WVUMedicine	Procedure Name	**Investigational Product Temperature Monitoring and Excursion Procedures**
	SOP #07	**WVU IDS Pharmacy SOP-07**
	Date this Version is Effective	**01 January 2024**
	Responsible for Content	**IDS Pharmacy Manager**

I. Description

This SOP describes the process of product storage, temperature monitoring, and excursion procedures with investigational product (IP) at WVU Hospitals (WVUH).

II. Rationale

The Department of Pharmaceutical Services inspects, tests, and maintains equipment used in the storage of IP including performing preventative maintenance, periodic inspection, and performance testing of equipment and instruments.

The goal of this SOP is to create procedures for temperature monitoring and temperature excursions to ensure that IP is stored according to study protocol specifications and Joint Commission Regulations.

III. Procedures

1. IP Storage
    a. IP will be stored in a secure manner with sufficient back up procedures to address and maintain proper storage of IP in an emergency such as a power outage.
2. Temperature Monitoring
    a. IDS staff will monitor temperature conditions in all locations in which IP is stored onsite continuously. Data from temperature monitoring will be maintained by IDS staff in an accessible format through Temp Trak®.
        i. Temp Trak® is a 24/7 wireless monitoring software that continuously monitors temperature in medication and IP storage areas/locations.
    b. Temp Trak® logs are uploaded to WVUH licensed Vestigo IP management software at the close of each month. The logs will be displayed graphically. Only in the event of a temperature excursion will specific date and time readings be reported.
    c. Transport of IP less than 30 minutes duration will not be temperature monitored.
    d. Temperature requirements comply with the standards outlined below. Excursions are defined as:
        i. Controlled room temperature (20ºC-25ºC):
            1. Greater than or equal to 5ºC from acceptable range, sustained for a contiguous time of greater than 24 hours.

ii. Refrigerated temperature (2ºC-8ºC), freezer temperature (-25ºC- -10ºC), ultra-low freezer temperature (-90ºC- -60ºC).

1. Greater than or equal to 1ºC from acceptable range, sustained for a continuous time of greater than 30 minutes.

e. WVUH IDS will only use WVUH approved temperature monitoring systems (Temp Trak or Igloo). Any request to use a different or second temperature monitoring system will be denied. Sponsors have access to Vestigo to view and retrieve temperature monitoring logs on a monthly basis.

3. Temperature Excursions

a. In the event of a temperature excursion, IP will be quarantined, and the IDS pharmacist and Pharmacy Administrator on Call (AOC) will be immediately notified.

i. If proper storage temperature cannot be obtained, the IP will promptly be moved to an alternate location as outlined below:

1. IP from the CC-Pharmacy Stock room single door freezer 1965B will be relocated to the Main Pharmacy, Single Door-Central Pharmacy-Freezer and be kept separate from other pharmacy product.

2. IP from the CC-INV Drug Double Door Refrigerator 1965B will be relocated to the Main Pharmacy, IDS Storage Room, Investigational Drug-Pharmacy Cooler.

3. IP from an Ultra-Low Freezer in the MBRCC will be relocated to another Ultra-Low Freezer in the Main Pharmacy.

ii. The time and date of the IP relocation will be recorded. The study coordinator, principal investigator, and sponsor will be notified.

iii. Product will be quarantined until direction is provided by the sponsor as to how to proceed with the product (e.g., use for study participants, destruction, or return to sponsor).

iv. WVUH IDS Pharmacy will complete the WVUH Pharmacy IDS Temperature Excursion Form and submit it to the sponsor (see Appendix A). Any request to complete sponsor forms related to temperature excursions will be denied.

4. TempTrak® Calibration

a. Each TempTrak® sensor calibration should be verified at initial use and annually thereafter for all IDS storage locations.

b. Equipment utilized to verify TempTrak® devices:

i. NIST Traceable Standard Thermometer with certification for room temperature and refrigerator temperature storage

ii. NIST Traceable Standard Thermometer with certification for freezer

iii. TempTrak® sensors/probes

c. Process to verify TempTrak® devices:

   i. Obtain the NIST Standard thermometer(s) from the IDS office.

   ii. Place the appropriate NIST Standard thermometer's probe next to the TempTrak® sensor probe.

   iii. Allow adequate time for temperatures to equilibrate (approximately 15-30 minutes).

   iv. Remove the cover from the TempTrak® sensor.

   v. Carefully press the black reset button three times, waiting 5 seconds between each press.

   vi. Document the NIST Standard thermometer reading.

   vii. Log onto TempTrak® and access the appropriate sensor.

   viii. Document the "actual" TempTrak® reading that is found by clicking the "Data Table" button under "TempTrak® Sensor History".

      1. Acceptable limit is within +/- 1ºC of the NIST Standard thermometer for the refrigerated and room temperatures and +/- 2ºC for the freezer temperatures.

      2. Perform corrective actions if the acceptable difference cannot be met.

         a. Contact the Facilities Management department to access TempTrak® performance.

         b. If needed, TempTrak® Support may be reached at 1-888-533-6900.

d. Complete the Temp Trak Calibration Document (Appendix B) and have it signed by the IDS pharmacy manager.

IV. Original Procedure Date and Revisions

16 March 2022, 01 January 2024

V. Notes

a. NIST Standard Thermometers are used to verify temperatures ranging from -99.9ºC-199.9ºC
b. If adequate time is not allowed for thermometers to equilibrate, false readings will result.
c. The NIST Standard probe must be placed close to the TempTrak® probe for the most accurate reading.
d. Low batteries on the NIST thermometers may cause erroneous results.

VI. References

a. TempTrak® Reference Guide 2002-2006 Cooper Atkins

Appendix A: the WVUH Pharmacy IDS Temperature Excursion Form

WVUH Pharmacy IDS

Temperature Excursion Reporting Form

Sponsor	**Protocol Number**
Principal Investigator	**Site #**

Reporter's Name/Role **Date Reported (DDMMMYYYY)**	**IP Shipping Address**
Telephone number	**Email address**

In Transit Temperature Excursion		
Shipping Date (DDMMMYYYY)	Date Received at Site (DDMMMYYYY)	
Order Number		
Temperature Logger ID		
☐ **Copy of packing list and temperature logger report attached.**		
Submitted by (print name)	**Signature**	**Date** (DDMMMYYYY)

On Site Temperature Excursion					
Date Excursion Detected (DDMMMYYYY)					
Date(s) of Temperature Excursion (DDMMMYYYY)					
Minimum Temperature		Maximum Temperature		Duration	
Affected Investigational Product (IP)					
Product Name	**Lot #/Batch #**	**Expiry Date**	**Kit number(s)**	**Assigned kits? Y/N**	

Reason for Temperature Excursion
Action to Prevent Recurrence
☐**Confirm IP impacted by temperature excursion has been segregated and placed in quarantine.** ☐**Confirm copy of temperature monitor logs for date(s) of excursion are attached.**

Submitted by (print name)	**Signature**	**Date** (DDMMMYYYY)

To be Completed by Sponsor Personnel ***Executed forms to be returned to the site IDS.***	
☐ **All** investigational product(s) are suitable for continued use. ☐ **All** investigational product(s) are <u>not</u> suitable for further use/dispensation. ☐ **Other** (Please see details below):	
Assessment completed by (print name)	
Signature/Title	**Date** (DDMMMYYYY)

Appendix B: Temp Trak Calibration Document

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INVESTIGATIONAL DRUG SERVICES

CALIBRATION DOCUMENTATION

Date Of Testing: _____

Performed By: _____

NIST Standard Traceable Thermometer 0°C to 50°C ID:

S/N: _____ Cert. No.: _____

NIST Traceable -100°C - 100°C Platinum Freezer Thermometer ID:

S/N: _____ Cert. No.: _____

TEMP TRAK SENSOR ID	LOCATION	TEMP TRAK PROBE °C	NIST TRACEABLE THERM. °C	ACCEPTABLE +/- 1°C (ambient/refrigerator) +/- 2°C (freezer)	DATE/TIME
_____/_	Central INV Refrigerator #1	___°C	___°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	Central INV Refrigerator #2	___°C	___°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	Central INV Ambient #1	____°C	____°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	Central INV Ambient #2	____°C	____°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	MBRCC-INV Ambient Drug Cabinet	____°C	____°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	MBRCC - INV Refrigerator	___°C	___°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	MBRCC INV Ultra-Low Freezer	_____°C	_____°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	Central INV Vault Ambient	____°C	____°C	NIST S/N: _____	DD MMM YYYY __:__
_____/_	MBRCC Pharmacy Stock room -20 freezer	_____°C	_____°C	NIST S/N: _____	DD MMM YYYY __:__

Results Acceptable? ___Yes ___No

Pharmacy Management Review: Signature _____ Date: _____