Policy Title: FMLH Pharmacy Investigational Drug Monitor Visit Standard Operating Policy	**Last Review Date:** 09/27/2022
Policy Number: 4920	**Next Review Date:** 09/27/2025

Name: FMLH Pharmacy Investigational Drug Monitor Visit Standard Operating Policy

Last Review Date: 09/27/2022
Next Review Date: 09/27/2025
Origination Date: 03/30/2016

Key Words: PHRM.IDS.501
Supersedes: PHRM.IDS.501

Purpose:
To establish a process for the Froedtert Pharmacy Department to participate in sponsor-conducted monitoring visits and make requested pharmacy records available for review.

Definitions:
Monitor: Any person responsible for auditing or monitoring research documentation for a specific trial or study sponsor

Unscheduled visit: Any unannounced visit by the sponsor or Clinical Research Organization (CRO) to pharmacy, including add-on visits

Close Out Visit (COV): The final visit to pharmacy by the study monitor intended to complete final disposition and reconciliation of study drug and accountability logs.

Study binder: A binder and/or electronic document storage: A binder and/or electronic storage prepared by pharmacy staff for a specific study protocol intended to organize essential pharmacy documents related to the study

Note to File (NTF): A note created and filed by the research site intended to document and communicate important information concerning subjects, the study, and study medications that was not specified by the sponsor. An NTF may be stored electronically or in a binder.
Used medication: Any investigational product included in the study that has been returned by the patient, including empty bottles.

Policy:
The Froedtert Pharmacy Department will participate in sponsor-conducted monitoring visits and make requested pharmacy records available for review.

Procedure:

A. Scheduling a Monitor Visit
    1. Monitors are given access to scheduling pharmacy visits Monday through Friday based on staff availability. Exceptions may be allowed for extenuating circumstances at the discretion of the Pharmacy Department.
    2. All monitors must schedule a monitor visit (MV) in advance for each study. Due to limited time, space and the number of studies supported by pharmacy, all MVs must be scheduled at least one week in advance.
    3. Pharmacy will schedule a maximum of four MV per day for oncology and four MV per day for non-oncology. If the number of MV requested exceeds four for each department, pharmacy will offer alternative dates for scheduling.
    4. Monitors should schedule a visit by contacting pharmacy directly via email at IDS.Pharmacy@froedtert.com. Contacting study coordinators for a MV is not sufficient for scheduling a MV with pharmacy. Failure to contact pharmacy may result in unavailability. This ensures that pharmacy is notified of the visit and can prepare documents for the monitor.
    5. Unscheduled MVs will not be given onsite access to pharmacy, unless time allows. If pharmacy is unable to accommodate unscheduled MV, the monitor will be given the option to reschedule the MV.
    6. In the event of a staffing shortage, pharmacy reserves the right to cancel any monitor visits if not staff are available to meet with monitors due to patient care volume.
    7. Fees for monitoring visits are outlined in the study budget provided by pharmacy to the study team.

B. Conduction of the visit
    1. F&MCW Pharmacy Department supports remote monitoring visits, and remote monitoring is strongly preferred.
    2. On-site visits are only allowed if there is IP on-site.
    3. Monitors are expected to prepare for on-site visits in advance. On-site visits will be limited to 30 minutes to view IP.
    4. During the MV, monitors will be assisted by pharmacy technicians. Monitors should contact the pharmacy via email at the following address: IDS.Pharmacy@froedtert.com.
    5. During the visit, monitors will be provided the study binder or access to electronic accountability logs, as applicable by site. Monitors coming on-site must prepare for the visit in advance. Monitors are expected to bring their own devices to access the electronic accountability logs during the visit, if needed. Vestigo access will be provided to monitors by pharmacy. Paper logs will not be printed if they are available in the electronic accountability system.

6. Disposition of subject returned medication will follow the pharmacy drug disposition and destruction policy. Drug will be documented as destroyed upon return by the subject.
7. Monitors will not be allowed on-site for the sole purpose of over labeling.
8. 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.
9. Unused or expired drug will be returned to the depot or destroyed onsite (Final Disposition), per IDS Drug Destruction policy, at the time the close out visit (COV) is completed by the monitor. Any medication left onsite at the conclusion of the COV will be destroyed onsite per IDS policy.
10. A certificate of destruction may be supplied upon request.
11. Unused or expired drug will be returned to the depot or destroyed onsite (Final Disposition), per Drug Destruction Policy, at the time the COV is completed by the monitor. Any medication left onsite at the conclusion of the COV will be destroyed onsite.
12. At the conclusion of the MV, monitors are required to complete a study monitor exit summary and email it to IDS.Pharmacy@froedtert.com. Any issues identified during the visit should be written in the exit summary.

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: Investigational Drug Disposition and Destruction
Issuing Authority: FMLH Pharmacy Operations Committee
Reference Type:
Content Details URL: http://fhpolicy.s1.fchhome.com/d.aspx?d=A934BWfCUyd0
Constant Content File URL: http://fhpolicy.s1.fchhome.com/d.aspx?c=6k4HeB7n91Cg
Expiry Date: 6/29/2073 12:00:00 AM