Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI

Policy and Guidelines for INVESTIGATIONAL AGENT LOCAL DESTRUCTION

Policy:

Investigators/Designees must request local destruction of <u>un-dispensed</u> PMB-supplied agents when special circumstances prohibit the return of agent to the NCI Clinical Repository.

Guidelines:

- PMB requires that all PMB-supplied agents are returned to the DCTD, NCI for accountability and final disposition.
 - See FAQ: "Returning agent to NCI Clinical Repository" for detailed instructions
- There are special circumstances when local destruction authorization should be requested instead of returning investigational agents to the NCI Clinical Repository.
 - o If the agent is considered a Dangerous Good (DG) or infectious substance for shipping purposes (as noted by **DG** on the Shipping Record or in a stock recovery notice), sites may request local destruction authorization. Sites must request local destruction if they do not have personnel who are duly trained and certified in Dangerous Goods Regulations and do not have access to the necessary packaging, labels and documentation to execute such shipments.
 - International sites are to request local destruction authorization for all PMB supplied investigational agents to avoid complications with international shipping.
 - When otherwise directed by PMB.
- See Investigational Drug Accountability Training Video: Local Destruction at https://ctep.cancer.gov/branches/pmb/drug training videos.htm for detailed instructions on:

- Submitting the Request for Authorization for Local Destruction form to PMB by e-mail to <u>PMBafterhours@mail.nih.gov</u>, ATTN: Local Destruction Coordinator.
- Receiving authorization from PMB to perform the local destruction according to institutional policy and applicable regulations.
- o Performing the destruction at the site and documenting on the DARF.
- Certifying the destruction by signing the authorization letter and returning to PMB with a copy of the DARF.
- Obtaining a Return Number from PMB once all documentation is reviewed and confirmed.

Questions or comments regarding investigational agent local destruction should be addressed to the Pharmaceutical Management Branch by telephone (240-276-6575) Monday through Friday between 8:30 am and 4:30 pm (ET) or email PMBAfterHours@mail.nih.gov anytime.

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