

| | | |
|---|-----------------------------------|---|
|  | Procedure Name | Investigational Product Temperature Monitoring and Excursion Procedures |
| | SOP #06 | WVU IDS Pharmacy SOP-06 |
| | Date this Version is Effective | 01 January 2026 |
| | 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 in conjunction with WVUH Facilities Department inspects, tests, and maintains equipment used in the storage of IP by 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 all regulatory body requirements.

III. Procedures

1. IP Storage

- a. IP will be stored in a secure manner with sufficient backup 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. TempTrak® is a 24/7 wireless monitoring software that continuously monitors and records temperature in medication and IP storage areas/locations.
- b. TempTrak® 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 (20C-25°C):
 1. Greater than 5°C from acceptable range, sustained for a time of greater than 24 hours.

ii. Refrigerated temperature (2°C-8°C), freezer temperature (-25°C to -10°C), ultralow freezer temperature (-90°C to -60°C).

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

e. WVUH IDS will only use WVUH approved temperature monitoring systems (TempTrak or Igloo). Any request to use a different or second temperature monitoring system will be denied. IDS staff will not log into a separate temperature monitoring system to upload TempTrak captured temperature data.

i. Sponsors have access to Vestigo to view and retrieve monthly temperature monitoring logs

i.i. In the event of a planned TempTrak downtime, IDS staff will manually record equipment and room temperature readings every 30 minutes for the duration of downtime.

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-HSC 1850-INV Pharmacy Investigational Drug freezer will be relocated to the Adult Central Pharmacy, single door freezer and be kept separate from other pharmacy product.

2. IP from the CC-HSC 1850-INV Pharmacy Investigational Drug refrigerator will be relocated to the Adult Central Pharmacy IDS Storage Room, Investigational Drug refrigerator.

3. IP from the CC Pharmacy Negative Pressure Buffer Room (1965C) freezer will be relocated to another Ultra-Low freezer in the Central Pharmacy.

4. IP stored in any IDS area of Adult Central Pharmacy may be moved to an appropriate alternate location within the pharmacy or relocated to corresponding temperature storage in CC-HSC room 1850.

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 +/- 1°C of the NIST Standard thermometer for the refrigerated and room temperatures and +/- 2°C 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 1-888-5336900.
- 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, 01 January 2025, 01 January 2026

V. Notes

- a. NIST Standard Thermometers are used to verify temperatures ranging from -99.9°C-199.9°C
- 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 (DDMMYYYY) | IP Shipping Address |
| Telephone number | Email address |

| | |
|---|----------------------------------|
| In Transit Temperature Excursion | |
| Shipping Date (DDMMYYYY) | Date Received at Site (DDMMYYYY) |
| Order Number | |
| Temperature Logger ID | |
| <input type="checkbox"/> Copy of packing list and temperature logger report attached. | |

| | | |
|---------------------------|-----------|-----------------|
| Submitted by (print name) | Signature | Date (DDMMYYYY) |
| | | |

| | | | | | |
|---|--|---------------------|--|----------|--|
| On Site Temperature Excursion | | | | | |
| Date Excursion Detected (DDMMYYYY) | | | | | |
| Date(s) of Temperature Excursion (DDMMYYYY) | | | | | |
| 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 | | |
| | | |
| <input type="checkbox"/> Confirm IP impacted by temperature excursion has been segregated and placed in quarantine. | | |
| <input type="checkbox"/> 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 not suitable for further use/dispensation.

Other (Please see details below):

Assessment completed by (print name)

| | |
|-----------------|-----------------|
| Signature/Title | Date (DDMMYYYY) |
|-----------------|-----------------|

| |
|--|
| |
| |
| |
| |

Appendix B: Temp Trak Calibration Document



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: _____