| **TITLE:** Transfer of Investigational Drug | | |
|---|---|---|
| **POLICY #:** INV-101 | **Page:** 1 of 5 | **Effective Date:** ~~8/31/17~~1/31/2020 |

## 1. POLICY STATEMENT:

The transfer of investigational drug from main DF/HCC delivery site to another location is permissible and may require authorization from the Sponsor.

## 2. BACKGROUND:

It is not advisable to ship investigational drug received from the sponsor to another location. Beyond the specific regulations that prohibit the interstate shipping of investigational drug, there are security and storage constraints that would limit the feasibility of transferring investigational drug to another location. However, during the study, there may be circumstances where transfer of investigational drug may be requested or required by the sponsor or the DF/HCC site research pharmacy. Such circumstances should be evaluated carefully by the ~~Overall~~ Principal Investigator in conjunction with the sponsor to determine if transferring drug to another location would violate any federal or state law.

## 3. RESPONSIBLE PERSONNEL:

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

## 4. DEFINITIONS:

4.1. None

## 5. POLICY:

5.1. **Transfer between DF/HCC Sites:**

5.1.1. Procedures at DF/HCC Transferring Site

5.1.1.1. If it is determined that transferring of investigational drug to another DF/HCC site is necessary during the study and that no federal or state laws would be violated, the research pharmacy may transfer investigational drug to another DF/HCC site provided appropriate documentation is maintained, including the following:

**Commented [SC1]:** Minor updates throughout to remove old terminology and clarify investigator responsibilities.

5.1.1.1.1. Condition of transfer (i.e., if investigational drug will be transferred in a locked box or in ambient, refrigerated, or frozen condition)

5.1.1.1.2. Quantity and identity of the investigational drug to be transferred

5.1.1.1.3. Screening/randomization number for the subject who will receive the investigational drug at the receiving site, if known

5.1.1.1.4. Receiving site and site contact person's contact information

5.1.1.2. Appropriate documentation to support the transportation activity will include:

5.1.1.2.1. Transfer record that documents and confirms each step of the transfer is controlled and secured such as:

5.1.1.2.1.1. Pick-up date

5.1.1.2.1.2. Pick-up condition of the investigational drug

5.1.1.2.1.3. Delivery date

5.1.1.2.1.4. Receipt individual's name and signature

5.1.1.2.1.5. Delivery condition of the investigational drug

5.1.1.2.2. Correspondence documentation that confirms the receiving site's knowledge and readiness to receive the investigational drug.

5.1.1.2.3. Drug Accountability Record updated to reflect the change in investigational drug inventory.

5.1.2. Procedures at DF/HCC Receiving Site

5.1.2.1. Upon receipt of investigational drug from another DF/HCC research pharmacy, an authorized pharmacy staff member will unpack the investigational drug and verify the accuracy of the transfer form against the physical inventory in the shipment. If the inventory matches the

investigational drug present, the Transfer Form is completed and sent to the DF/HCC transferring site. The drug accountability record at the DF/HCC receiving site is updated to reflect the change in investigational drug inventory.

5.1.2.2. In instances where there is a discrepancy, the DF/HCC receiving site will contact the DF/HCC transferring site to reconcile the shipment.

5.2. **Transfer between DF/HCC Site and DF/HCC Subject**

5.2.1. Sending Investigational Drug to DF/HCC Subjects

5.2.1.1. The ordering physician or designated research team member will obtain prospective, written approval from the study's sponsor and the ~~Overall~~ PI to ship investigational drug to a subject. Sponsor and ~~Overall~~ PI authorization can be documented in an email or Note to File. Records will be maintained with the essential regulatory documents.

~~5.2.1.1.1. Note: A sponsor may be a pharmaceutical company or an investigator, in the case of PI initiated~~investigator-sponsored ~~research.~~

5.2.1.2. Upon receiving copies of the authorizations, DF/HCC research pharmacy personnel will package the investigational drug, so the contents cannot become damaged or dislodged during shipment. They will provide the package to the ordering physician or designated research team member for shipping and tracking.

5.2.1.3. Upon receipt of the package, the ordering physician or designated research team member will address the package to the subject, being careful not to identify the nature of the contents on the outside of the mail piece. The outer mailing wrapper or container must be free of markings that indicate the nature of the content.

5.2.1.4. The ordering physician or designated research team member will ship the package via a traceable courier service (e.g., Fed Ex, UPS, etc.) to ensure proper disposition control of the investigational drug and temperature control during shipment. Packages must not be shipped via the US Postal Service.

5.2.1.5. The ordering physician or designated research team member will attach the shipping form to the sponsor and ~~Overall~~ PI authorizations and file these documents with the essential regulatory documents for the site.

5.2.1.6. The ordering physician or designated research team member will contact the subject within 2 business days to confirm receipt of the investigational drug. Contact efforts and confirmation of receipt of the investigational drug will be documented in the medical record or research chart.

### 5.2.2. Receiving Investigational Drug from DF/HCC Subjects

5.2.2.1. The ordering physician or designated research team member will obtain prospective, written approval from the study's sponsor and the ~~Overall~~ PI for the subject to return investigational drug through the mail. Sponsor and ~~Overall~~ PI authorization can be documented in an email or Note to File.

~~5.2.2.1.1. Note: A sponsor may be a pharmaceutical company or an investigator, in the case of PI initiated~~investigator-sponsored ~~research.~~

5.2.2.2. The ordering physician or designated research team member will file the sponsor and ~~Overall~~ PI authorizations with the essential regulatory documents for the site.

5.2.2.3. After receiving authorization, the ordering physician or designated research team member will provide the subject with a prepaid mailer or account number for a traceable courier service (e.g., Fed Ex, UPS, etc.) to ensure proper disposition control of the investigational drug and temperature control during shipment. Packages must not be shipped via the US Postal Service. Confirmation of the return will be assessed within 10 calendar days.

5.2.2.4. The ordering physician or designated research team member will instruct the subject on the following packaging and shipping requirements:

5.2.2.4.1. Put all unused investigational drug (bottles, blister packs, etc.) in a padded or bubble envelope so that the contents cannot

become damaged or dislodged during shipment. Used syringes, vials and bottles of liquid will not be collected.

5.2.2.4.2. Use the pre-addressed label. Do not identify the nature of the contents on the outside of the mail piece. The outer mailing wrapper or container must be free of markings that indicate the nature of the content.

5.2.2.4.3. Ship the package via the traceable courier service.

5.2.2.4.4. Contact the ordering physician or designated research team member to confirm shipment of the investigational drug.

5.2.2.5. The ordering physician or designated research team member will document receipt of the investigational drug in the medical record or research chart.

5.2.2.6. Assessment of drug adherence will follow the practices outlined in the protocol and/or according to DF/HCC policy.

## 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