Policy Title:	Last Review Date:
FHFMH, FMFH, FMLH, FWBH Pharmacy Investigational Drug Vestigo Accountability and Inventory Management Policy	11/30/2022
Policy Number:	**Next Review Date:**
5017	11/30/2025

Name: FHFMH, FMFH, FMLH, FWBH Pharmacy Investigational Drug Vestigo Accountability and Inventory Management Policy

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Supersedes: PHRM.IDS.106
Key Words: PHRM.IDS.106
Origination Date: 06/21/2017

Purpose:
To define the accountability process for the management of Investigational Product (IP) that ensures accuracy, safety, and efficiency. All accountability and documentation occurs electronically. Sponsor provided binders will not be accepted.

Definitions:

Vestigo: A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by Froedtert & Medical College of Wisconsin. Refer to www.mccreadiegroup.com/vestigo/ for additional information.

Policy:

A. Froedtert Hospital Pharmacy Department will utilize Vestigo, a web-based software, for the management of IP used as a part of a research protocol using an electronic drug accountability record form (eDARF). In the event the use of an eDARF is not feasible due to limited accessibility with a 24/7 trial, the drug accountability SOP will be followed on a paper accountability log.

B. Compliance

1. Vestigo is compliant with Health Insurance Portability and Accountability Act (HIPAA)
2. Vestigo is compliant with part 11 of Title 21 of the Code of Federal Regulations

C. Electronic Inventory Maintenance

1. Vestigo will be the sole system utilized to monitor inventory receipt, transfer, dispensing, returns, and expiration dates. Sponsor provided forms or other additional documentation will not be completed, within the exception of IP receipt in IRT if required.

2. Drug dispense will be entered in Vestigo in real time.
3. Accountability will be maintained for IP supplied by the sponsor or procured by Investigational Drug Service (IDS). No accountability will be completed for non-study-supplied commercial agents, standard of care medications, or other medications involved in a study not maintained or dispensed by IDS.
4. Monitors may use Vestigo to review DARFs electronically; copies of DARFs will not be printed, emailed or mailed to monitors; access to Vestigo for monitors will only be made available during monitor visits, during which they may save or email themselves an electronic copy of the DARFs

D. Documentation in Vestigo

1. The following information will be captured on Vestigo accountability logs for non-parenteral medications:
    a. Date of receipt and date of dispense
    b. Subject initials and Subject ID number
    c. Dose
    d. Quantity received and dispensed
    e. Balance Forward (Quantity on Hand)
    f. Manufacturer and Lot number/ Batch number
        1. Kit / Bottle numbers will be documented, only if required for IP assignment through an IRT system
    g. Recorder's Initials (dispense or receipt) and Initials of pharmacist verifying dispense
    h. Expiration Date (provided on shipping documents)
    i. Date Patient Returned
    j. Quantity Patient Returned
    k. Recorder's initials (Staff who recorded the returns)
    l. Final disposition of returned, unused, and expired medications
    m. Accountability log comments
2. The following information will be captured on Vestigo accountability logs for parenteral medications:
    a. Date of receipt and date of dispense
    b. Subject initials and Subject ID number
    c. Dose
    d. Quantity received and dispensed
    e. Balance forward (Quantity on Hand)
    6. Kit / vial numbers will be documented, only if required for IP assignment through an IRT system

f. Recorder's Initials (dispense or receipt) and Initials of pharmacist verifying dispense

g. Expiration Date (provided on shipping document)

h. Final disposition of returned, unused, and expired medications

3. The following will not be captured, unless specified in writing by the sponsor at time of study initiation. Retroactive requests for the following documentation will not be accommodated:

    a) Thaw Time or Time removed from refrigeration
    b) Preparation Time – Defined as actual time prepared in the biosafety cabinet. Time and date of prepared medication expiration will be documented on the label affixed to the medication, per institutional standards.
    c) Preparation and dose calculation worksheets will not be utilized.
    d) Expiration of prepared medications will not be documented on the eDARF.
    e) Vial labels will not be saved for monitor review

4. Additional Documentation Captured in Vestigo

    - Take home prescription or paper orders
    - IVRS
    - Shipping documents
    - Not to File (NTF), protocol and patient specific
    - Competency Module Training documentation
    - Temperature documentation (see temperature SOP for more information)

5. Patient specific eDARFs will be maintained for each patient in a placebo-controlled trial.
6. A separate eDARF for waste will not be provided. Documentation on the eDARF of destruction of used vials per institutional policy will serve as documentation for the destruction of waste and used vials.
7. A separate eDARF will be prepared for each agent, each dosage strength, and each formulation within a trial.
8. A separate eDARF may not be prepared for each arm if the same drug, dose, formulation is used in multiple arms.
9. A separate eDARF for each batch number (or lot number) may not be feasible, but the lot number and batch number will be captured within the eDARF.
10. IRT emails and/or screenshots confirming receipt of shipment will not be saved.

E. Vestigo Access

1. Pharmacy Department Staff and study team members will have access to Vestigo as it relates to their role and will have a unique login to the Vestigo system.
2. Control of access to Vestigo will be maintained by authorized IDS staff.

F. Monitors:

1. Monitors will have access to Vestigo. See Investigational Drug Monitoring Visit Standard Operating Procedure.
2. Monitors may contact pharmacy directly via email at IDS.Pharmacy@Froedtert.com
3. External monitors will be granted access to the Vestigo system by authorized IDS staff.

    - Access to a protocol will only be available during the dates and times set by the site.
    - When the visit (access) is closed by the site or expired, access will be revoked.
    - Access can be extended by contacting the site directly.

G. Vestigo Downtime:

1. Vestigo has a full daily backup that is transferred to a second data center for recovery purposes. Hourly backups of changed data occur throughout the day. Once a month, the full back up is archived for permanent storage.
2. In the event of a Vestigo unscheduled downtime, dispensing will be documented within 24 hours of Vestigo coming back on line. The documentation will be entered as a late entry, as indicated, depending on the duration of the downtime.

Related Policies: Investigational Drug Disposition and Destruction
Investigational Drug Monitor visit Standard Operating Policy
Investigational Drug Temperature Monitoring and Temperature Excursion
Issuing Authority: FMLH Pharmacy Operations Committee
Reference Type:
Additional Attachments: Appendix A - Vestigo and 21CFR Part11.pdf
Content Details URL: http://fhpolicy.s1.fchhome.com/d.aspx?d=DD47A21bZ8QR

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

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