DukeHealth

Procedure Title: DUHS Pharmacy – IDS Temperature Monitoring

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Applicability:

- ☐ Ambulatory Surgery Center Arringdon
- ☐ Davis Ambulatory Surgery Center (DASC)
- ☐ Duke Health Integrated Practice (DHIP)
- ☐ Duke Health Lake Norman Hospital (DLNH)
- ☐ Duke Health Technology Services (DHTS)
- ☐ Duke HomeCare & Hospice (DHCH)
- ☐ Duke Primary Care (DPC)
- ☒ Duke Regional Hospital (DRH)
- ☒ Duke University Hospital (DUH) (both campuses)
  - ☐ Duke Durham Campus Only
  - ☐ Duke Raleigh Campus Only
- ☐ Patient Revenue Management Organization (PRMO)
- ☐ Population Health Management Office (PHMO)

Purpose:
To define the temperature monitoring process for investigational products (IP) under the responsibility of the Investigational Drug Service Non-Oncology and Oncology Investigational Drug Service pharmacies.

Investigational Drug Service Non-Oncology and Oncology Investigational Drug Service store and manage all investigational products according to the parameters specified in the most current United States Pharmacopeia (USP) guidelines. All ambient temperature storage areas, refrigerators, and freezers utilized by the pharmacies are continuously monitored centrally, 24 hours a day, using a wireless temperature sensor with appropriate staff members notified in the event of an out-of-range temperature excursion.

Scope:
Pharmacy IDS Non-Oncology
Pharmacy Oncology IDS

Definitions/Acronyms:

A. IDS: Investigational Drug Service Non-Oncology, located in Duke Clinic Room 0101B, Yellow Zone
B. ONC IDS: Oncology Investigational Drug Service, located in Cancer Center Infusion Pharmacy Room 4N33, Duke Cancer Center
C. E&O: Duke Engineering and Operations Department
D. TempTrak®: Cooper-Atkins® wireless temperature monitoring system
E. Vestigo®: An electronic, web-based IP inventory management system used by IDS/ONC IDS

Procedure:

A. TEMPERATURE MONITORING OF INVESTIGATIONAL PRODUCTS
   a. Ambient temperature storage areas, refrigerators, and freezers utilized by IDS/ONC IDS are monitored centrally by the Duke University Hospital (DUH) E&O, 24 hours a day using the Cooper-Atkins® wireless temperature monitoring system, TempTrak®.
   b. IDS/ONC IDS cooling systems, refrigerators, freezers, and ambient storage areas are connected to emergency power. During power emergenices, backup generators are activated.
      i. DUH E&O maintain the generators and conduct routine systems checks to ensure proper working equipment.
      ii. Individual equipment maintenance records may not be available as they are owned and maintained by the health system.

c. Cooper Atkins® temperature probes are initially calibrated and verified according to manufacturer specifications. Thereafter, temperature probes are verified annually to prove accuracy. These certificates and the results of the testing are uploaded to Vestigo® annually.
d. TempTrak® logs provide the average, minimum, and maximum temperature in 15-minute intervals. IDS/ONC IDS do not provide temperature data for any other time intervals.
e. TempTrak® logs are uploaded to Vestigo® at the beginning of every month and are reviewed by an IDS/ONC IDS staff member. Copies will not be provided at any point as logs are available for review and documentation during monitoring visits.
    i. Temperature logs are watermarked with Duke Health identification only. Study specific information is not added to these logs.
f. Sponsor supplied temperature monitoring devices will not be used in addition to nor replace the TempTrak® system used by IDS/ONC IDS.
g. During hours of operations (M-F), staff members conduct daily temperature checks and also maintain a backup system using manual min/max thermometers.
h. IDS/ONC IDS do not provide temperature logs for IP stored in outpatient and inpatient care settings.
i. IDS/ONC IDS cannot guarantee temperature monitoring and integrity of IP that have been dispensed to a study team member.
    i. In the event that a study team member picks up prepared/dispensed IP from IDS/ONC IDS, it is the responsibility of the study team to maintain the temperature requirement until the expiration or when the IP are handed off to the participant.
j. When prepared/dispensed IP require being transported by a designated traceable courier, the sponsor must provide the site with a shipping label for transit. Costs associated with shipments may be billed in accordance with institutional billing practices and/or applicable study agreements.
    i. Sponsors who require special handling (e.g., temperature controlled) will be required to supply all shipping and temperature monitoring materials.
k. Stock IP requiring transportation from IDS/ONC IDS will be shipped using a designated traceable courier. A temperature monitoring device (TMD) will be included when required in accordance with sponsor requirements to maintain appropriate temperature conditions throughout transit. Costs associated with shipments may be billed in accordance with institutional billing practices and/or applicable study agreements.
l. IDS/ONC IDS do not provide temperature monitoring of IP being transferred within one physical address or a DUHS campus.
m. The transfer or transport of IP will be recorded within Vestigo® for review and documentation during monitoring visits.

B. ASSEST TEMPERATURE SETTINGS FOR INVESTIGATIONAL PRODUCTS
a. IDS/ONC IDS follow temperature requirements in compliance with USP standards.
b. Temperatures are rounded to the nearest whole number using standard rounding rules.
c. The TempTrak® System alarms are set within the standard temperature ranges so that IDS/ONC IDS staff members are notified before a storage area temperature goes out of range. This allows for preventative action to be taken in the event of equipment malfunction or failure.
d. IDS/ONC IDS do not have permanent liquid nitrogen storage.

Temperature Type	Standard Temperature Range (˚C)	Excursions (˚C)
Controlled Room Temperature	20 to 25	below 15 and above 30
Room/Ambient Temperature	15 to 30	below 15 and above 30
Refrigerator	2 to 8	below 2 and above 8
Freezer	-25 to -15	below -25 and above -10
Ultra Low Freezer	-90 to -60	below -90 and above -60

C. TEMPERATURE EXCURSIONS OF INVESTIGATIONAL PRODUCT SHIPMENTS
   a. IDS/ONC IDS will report temperature excursions of shipments received at the pharmacies.
   b. IDS/ONC IDS do not complete sponsor-specific documentation (paper or electronic) relating to temperature monitoring or reporting.
   c. Excursions are determined by the temperature monitoring device (TMD) or temperature-recording data that accompanies each shipment.
      i. In the event that a room temperature shipment is delivered to the pharmacy without a TMD or temperature-recording data, the pharmacy shall assume the sponsor intentionally elected not to monitor temperatures during transit. Accordingly, the shipment will therefore be accepted as having been compliant with sponsor-designated transport conditions and will be regarded as fit-for-use, unless the sponsor subsequently provides information indicating otherwise.
      ii. In the event that a refrigerated or frozen shipment is delivered to the pharmacy without a TMD or without accessible temperature-recording data, the pharmacy will document receipt of the shipment in Vestigo® under Quarantine status. When applicable, the shipment will likewise be recorded as Quarantined in the sponsor's Interactive Response Technology (IRT) system.
         1. The IP will remain in quarantine and must not be used, dispensed, or moved into active inventory until temperature compliance has been verified. IDS/ONC IDS will immediately notify the sponsor or sponsor representative for further instructions via the *Duke IDS Temperature Excursion Form* (Duke IDS Form – 006) and a copy of the TMD or temperature-recording data report.
         2. Sponsors are expected to provide written confirmation regarding product viability prior to release. If temperature data cannot be retrieved or if the sponsor cannot confirm IP integrity, the IP will be subject to Return to Sponsor or destruction in accordance with *DUHS Pharmacy – IDS Drug Destruction and Disposal.*

D. TEMPERATURE EXCURSIONS OF INVESTIGATIONAL PRODUCTS ON SITE
   a. A reportable temperature excursion is a temperature that has deviated from the standard temperature range, as described in the table above, that is sustained for a continuous period of at least 30 minutes with the temperature rounded to the nearest whole number.
   b. In the event of a **non-reportable** temperature excursion, the following steps will occur:
      i. Appropriate IDS/ONC IDS staff members are notified via alarm, page, and email. IDS/ONC IDS staff members will respond to the notification and investigate the alarming sensor. The TempTrak® alarm and escalation process can be found in the *DUH Pharmacy – Pharmaceutical Temperature Monitoring Policy*.
      ii. If a temperature excursion does not meet the reportable criteria as setforth in this policy, IDS/ONC IDS staff members will mark the alarm as acknowledged in the TempTrak® system.
      iii. IDS/ONC IDS staff members will record the non-reportable temperature excursion in Vestigo® as documented or no-action taken.
      iv. If the temperature of a storage location deviates from the labeled or study-specified allowable temperature range but does not meet the criteria for a reportable excursion as defined by this policy, IP may remain in active inventory and continue to be dispensed without requiring sponsor or sponsor representative fit-for-use approval.
      v. Once the temperature of a storage location has been corrected, IDS/ONC IDS staff members will mark the alarm as cleared in the TempTrak® system.
      vi. In the event that the temperature of a storage location cannot be maintained, appropriate action will be taken to transfer the drug to an alternative storage location that ensures compliance with the specified temperature requirements. This action will be documented and monitored to ensure the integrity of IP are preserved at all times.
   c. In the event of a **reportable** temperature excursion, the following steps will occur:
      i. Appropriate IDS/ONC IDS staff members are notified via alarm, page, and email. IDS/ONC IDS staff members will respond to the notification and investigate the alarming sensor. The

TempTrak® alarm and escalation process can be found in the *DUH Pharmacy – Pharmaceutical Temperature Monitoring Policy*.

ii. The sponsor will be notified via the *Duke IDS Temperature Excursion Form* (Duke IDS Form – 006) accompanied by an electronic copy of the temperatures from TempTrak® during the excursion event within one business day of excursion discovery.

iii. IDS/ONC IDS will not complete supplementary forms if the information requested is captured on our internal temperature excursion form. In the event that the sponsor presents requisites beyond the temperature excursion form, IDS/ONC IDS will make every effort to supply the necessary additional information.

iv. IP will be physically quarantined at the appropriate storage temperature and inventory will be designated as quarantined through documenting the excursion in Vestigo®.
    1. IDS/ONC IDS do not complete documentation or reporting in sponsor IRT systems relating to the quarantining or releasing of IP.
        a. The sponsor will be charged a fee if there is written documentation between the site and sponsor of the agreement to complete IRT functions outside the normal scope of IDS/ONC IDS.

v. Determination of fit-for-use must be communicated in writing by the sponsor and/or sponsor representative. When appropriate, IDS/ONC IDS will release IP back into active inventory in Vestigo®.

vi. If the sponsor determines that the integrity of the IP have been compromised, IDS/ONC IDS will destroy the IP per the *DUHS Pharmacy – IDS Drug Destruction and Disposal.*

Attachment Names: Duke IDS Form 006 – Temperature Excursion Form

References: N/A

Associated Regulatory Standards:
USP Chapter <1079> Drug Storage and Shipping
United States Pharmacopeia (USP) standards, (USP Standard 33-NF28, Sections 10.30.10, 10.30.40,10.30.60))

Associated Policies:
DUH Pharmacy – Pharmaceutical Temperature Monitoring
DUHS Pharmacy – IDS Drug Destruction and Disposal

Authoritative Source: Pharmacy Senior Management Group/Investigational Drug Service

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 ☐ Not Applicable
Was temperature monitor information downloaded? ☐ Yes ☐ No ☐ Not Applicable	
Date/Time shipment contents were put into site storage/quarantine:	
Temperature monitor Report attached to this Report? ☐ Yes ☐ No ☐ Not Applicable	
Shipment Record attached to this Report? ☐ Yes ☐ No ☐ Not Applicable	

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 006 – Temperature Excursion Form // 09 November 2020