

Stanley Manne Children's Research Institute™

Department Policy and Procedure Manual

Investigational Drug Service (IDS) Medication Storage Temperature Monitoring Procedure

Effective Date: 05/01/2023

Scope: Investigational Drug Service (IDS) Pharmacy

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I. Purpose

To outline the temperature storage of products in the IDS Pharmacy.

II. Definitions

- A. **Temperature Excursion:** A temperature reading outside of the acceptable temperature ranges.
- B. **Vestigo®:** A 21 CFR Part 11 compliant electronic accountability software application designed specifically for investigational pharmacy use and utilized by Lurie Children's Hospital of Chicago IDS Pharmacy. Refer to <https://www.mccreadiegroup.com/solutions/vestigo/> for additional information.

III. Policy Statements

- A. Temperatures for all pharmacy areas are maintained in accordance with the Lurie Children's Administrative Policy and Procedure Manual: Medication Storage.
- B. The IDS Pharmacy uses Fisher brand Traceable thermometers. These thermometers are placed in all storage locations (i.e., room temperature, refrigerator, freezer). These *primary temperature system* devices record continuously 7 days a week. The current, maximum, and minimum temperatures are noted on an Excel spreadsheet daily Monday through Friday excluding holidays.
- C. The hospital's Facilities Department is responsible for insuring appropriate functioning of all heating, air conditioning, refrigerators, and freezers. The hospital uses Johnsons Controls for continual monitoring of room, refrigerator, and freezer temperatures. These devices are used as a *secondary temperature system* during a temperature excursion and record temperatures every 60 minutes. Electronic temperature records from these devices are only provided in the event of a temperature excursion.
- D. The hospital's Facilities Department has set the following alarms:
 - Room temperature range at 15-25°C
 - Refrigerator temperature range at 2-8°C
 - Freezer temperature range at -25°C to -15°C (-20°C, +/-5°C)
 - Ultra-Low freezer temperature range at -90°C to -70°C (-80°C +/- 10°C)
- E. No sponsor provided temperature logs/monitors will be used in addition to or in place of IDS Pharmacy's temperature logs/monitors.
- F. All temperature records are converted into a searchable PDF document at the end of each month and stored on a secure hard drive and uploaded into Vestigo®. Temperature records will not be filed in each individual study binder.
 - a. IDS Pharmacy will not run temperature reports for mid-month data for individual monitor visits. This data will be available at the next monitoring visit.

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- b. In the event of an audit or study close-out, an exception will be made, and the most up-to-date temperature reports will be generated.
- G. All thermometers are replaced based on the due date noted on each calibration certificate.
- H. All calibration certificates are uploaded into Vestigo® or will be available upon request. Calibration certificates will not be filed in each individual study binder.
- I. All refrigerators and freezers are plugged into emergency power outlets and will switch to the emergency power generators should there be a hospital-wide power failure.

IV. Procedures

- A. Investigational medications affected in a temperature excursion will be quarantined and relocated to an appropriate temperature location (i.e., room, refrigerator, freezer, or ultra-low freezer) within the Pharmacy Department.
- B. The Investigator/Clinical Research Professional and the study monitor/supplier will be notified of any temperature excursion.
- C. If required, a Note to File will be generated by the IDS Pharmacy and stored with the study records for all affected medications once the issue is resolved.

V. Cross References / Related Policies

Administrative Policy and Procedure Manual-Medication Storage

Date Written: 03/01/2023

Date Reviewed/Revised:

Approvals [as applicable]:

Key Stakeholders (e.g., ACRO for Clinical Trials, Pharmacy, etc.):

Director, Research Compliance: 4/26/2023

Director, Clinical and Community Trials (OCCT): 4/27/2023

Manager, IDS Pharmacy: 4/27/2023

Chief Operating Officer, Manne Research Institute: N/A

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