TITLE: Research Pharmacy Standard Policy		
POLICY #: INV-100	**Page:** 1 of 5	**Effective Date:** 8/31/17

1. POLICY STATEMENT:

DF/HCC research pharmacies follow a standard set of policy requirements for clinical trials.

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

3.1. Research Pharmacy Personnel

4. DEFINITIONS:

4.1. None

5. POLICY:

5.1. **Drug Accountability**

5.1.1. At MGH, DFCI, and BIDMC a standardized electronic drug accountability form is utilized for maintaining drug accountability records for all DF/HCC clinical trials, except those which are sponsored by the NCI. In those cases, the MGH, DFCI and BIDMC can print the electronic drug accountability forms in either standard NCI DARF (drug accountability record form) format or in the NCI oral DARF format.

5.1.2. Elements of the DARF:

- Institution Name
- Investigator Name
- Protocol Title and Number
- Agent Name, Strength, and Formulation
- Dispensing Location
- Recorder Date and Initials
- Transactions (receipts, dispensing, transfers, disposition)
- Receipt
- Date, Quantity, Lot Number
- Dispensing
- Subject Information, Date, Quantity, Lot Number

- Dosing Information
- Transfers
- Date, Quantity, Location
- Disposition
- Unused Drug Returns and/or Destruction
- Lot Number and Quantity on Hand

5.1.3. No sponsor-provided forms will be utilized for drug accountability. Drug accountability will only be maintained for the investigational drugs supplied by the sponsor or procured by the pharmacy on behalf of the sponsor for use on the clinical research trial (i.e., agents provided at no cost to the patient). The research pharmacies will not provide lot numbers or expiration dates to sponsors for commercial agents.

5.2. **Storing Used Supplies (vials, syringes, bags, tubing)**

5.2.1. Only oral investigational drugs, which are not liquids, will be stored. For further information please see INV #102.

5.2.2. IV bags, unit dose bottles, used syringes/bags, tubing, liquids and used vials will not be stored nor will any record of destruction be kept.

5.3. **Temperature Monitoring and Excursion Procedures**

5.3.1. The research pharmacies will follow the temperature requirements that comply with the United States Pharmacopeia (USP) standards, as defined below (USP Standard (USP 33-NF28, Sections 10.30.10, 10.30.40, and 10.30.60)):

- Controlled Room Temperature: 20˚ to 25° Centigrade (C) (68 to 77° Fahrenheit (F)); excursions between 15 and 30 C (59 and 86 F) allowed as experienced in pharmacies and hospitals.
- Refrigerated Temperature: 2° to 8° C (36 to 46 F)
- Freezer Temperature: - 25° to -10° C (-13 to 14 F)
  Currently, there are not established USP standards for Ultra Low Freezer Temperatures. The research pharmacies will follow: - 80 to -60 C (-112 to -76 F)

5.3.2. Controlled Room Temperature: Reportable excursions are defined as a temperature deviation of >±5˚C from the acceptable temperature range as defined above, sustained for a contiguous time period of up to twenty-four

hours as experienced in pharmacies and hospitals.

5.3.3. Refrigerated, Freezer, and Ultra Low Freezer Temperature: Reportable excursions are defined as a temperature deviation of ±1˚C from the acceptable temperature ranges as defined above, sustained for a contiguous time period of 30 minutes or more.

5.3.4. The research pharmacies will use only the Standardized Temperature Excursion Form for reporting all temperature excursions.

5.3.5. The research pharmacies will quarantine IP until written approval is received from the sponsor.

5.3.6. The research pharmacies will use only the institutional based temperature monitoring system.

5.4. **Transfer of Investigational Drug(s) between DF/HCC Sites**

5.4.1. Investigational drug must be shipped from the sponsor to each of the participating DF/HCC pharmacies.

5.4.2. In limited situations for investigator-sponsored studies only, if the drug company does not agree to send drug to each of the participating DF/HCC pharmacies, the lead institutional pharmacy may approve transfer of drug to the other participating DF/HCC pharmacies. Refer to INV-101 for more information.

5.5. **Investigational Product Handling**

5.5.1. All empty and partially used containers of investigational drugs are to be treated as hazardous substances with disposal occurring immediately after use into the hazardous drugs waste stream containers. The research pharmacies under no circumstances will store used product containers (vials, bottles, empty boxes etc.), un-blinded/open label tear off labels, or ancillary supplies for accountability purposes. Products will be prepared per standard pharmacy guidelines and used vials (or other products) will be destroyed as per institutional policy. Samples derived from prepared doses or packaged products will not be retained for sponsor purposes (IE. Testing for Bioavailability, stability, etc.)

5.5.2. The DF/HCC research pharmacies will not perform any weighing of IV bags or bottles.

5.5.3. Onsite destruction is permitted per institutional policy.

5.6. **Destruction of Used Oral Agents**

5.6.1. Returned supply by a participant will be destroyed per institutional guidelines following reconciliation by the study staff and the pharmacy in accordance with INV-102.

5.7. **Disposition of Remaining Investigational Drug Not Dispensed to Subjects**

5.7.1. Unused drug is defined as drug remaining after all patients have completed treatment. Unused drug remaining after all patients have completed treatment will be retained for 30 days unless agreement is made with the research pharmacies.

5.7.2. Expired drug is defined as drug whose expiration date has passed.

5.7.3. Medications that expire will be held for 30 days from date of expiration for sponsor disposition. At the end of the 30 days, any remaining expired drug will be destroyed per each research pharmacy's institutional policy.

5.8. **Pharmacy Monitoring Visits**

5.8.1. External Sponsors conducting routine monitoring visits of any DF/HCC research pharmacy must do so in accordance with MON-101: Research Conduct Oversight by External Sponsors and INV-OP-1: Mandatory Research Pharmacy Standard Procedures

5.9. **Delegation of Authority**

5.9.1. One research pharmacist from each DF/HCC participating site will be documented in the Delegation of Authority log in accordance with RCO-200: Documenting Delegation of Authority.

5.10. **Control of Investigational Product**

5.10.1. Unless approved by the sponsor, the PI, and the IRB, the research pharmacy will not supply or dispense an investigational drug to any person not authorized to receive it under the protocol.

5.11. **Training**

5.11.1. The institution will decide on the relevance and acceptable mode of training for the research pharmacy staff needed to execute clinical trial operations. The ancillary research pharmacy staff involved in execution of the trial will receive adequate training provided by the research pharmacy per institutional guidelines.

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 Harmonization – E6

8. RELATED PROCEDURES & TOOLS:

INV-OP-1: Mandatory Research Pharmacy Standard Procedures
Standardized Temperature Excursion Form