

Department Policy and Procedure Manual

Investigational Drug Services (IDS) Medication Storage Temperature Monitoring Procedure for Room Temperature and Refrigerator Temperature Monitoring

Effective Date: November 20, 2018

Scope: Department wide

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**I. Purpose:** To outline the room and refrigerated storage of products in the IDS Pharmacy.

**II. Policy Statements**

- A. **Temperatures are maintained in accordance with the Lurie Children's standard procedure for all pharmacy areas in accordance with Administrative Policy and Procedure Manual: Medication Storage.**
- B. **The hospital facilities/maintenance department is responsible for insuring appropriate functioning for all heating, air conditioning and refrigerators. The hospital uses Johnson controls for continual monitoring of room and refrigerated temperatures. The facilities/maintenance department has set the room temperature alarm at 15-25 C and refrigerator alarm at 2-8 C.**

**III. Procedures**

A. Room Temperature

**IDS Monitoring Record** - The IDS Pharmacy uses Control Company Traceable thermometer to measure the room temperature. The device records continually 7 days a week. The current, maximum and minimum temperatures are noted on an Excel spreadsheet daily Monday through Friday excluding holidays. Thermometers are replaced based on the retest date on the back of each thermometer.

**Temperature excursion** - The Investigator/Clinical Research Professional and the study monitor/supplier will be notified of any temperature excursions and the investigational medications will be quarantined until further notice from the study monitor/supplier. 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.

**Location of Records** - All temperature records are converted into a searchable PDF document at the end of each month and stored on a secure hard drive.

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B. Refrigerator Temperature

**IDS Monitoring Record** - The IDS Pharmacy uses Fisher brand Traceable thermometer to measure the refrigerator temperature. The device records continually 7 days a week. The current, maximum and minimum temperatures are noted on an Excel spreadsheet daily Monday through Friday excluding holidays. Thermometers are replaced based on the retest date on the back of each thermometer.

**Temperature excursion** - The investigational medications in the affected refrigerator will be quarantined and temporarily relocated to one of the other refrigerators in the IDS Pharmacy. The temporary location of the product will be tracked on a log. The Investigator/Clinical Research Professional and the study monitor/supplier will be notified of any temperature excursions. 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.

**Emergency Power** - All refrigerators will switch to the emergency power generators should there be a hospital power failure.

**Location of Records** - All temperature records are converted into a searchable PDF document at the end of each month and stored on a secure hard drive.

**IV. Cross References / Related Policies**

**Administrative Policy and Procedure Manual-Medication Storage**

Date Written: November 20, 2018

Date Reviewed/Revised: 02/11/2021