Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**
Date Created: **January 1, 2025**
Title: **Investigational Product Handling**
Version Date: **January 1, 2025**
SOP Number: **CO06**

PURPOSE: The purpose of this standard operating procedure (SOP) is to describe the process for the Clinical Research Center's handling of investigational products received from the Investigational Drug Service (IDS) Pharmacy that are to be administered in the Clinical Research Center (CRC).

SCOPE: This SOP applies to all Investigational Product (IP) administered by study staff using CRC space, including non-CRC employed coordinators, and all CRC Staff involved in the care of clinical research subjects who are receiving an IP in a CRC CRU.

PERSONNEL RESPONSIBLE: Clinical research nurse(s) and/or any other research study personnel that may be delegated the task of obtaining IP from IDS. Only registered nurses (RN), who are appropriately trained and credentialed with Nebraska Medicine, will administer the IP. Home prescriptions for oral medications can be self-administered in the CRC and documented by RN or non-RN staff on study specific documents. Oral medications and/or home prescriptions will be picked up by the study specific coordinator.

DEFINITIONS:
Investigational Product (IP): A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

PROCEDURES:
1. All IDS policies and procedures will be followed. Once IDS has prepared the IP and it is ready for pick up, IDS will call the CRC clinic main number at 402.559.7685.
    a. If the call is not answered, IDS staff will email CRCResearchNurses@unmc.edu.
2. A CRC RN or a CRC delegated staff member will complete an IDS pickup form and go to the Pharmacy at Durham Outpatient Center, located on level two of Durham Outpatient Center, as soon as it is feasible to do so.
3. CRC staff members will pick up IP from Pharmacy staff members at the counter. If a long line is noted, CRC staff member can call IDS at 402.559.6600 so drug can be delivered to CRC staff member outside of the standard process.
    a. If the IP is blinded, no staff that is considered blinded to the study may handle the unblinded product.

4. IP is internally transferred to the CRC CRU.
    a. Internal transfers consist of IP transfer within the walls of the medical center and occur in a timely fashion (e.g., within 5-minute walk). Internal transfers consist of IP movement from the control location to an alternate location for continued storage or to be provided directly to a research participant. Temperature monitoring is not conducted during internal transfers due to limited time and exposure to external elements.
    b. External transfers of IP will be discussed with IDS prior to their transfer to ensure all policies and procedures are followed.

RESOURCES:

Nebraska Medicine:

Research Pharmacy | CCTR | University of Nebraska Medical Center

Other:

ICH GCP - 1. GLOSSARY

Department Approval

Signed Serena Gaines Signed: 1/26/2025

Research Nurse Manager

Signed Signed: 1/31/2025

Assistant Vice Chancellor for Clinical Research