Policy Title: FMFH, FMLH, FWBH Pharmacy Investigational Drug Temperature Monitoring and Excursion Policy	**Last Review Date:** 03/11/2025
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Policy Title: Pharmacy Investigational Drug Temperature Monitoring and Excursion Policy

Origination Date: 08/03/2011
Key Words: PHRM.IDS.101
Supersedes: PHRM.IDS.101
Owner's Title; Department: Manager, Pharmacy; Pharmacy-Investigational Drugs

Applies to:
☐ North Region Froedtert ThedaCare Health, Inc.
☐ South Region Froedtert ThedaCare Health, Inc. – Only check if applies to ALL entities below

Or only to the South Region entities checked -

Hospitals	Physician Practices	ASCs	Other
☐ FCH ☐ FHFMH ☒ FMFH ☒ FMLH ☒ FWBH	☐ CP ☐ NEMG	☐ DTSSC ☐ FSC ☐ MFASC ☐ WBSC	☐ FH Pharmacy Solutions ☐ Inception Health ☐ Workforce Health ☐ _____

I. Scope

A. The Investigational Drug Temperature Monitoring and Excursion Policy ("Policy") establishes the standards and processes for monitoring temperature and managing temperature excursions for Investigational Product (IP) and applies to Pharmacy Department Team Members at FMFH, FMLH, and FWBH Pharmacy.

II. Purpose Statement

A. This Policy describes procedures for temperature management for Investigational Product (IP) by the Investigational Drug Service (IDS) and Pharmacy Department Team Members at Froedtert & Medical College of Wisconsin.

III. Definitions

A. **Team Member**: Any employee of Froedtert ThedaCare Health, Inc. South Region.

IV. 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 is maintained within the recommended temperature ranges described below to ensure
C. All refrigerators, freezers used for the storage of IP are supplied with power connected to a backup generator to maintain appropriate storage conditions in the event of power outage.

D. If a transfer of IP occurs between two locations where the transfer path does not exit the interior of a controlled facility, temperature is not monitored.
E. IDS will not monitor temperature if IP shipped directly to patients.
F. IDS will not monitor the temperature of IP after it has been dispensed to the research patient, or the patient's representative.
G. IDS will not use sponsor provided temperature logs.
H. IDS will not use sponsor provided temperature monitoring equipment, and will not accept, or operate, monitoring equipment provided by sponsors or study teams.
I. All storage locations for IP are maintained according to temperature ranges as defined by United States Pharmacopeia (USP) standards within USP standard chapters 659, 1079.1, 1079.2, 1079.3.
    1. Refrigerated: 2 degree C to 8 degree C
    2. Controlled Room Temperature: 20-25 degree C (excursions between 15-30 degrees are allowed as defined in section V, L, 1)
    3. Freezer: -25 degree C to -10 degree C
    4. Ultra-Low Freezer: ≤ -90 to -70 degree C
J. Any request to comply with temperature conditions or temperature limits other than above standard ranges will be denied unless the request is supported by the robust data to justify the request. This determination is made at the discretion of the IDS pharmacy manager.
K. For temperature measurements that are reported and recorded, temperatures are rounded to the nearest whole degree Celsius. In determining a reportable excursion, the temperature is rounded to the nearest whole degree.
    1. For a tenth decimal digit greater than or equal to 5, the value will be rounded up to the nearest whole number (e.g., 3.5 rounded to 4).
    2. For a tenth decimal digit less than 5, the value will be rounded down to the nearest whole number (e.g., 3.4 rounded to 3).

V. Procedure

A. Temperatures of IP stored in refrigerators, freezers or ambient storage temperature locations are recorded using a wireless temperature monitoring system. Each wireless temperature monitoring probe is replaced prior to the expiration date on the calibration certificate.
B. The wireless system records the temperature every 4 minutes and documents the temperature every 15 minutes.
C. Temperature reports are run for the previous month on the nearest business day to the 1st of the new month at Froedtert Hospital. These monthly temperature reports are uploaded to Vestigo and are available for monitor review. Temperature reports for mid-month data are not run for individual monitor visits. This data is available at the next monitoring visit. Temperature reports for IP at other sites can be pulled on demand as requested from the wireless monitoring system.
    1. In the event of an audit or study close-out, an exception will be made and a report run to provide the most up to date temperature reports.

D. IDS does not have permanent liquid nitrogen storage but will accept liquid nitrogen dry vapor shippers and sponsor provided monitoring equipment for nitrogen shippers.
E. If a refrigerator or freezer malfunctions causing temperatures to exceed the acceptable range, Pharmacy Department Team Member will transfer IP to a similar working, monitored unit. The temperature and condition of the malfunctioning unit is observed for at least 24 hours prior to returning IP to that unit.
F. In the event a storage area's temperature exceeds the acceptable range, Pharmacy Department Team Member will transfer IP to a similar temporary secure storage location where the temperature continues to be monitored continuously until the issue causing the temperature deviation in the primary storage area can be corrected. The primary storage area is observed for at least 24 hours before returning IP to that area.
G. Alarms and notifications are generated for any temperature readings outside of the ranges defined above. Email and pager notification will result per department of pharmacy site-based procedures and/or policies.
H. IDS will be notified of any alarms pertaining to storage areas containing IP.
I. IDS maintains an on-call response to temperature alarms.
J. If the wireless system detects that a sensor device has not checked in, the system goes into alarm state and it will send an email or text page to the system administrator. Upon receiving this notification, the system administrator will attend to the affected storage area and determine the cause and resolve it.
K. Humidity conditions are not routinely monitored. If strict humidity control beyond typical conditions within Froedtert sites is required, the drug must be stored in a container provided by the sponsor and validated to protect the article from moisture vapor, per USP guidelines, and/or a suitable humidity monitoring device must be provided by the sponsor.
L. In determining a reportable excursion, the temperature is rounded to the nearest whole degree (e.g. room temperature at 14.5° C will not be considered an excursion since it rounds to 15° C).
    1. Controlled Room Temperature: a temperature deviation ≥5 degree C from the acceptable temperature ranges described in section (IV, I, 2), sustained for a continuous period of 30 minutes or longer or a temperature deviation < 5 degree C sustained for longer than 24 hours.
    2. Refrigerated, Freezer or Ultra-Low Freezer: a temperature deviation from the acceptable temperature ranges described in section (IV, I, 1, 3, 4) sustained for a continuous period of 30 minutes or longer. Temperatures excursions lasting < 30 minutes will not be reported.
M. In the event of a temperature excursion as defined above, the sponsor is notified with the Froedtert Investigational Drug Services Investigational Product (IP) Temperature Excursion Form.
N. In the event of a temperature excursion, IP in question is quarantined in the appropriate storage conditions until the IP is deemed acceptable for use by the sponsor and/or sponsor representative. The quarantined inventory is separated from other IP and clearly marked as not for patient use.

O. Monitors, sponsors, or the study team are expected to respond to temperature excursion notifications within two business days.
P. All e-mail and other communications with the study monitor regarding the temperature excursion should be retained in the study folder located on the secure electronic (I:) drive or the study binder.
Q. Temperature excursions during shipment of IP to Froedtert sites are managed according to sponsor instructions.

VI. Related Information

A. None

VII. Statements

A. None

VIII. References

A. None

IX. Attachments

A. IDS Temperature Excursion Form