Froedtert Pharmacy Policy

Title: Investigational Drug Disposition and Destruction

Policy Number: PHRM.IDS.103
Effective Date: 3/30/2016

Date Revised: 6/28/17
Supersedes: 4/19/16

Entities Impacted: CMH ( ) FH (x) FMLH ( ) FHMG ( ) SJH ( )

PURPOSE:

A. To provide uniform methodology on handling of investigational drugs after medications have been dispensed and/ or returned to Investigational Drug Pharmacy.

DEFINITIONS:

A. Hazardous drug: drugs included CPM.0183 – Hazardous Medications, Administration and Safe Handling Across all Environments of Care Policy

B. Pharmacy Summary: a study specific document that is prepared by the lead Investigational Drug Service (IDS) pharmacist using information from the study protocol, pharmacy manual, site initiation meeting, the Investigator's Brochure, etc. Pharmacy summaries provide protocol-specific information that the pharmacy must perform for adherence to the protocol.

POLICY:

A. Froedtert Hospital IDS will maintain accurate and complete drug accountability records, including accountability of patient returned medication and final disposition.

B. Code of Federal Regulations:
21 CFR 312.59 Disposition of unused supply of investigational drug. The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with §312.57.

21 CFR 312.62 Disposition of drug: An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under Sec. 312.59.

PROCEDURE:

A. All vials used for the preparation of investigational drugs will be documented as destroyed onsite on the accountability log upon usage.

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B. Investigational drugs returned from subjects

1. IDS is responsible for destruction of investigational drugs returned from subjects following documentation of returns as described below. IDS will not save subject returned medications for monitor review.

2. IDS is responsible for accountability of unused drug returns from subjects and documentation of final disposition. Verification of subject returned medication will be independently completed by two IDS staff members. For electronic documentation of returns, one staff member will document returns on the accountability log and a second staff member will document destruction. IDS will document the date returned by the subject on the accountability log and documentation will occur within 3 business days of receipt by IDS pharmacy.

3. Documentation will be completed at the time of destruction. IDS pharmacy will document the disposition of the study medication on the accountability log. Documentation will include the date, lot/kit/bottle number of the investigational drug destroyed onsite, as well as the name and signature of IDS staff. Sponsor supplied destruction forms will not be used for individual subject returned medications.

4. Only waiver requests due to drug integrity or patient safety purposes will be considered for approval. An additional fee will be incurred for storage of subject returned medication bottles.

C. Onsite destruction will consist of placing the investigational drug in the appropriate waste bin. Waste will be removed daily per EVS waste handling policy SP3.012ic or by Clean Harbors facility representative.

D. Pharmaceutical waste is disposed and processed by Clean Harbors®, http://www.cleanharbors.com, 309 American Circle, El Dorado, AR 71730. Waste manifests are maintained on site for three years.

E. Return or Destruction (Final Disposition) of unused or expired investigational drugs

1. If return to the sponsor is required per the study protocol, instructions on the return procedures, if available, will be included in the pharmacy summary.

2. If the sponsor is unwilling or unable to accept unused or expired investigational drugs, IDS will dispose of the unused investigational drug as hazardous drugs, per EVS waste handling policy SP3.012ic. The cost incurred will be charged to the study account.

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3. Unused or expired investigational drugs that are either returned to the sponsor or destroyed onsite, will be documented by IDS on the accountability record.

4. If the sponsor requests utilization of a destruction form, IDS will request the monitor to complete the form when expired or unused drug is returned to the depot or destroyed on site Otherwise, all final drug dispositions will be documented on the accountability log by IDS. An internal certificate of destruction will be provided upon request by the sponsor.

RELATED POLICIES: Clinical Research and Investigational Drugs (CPM.0152)

Authors: Investigational Drug Service Team 3/30/2016

APPROVAL: Pharmacy Leadership Team