

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. Room temperature range is from 20-25 C and refrigerated range is from 2-8 C.**
- 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.**

III. Procedures

A. Room Temperature

IDS Monitoring Record-IDS 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 thru 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 printed at the end of each month and maintained in a file folder located in the IDS pharmacy.

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B. Refrigerator Temperature

IDS Monitoring Record- IDS 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 thru 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 printed at the end of each month and maintained in a file folder located in the IDS pharmacy.

IV. Cross References / Related Policies

Administrative Policy and Procedure Manual-Medication Storage

Date Written: November 20, 2018

Date Reviewed/Revised: