FROEDTERT PHARMACY POLICY

Title: Investigational Drug Temperature Monitoring and Temperature Excursion
Entities Impacted: FHMF( ) FMLH(x) FMCWCP( ) FHWB( )

Effective Date: 08/03/2011
Revised Date: 9/25/2020
Policy Number: (WAS AD33.001)

PURPOSE: This policy describes procedures for temperature management for Investigational Product (IP) by the Investigational Drug Service (IDS) at Froedtert & Medical College of Wisconsin.

DEFINITIONS: A.

B.

POLICY:

A. IDS is responsible for monitoring the temperature of all medication refrigerators, freezers, and ambient temperature in areas where IP is stored.

B. All IP will be maintained within the recommended temperature ranges described below to ensure integrity and potency of the product. All refrigerators, freezers, and ambient temperature locations used for the storage of IP require temperature monitoring. All refrigerators and freezers in Froedtert Hospital are supplied with power connected to a backup generator, in the event of power outage.

C. If a transfer of IP occurs between two locations where the transfer path does not exit the interior of our controlled facility, temperature will not be monitored. See Investigational Drug Transport policy PHRM.IDS.105 for any transfers that leave the interior of our facility. IDS will not monitor temperature of IP shipped directly to patients.

D. IDS will not monitor the temperature of IP after it has been dispensed to the research patient, or the patient's representative.

RELATED POLICIES/ PROCEDURES:

A. Investigational Product Temperature Documentation

1.) Temperatures of IP stored in refrigerators, freezers and ambient storage temperature locations are recorded utilizing a wireless temperature monitoring system. Each wireless temperature monitoring probe is calibrated on an annual basis.

2.) The wireless system will record the temperature every 4 minutes, and document the temperature every 15 minutes.
3.) IDS will not utilize sponsor provided temperature logs.
4.) Temperature reports will be run for the previous month on the nearest business day to the 1st of the new month. The monthly temperature reports will be uploaded to Vestigo® and will be available for monitor review. Temperature reports for mid-month data will not be run for individual monitor visits. This data will be available at the next monitoring visit.
    a. In the event of an audit or study close-out, an exception will be made and a report will be run to provide the most up to date temperature reports.
5.) IDS will not use sponsor provided monitoring equipment and will not accept or operate monitoring equipment provided by sponsors or study teams.
6.) IDS does not have permanent liquid nitrogen storage, but will accept liquid nitrogen dry vapor shippers and sponsor provided monitoring equipment for nitrogen shippers.

B. Temperature Ranges and Alarms

1) All storage locations for IP will be maintained according to standard temperature ranges as defined by United States Pharmacopeia (USP) standards within USP standard 33-NF28 Sections 10.30.10, 10.30.40, 10.30.60 and according to USP <1079>.

For temperature measurements that are reported and recorded, temperatures

4) In the event a storage area's temperature exceeds the acceptable range, IDS will transfer IP to a similar temporary secure storage location where the temperature will continue to be monitored continuously until the issue causing the temperature deviation in the primary storage area can be corrected. The primary storage area will be observed for at least 24 hrs before returning IP to that area.

5) Alarms and notifications will be generated for any temperature readings outside of the ranges defined above. Email and pager notification will result per department of pharmacy policy "Wireless Monitoring of Medication ğ