Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute
NCI Shady Grove * Room 5W228 * 9609 Medical Center Drive * Rockville, Maryland 20850
Phone: (240) 276-6575 * Fax: (240) 276-7893 * E-mail: pmbafterhours@mail.nih.gov

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

Answer: If the medication error involves patient-specific supplies (e.g. blinded studies), report the incident immediately to PMB by calling 240-276-6575 and asking for the pharmacist responsible for the blinded agent supply. All medication errors involving CTEP IND agents are reported as soon as possible according to the instructions below.

Send your report to the attention of the PMB Branch Chief at PMBAfterHours@mail.nih.gov.

The local principal investigator (PI) is ultimately responsible for all aspects of study conduct. Other staff members may develop and collate reports of the medication error, but the local PI must be copied on the final report sent to PMB. This provides adequate documentation of the local PI's knowledge and involvement in the error reporting process. In most instances, the overall study PI and treating physician should also be notified of the incident.

Please provide the following information:

Contact information

Person completing this submission	Name, mailing address, phone number, e-mail address
Local PI	Name, CTEP investigator number, mailing address, phone number, e-mail address
Institution	Name, CTEP institution number, mailing address

Details of the incident (de-identify any patient information)

Protocol	NCI number and protocol title
Agent/s	Name and NSC number of CTEP IND agent/s
Type of supplies	If patient-specific supplies (blinded supplies) are involved: • Notify PMB first at 240-276-6575 • Provide the patient ID
Treatment cycle	Cycle number and day of cycle that event occurred
Incident	Date and time incident was discovered
Description	Provide a detailed description of what happened • For example, was commercial drug used instead of investigational supply for a CTEP-sponsored trial or PMB-supplied investigational agent used for a patient not enrolled on a CTEP-sponsored trial?* • 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?
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 • Provide the CTEP-AERS ticket number

	• Did the patient have to be removed from the study? • Other impact

Action Items

Notifications	Date Study PI, local PI and treating physician were notified: Date the IRB of record was notified: Date the patient was notified: Was the Group or Coordinating Office notified (if applicable)? • Point of Contact and e-mail address: • Date:
Actions taken following the incident	Revised SOPs? Pre-printed or protocol-specific order sets? Physician, nursing or pharmacy in-services? Other actions? Was the patient or third-party payor charged for agent in the case of a commercial/investigational switch?*
Documents to include in this submission to PMB	A copy of the Corrective and Preventive Action (CAPA) plan that addresses preventing future incidents of this type, if necessary A copy of the Standard Operating Procedure for dispensing and administering investigational agents

*Using commercial drug instead of investigational supply for a CTEP-sponsored trial or PMB-supplied investigational agent for a patient not enrolled on a CTEP-sponsored trial is an audit compliance concern and requires specific actions in addition to reporting the information requested in the tables above.

- On the drug accountability log, clearly document that commercial agent was dispensed in error (when it should have been investigational supply) or that an investigational agent was dispensed to a non-study patient in error (when it should have been commercial supply).
- Do not replace the pharmacy's supply of commercial agent with the PMB-supplied, investigationally-labeled agent or vice versa.
- Do not charge the patient or third-party payor.

Questions regarding reporting errors to PMB can be directed to the Pharmaceutical Management Branch (PMB), CTEP, NCI by calling (240) 276-6575 Monday through Friday from 8:30am to 4:30pm Eastern Time or by emailing PMBAfterHours@mail.nih.gov at any time.

April 15, 2016