FROEDTERT PHARMACY PROCEDURE

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

Effective Date: 03/30/16
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Procedure Number:

PURPOSE: 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.

DEFINITIONS:

A. Monitor: Any person responsible for auditing or monitoring research documentation for a specific trial or study sponsor
B. Unscheduled visit: Any unannounced visit to IDS, including add-on visits
C. Study binder: A binder prepared by IDS staff for a specific study protocol intended to organize essential pharmacy documents related to the study
D. 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.
E. Used medication: Any investigational product included in the study that has been returned by the patient, including empty bottles.

PROCEDURE:

A. Scheduling and visit hours
   1. Monitors are given access to scheduling IDS visits on Monday through Friday between 8:30AM and 1:00PM based on staff availability. Exceptions may be allowed for extenuating circumstances at the discretion of IDS.
   2. All monitors must schedule a monitor visit (MV) in advance for each study. Due to limited space and the number of studies supported by IDS, MVs should be scheduled at least one week in advance. At the time of scheduling an appointment, monitors should provide an estimate of the time required for the MV and the name of the study/studies to be reviewed.
   3. IDS will schedule a maximum of three MV per day for oncology and three MV per day for non-oncology. If the number of MV requested exceeds three for each department, IDS will create a waiting list in the order requests were received. IDS will notify monitors on the waiting list of their current status and will contact the monitor if an opening is available.
   4. Monitors should schedule a visit by contacting IDS directly. Contacting study coordinators for a site visit is not sufficient for scheduling a MV with IDS. Failure to contact IDS may result in unavailability. This ensures that IDS is notified of the visit and can prepare documents for the monitor.
   5. Unscheduled MVs will not be given onsite access to IDS, unless time allows. If IDS is unable to accommodate unscheduled MV, the monitor will be given the option to reschedule the MV or proceed as a remote monitoring visit. All remote monitoring visits will incur a remote monitoring visit fee and the study sponsor will be charged accordingly. For remote visits, the monitor should email IDS requesting the items needed to complete the visit; IDS will provide electronic copies of the requested

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

B. Conduction of the visit
   1. 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.
   2. 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.
   3. Monitors must sign-in upon arrival to the IDS office and will be directed to a designated workspace to use throughout the MV.
   4. 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).
   5. 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.
   6. 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 and the monitor.
   7. At the conclusion of the MV, monitors are required to complete a study monitor exit summary. Any issues identified during the visit should be written on the exit summary. If possible, all issues will be resolved at the conclusion of the MV prior to the monitor departing from IDS pharmacy.

C. Handling of hazardous drugs
   1. Froedtert and the Medical College of Wisconsin classifies hazardous drugs according to the Hazardous Medications, Administration, and Safe Handling Across all Environments of Care Policy.

RELATED POLICIES/PROCEDURES:	Investigational Drug Disposition and Destruction, CPM.0183 – Hazardous Medications, Administration and Safe Handling Across all Environments of Care Policy
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