University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section **Clinical Research Center** Date Created: **November 1st, 2010**

Title: **Pharmacy Services** Date Reviewed/Modified: **April 1, 2019**

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PURPOSE: Prior to any clinical trial utilizing an investigational product, the protocol must be reviewed and approved by the Pharmacy & Therapeutics (P&T) Committee and the Institutional Review Board (IRB) for safety and adequate monitoring of subjects. The purpose of this standard operating procedure (SOP) is to describe the process for the storing, dispensing, administration and accountability of investigational products after these approvals.

SCOPE: This SOP applies to all site personnel involved in the appropriate storing, dispensing, administration and accountability of investigational products in a clinical trial in the Clinical Research Center (CRC).

PERSONNEL RESPONSIBLE:

- **Principal Investigator** is responsible for ensuring investigational products are dispensed and administered safely to research subjects and accounted for accurately in accordance with the research protocols.

- **Research coordinators** work collaboratively with the Investigators, Investigational Pharmacist, Nebraska Medicine Nursing Staff, and the Pharmaceutical Sponsor to ensure investigational products are handled according to the research protocol and comply with Nebraska Medicine system policies throughout the clinical trial.

DEFINITIONS:

- **Investigational Product (IP) -**A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes 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.

- **Investigational Device Exemption (IDE) -** as defined in 21 CFR Part 812 allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by the FDA and by an institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

- **The Medical Staff Pharmacy & Therapeutics (P&T) Committee** – This is a committee that reviews Institutional Review Board (IRB) protocols studying the effects of investigational or marketed drugs. The purpose of the review is to ensure safety and adequate monitoring of Nebraska Medicine patients in the clinical setting.

- **Institutional Review Board (IRB) -** An independent group made up of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by reviewing and approving the clinical protocol, informed consent forms, and the methods and materials used in the trial.

PROCEDURES:

A. Investigational Product Storage and Dispensing
   1. Investigational medications used for both in-patient and outpatient studies are received, stored and dispensed through the Investigational Pharmacy at Nebraska Medicine.
   2. Investigational product receipt, storage, and dispensing by the Pharmacy are completed per the Nebraska Medicine Policies and Procedures.
   3. Investigational product is only stored with the coordinator when it is picked up early for a same day visit. When this occurs, the IP should be stored appropriately in either a locked drawer or IP refrigerator in the CRC.
   4. Temperature control of IP
      - Investigational products requiring specific temperatures for storage (i.e. refrigeration) shall be stored in the Investigational Pharmacy until it is needed and dispensed.
      - Temperature logs will be maintained according to Nebraska Medicine Pharmacy Policy. Temperatures are monitored 24hours a day/7 days a week and is set up on an alarm system.
      - In the CRC, room temperatures and refrigerators logs, where IP may be stored are maintained. A standard CRC log will be used unless a sponsor requests the use of a study specific log. Ranges of temperatures are recorded daily when the CRC is open (not recorded on holidays or weekends).
      - If required, per protocol procedures IP temperatures will be documented during transport, using sponsor provided devices.
   5. Controlled substances
      - Security measures will be established per the Investigational Pharmacist's recommendations.
      - Sponsor representatives may inspect Nebraska Medicine pharmacy or CRC office storage areas for IP accountability at any time. Appointments can be scheduled with the Investigational Pharmacist as needed by contacting 402-559-5255.
      - Controlled substances will never be left in an unlocked area or left unattended in the CRC.

6. Follow institutional Policy for Investigational Drugs (NM MSO5)

B. The Investigational Pharmacy, in collaboration with the CRC, determines whether the Pharmacy or CRC nursing personnel complete the protocol-specific randomization process.

C. Investigational Product Administration
   1. If the study requires randomization this is completed prior to ordering the drug/study kit using sponsor provided system such as IXRS.
   2. For Outpatient prescriptions - the CRC coordinator orders the IP from the pharmacy via One Chart. The coordinator scans the order to the outpatient pharmacy to be filled. The coordinator then picks up the IP and double checks that it is the correct kit#, drug and dosage and verifies that he/she is giving it to the correct participant (verify participant's full name and date of birth) with correct instruction on how to take the IP.
   3. For Inpatient prescriptions - the coordinator orders the IP from the pharmacy via One Chart. Arrangements are made ahead of time with the Investigational pharmacist as to how it is labeled, dispensed, and administered (verify participant's full name and date of birth).

D. Investigational Product Accountability
   1. It is the Investigator's responsibility to ensure accurate documentation for all IPs dispensed under their medical authority.
   2. The CRC coordinator works collaboratively with the Investigator to reconcile the IP accountability records and document discrepancies. Discrepancies may include, but are not limited to, participant compliance and variances in "pill" counts.
   3. The sponsor's representative periodically and at study close out reviews the study specific drug accountability record and may facilitate return of IP supply or request the site pharmacy to dispose of the IP.
   4. Investigational product records are to be maintained by the CRC coordinator and/or investigational pharmacist with oversight by the study Investigator.
   5. IP returned by the study participant is returned to Investigational Pharmacy or locked in a drawer/cabinet until it can be returned to the pharmacy.
   6. All IP accountability records are stored with the research records and stored by the investigator's department.
   7. Reorder process for investigational product is protocol specific.

E. Emergency Unblinding

1. Unblinding of investigational product is done when the safety of the study participant is compromised making it necessary to know the assignment of the study drug or dose. The Investigator determines unblinding (if a sponsor is involved they are to be consulted).
2. Unblinding procedures are protocol specific and may include a tear-off label, sealed envelopes, or calling an automated system for example.
3. Prior to enrollment, the study specific procedures for unblinding a study are documented in a central regulatory binder by the coordinator. The Investigator and all study-related personnel retain copies.

RESOURCES:

Nebraska Medicine:

- Nursing Policy MED-2 Medication Administration
- Nursing Policy MED-7 Intravenous Medication & Solution Administration
- MS05 Investigational Drugs
- MS07 Medical Staff Pharmacy and Therapeutics Committee
- RI10 Patient Identification
- MS09 Medication Orders
- MI29 Investigational Device
- EC20 Disposal of Pharmaceutical Products

ICH GCP Guidelines E6 document, section 5.16 Safety Information
21 CFR 312.32 IND Safety Reports
Epic-Research Learning Home One Chart Tip Sheets-Transitioning to the Visit Taskbar
(This is how to enter orders into Epic for the IP)

Staff Accountability:

Developed By: Director of Clinical Research Center, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Research Coordinator, Clinical Research Center

Department Approval

Signed _____
Director of Clinical Research Operations

Signed _____
Medical Director of Clinical Research Center