1. BACKGROUND:

DF/HCC research pharmacies may follow different institutional processes; however, there are certain mandatory procedures that apply to all DF/HCC institutional research pharmacies.

2. ASSOCIATED DF/HCC POLICIES:

2.1. INV-100
2.2. INV-101
2.3. INV-103

3. PROCEDURE:

3.1. Investigational Drug Receipt

3.1.1. The sponsor is required to provide the research pharmacies with the expiration or a re-test date for the investigational drug at the time of shipment or upon request. This can be labeled on the container or equivalent documentation. Not receiving expiration or re-test information in that time frame could result in the investigational drug being placed into quarantine. This may result in unavailability of the investigational drug to patients.

3.1.2. In the event that the investigational drug container needs to be re-labeled with updated re-test information, the research pharmacies will not assume the responsibility of the task. The sponsor shall send a representative/study monitor to the research pharmacy for re-labeling purposes. This task shall be completed in a timely manner before the expiration otherwise the investigational drug could be temporarily quarantined which may result in unavailability to patients.

3.2. Ambient Temperature Monitoring

3.2.1. The research pharmacies will not retain template. Should the sponsor require return of the template, a prepaid shipping method will be provided at the time the investigational drug is shipped and the shipping receipt must clearly indicate that return is necessary. The template product should enable the staff to retrieve the necessary information, which will be retained in the research pharmacy as soon as the shipment is checked in by attaching it to the shipping receipt.

3.3. Product Labeling by Suppliers

3.3.1. The supplier must deliver inventory with labeled immediate containers (individual bottle or vial). Nude containers will not be accepted. Inventory that does not include labeling as described below will be reviewed by each institutional pharmacy and a decision will be rendered as to its acceptability.

3.3.2. Labeling Standards: (*=Mandatory)

- *Complete Name of Product (eg, nab-paclitaxel, or salt form when more than one exists)
- *Dosage/Concentration
- *Formulation
  - *Quantity
  - *Lot/Batch Number
- *Storage Conditions
- Name and Address of Manufacturer
- Expiration Date (if available)
- CFR Statement: Caution; new drug – limited by US or Federal law to investigation use
- Recommendation of minimum size 8 font with name in bold

3.4. **Research Pharmacy Start Up Drug Supplies**

3.4.1. Starter Supply: To initiate the trial in a timely manner, the sponsor shall supply sufficient study drug as designated by institutional target accrual. In those rare instances where starter supply cannot be shipped, the PI or institutional designee will be notified and confirm agreement to proceed.

3.4.2. Resupply- If the sponsor is controlling drug re-supply, it is their responsibility to ensure that the research pharmacy has adequate supply on hand for trial continuation and future enrollment.

3.4.3. Commercial Supply medications on Investigational Protocols: Sponsor shall provide or provide funding for purchase of study supply of commercial drug being used in a research protocol so that it may be provided at no cost to the organization or the patient. Lot numbers of commercial drugs provided free of charge will be recorded.

3.5. **Interactive Web, Voice Response Systems (IWRS/IVRS)**

3.5.1. Upon receipt of a shipment of investigational drug, the research pharmacies will acknowledge in the sponsor-based IVRS/IWRS system if indicated for that particular clinical trial.

3.5.2. The following outlines the scope of research pharmacy responsibility:

3.5.2.1. Verification in IVRS/IWRS of drug receipt will be the only function. Additional manual management will not be performed. Special functions for blinded trials in which pharmacy controls the blind will be decided on a case by case basis.

3.5.2.2. The research pharmacies will not utilize IVRS/IWRS to document drug accountability, which is already documented in the electronic or paper DARF. This includes documentation of oral

patient returns.

3.5.2.3. The sponsor must ensure IVRS/IWRS study drug assignments will be sent to research pharmacy. A mechanism must be designed by the sponsor and or study team to allow assignments to be relayed to research pharmacy via a secured fax system or email.

3.5.2.4. The research pharmacies must be provided with an adequate number of access codes determined by the site for IVRS/IWRS access prior to the initiation of a trial and if required, will participate only in pharmacy-based training for the system.

3.6. **Training**

3.6.1. Training requirements per DF/HCC Policy EDU-100 apply to pharmacy research staff.

3.6.2. Examples of modes of training include the following but not limited to:

3.6.2.1. In-service education: The principle investigator and/or designee will provide an educational in-service when requested.

3.6.2.2. Pharmacy Staff communication: The clinical research pharmacists notify the pharmacists of newly activated protocol and highlight key points of the protocol as needed. Notification of new protocols may be given at staff meetings, via email or through direct verbal communication.

3.6.3. Self-Education: The pharmacist can review the most current version of the protocol document which is posted to OncPro.