returns

- Do not order starter supplies
- Restrict requests to an 8 week supply per patient
- Use supplies up to the expiration date, when possible
- Order replacement supplies only if you have active patients
- Transfer excess supplies to another trial, when appropriate

Here are some strategies to reduce the need for returns:
- Do not order starter supplies. At a minimum, there should be a patient in screening before supplies are requested.
- Restrict requests to an 8 week supply per patient.
- Use supplies up to the expiration date, when possible.
- Do not immediately replace supplies on hand when stock recovery letters are received. Order replacement supplies only if you have active patients receiving that strength.
- Transfer excess supplies to another trial when appropriate. Refer to the Agent Transfers video for specifics.
The policies and guidelines for agent returns and other topics mentioned in this video can be found on the PMB website under Agent Management. Our FAQs also provide information on related topics.
Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist. Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone 240-6575, Monday through Friday, from 8:30am to 4:30pm Eastern Time or by email at PMBAfterHours@mail.nih.gov any time.

Check back periodically for updates. Please note that the video and any items displayed within the videos are subject to change.