



Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute
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FAQ: How do I return investigational agent that I don't need anymore?

Make every effort to minimize the amount of agent ordered and returned unused. Everything you return to the NCI must be destroyed. Limit orders to an 8 week supply or less. Investigators or their designees should return unused NCI supplied investigational agent to the NCI Clinical Repository when:

- The agent is no longer required because the study is completed or discontinued and the agent cannot be transferred to another protocol.
- The agent is outdated. Return outdated agents with a firm expiration date, or when written notification is received from PMB.
- The agent is unfit for use. Contact the PMB prior to returning investigational agents because of stability concerns. This could be loss of refrigeration or if the agent becomes unfrozen. Do NOT return broken vials. Destroy broken vials at your clinical site according to your local destruction policy, and state and federal law after documentation on the DARF.

When you cannot transfer in-date agents to another NCI sponsored protocol, use these guidelines to return them to the NCI Clinical Repository.

1. Regulations require that the NCI destroy all returned agents, so please be prudent about ordering just what you need.
2. Do not return opened or partially used vials or bottles. Do not return agent that has been dispensed to a patient and returned.
3. Return only NCI supplied agents to the NCI Clinical Repository. Do not send agents from other sources to the NCI Clinical Repository.
4. Return items within 90 days of their expiration.
5. If the agent is considered a dangerous good (DG) for shipping purposes (as noted by ****DG**** on the Shipping Record), call PMB if your site does not have an individual certified to do DG shipping to inquire about approval for local destruction.

Complete all sections of the Drug Return List (NIH-986, available on the CTEP web site—<http://ctep.cancer.gov>) neatly and accurately.

- Please double check all quantities and lot numbers.
- Follow the instructions exactly as they are stated on the form.
- Fill out the area on the bottom right of the form if you want a faxed return receipt confirmation.
- Keep a copy for your records. Maintain this form, as with all other forms, for 2 years after the IND withdrawal letter designating an actual withdrawal effective date is received by your site. Your records should be readily retrievable.
- Enclose the Return Drug List with the agents you are returning.
- Package agents securely to prevent breakage. We recommend double bagging to minimize the risk to couriers and the NCI Clinical Repository staff.
- Ship all agents at room temperature. Express courier is not required.
- The "ship-to" address is located on the form. All shipping costs are the investigator's responsibility.
- The NCI repository does not accept Collect or COD shipments.

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*Prepared and distributed by the Pharmaceutical Management Branch, CTEP, NCI.
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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.*