

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.


http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm



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.

“DG”= Dangerous Goods

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 07/28/2014 Date Needed: 07/30/2014	Courier: Federal Express Account # XXXXX Acct Ref # XXXXX Order # 2014209-0037 Order Ref # O-1038533		
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1212	683864	Temsirolimus (CCI-779)	25 mg For Injection 1.2 mL Vial dual pack	4	WYP AI3V/1G
DG Affix Excepted Quantity Label for each shipment					

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.

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI

REQUEST FOR AUTHORIZATION FOR LOCAL DESTRUCTION
(Email completed request to PMBAfterhours@mail.nih.gov)

Investigator Name: _____

CTEP Investigator ID: _____

Complete shipping address of site: _____

NCI protocol number: _____

Agent name: _____ NSC number: _____

Agent strength	Lot number	Quantity to be destroyed
_____	_____	_____
_____	_____	_____

Reason the agent will not be used:
(expired, protocol complete, etc) _____

Name of requestor: _____
(Investigator, shipping designee, or authorized ordering designee)

Telephone number of requestor: _____

Email address of requestor: _____

Date

Signature

Local destruction may NOT occur before receipt of written authorization from PMB

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.

Local Destruction Request Form

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI

REQUEST FOR AUTHORIZATION FOR LOCAL DESTRUCTION
(Email completed request to PMBAfterhours@mail.nih.gov)

Investigator Name:

CTEP Investigator ID:

Complete shipping address of site:

NCI protocol number:

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.

DARF

Print Form
Save As
Reset Form

Collection of this information is authorized under 21 CFR 312.57. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and that investigational agents are under the control and accounted for by competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary; however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.

Public recording burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: USA, Project Clearance Branch, 6733 Rockledge Drive, NCI, Bethesda, MD 20892-7124, 01511; FDA (0925-0033). Do not return the completed form to this address.

Investigational Agent Accountability Record
Oral agents ONLY

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO. 1
CONTROL RECORD
SATELLITE RECORD

Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.				CTEP Investigator ID: 999999	
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispensing Area: IDS Pharmacy - 5th Floor Room A100	
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets				Bottle size (e.g. # tablets/bottle): 34 Tablets/bottle	

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials

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.

Authorized Signature

(expired, protocol complete, etc)

Name of requestor:
(Investigator, shipping designee, or authorized ordering designee)

Telephone number of requestor:

Email address of requestor:

10/27/14, _____
Date Signature

Local destruction may NOT occur before receipt of written authorization from PMB

The form must be signed by the investigator, shipping designee, or an authorized ordering designee prior to emailing to the PMB.

Local Destruction Authorization

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI
PMB-Supplied Agent Destruction Authorization

To: John Smith, M.D.
c/o John Doe, Pharm.D.
State University Hospital
Main Pharmacy
321 Main Street
Nowhere, US

CTEP Investigator ID: 999999
Requestor's email: JohnDoe@state.edu
Requestor's Phone: 123-456-7890

You have been granted authorization by the Pharmaceutical Management Branch, NCI to arrange for the destruction of the agent listed below. This disposition has been requested because the agent is expired.

NCI Protocol 1234
Pazopanib, 200 mg tablets NSC # 737754
Lot: GLX09735555 Quantity: 8 bottles

Please certify destruction below. Email this form to the Pharmaceutical Management Branch, NCI at PMBAfterhours@mail.nih.gov with a copy of the NCI Investigational Agent (Drug) Accountability Record Form (DARF) page that documents the destruction. If the destruction certification and DARF are not received by the PMB within 30 days of the authorization date, approval for local destruction is rescinded.

PMB Authorized Signature

10/28/14
Authorization Date

I certify that I have destroyed the above listed PMB-supplied agent in accordance with the appropriate institutional policies for the destruction of chemical, hazardous, or infectious waste.

11/4/14
Date of Destruction

John Doe
Name and Title

Signature

For PMB use only:

Final Disposition:
 RETURN NUMBER: _R14318-0023 RESCIND: _____

PMB Signature: _____ Date: _____

Retain this completed document, attached to the appropriate DARF, for as long as the DARF is retained.

cc: PMB Agent Destruction Authorization File

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

11.	7/11/2014	Received from the NCI		+ 20	22	GLX 09735555	JT				
12.	7/23/2014	BT	1234-002	800 mg daily	- 2	20	GLX 87654321	AB	8/24/2014	4 tabs	ZA
13.	7/23/2014	BT	1234-002	800 mg daily	- 2	18	GLX 09735555	AB	8/24/2014	1 Btl + 4 tabs	ZA
14.	8/1/2014	Returned from Med. Off. Build. A Satellite		+ 4	22	GLX 87654321	JT				
15.	8/2/2014	Return to the NCI Clinical Repository		- 4	18	GLX 87654321	AB	8/31/2014			
16.	9/30/2014	Transfer to NCI Protocol 2341 (T14273-0001) - 10		- 10	8	GLX 09735555	ZA				
17.	11/4/2014	Local Destruction per PMB Authorization		- 8	0	GLX 09735555	ZA				

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.

Certification of Destruction

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI
PMB-Supplied Agent Destruction Authorization

To: **John Smith, M.D.**
c/o John Doe, Pharm.D.
State University Hospital
Main Pharmacy
321 Main Street
Nowhere, US

CTEP Investigator ID: 999999
Requestor's email: JohnDoe@state.edu
Requestor's Phone: 123-456-7890

You have been granted authorization by the Pharmaceutical Management Branch, NCI to arrange for the destruction of the agent listed below. This disposition has been requested because the agent is expired.

NCI Protocol 1234
Pazopanib, 200 mg tablets NSC # 737754
Lot: GLX09735555 Quantity: 8 bottles

Please certify destruction below. Email this form to the Pharmaceutical Management Branch, NCI at PMBafterhours@mail.nih.gov with a copy of the NCI Investigational Agent (Drug) Accountability Record Form (DARF) page that documents the destruction. If the destruction certification and DARF are not received by the PMB within 30 days of the authorization date, approval for local destruction is rescinded.

I _____ 10/28/14 _____
PMB Authorized Signature Authorization Date

I certify that I have destroyed the above listed PMB-supplied agent in accordance with the appropriate institutional policies for the destruction of chemical, hazardous, or infectious waste.

11/4/14
Date of Destruction

John Doe _____
Name and Title Signature

For PMB use only:

Final Disposition:
 RETURN NUMBER: _R14318-0023 RESCIND: _____

PMB Signature: _____ Date: _____

Retain this completed document, attached to the appropriate DARF, for as long as the DARF is retained.

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.

Final Disposition

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI
PMB-Supplied Agent Destruction Authorization

To: **John Smith, M.D.**
c/o John Doe, Pharm.D.
State University Hospital
Main Pharmacy
321 Main Street
Nowhere, US

CTEP Investigator ID: 999999
Requestor's email: JohnDoe@state.edu
Requestor's Phone: 123-456-7890

You have been granted authorization by the Pharmaceutical Management Branch, NCI to arrange for the destruction of the agent listed below. This disposition has been requested because the agent is expired.

NCI Protocol 1234
Pazopanib, 200 mg tablets NSC # 737754
Lot: GLX09735555 Quantity: 8 bottles

Please certify destruction below. Email this form to the Pharmaceutical Management Branch, NCI at PMBafterhours@mail.nih.gov with a copy of the NCI Investigational Agent (Drug) Accountability Record Form (DARF) page that documents the destruction. If the destruction certification and DARF are not received by the PMB within 30 days of the authorization date, approval for local destruction is rescinded.

I _____
PMB Authorized Signature 10/28/14
Authorization Date

I certify that I have destroyed the above listed PMB-supplied agent in accordance with the appropriate institutional policies for the destruction of chemical, hazardous, or infectious waste.

11/4/14
Date of Destruction

John Doe _____
Name and Title Signature

For PMB use only:

Final Disposition:
 RETURN NUMBER: R14318-0023 RESCIND: _____

PMB Signature: _____ Date: _____

Retain this completed document, attached to the appropriate DARF, for as long as the DARF is retained.

cc: PMB Agent Destruction Authorization File

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.

Example of Local Destruction Warning Letter

******LOCAL DESTRUCTION WARNING LETTER******

Date: 11/11/2014

To: **John Smith, M.D.**
c/o John Doe, Pharm.D.
State University Hospital
Main Pharmacy
321 Main Street
Nowhere, US

CTEP Investigator ID: 999999
Requestor's email: JohnDoe@state.edu
Requestor's Phone: 123-456-7890

Subject: **NCI Protocol: 1234**
Agent Name: Pazopanib, 200 mg tablets NSC # 737754
Lot: GLX09735555 Quantity: 8 bottles

Both the certified destruction letter and the appropriate NCI Investigational Agent (Drug) Accountability Record Form (DARF) must be received by the PMB within 30 days of the authorization for destruction dated 10/28/2014. This **Local Destruction Authorization will be Rescinded (withdrawn) on 11/25/2014 if the required documentation is not received.** Please contact the local destruction coordinator if you have questions.

Thank you,
Local Destruction Authorizer
Professional and Scientific Associates, Contractor for
Pharmaceutical Management Branch (PMB)
Phone (240) 276-6575
Email PMBAfterhours@mail.nih.gov

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

I certify that I have destroyed the above listed PMB supplied agent in accordance with the appropriate institutional policies for the destruction of chemical, hazardous, or infectious waste.

____ 11/4/14 _____
Date of Destruction

____ John Doe _____
Name and Title Signature


For PMB use only:

Final Disposition:
 RETURN NUMBER: _____ RESCIND: ___ incomplete documents > 30 days__

PMB Signature: _____ Date: ___ 12/1/14 _____

Retain this completed document, attached to the appropriate DARF, for as long as the DARF is retained.

cc: PMB Agent Destruction Authorization File



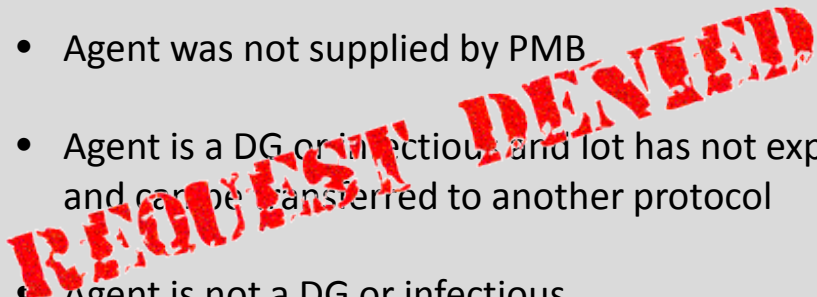
The most common reasons for rescission of local destruction authorization include:

- 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.

http://ctep.cancer.gov/branches/pmb/agent_management.htm

The screenshot displays the National Cancer Institute (NCI) website, specifically the PMB (Pharmaceutical Management Branch) Agent Management page. The page header includes the NCI logo and the text "NATIONAL CANCER INSTITUTE DCTD Division of Cancer Treatment & Diagnosis". The main navigation bar lists "CTEP Cancer Therapy Evaluation Program" and various menu items like "Home", "Investigator Resources", "Protocol Development", "Industry Collaborations", "Initiatives / Programs", "More Links", and "About CTEP".

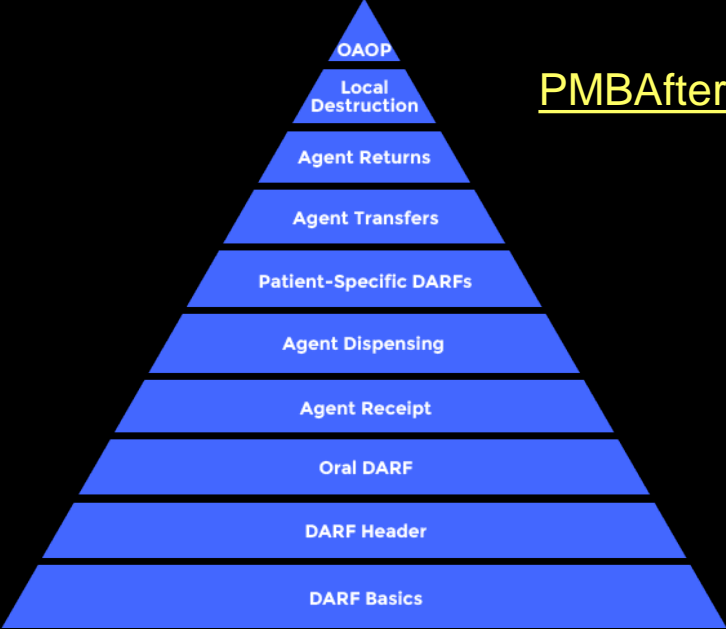
The left sidebar contains a "PMB Main" section with a "Subscribe" button and a "CTEP Branches and Offices" section. A red arrow points from the "CTEP Branches and Offices" link to the "Agent Management" section in the main content area.

The main content area is titled "Agent Management" and lists several policies and guidelines:

- Policy and Guidelines for Investigational Agent Distribution (PDF) (06/14)
- Policy and Guidelines for Investigational Agent Ordering (PDF) (09/15)
 - Online Agent Order Processing (OAOP)
 - Register for an IAM Account (Required)
 - Submit OAOP Orders
- Policy and Guidelines for Accountability and Storage of Investigational Agents (PDF) (12/13)
 - NCI Investigational Agent Accountability Record Form (PDF)
 - NCI Investigational Agent Accountability Record Form for Oral Agents (PDF)
- Policy and Guidelines for Investigational Agent Transfers (PDF) (06/14)
 - NCI Transfer Investigational Agent Form (PDF)
- Policy and Guidelines for Investigational Agent Returns (PDF) (06/14)
 - NCI Return Investigational Agent Form (PDF)
- Policy and Guidelines for Investigational Agent Local Destruction (PDF)
- Links to Commercial Drug Shortage Resources
 - <http://www.fda.gov/medwatch> — to enroll in Medwatch and receive e-mails when shortages are identified by FDA
 - <http://www.fda.gov/cder/drug/shortages/> — FDA Web site for drug shortages. Provides most current information from FDA
 - <http://www.ashp.org/shortage> — ASHP web site for drug shortages. Information regarding shortages from American Society of Health Systems Pharmacists.
 - <http://www.cdc.gov/vaccines/gen/shortages/default.htm> — CDC website for Vaccine shortages
 - <http://www.pharmacyonesource.com> — Pharmacy One Source (Free Subscription), provides MEDWATCH and other information

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.

Pharmaceutical Management Branch, CTEP, NCI



Email
PMBAfterHours@mail.nih.gov
Phone
(240) 276-6575

NCI YouTube
<https://www.youtube.com/user/NCIgov/>

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.

U.S. Department of Health and Human Services
National Institutes of Health | National Cancer Institute

<http://ctep.cancer.gov/>

1-800-4-CANCER

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