University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Date Created: **January 5th, 2024**

Title: **Medication Storage**

Version Date: **January 5th, 2024**

SOP Number: **CO43**

PURPOSE: Medications will be stored securely in the Clinical Research Center (CRC) for patient safety, the promotion of prompt delivery, and in compliance with regulatory agencies.

SCOPE: This policy applies to all investigational product and/or study related medication to be stored in the Clinical Research Center and administered to patients onsite for a specific study protocol.

PERSONNEL RESPONSBILE: CRC registered nurses (RNs), CRC staff, Investigational Drug Services (IDS) Pharmacy, Research Nurse Manager

PROCEDURES:

1. Only medications approved by the CRC leadership team and IDS will be stored in the CRC Clinical Research Unit (CRU).
2. Medications will be stored under necessary conditions to ensure stability including proper temperature and limiting light exposure when indicated.
3. Medications will be dispensed by IDS Pharmacy in accordance with their policy and procedures. An EPIC order will be required for the medication to be dispensed.
4. The research coordinator and/or CRC RNs will obtain the medication from an IDS staff member. Upon receipt of the medication in the CRC, the CRC RN will verify the label.
5. The medication will be labeled with the patient's name, date of birth, product name, administration instructions, expiration date, protocol pet name, and IRB number. If the medication is stored in a product box (e.g., albuterol), both the box and individual administration device will be labeled.
6. When not in use, the medication will be stored in a designated locked cabinet in the CRC. Stored medication will be kept in separate bins and/or Ziplock bags to prevent cross contamination. CRC staff will check the medication's expiration date monthly and document this check on a log (see Attachment A).
7. Once an order is placed for a research subject to receive the stored medication, the CRC RN will unlock the storage cabinet, and pull the appropriate medication. The medication will be checked by the RN with at least two patient identifiers (e.g., name and date of birth). A second RN will independently verify the medication with at least two patient identifiers.
8. Medication will be administered and documented in line with study protocol, and CRC and Nebraska Medicine policy.
9. Any empty, damaged, expired, or unused product will be returned to IDS Pharmacy, who will follow their destruction policy ADM019.

RESOURCES:

Nebraska Medicine:

MM05: Medication Security and Storage
ADM019: Destruction of Investigational Products
IDS SOP-03: Investigational Product Returns and Destruction

21CFR205.50

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ATTACHMENTS:
Medication Check Log

Department Approval

Signed Serena Gaines
Research Nurse Manager
Signed: 1/5/2024

Signed
Assistant Vice Chancellor for Clinical Research
Signed: 1/5/2024

University of Nebraska Medical Center
Nebraska Medicine

Clinical Research Center

Monthly Medication Check Log

Date: DD-MMM-YYYY	Medications Checked	If required, medications discarded and coordinator notified:	Initials	Comments