TITLE: Research Pharmacy Standard Procedures	
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Applicable Regulations & Guidelines: N/A

Other References: Institutional Pharmacy Policies and Procedures
PM-404 Return of Unused Study Medications to Pharmacy
DF/HCC Site Management Plan
DF/HCC Research Pharmacy Contact List

Responsible Personnel: Research pharmacists, pharmacy technicians, research study team

Policy Statement: DF/HCC institutional research pharmacies follow a standard set of procedures for DF/HCC clinical trials

Procedure:

1) Drug Accountability

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

    b) It is not DF/HCC practice to record lot number for commercially available study medications.

2) Storing Used Supplies (vials, syringes, bags, tubing)

    a. Only oral IND drugs which are not liquids will be stored
    b. IV bags, unit dose bottles, used syringes/bags, tubing, and used vials will not be stored

3) Temperature Monitoring
    a. Temperatures of pharmacy refrigerators, freezers, and outpatient storage areas are maintained within acceptable ranges.

4) Transfer of study drug(s) between sites
Study drug must be shipped from the sponsor to each of the participating sites.

In special circumstances, study drugs may be transferred between sites listed on the protocol front sheet with written sponsor approval at the beginning of the trial or on a case by case basis, if applicable.

5) Destruction of used chemo/bio

   Onsite destruction is permitted. Institutional policy will be provided upon request.

6) Return or destruction on unused/unopened study medications

   For sponsor-initiated trials: Any unused/unopened study medication should be returned to the sponsor or destroyed onsite per institutional guidelines **within 90 days** following the completion of study drug treatment by the last participant on the study. The study team should notify the research pharmacy when the last participant on the study at that site has completed study drug treatment.

   If the sponsor does not ship back unused/unopened study medication within 90 days following study closure to enrollment AND the protocol or other study document does not give specific instruction for the return of the unused/unopened study medication, then the pharmacy may destroy unused /unopened study medication per institutional guidelines.

7) Pharmacy Monitoring Visits

   a. A minimum of 2 weeks advance notice must be given to the pharmacy.
   b. Visits may be booked by the study coordinator or by the monitor directly.