



Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute  
6130 Executive Blvd \* Suite 7149 \* Rockville, Maryland 20852  
Phone: (301) 496-5725 \* Order fax: (301) 480-4612 \* Other fax: (301) 402-0429 \* E-mail: [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov)

**FAQ:** We just became aware of an error that involved CTEP-supplied investigational agent. How do we report it, and is there any specific information you need?

When you identify an error involving CTEP-supplied investigational agent, notify the Branch Chief, Pharmaceutical Management Branch, CTEP as soon as possible afterward. You can make this notification in writing or by e-mail. Using regular mail, send your report to this address:

Charles L. Hall, Jr.  
Chief, Pharmaceutical Management Branch/CTEP  
6130 Executive Boulevard  
Room 7149, MSC 7422  
Rockville, ND 20852

Using e-mail, send your report to either [PMBAfterHours@mail.nih.gov](mailto:PMBAfterHours@mail.nih.gov) or [hallch@mail.nih.gov](mailto:hallch@mail.nih.gov).

The local principal investigator (PI) is ultimately responsible for all aspects of the protocol. Other staff members may develop and collate reports of medication errors and copy the PI in the final e-mail report that you send to PMB. This provides adequate documentation of the local PI's involvement in the process. Please include all of the following information in the report:

- Mailing address, phone number and e-mail address of person completing the report.
- NCI Protocol Number:
- Title of Protocol:
  - Is this a Blinded Study?
    - If yes, what is/are the patient ID(s)
- Agents:
- Treatment cycle:
- Institution Name:
  - NCI Institution Number (CTEP ID)
  - Mailing address of institution:
- Local PI:
  - Name
  - Address and Phone Number
  - E-Mail Address
  - NCI Investigator Number:
- If you sent this to a Cooperative Group who was your point of contact?
  - Point of Contact and E-mail address if known
- Date and time of Incident
- Details of this incident. (Tell us what happened)
- Explain how the error occurred. (What factors contributed to the occurrence of this incident?)
  - Was a pharmacist or pharmacy personnel involved in the error? If so, is this pharmacist or pharmacy personnel regularly assigned to a position in oncology?

## Reporting a Medication Error Involving a CTEP-Supplied Investigational Agent (page 2)

- Actions that you have taken following the incident (revised SOPs, etc)?
  - Was the PI or enrolling physician notified?
    - Date
  - Was the IRB notified?
    - Date
  - Was the patient notified?
    - Date
  - Was the Group notified?
    - Date
- Impact of the error on the patient. If the patient(s) suffered no consequences, please state clearly that the patient did not suffer any consequences.
  - If there were any adverse effects (AE) describe the AE and resolution in detail.
  - Did the patient have to be removed from the study?
  - Other impact
- Please attach the following documents
  - A corrective action plan to prevent another incident of this type
  - A copy of the Standard Operating Procedure for dispensing and administering investigational agents.

April 21, 2011

*Prepared and distributed by the Pharmaceutical Management Branch, CTEP, NCI.  
Please do not re-distribute or post without permission.  
Information in this FAQ is subject to change without notice; check periodically for updates.  
Please contact PMB at (301) 496-5725 if you have questions.*