

Department Policy and Procedure Manual

Investigational Drug Services (IDS) Medication Storage Temperature Monitoring Procedure for Freezer (-15C and -70C) Temperature Monitoring

Effective Date: November 20, 2018

Scope: Department wide

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I. Purpose: To outline the freezer 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. Deep freezer temperature range is below -70C +/- 10C and the other freezer range is -15C or cooler.**
- B. **The hospital facilities/maintenance department is responsible for insuring appropriate functioning for all freezers. The hospital uses Johnson controls for continual monitoring of freezer temperatures.**

III. Procedures

A. Freezer (-20C) Temperature

IDS Monitoring Record- IDS uses Fisher brand Traceable thermometer to measure the freezer 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 freezer will be quarantined and temporarily relocated to a freezer in the inpatient 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.

B. Freezer (-70C) Temperature

IDS Monitoring Record- IDS uses the manufacturer supplied thermometer to measure the freezer temperature (Thermo Scientific). The device records continually 7 days a week. The current temperature is noted on an Excel spreadsheet daily Monday thru Friday excluding holidays.

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Temperature excursion- The investigational medications in the affected freezer will be kept in the freezer and quarantined as there is not another location for the product to be stored. If the freezer is down for an extended period of time, the product will be stored at room temperature. 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 freezers 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: March 20, 2019