DukeHealth

| Policy/Procedure: | DUHS Pharmacy IDS - Temperature Monitoring | |
|---|---|---|
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| Entity: ☐ AHS ☐ DHCH ☐ DHTS ☐ DPC ☒ DRAH ☒ DRH ☒ DUH ☐ PDC ☐ PHMO ☐ SOM | | |

**Review Dates:** January 2012, April 2016, August 2019, April 2021, August 2022 **,** December 2022

**Purpose:**
The purpose of this policy is to define the temperature monitoring process for investigational products (IP).

**Policy Statement:**
The Investigational Drug Services manages all investigational products stored according to the parameters specified in the most current USP. Ambient temperature, all refrigerators and freezers in the IDSs are monitored centrally, 24 hours a day using wireless temperature sensor with appropriate on-call IDS personnel notified in the event of temperature excursion.

**Level:**

☐ **Interdependent** - asterisked [*] items require an order from a health care practitioner licensed to prescribe medical therapy.
☒ **Independent** – no provider order required.

**Personnel:**
IDS
ICS
IDRP

**Competencies/Skills:**
NONE

**Required Resources:**
United States Pharmacopeia (USP) standards, (USP Standard 33-NF28, Sections 10.30.10, 10.30.40,10.30.60))

**Definitions:**

A. Investigational Drug Services (IDSs) includes: ICS, IDRP, and IDS
B. ICS: Investigational Chemotherapy Service, located inside the Cancer Center Infusion Pharmacy Room 4N33 Duke Cancer Center
C. IDS: Investigational Drug Service, located in Duke Clinic Room 0101b, Yellow Zone
D. IDRP: Infectious Disease Research Pharmacy, located in Duke Clinic, Clinic 1K
E. TempTrak: Cooper-Atkins wireless temperature sensor

# Policy/Procedure: DUHS Pharmacy IDS - Temperature Monitoring

**Procedure:**

A. The IDSs follow temperature requirements in compliance with the United States Pharmacopeia (USP) standards, as defined below (USP Standard 33-NF28, Sections 10.30.10, 10.30.40,10.30.60))

B. Temperatures are rounded to whole numbers using standard rounding rules. The Temp Trak System is set to alarm at the following:

| | USP Temperature Range | Alarm Set (from Temptrak) | Reportable Temperature Excursions |
|---|---|---|---|
| Room Temperature | 20 to 25˚C (excursions allowed between 15-30°C) | 20°C to 24.8°C | Below 15 and over 25 for greater than 30 minutes |
| Refrigerated | 2˚C to 8˚C | 2.5°C to 7.5°C | Below 2 and above 8 for greater than 30 minutes |
| Freezer -20C | -25˚C to -10˚C | -25°C to -15°C | Above -15 and below -25 for greater than 30 minutes |
| Ultra-Low Freezer | -90˚C to -60˚C | -88°C to -68°C | Above -60 and below -90 for greater than 30 minutes |

C. A reportable temperature excursion is defined asa temperature deviation from the acceptable temperature ranges, described in the table above, sustained for a continuous period of 30 minutes or longer with temperature rounded to the nearest whole number.

D. In the event of a temperature excursion as defined above:
   a. The sponsor will be notified with the Duke IDS Temperature Excursion Form (Appendix A). Sponsor-specific temperature excursion forms will not be completed by IDSs.
   b. IP will be physically quarantined at the appropriate storage temperature, and inventory will be marked in Vestigo as quarantined until determined by the sponsor if the drug may be released or destroyed per policy. See IDS Drug Destruction Policy.

E. The ambient temperature in the IDSs pharmacies, all refrigerators and freezers are monitored centrally by the Duke University Hospital (DUH) Engineering and Operations department, 24 hours a day using Cooper-Atkins wireless temperature sensor, TempTrak®. Appropriate on-call IDSs personnel are notified via alarm, page and email in the event devices move out of range and arrangements are made with hospital maintenance to quickly identify and correct the fluctuation.

F. Alarm parameters are pre-set to alert staff if devices move out of the appropriate range.

G. In the event of a storage area's temperature going out of acceptable range, IP will be moved to another storage location until the issue can be fixed. If the IP labeling or study materials indicate that the maximum allowable temperature range was not reached, the study drug may continue to be dispensed without prior approval from the sponsor.

H. All IDSs cooling systems, refrigerators and freezers are connected to back-up generator power.

I. Cooper Atkins temperature probes do not require calibration. Temperature probes are verified annually to prove accuracy. The Certificate of Calibration for the SysCal device (NIST probe calibration) and the results of testing are uploaded to Vestigo annually.

J. The IDSs will not complete study-specific temperature logs. Temperature logs are uploaded to Vestigo at the beginning of every month and are available for review and documentation during monitoring visits. Copies will not be provided, even at the close of study. IDSs do not add study specific information to the temperature logs.
K. IDSs do not have permanent liquid nitrogen storage.

## REFERENCES

**Citations:**
USP Chapter <1079> Drug Storage and Shipping

**Authoritative Source:** DUH Pharmacy Senior Management Group/Investigational Drug Service

**Additional References:**
NONE

**Associated Policies:**
NONE

**Appendix Name:** IDS Temperature Excursion Form (below)

DukeHealth
Investigational Drug Service Pharmacy
Investigational Chemotherapy Service Pharmacy

## Temperature Excursion Form

| | |
|---|---|
| **IDS/IRB Number:** | **Site Number:** |
| **Sponsor:** | **Protocol Number:** |
| **Primary Investigator:** | |
| **Type of Temperature Excursion:** □ Related to Shipment to Clinical Site **(1)** | □ Related to On-Site Storage **(2)** |

| **1. Shipment Excursion** | |
|---|---|
| **Shipment Number:** | **Has investigational product been quarantined at its specified storage temperature?** □ Yes □ No |
| **Was temperature monitor information downloaded?** □ Yes □ No | |
| **Date/Time shipment contents were put into site storage/quarantine:** | |
| **Temperature monitor Report attached to this Report?** □ Yes □ No | |
| **Shipment Record attached to this Report?** □ Yes □ No | |

| **2. On-Site Storage Excursion** | | | |
|---|---|---|---|
| **Date of Excursion:** | | **Storage Location:** | |
| **Overall Maximum Temperature** | | **Overall Minimum Temperature:** | |
| **Length of Time (in minutes) of Excursion:** | | | |
| **Has investigational product been quarantined at its specified storage temperature?** □ Yes □ No | | **Were any patients dosed with the affected IMP?** □ Yes □ No | |
| **Date/Time affected IMP was put into quarantine:** | | | |
| **Has investigational product (same LOT#/Kit #) experienced previous temperature excursion?** □ Yes □ No | | | |
| **Investigational Product Name** | **Lot Number** | **Number of Units Affected** | **Comments/Other** |
| | | | |
| | | | |
| | | | |
| | | | |
| □ Check if continued on additional pages | | | |

| **Cause of Excursion and Additional Comments:** |
|---|
| |

| **Information Completed By:** | |
|---|---|
| **Name:** | **Email Contact:** |
| **Signature:** | **Date Reported:** |

| **Sponsor's Comments:** | |
|---|---|
| **Investigational product** □ Approved for use | □ Approved for destruction |
| **Name:** | **Email Contact:** |
| **Signature:** | **Date:** |

Duke IDS Form 001 – Temperature Excursion Form // October 18, 2018 ; Reviewed November 09,2020