Welcome to this video tutorial on Local Destruction in the PMB Investigational Drug Accountability series.

This video will review when and how to perform local destruction of PMB-supplied agents.
During the course of a clinical trial, it may become necessary to return PMB-supplied agents. There are special circumstances when the PMB directs sites to request local destruction. These special circumstances involve Dangerous Goods (DGs) or infectious agents, clinical trial sites located outside the United States or when otherwise directed by the PMB.

Refer to the Agent Returns video for the returns process for agents that are not DGs and for sites that are located in the US.
A DG is a compound requiring special labelling and packaging for shipping. The **DG** notation is located on the Shipment Record under the agent name. Any stock notifications issued for a DG will have specific instructions for requesting local destruction.

If your institution does not have the capability for shipping DGs or infectious agents, approval is required from the PMB for local destruction. This approval must be received prior to destruction. Local destruction is performed according to your institution’s standard operating procedures.

International sites should request local destruction for all PMB-supplied agents.
To begin the process, obtain the “Request for Authorization for Local Destruction” form. If you do not have this form, contact the Local Destruction Coordinator at PMBafterhours@mail.nih.gov.
Complete each field in the form. The Investigator on the form should be the same investigator on whose behalf agent was ordered or transferred. This is also the same investigator who is listed on the DARF.
Notice in the example provided here that local destruction is being requested on behalf of Dr. John Smith for pazopanib 200 mg tablets used on NCI study 1234.
The form must be signed by the investigator, shipping designee, or an authorized ordering designee prior to emailing to the PMB.
If approved, the PMB will send a signed authorization letter that contains details of the request and authorizes you to destroy the approved quantity. Proceed with destruction according to institutional policy and applicable regulations and record destruction of the supply on the appropriate DARF.
Documentation on DARF

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Lot Number</th>
<th>Number</th>
<th>Drug</th>
<th>Lot Number</th>
<th>Date</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/11/2014</td>
<td>Received from the NCI</td>
<td></td>
<td>+ 20</td>
<td></td>
<td>GLX 09735555 JT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/23/2014</td>
<td>BT</td>
<td>1234-002</td>
<td>20</td>
<td>GLX 87654321 AB</td>
<td>6/24/2014</td>
<td>4 tabs ZA</td>
<td></td>
</tr>
<tr>
<td>7/23/2014</td>
<td>BT</td>
<td>1234-002</td>
<td>20</td>
<td>GLX 09735555 AB</td>
<td>6/24/2014</td>
<td>4 tabs ZA</td>
<td></td>
</tr>
<tr>
<td>8/2/2014</td>
<td>Return to the NCI Clinical Repository</td>
<td>- 4</td>
<td>18</td>
<td>GLX 87654321 AB</td>
<td>8/31/2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8/30/2014</td>
<td>Transfer to NCI Protocol 2941 ('14273-001)</td>
<td>- 10</td>
<td>8</td>
<td>GLX 09735555 ZA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11/4/2014</td>
<td>Local Destruction per PMB Authorization</td>
<td>- 8</td>
<td>0</td>
<td>GLX 09735555 ZA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Documentation should be made for the proper lot, quantity and date of destruction. If more than one lot was destroyed, use more than one line.

In our example DARF, destruction of pazopanib 200 mg tablets occurred on November 4, 2014 and is documented on line 17 as having been authorized by the PMB.
After destruction has occurred, certify by signing the form and then email it to the PMB with a copy of the appropriate page of the DARF documenting the destruction. Only the page of the DARF reflecting the destruction should be submitted. If this documentation is not received by the PMB within 30 days, the local destruction authorization is rescinded.
Once the PMB reviews and approves the submitted documents, the completed destruction authorization form will be emailed to you with a return number.

If authorization is rescinded, this will be documented as the final disposition instead of a return number.

Regardless of the final disposition, the authorization form must be retained with your accountability records to have available for auditing purposes.
If authorization for destruction has been granted and the required documentation has not been provided 2 weeks after the date of authorization, the local destruction coordinator will email a warning letter to the requestor. The authorization will be rescinded after 30 days if required documentation is not received.

In this example warning letter, the PMB is reminding John Doe that he has not yet adequately documented destruction of expired pazopanib 200 mg tablets for Dr. Smith’s protocol after authorization was granted on October 28.
Example of Rescission

The most common reasons for rescission of local destruction authorization include:

- Date of destruction occurs before date of authorization
- Destruction is not reported within 30 days of authorization

In our example, destruction authorization was rescinded because the required documents were not provided within 30 days of authorization.
Reasons for Denial of Local Destruction Request

- Agent was not supplied by PMB
- Agent is a DG or infectious and lot has not expired and can be transferred to another protocol
- Agent is not a DG or infectious

Keep in mind there are several reasons why your initial request for local destruction may be denied.

- Agent was not supplied by PMB
- Agent is a DG or infectious and lot has not expired and can be transferred to another protocol
- Agent is not a DG or infectious

If your local destruction request is denied, follow the directions specified by the study sponsor.
The Policy and Guidelines for Investigational Agent Local Destruction 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. 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 240-276-6575, Monday through Friday from 8:30am to 4:30pm Eastern Time or by email at PMBAfterhours@mail.nih.gov any time.