

Department of Pharmaceutical Care  
University of Iowa Hospitals and Clinics

Section Research

Related Policy None

**Operating procedure RES-NP002**

INVESTIGATIONAL DRUG TEMPERATURE MONITORING  
AND ACTIONS FOR TEMPERATURE EXCURSIONS

Definitions:

Temperature Excursion: A temperature reading outside of the acceptable temperature ranges and outside of the acceptable storage temperatures as defined per individual protocol AFTER rounding rules are applied.

Investigational product (IP): A new drug or biological drug that is used in a clinical trial. A medication or dosage form that is not approved by the Food and Drug Administration for use in humans (e.g., not commercially available in the US); this includes non-FDA approved medications that are obtained for individual patients as part of a treatment IND, single-patient use, emergency use, compassionate use, or similar protocol. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous. Investigational drug may also refer to any drug which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.

Rounding Rules: When determining an excursion, the temperature will be rounded to the nearest degree (e.g. a room temperature at 14.5° C will not be considered an excursion since it rounds to 15° C.).

General procedures:

- I. Temperature Settings
  - A. The IDS pharmacy will follow USP standards for controlled temperature storage:
    1. Controlled Room Temperature: 20°C to 25°C. with excursions permitted between 15°C and 30°C that are experienced in pharmacies and hospitals.
    2. Refrigerator Storage: 2°C to 8°C
    3. Freezer Storage: -25°C to – 10°C
    4. Currently, there is not established USP standards for Ultra Low Freezer Temperatures. IDS will follow: -60°C to -86.5°C

## II. Temperature Monitoring

- A. IDS uses a continuous temperature monitoring system, TempTrak. The system will be calibrated on an annual basis by internal Engineering Services Department. A Note to File will be generated documenting the calibration and will be provided in lieu of a calibration certificate.
1. Pharmacy staff are notified via page, e-mail, and text to personal phones if the temperature varies from an acceptable range.
  2. If a refrigerator or freezer malfunctions and temperatures exceed the acceptable range, maintenance is being performed on a refrigerator or freezer, or an equipment failure is felt to be imminent, IP will be transferred to a similar, working, monitored unit within the Pharmacy Department. IDS staff will observe the temperature and condition of the malfunctioning unit and will return IP to the unit once any issues have been corrected and temperatures are back within range. In the event of a temperature excursion, any IP involved in the excursion will be quarantined in the appropriate storage conditions and segregated from active IP inventory.
  3. All refrigerators and freezers used to store IP are on emergency backup power.
  4. Temperature reports for any IP stored on patient care units will not be provided.
  5. No sponsor provided temperature monitors will be used in addition or in place of TempTrak.

## III. Temperature Excursions

- A. Controlled Room Temperature: Reportable excursions are defined as a temperature deviation of  $>\pm 5^{\circ}\text{C}$  from the acceptable temperature range as defined above (15-30 $^{\circ}\text{C}$ ), sustained for time of 24 hours. When determining an excursion, the temperature will be rounded to the nearest degree.
1. Reporting of any excursion more than 5 $^{\circ}\text{C}$  from the acceptable temperature range AND for a sustained period of 24 hours (must meet both criteria)
  2. Excursions more than 5 $^{\circ}\text{C}$  from the acceptable temperature range lasting less than 24 hours will not be reported
    - Extreme temperature excursions below 2 $^{\circ}\text{C}$  or above 40 $^{\circ}\text{C}$  for any duration will be reported.
  3. Any temperature from 15-20 $^{\circ}\text{C}$  or 25-30 $^{\circ}\text{C}$  for any duration will not be reported and no excursion form will be completed.
- B. Refrigerated, Freezer, and Ultra Low Freezer Temperature: Reportable excursions are defined as a temperature deviation of  $\pm 1^{\circ}\text{C}$  from the acceptable temperature ranges as defined above AFTER rounding, sustained for a contiguous period of 30 minutes or more.

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1. Reporting of any excursion more than 1°C from the acceptable temperature range AND lasting longer than 30 minutes (must meet both criteria).
2. Excursion more than 1° C lasting 30 minutes or less will not be reported.
3. Any temperature less than or equal to 1° C outside of the standard range for any duration will not be reported and no excursion form will be completed.

#### C. Documentation

1. The IDS pharmacy will use only the University of Iowa Hospitals Investigational Drug Service Pharmacy Standardized Temperature Excursion Form for reporting all temperature excursions.
2. The IDS pharmacy will quarantine IP until written approval is received from the sponsor.

Approved by the Pharmacy Administrative Staff: 9/2021.

Revised:

Reviewed:

## Standardized Temperature Excursion Report Form

<b>Protocol No.:</b>	<b>Investigational Product(s):</b>	
<b>Location reporting temperature excursion:</b>	<input type="checkbox"/> <b>Site</b> <b>Site No.:</b>	<input type="checkbox"/> <b>Shipment</b>
<b>Pharmacy Reporter Name:</b>	<b>Telephone No.:</b>	<b>Email Address:</b>

## 1. IMMEDIATE ACTION TAKEN

- a) Has the IP been physically quarantined, according to the temperature range on the IP label?
- YES  NO

## 2. DETAILS OF TEMPERATURE EXCURSION

<input type="checkbox"/> <b>TEMPERATURE EXCURSION DURING IP SHIPMENT Section I</b> (Skip to Section II if the excursion occurred during IP Storage)	
<b>Shipment arrival date.</b> <b>Time:</b>	<b>Serial No. of Temperature Monitoring Device:</b>
<b>Additional comments:</b>	
<b>Probable cause(s) for temperature excursion:</b>	<input type="checkbox"/> <b>Shipment delayed</b> <input type="checkbox"/> <b>Packaging opened/damaged on receipt</b> <input type="checkbox"/> <b>Temperature monitoring device not stopped in time</b> <input type="checkbox"/> <b>Other:</b>

<input type="checkbox"/> TEMPERATURE EXCURSION DURING IP STORAGE (Section II)
<b>IP lot number and quantity affected due to temperature excursion:</b>
<b>Serial Number of Temperature Monitoring Device:</b>
<b>Data (high/low temps) for the refrigerator/freezer/ambient, and for how long the temperature was outside the limits:</b>
<b>Additional comments:</b>
<b>Probable cause(s) for temperature out-of-range:</b> <input type="checkbox"/> Prolonged opening of refrigerator <input type="checkbox"/> Temperature Monitoring device moved/misplaced <input type="checkbox"/> Power Outage <input type="checkbox"/> Routine maintenance of refrigerator <input type="checkbox"/> Equipment failure <input type="checkbox"/> Other:
<b>Is the last temperature data point for this temperature excursion outside the acceptable range for this IP?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No

## 4. SPONSOR RESPONSE

<input type="checkbox"/> <b>Quality of IP has not been compromised and may continue to be used in the clinical trial. Release the IP for clinical use.</b>		
<input type="checkbox"/> <b>IP is not approved for further use and should be identified as “damaged.” If temperature excursion is reported by the site, retain damaged IP until further instructions are provided.</b>		
<b>NAME:</b>	<b>SIGNATURE</b>	<b>DATE</b>