FROEDTERT PHARMACY POLICY

Title: Investigational Drug Accountability and Inventory Management
Entities Impacted: CMH ( ) FMLH (x) FMCWCP ( ) SJH ( )

Effective Date: 6/21/17
Revised Date:
Policy Number: PHRM.IDS.106

PURPOSE: To define the investigational drug accountability process for the management of investigational drugs that ensures accuracy, safety, and efficiency.

DEFINITIONS:

A. Vestigo®: a web based application used to manage the Investigational Drug Service (IDS) inventory through record keeping functions.

POLICY:

A. Froedtert Hospital IDS will utilize Vestigo®, a web-based software, for the management of investigational drugs 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. Background

1. In 2014, the Hematology Oncology Pharmacy Association published Investigational Drug Service Best Practice Standards. One of the best practice standards includes implementation and use of computer software for investigational medication management.

C. 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; Electronic Records; Electronic Signatures (21 CFR Part 11) (see appendix A)

D. Electronic Inventory Maintenance

1. Vestigo® will be the sole system utilized to monitor inventory and expiration dates. Sponsor provided forms will not be utilized.
2. On the day of receipt of investigational drugs at Froedtert Hospital, IDS will be notified of the shipment. Upon receipt by IDS, the shipment and will be confirmed and receipt entered in the eDARF in Vestigo®.
3. Drug dispense will be entered in Vestigo® in real time. The pharmacist double checking the dispense will do so prior to dispensing to the subject and documentation of this second check will be documented in Vestigo® in real time, whenever possible, or within 2 business days, in order to maintain up-to-date and accurate accountability logs.

4. Drug returns will be entered into Vestigo® within 3 business days of receipt by IDS pharmacy.
5. Drug destruction and final disposition will be entered in Vestigo in real time. See Investigational Drug Disposition and Destruction Policy.
6. IDS will not account for medications not provided for or funded by the study sponsor. An eDARF will not be kept for commercial products.
7. A copy of the electronic DARFs will be printed upon study closure and kept with study files.

E. 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, if required
         (2) If package labels are required to be saved, they will be affixed to the corresponding Interactive Voice Response System vial assignment confirmation for each dispensing visit and kept in the study pharmacy file.
      g. Recorder's Initials (dispense or receipt) and Initials of pharmacist verifying dispense
      h. Expiration Date (if available)
      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)
      f. Manufacturer and Lot number/Batch number
         (1) Kit / vial numbers will be documented, if required
      g. Recorder's Initials (dispense or receipt) and Initials of pharmacist verifying dispense
      h. Retest Date (if available)
      i. Final disposition of returned, unused, and expired medications
      j. 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:

(1) Thaw Time or Time removed from refrigeration

(2) 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. Expiration of prepared medications will not be documented on the eDARF.

(3) If vial labels are required to be saved, they will be affixed to the corresponding Interactive Voice Response System vial assignment confirmation for each dispensing visit and kept in the study pharmacy file.

3. Patient specific eDARFs will be maintained for each patient in a placebo-controlled trial.
4. 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.
5. A separate eDARF will be prepared for each agent, each dosage strength, and each formulation within a trial.
6. A separate eDARF may not be prepared for each arm if the same drug, dose, formulation is used in multiple arms.
7. 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.

F. Vestigo® Access
   1. Each member of the IDS team will have a unique login to the Vestigo® system.
      a. Control of access to Vestigo® will be maintained by authorized IDS staff.
      b. Authorization capability will only be provided to the IDS pharmacists and IDS manager.
   2. External monitors will be granted access to the Vestigo® system by authorized IDS staff.
      a. Authorization capability will only be provided to the IDS pharmacists and IDS manager and IDS technicians.
      b. Access to a protocol will only be available during the dates and times set by the site.
      c. When the visit (access) is closed by the site or expired, access will be revoked.
      d. Access can be extended by contacting the site directly.

G. Monitors:
   1. Monitors will have access to Vestigo®. See Investigational Drug Monitoring Visit Standard Operating Procedure.

H. 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.

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APPROVAL: Pharmacy Leadership Team 06/21/17

References:

Hematology/Oncology Pharmacy Association. HOPA Investigational Drug Service Best Practice Standards. http://www.hoparx.org/images/hopa/resource-library/professional-tools/HOPA16_IDS_Guidelines.pdf. Accessed May 4, 2017.

U.S. Food and Drug Administration. Code of Federal Regulations Title 21, Part 11. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=11&showFR=1. Accessed May 4, 2017.

ATTACHMENTS/APPENDICES:

Appendix A: Vestigo and 21 CFR part 11