



Standard Operating Procedures Clinical and *T*ranslational *R*esearch *C*enter

Title:	Medication Administration		
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Purpose: To provide a regulatory framework and guidelines for the safe and appropriate administration of medication to research protocol participants.

Procedure: The administration of medication to research participants will be aligned with an Institutional Review Board (IRB) approved protocol. All personnel administering medications must do so within the confines of their scope of licensure while adhering to the protocol in which the participant has been enrolled. Regulatory procedures may differ from site to site

A. Drug Administration

1. Use the RIGHT:
 - a. Medication
 - b. Dose
 - c. Route
 - d. Time
 - e. Patient(participant)

2. Two unique participant identifiers must be used to verify identity
3. Read label three times
 - a. Before removing medication from the stored location
 - b. Before removing from original the container/prepping for participant administration (i.e., pouring, aspirating in a syringe, spiking I.V. bag, etc.)
 - c. Before returning to storage area or discarding the unit dose wrapper.
4. Examine medications to ensure they are without any indication of tampering, contamination, deterioration or expiration
5. Document all medication administration
 - a. Date and time
 - b. Name of medication
 - c. Dose
 - d. Route
 - e. Site (if appropriate)
 - f. Initial's and class of person(s) administering
 - g. Response and action of any adverse drug reaction

B. Study Medication

1. Stock Approval
 - a. Medical Director
 - b. IRB Protocol Study Drugs

C. Controlled/Investigational Drugs

1. Only members of the clinical staff duly registered with the Federal Drug Enforcement Administration (DEA) and holding a valid and current DEA registration may prescribe controlled drugs.
2. Controlled/Investigational Drugs must be included in the IRB approved study protocol and signed consent given by the participant.
3. Only members of the clinical staff duly licensed and holding a valid and current license may administer controlled/investigational drugs.
4. An order for a controlled/investigational drug for use in CTRC shall be written on the participant's record, signed and dated by the prescribing PI/ Co-I.
5. The loss or destruction of controlled/investigational drugs must be reported in accordance to the regulatory bodies

D. High Alert Medications

1. Must be labeled as such and given careful attention to safeguard the participant from dosing errors
2. Assessed for the correct name and dose by at least two licensed medical staff members prior to administering to the participant.

E. Order and Delivery

1. The burden of prepackaging and labeling protocol specific medications for participant distribution shall lie solely with the pharmacist or under the pharmacist supervision.
 - a. Protocol Specific Medications are maintained in the CTRC based on participant's visit schedule and study protocol status

2. Principal Investigators or their designee purchasing /receiving medication should make arrangements with the pharmacist prior to delivery
 - a. Medication must be received in its original shipping container, sealed and without evidence of tampering
 - b. An invoice indicating contents of container should be attached whenever possible so that parties exchanging packages

F. Storage

1. Medication Room
 - a. Temperature 59 – 86 Fahrenheit

2. Refrigerator
 - a. Temperature 36-46 Fahrenheit
 - b. Must contain only medications labeled for refrigeration(enteral/parenteral)
 - c. Shall be connected to an emergency power outlet

3. Recording/Monitoring
 - a. Temperature recorded in a log daily during hours of operation by a designated CTRC clinical staff member.
 - b. Records are to be retained on the unit for three years.

G. Expiration of Multi-Dose Parenteral Medication Vials

1. Date

- a. Unopened vials maintain the manufacturer's listed expiration date.
- b. Opened vials (e.g., an individual removes a vial cap or punctures a vial) revised 28 day is identified and the vial labeled as such.

Note: An exception applies only if the manufacturers' original expiration date is less than 28 days or packet insert specifies otherwise.

2. Manufacturer Expiration Date

- a. Where the date is expressed in three time elements (i.e., month, day, and year) the expiration date is that date.
- b. Where the date is expressed in only the month and year the expiration date is the last day of the month indicated

H. Single Dose (preservative free) Vials

1. Single-Dose vials are not to be used as multi-dose
2. Discarded after initial use/opening regardless of their size or capacity

I. Unused Medication (e.g. , outdated , contaminated, discontinued)

1. Unused medication should be returned to the pharmacist for proper disposal
 - a. Exception controlled substances which should be appropriately wasted

J. Medication Security

1. Designated drug preparation areas and medication rooms/carts must be kept locked
2. Only the pharmacist and approved CTRC clinical staff may have access
3. Licensed medical staff must be present if any other non-approved persons need gain entry(e.g., housekeeping, maintenance workers)
4. In the event of a breach of security, CTRC Nurse Managers will notify the proper authorities(e.g., public safety, local policing agency),secure the area upon discovery and ensure the restoration of security.

K. Drug Recalls

1. Pharmacy manages the recall of pharmaceuticals by vendors, distributors, or the FDA
2. Drug recall notices will be sent to CTRC Nurse Managers and Principal Investigators when appropriate