

Pearls of Wisdom: Pharmacy

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Pharmacy: Common Problems

- NCI Drug Accountability Record Form (DARF) not correctly filled out.
- Unable to track study supplied agents.
- Inadequate storage or security of study agent.

NCI Drug Accountability Record Form (DARF) not correctly filled out

- Pearl: Refer to Pharmaceutical Management Branch (PMB) website for guidelines and video tutorials:
http://ctep.cancer.gov/branches/pmb/agent_management.htm

Collection of this information is authorized under 21 CFR 312.57. The 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 the 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.

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National Institutes of Health National Cancer Institute Investigational Agent Accountability Record	Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO. CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>
Name of Institution:	NCI Protocol No.:	
Agent Name:	Dose Form and Strength:	
Protocol Title:	Dispensing Area:	
Investigator Name:	CTEP Investigator ID:	

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								



Unable to track study supplied agents

- Pearl: Keep all records!



Transfer Investigational Agent Form

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

This form is to be used for an intra-institutional transfer, one transfer/form.

TRANSFER FROM:

Investigator transferring agent: Dr.	CTEP Investigator ID:	Date of transfer:	
Name of institution:			
Street Address:	City:	State:	Zip Code:

Reason for transfer request: Protocol closed/complete Unused agent obtained for Special Exception Agent has short dating Other** _____

(**Requires verbal clarification with PMB before approval)

TRANSFER TO:

Investigator receiving agent: Dr.	CTEP Investigator ID:
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The following PMB-supplied agent for NCI-approved protocol is being transferred to NCI-approved protocol:

Received on NCI Protocol Number	Transferred to NCI Protocol Number	NSC Number	Agent Name	Strength and Formulation	Quantity	Manufacturer and Lot Number

Authorized Signature (Investigator or Designee)

Printed Name

Telephone Number

Fax Number

Email Address

Return form to:
Pharmaceutical Management Branch, CTEP, DCTD
NCI Shady Grove
Room 5W228, MSC 9725
9609 Medical Center Drive
Bethesda, MD 20892-9725

PMBAfterhours@mail.nih.gov

FAX: 240-276-7893

See http://ctep.cancer.gov/branches/pmb/agent_management.htm for further information.

All requested information MUST be supplied for form to be valid.

National Institutes of Health
 National Cancer Institute
Return Drug List

Division of Cancer Treatment and Diagnosis
 Cancer Therapy Evaluation Program

Address: (Including Institution)

FOR NCI USE ONLY

***Return only agents supplied by:
 CTEP, DCTD, National Cancer Institute***

The agents listed below were ordered by (one investigator per form only):

Dr.

NCI Investigator No.:

Check here if returned receipt should be mailed to the above address, OR fill in a fax number below

Return No.:

Signature of Authorizing Official:

Date of Authorization:

NSC Number	Agent Name	NCI Protocol Number	Strength & Formulation (Specify vials, capsules, or tablets)	Lot Number (or Patient ID for Blinded Trial)	Manufacturer	Quantity (Specify whole or partial containers)	Container Number	Action
1								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
2								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
3								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
4								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								

REPOSITORY COMMENTS

INSTRUCTIONS:

- Properly complete all sections to receive credit for the return.
- Type all information-one item, lot, or protocol per line.
- DO NOT mark in shaded areas.
- Investigator signature or signature of individual preparing this form:
- Pack the agent(s) well to minimize breakage and leakage.
- All agents may be returned via room temperature
- Enclose the completed list with the agent(s) and return to:

✂
 NCI Clinical Repository
 627 Lofstrand Lane
 Rockville, MD 20850
 Attn: Returns

Date Received:

RETURN RECEIPT: To obtain a return receipt by fax, provide your number in the space below.

Signature / Printed Name

Date

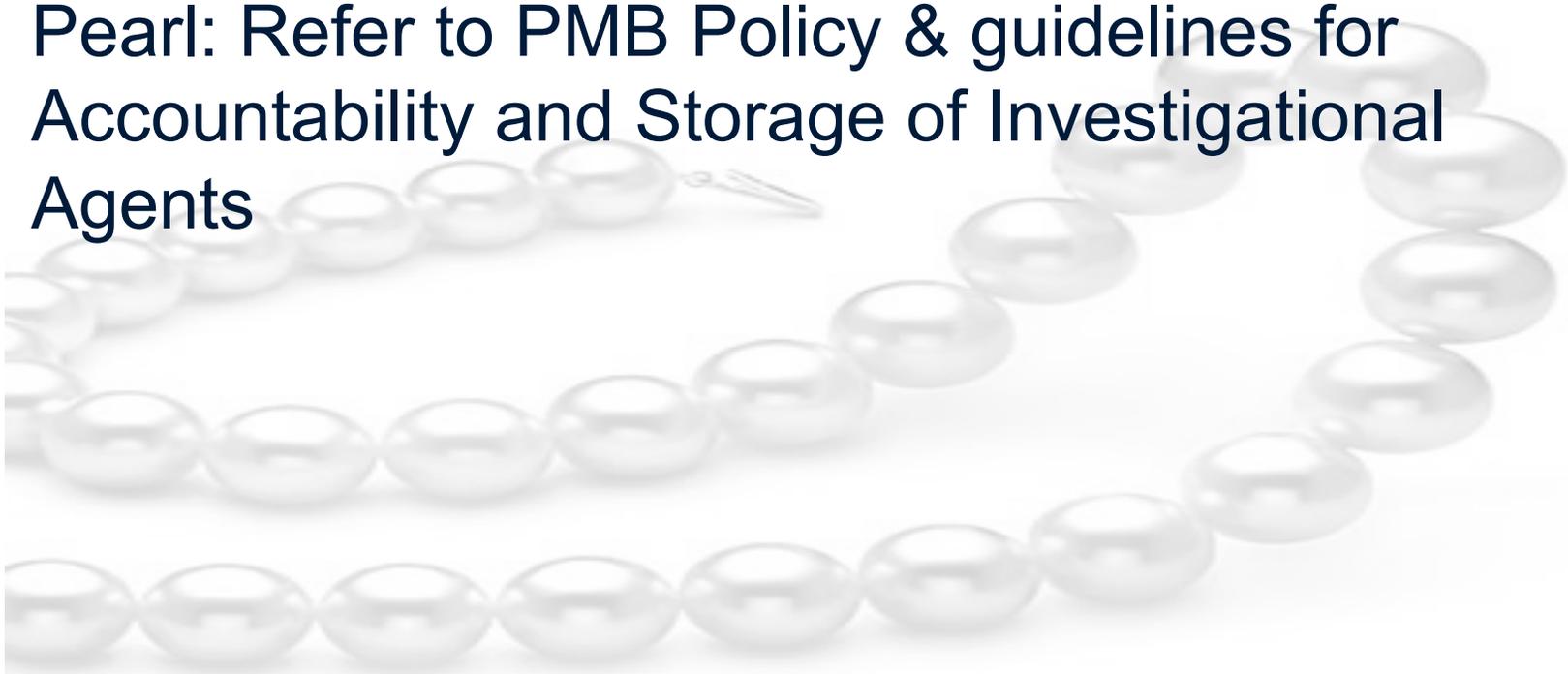
Title

Phone No.

FOR NCI USE ONLY

Inadequate storage or security of study agent

- Pearl: Refer to PMB Policy & guidelines for Accountability and Storage of Investigational Agents



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**Please save questions for the panel at
the end of the presentations.**