DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH

TITLE: Return of Unused Investigational Drug from Subject to the Pharmacy		
POLICY #: INV-102	**Page:** 1 of 3	**Effective Date:** ~~8~~1/31/~~17~~2020

1. POLICY STATEMENT:

There is a standard procedure for returning unused investigational drug, received from a subject, to the pharmacy.

Commented [SC1]: Minor edits to remove old terminology

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

3.1. ~~Overall~~ Principal Investigator (PI)
~~3.2. Site Responsible Investigator~~
~~3.3.~~3.2. Subinvestigator
~~3.4.~~3.3. Research Nurse
~~3.5.~~3.4. Study Coordinator
~~3.6.~~3.5. Research Pharmacy Personnel

4. DEFINITIONS:

4.1. None

5. POLICY:

5.1. The ~~Overall~~ PI or designated research team member will instruct research subjects to return all of their unused investigational drug dispensed on a protocol, including all empty containers (bottles, blister packs etc.), to the research nurse or study coordinator at the next scheduled visit. Used syringes, vials and oral liquids will not be collected.

5.1.1. Receiving investigational drug from subjects via mail is not encouraged. See INV-101 for more information.

5.2. The ~~Overall~~ PI or designated research team member is responsible for assessing drug compliance for all drugs used on a protocol, regardless of IND status. See INV-103 for more information.

5.3. Unused drug, under an IND, dispensed by the research pharmacy will be returned to the research pharmacy as soon as possible, with the returned date written on the packaging.

Version: 9
Effective Date: 1/31/20
Last Reviewed Date: 11/12/19

5.3.1. For industry sponsored trials: The DFCI, MGH, and BIDMC research pharmacies will not retain any returned unused investigational drug. Returned unused investigational drug will be destroyed as soon as possible per institutional guidelines.

5.3.2. For non-industry sponsored trials: The returned unused investigational drug will not be retained by the research pharmacy. Returned unused investigational drug will be destroyed as soon as possible per institutional guidelines.

5.4. **Destruction of Returned Empty and Partially Used Investigational Drug under an IND that was dispensed to a subject**

5.4.1. At MGH: The MGH Oncology Clinical Trials Pharmacy will not save subject returns. The research nurse will review subject compliance at the protocol mandated visits and complete an internal form entitled "MGH Cancer Center Medication Return Form," which will document the amount of unused investigational drug. The completed form along with empty and/or partially used investigational drug containers will be taken to the pharmacy for review. Pharmacy personnel will verify the accuracy of the completed cancer center return form against the physical count of empty and/or partially used investigational drug containers. In instances where there is a discrepancy, the empty and/or partially used investigational drug containers will be saved for the clinical trials monitor to review at the next scheduled visit, or for 90 days, whichever comes first. Otherwise the empty and/or partially used investigational drug containers will be sent to destruction per MGH pharmacy standard operating procedure. The completed form will be saved in the pharmacy binder or protocol file and made available for review for the clinical trial monitor.

5.4.2. At DFCI and BIDMC: The research pharmacy will not save subject returns. A research team member will review subject compliance at the protocol mandated visits and document the amount of unused investigational drug in the subject's medical record or research chart. The empty and/or partially used investigational drug containers will be taken to the DFCI outpatient Pharmacy or the BIDMC East Campus Research Pharmacy for review and documentation on the protocol-specific patient return log. Once in the pharmacy, the investigational drug containers are held securely at all times. Research pharmacy personnel will double count the return and sign in the appropriate column of the protocol-specific patient return log. If there is

a discrepancy in the count, research pharmacy personnel will contact the research team. If there is no resolution for the discrepancy, the empty and/or partially used investigational drug containers will be saved for the clinical trial monitor to review at the next scheduled visit or for 90 days, whichever comes first. If there is no discrepancy in the count, the empty and/or partially used investigational drug containers will be de-identified, placed in the secure chemotherapy waste bin and sent to destruction per DFCI and BIDMC pharmacy standard operating procedure. The completed protocol-specific patient return log will be available for the clinical trial monitor to review.

5.5. When investigational drug is dispensed but not returned by the subject, the research team will make attempts to acquire the unused investigational drug from the subject or the family.

5.5.1. All attempts to retrieve the investigational drug will be noted in the subject's medical record or research chart.

5.5.2. A protocol violation report to the IRB is not required.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED FORMS & TOOLS:

None