Policy Statement

There is a standard procedure for processing study medications returned by the Patient. Any study medication returned by the patient is considered cytotoxic waste and cannot be distributed for further or subsequent use. The procedure for documentation and destruction of used study medication is outlined below.

Definition

Study Medication: Investigational medications supplied by M.D Anderson pharmacy for a designated protocol. This does not include commercially available medications used on a clinical trial.

Protocol Mandated Medications: Medications required by the protocol which impact patient safety and or the scientific integrity of the study regardless of whether they are investigational or commercially available.

Patient Returned Medication (PRM): Medications dispensed to the patient and returned to the study team for accountability and destruction.

Responsible Personnel

Principal Investigators, Research Nurses, Nurse Practitioners, Physician Assistants, Pharmacists, Study/Data Coordinator and licensed healthcare provider
Procedure

Patient Returned medications (PRM) must be placed in the blue biohazard waste drum or delivered to Investigational Pharmacy Services for proper destruction. Prior to delivery of PRM to the Investigational Pharmacy or destruction by Environmental Health and Safety, the following steps must be followed and documented:

The study team will instruct research participants to return all unused study medication as required by the protocol, including all empty containers (bottles, blister packs etc.) to the study team designee.

1. The Principal Investigator or study team designee is responsible for assessing study medication compliance according to protocol requirements. Drug accountability will be captured on the MD Anderson Standard Investigational Drug Accountability/Reconciliation Form (IDRF) in lieu of sponsor based forms. The IDRF is a sample template. Departments can use their own forms as longs as it captures the quantity of drug returned and destroyed in a consistent manner. Final accountability of all PRM will be documented and maintained by the study team according to departmental standard operating procedures. This record will serve as source documentation and final accountability and will be made available to the Sponsor and/or IND holder.

2. Attempts to retrieve unused study medication and/or medication containers will be documented according to departmental standard operating procedures by the study team.

3. The study team designee will deliver the PRM to the Investigational Pharmacy after accountability has been completed for destruction per institutional policy (Policy ADM0166). The department may also call Environmental Health and Safety for pick up and destruction of the PRM in the blue biohazard drum. No PRM is to remain in the departments after accountability has been completed by the study team.

References:

21 CFR 312.59
21 CFR 312.61
ICH GCP Guidelines, Sections 4.6 and 5.14
MDACC Pharmacy Policy & Procedures

Strategic Vision: From the following, please select the appropriate goal(s) applicable to this policy and identified in the 2005-2010 Strategic Vision:
Goal 2: Enhance the quality of existing research programs and develop priority programs for the future.
**Approvals:**
Committee Review
Committee: Institutional Review Board 3
Names: Ralph S. Freedman, M.D., Ph.D.
Approval Date: 07/28/2010
Updated Date: 06/10/2014

**Revisions:**
Designee Review
Names:
Approval Date:
Description:

**Policy Stewards:**
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