

January 29, 2013

**RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Handling of Inpatient Investigational Drugs**

1. PURPOSE: To establish a standard operating procedure for the handling of inpatient investigational drugs utilized in clinical research at the South Texas Veterans Health Care System (STVHCS).

2. POLICY: It is STVHCS policy that nursing, research pharmacy, investigators, study coordinators and designated study staff, house staff and attendings will collaborate to accommodate the dispensing and/or administration of investigational drugs to inpatients as detailed in this standard operating procedure.

3. ACTION:

a. **Procedures**

(1) **Principal Investigator**

- (a) The Principal Investigator will be responsible for ensuring study protocol approval by the Research and Development (R&D) Committee and the Institutional Review Board (IRB) prior to study initiation.
- (b) The Principal Investigator will ensure appropriate training to house staff has been provided for study protocols conducted on inpatients.
- (c) The Principal Investigator will communicate the status of protocols and study participants receiving investigational drugs to the Research Pharmacist.

(2) **Research Pharmacist**

- (a) The Research Pharmacist will coordinate with the Principal Investigator and/or Study Coordinator/Staff training and education of inpatient study procedures to the house staff.

(3) **Nursing Inservice**

- (a) The Principal Investigator (PI), study coordinator and/or research pharmacist will conduct an inservice for nursing units of inpatient wards subject to participants selected for the study protocol.
- (b) The inservice will provide pertinent information involved in nursing's receipt, storage, security, administration, transfer and final disposition of the investigational drug.
- (c) The PI, study coordinator or research pharmacist will provide a brief nursing procedure handout to each of the nurse managers and nursing units designed to educate nursing staff. This handout should also be displayed in each of their respective medication rooms.
- (d) Nurse managers will be responsible for ensuring the dissemination investigational drug information and procedures to their respective nursing staff.

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(4) Research Consent/Enrollment Note

- (a) The PI or designated, trained study staff must enter a "Research Consent/Enrollment Note" in the computerized patient record system (CPRS) after informed consent is obtained. The note should be co-signed by the attending physician, the nurse manager and the assistant nurse manager of the inpatient ward.

(5) Ordering

- (a) An authorized prescriber will place electronic orders for investigational drug(s) in the study participant's CPRS record. If written orders signed by an authorized prescriber are provided to the research pharmacist, then the research pharmacist will enter electronic orders for the investigational drug(s) in the study participant's CPRS record. *NOTE: Only those authorized prescribers listed on VA Form 10-9012, Investigational Drug Information Record, can electronically sign the investigational drug order.*

(6) Preparation and Dispensing by the Research Pharmacist

- (a) The research pharmacist will confirm and document the study participant's signed Informed Consent Form and copy of VA Form 10-9012 are scanned into the study participant's CPRS record.
- (b) If applicable, the research pharmacist will randomize the patient pursuant to the study protocol.
- (c) The research pharmacist will be responsible for preparing the investigational drug for delivery to the inpatient ward or to the Principal Investigator and/or designated study staff. All investigational drugs will be provided with BCMA barcodes and labeled specific to each study participant's name in accordance with STVHCS pharmacy labeling requirements. The investigational drug will be packaged in a plastic bag containing an insert describing the study protocol, study medication and contact information (Attachment 1).
- (d) The research pharmacist or designated study staff will deliver investigational drugs accompanied by hard chart flyer (Attachment 2) to the study participant's assigned nurse on the ward.
 - 1. The function of the hard chart flyer is two-fold:
 - a. To alert nursing staff that the patient is enrolled in a study protocol (this hard chart flyer will be posted on the head of the study participant's bed); and
 - b. To serve as a chain of custody ensuring investigational drugs are transferred with the patient when transferred to another ward

(7) Receipt by Nursing

- (a) The nurse or designated study staff receiving the study medication will sign the investigational medication pick-up log provided by the research pharmacist at the time of receipt.

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(8) Storage

- (a) A cassette in the medication cart will be labeled as “Investigational Drug”.
 - 1. The cassette will not be changed out by inpatient pharmacy.
 - 2. The cassette will contain investigational drug for only one participant on study. If more than one participant is on study on any given ward, an additional cassette will be labeled “Investigational Drug”. Each cassette labeled “Investigational Drug” will also have the name of one study participant.
- (b) The nurse will store and secure the investigational drug in the “Investigational Drug” cassette in the medication cart.
- (c) The nurse securing the investigational drug in the appropriate cassette will complete and sign the form on the back of the hard chart flyer prior to posting it on the head of the study participant’s bed.

(9) Administration

- (a) The nurses should administer investigational drugs in accordance with STVHCS inpatient medication administration policy.
- (b) Bar codes associated with the investigational drugs will be affixed to the label to aid the documentation of administration through the BCMA system. *NOTE: Investigational drugs are specific for each individual study participant and should only be administered to the participant whose name is included on the label affixed to the investigational drug.*

(10) Transfer to another ward

- (a) Nursing staff will ensure investigational drugs are transferred with study participants as they are moved between inpatient wards.
 - 1. Nursing staff will transfer both the investigational drug and the hard chart flyer to the appropriate ward.
 - 2. The receiving nurse will secure the investigational drug in the medication cart as previously detailed.
 - 3. The transferring nurse and the receiving nurse will complete and sign the form on the back of the hard chart flyer documenting the transfer and newly secured storage of investigational drug.

(11) Final Disposition

- (a) At discharge, nursing staff will contact the PI, study coordinator and/or research pharmacist. Contact information for these individuals is located on the hard chart flyer and on the investigational drug insert.
- (b) The research pharmacist or designated study staff will collect the remaining investigational drug from nursing on the respective wards.

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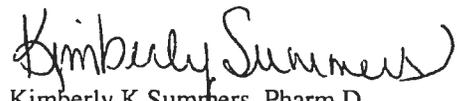
- (c) The research pharmacist and designated study staff or transferring nurse must complete and sign the form on the back of the hard chart flyer to document return of study medication to the research pharmacy.

4. REFERENCES: None

5. RESPONSIBILITY: ACOS for Research and Development (151)

6. RESCISSIONS: Research Service SOP for Handling of Inpatient Investigational Drugs dated October 7, 2011

7. RECERTIFICATION: October 2016



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Attachments (2)