

Department Policy and Procedure Manual

Investigational Drug Services (IDS) Medication Storage Temperature Monitoring Procedure for Freezer (-20C and -80C) Temperature Monitoring

Effective Date: November 20, 2018

Scope: Department wide

Page 1 of 2

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 -80C +/- 10C.

Freezer temperature range is -20C, +/-10C.

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 Pharmacy 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 (-80C) Temperature

IDS Monitoring Record - IDS Pharmacy 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.

Department Policy and Procedure Manual

Investigational Drug Services (IDS) Medication Storage Temperature Monitoring Procedure for Freezer (-20C and -80C) Temperature Monitoring

Effective Date: November 20, 2018

Scope: Department wide

Page 2 of 2

Temperature excursion – Since this is the only -80C medication freezer in the hospital, the affected investigational medications will be quarantined in the -80C freezer. If the freezer is down for an extended period, 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 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: 03/20/2019, 02/11/2021