TITLE: Research Pharmacy Standard Procedures		
SOP #: INV-100 *(formerly PM-403)*	**Page:** 1 of 3	**Effective Date:** 3/1/14

1. POLICY STATEMENT:

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

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

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

4. DEFINITIONS:

4.1. None

5. PROCEDURE:

5.1. Drug Accountability

5.1.1. NCI Drug Accountability Record (NCI DAR) is the form utilized for maintaining drug accountability records for all DF/HCC clinical trials.

5.1.2. It is not DF/HCC practice to record lot number for commercially available drugs.

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

5.2.1. Only oral investigational drugs under an IND, which are not liquids, will be stored.

5.2.2. IV bags, unit dose bottles, used syringes/bags, tubing, and used vials will not be stored.

5.3. Temperature Monitoring

5.3.1. Temperatures of pharmacy refrigerators, freezers, and outpatient storage areas are maintained within acceptable ranges determined by protocol.

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 sites.

5.4.2. In special circumstances, investigational drug may be transferred between DF/HCC sites listed on the IRB-approved protocol front sheet with written sponsor approval at the beginning of the trial or on a case by case basis, if applicable. *Refer to the DF/HCC policy on transfer of investigational drug for more information.*

5.5. Destruction of Used Chemotherapy Vials

5.5.1. Onsite destruction is permitted. Institutional policy will be provided upon request. Vials cannot be stored due to biohazard 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 pharmacy staff. Supply will be destroyed within 72 hours of being returned to the pharmacy. There will be no written documentation regarding the time of destruction.

5.7. Disposition of Remaining Investigational Drug Not Dispensed to Subjects

5.7.1. Any undispensed/unopened investigational drug will be returned to the sponsor or destroyed onsite per institutional guidelines **within 90 days** following the completion of research drug dosing by the last subject on the protocol. The sponsor must be notified and indicate whether the drug should be returned or destroyed. If no response is received within 10 business days, destruction will occur. A member of the research team must notify the research pharmacy at all sites at which the trial is being conducted when the last subject on the protocol at that site has completed research drug dosing.

There will be no written documentation regarding the time of destruction.

5.8. Pharmacy Monitoring Visits

5.8.1. A minimum of 4 weeks advance notice must be given to the research pharmacy.

5.8.2. Visits may be booked by a member of the research team or by the monitor directly.

5.9. Delegation of Authority

5.9.1. One research pharmacist from each DF/HCC participating site will sign the Delegation of Authority Log as the pharmacy representative for that site. Pharmacy technicians and other ancillary staff will not be listed as they work under the supervision of a pharmacist.

5.10. Control of Investigational Product

5.10.1. Unless authorized by the sponsor, the research pharmacy will not supply or dispense an investigational drug to any person not authorized to receive it.

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