FROEDTERT PHARMACY PROCEDURE

Title: Investigational Drug Monitoring Visit Standard Operating Procedure
Entities Impacted: CMH ( ) FMLH (x) FMCWCP ( ) SJH ( )

Effective Date: 03/30/16
Revised Date: 06/21/16
Procedure Number:

Froedtert and the Medical College of Wisconsin Investigational Drug Service (IDS) shall participate in sponsor-conducted monitoring visits and make requested pharmacy records available for review.

Monitor: Any person responsible for auditing or monitoring research documentation for a specific trial or study sponsor
Unscheduled visit: Any unannounced visit to IDS, including add-on visits
Study binder: A binder prepared by IDS staff for a specific study protocol intended to organize essential pharmacy documents related to the study
Note to File: An IDS-created note filed in the study binder intended to document and communicate important information concerning subjects, the study, and study medications that was not specified by the sponsor.
Used medication: Any investigational product included in the study that has been returned by the patient, including empty bottles.

information to the monitor in a timely manner. To prevent future fees, IDS recommends that monitors schedule their next onsite visit at this time.

Conduction of the visit

During the MV, monitors will be assisted by IDS technicians. An IDS pharmacist will also be available for questions and to discuss any follow up action items identified by the monitor.

At the time of the scheduled visit, monitors are expected to meet IDS staff at the IDS pharmacy monitor visit area. IDS will provide directions to the appropriate location, if needed.

Monitors must sign-in upon arrival to the IDS office and will be directed to a designated workspace to use throughout the MV.

During the visit, monitors will be provided the study binder or access to electronic accountability logs, as applicable. Disposition of subject returned medication will follow the IDS drug disposition and destruction policy. Drug will be documented as destroyed upon return by the subject. If the sponsor is unwilling to approve destruction of investigational drugs returned by subjects prior to monitor review, then a waiver form must be on file documenting the deviation from IDS policy. Only if a waiver is on file, will monitors then be able to review and count drug that is returned from subjects (see handling of hazardous drugs, below).

It is expected that drug disposition (either return to sponsor or destroy onsite) of patient returns and/or expired medications is specified at the time of scheduling each MV. The monitor is responsible for collecting medications to be returned to the sponsor at the time of the MV. Any used medications that are left onsite after the MV will be destroyed according to IDS policy.

If the sponsor does not specify documentation or have a required form available, IDS pharmacy will create a Note to File documenting the disposition of the study medication. The note will include the date, lot/kit/bottle number of the investigational product (IP) destroyed or sent off site, as well as the name and signature of IDS staff aTj ( )Tj 22.45700073 0 Td (aTj (have)Tj ( )Tj 23.97702o.01100159 (