DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404

Pharmacy Service
119PR-15-003
December 12, 2014

RESEARCH PHARMACY STANDARD OPERATING PROCEDURES (SOP)
Handling of Investigational Drugs Obtained from a VA Affiliate

1. **PURPOSE**: To establish policy and procedures for the verification and accounting of investigational drugs delivered to the South Texas Veterans Health Care System (STVHCS) from a University or Veterans Affairs (VA) Affiliate or of investigational drugs provided to a University of VA Affiliate under an existing letter of understanding (LOU) which will provide adequate safeguards for protecting patients, staff and the quality of study protocols involving investigational drugs.

2. **POLICY**:

   a. Definitions

      (1) Letter of Understanding (LOU): An understanding between a University Affiliate or VA Affiliate and the South Texas Veterans Health Care System (STVHCS) regarding the circumstances under which the Affiliate agrees to provide investigational drug(s) to STVHCS for a specified study protocol (Attachment 1) or under which STVHCS agrees to provide investiational drug(s) to the Affiliate (Attachment 2).

3. **ACTION**: The procedures described below will be followed for all study protocols involving investigational drugs obtained from or provided to an Affiliate:

   a. **Protocol Review and Set-up**

      (1) For each approved research study protocol where the drug being tested or evaluated in a study protocol is prepared by an Affiliate for administration or dispensing to a study participant at STVHCS or STVHCS prepares the drug for administration or dispensing to a study participant at an Affiliate, an LOU will be drafted by the Research Pharmacist.

      (2) The LOU will be finalized at the administrative review meeting with the principal investigator and/or study coordinator held by the Research and Development Service prior to study initiation. Any necessary modifications to the form will be made at this time. The principal investigator, ACOS for Research, and Chief of Pharmacy will then sign approval of each form which are to be filed in the Research Pharmacy.

   b. **Procedures involoving drugs obtained from an Affiliate**

      (1) If drugs being tested or evaluated in a study protocol are antineoplastics, then written order templates will be requested at the administrative review meeting. The orders will be reviewed by an Oncology Clinical Pharmacy Specialist, and any modifications or questions will be addressed to the study coordinator by the Oncology Clinical Pharmacy Specialist. Finalized order templates will be filed in the Research Pharmacy. If drugs being tested or evaluated in a study protocol are not antineoplastics, then the research pharmacist will develop drug file entries as described below, and the principal investigator or designee will place electronic orders in accordance with STVHCS pharmacy policy.

(2) The research pharmacist will develop the drug file entries for investigational drugs which are to include an "INV" designation, the Principal Investigator (PI), VA project number or study acronym, drug name (and placebo, if applicable) and strength. The Automated Data Processing Application Coordinator (ADPAC) for pharmacy service will work with the Research Pharmacist to input each orderable entry item into the Veterans Health Information Systems and Technology Architecture (VISTA) drug file prior to study initiation.

(3) Initial orders written by an authorized prescriber will be sent to the Affiliate by nursing staff or Oncology Clinical Pharmacy Specialist as applicable. They will be processed, prepared and dispensed by the Affiliate in accordance with their standard operating procedures which meet all rules and regulations for safe and sterile compounding practices and drug dispensing.

(4) A copy of the original orders will be provided to the Research Pharmacy by nursing staff and maintained within the appropriate protocol file and subsection for patient-specific written orders.

(5) The research pharmacist will review the patient's computerized patient record system (CPRS) record to confirm VA Form(s) 10-9012 and the signed informed consent form have been scanned; the study coordinator will be contacted if the forms have not been scanned. ***Note:*** *Drug(s) being tested or evaluated in a study protocol will only be dispensed to the patient, authorized representative of the patient, study personnel or nursing staff for provision or administration after both forms have been scanned.*

(6) The Research Pharmacist will document the dispensing or administration of the drug to the patient by placing an entry for the drug being tested or evaluated in that study protocol in VISTA. Intravenous (IV) medications will be entered in the IV order entry menu and oral medications will be entered in the outpatient prescription menu in accordance with STVHCS pharmacy policy

(7) All drugs being tested or evaluated in a study protocol that are transported from an Affiliate will be delivered to the research pharmacy, Room D705.

(8) The Research Pharmacist will sign the drug delivery tracking log provided by the transporting designee after verifying the patient, study and drug as labeled by the Affiliate are accurate and not damaged during transport. This delivery log will be maintained by the Affiliate for the duration of the study. If the affiliate maintains different pump supplies than those required by STVHCS, these supplies will be provided to the Affiliate for dispensing with medications. These supplies will be replenished as needed and sent via the transporting designee.

(9) The Research Pharmacist will initial and date the prescription label provided by the Affiliate indicating the product was checked and approved by the research pharmacist.

(10) The research pharmacist will place an entry in the electronic drug accountability record specific to that study protocol indicating the receipt of drug from the Affiliate. The information entered will include: date, prescription number, drug name (and placebo, if applicable), quantity, patient name, study identifier, and the research pharmacist's initials.

(11) Each patient will also have an entry for the drug being tested or evaluated in that study protocol within their computerized patient record system (CPRS) medication profile history

(12) The medication will be dispensed to the patient, authorized agent of the patient, study personel or nursing staff. The respective individual accepting the investigational drug will sign the outpatient prescription label or the investigational medication pick-up log.

(13) The Affiliate will maintain drug accountability records of all drugs that were dispensed to STVHCS.

c. **Procedures involving drugs provided to an Affiliate**

(1) Written order templates will be requested at the administrative review meeting. The orders will be reviewed by the research pharmacist, and any modifications or questions will be addressed to the study coordinator. Finalized order templates will be filed in the Research Pharmacy.

(2) Study personnel will ensure signed consent forms for each patient are appropriately documented prior to writing orders for an investigational drug.

(3) Initial orders written by prescriber listed on both the approved IRB form B-2 and the VA Approved Personnel will be faxed to the research pharmacy by the Affiliate by. The drug will be processed, prepared and provided by the research pharmacy in accordance with the standard operating procedures that meet all rules and regulations for investigational drug dispensing.

(4) The faxed orders will be maintained within the appropriate protocol file and subsection for patient-specific written orders.

(5) All drugs being tested or evaluated in a study protocol provided by the research pharmacy will be picked up by study personnel.

(6) Study personnel will sign the outpatient prescription label or the investigational drug or device pick-up log acknowledging receipt of the investigationald drug.

(7) The research pharmacist will place an entry in the electronic drug accountability record specific to that study protocol indicating the provision of drug to the Affiliate. The information entered will exclude any patient identifiers.

d. **Transport**

(1) The Affiliate is responsible for transporting the investigational drugs or that reliable transport of the drug is available to ensure care is taken to maintain the stability of the drug product during delivery to the Affiliate or the patient.

(2) The affiliate will also provide adequate packaging for products, to prevent possible compromise of product integrity, and to make certain that patient confidentiality during transport is not compromised.

4. REFERENCES: VHA Handbook 1108.04, Research Service Standard Operating Procedure (SOP) Handling of Investigational Drugs and Devices

5. RESPONSIBILITY: Chief of Pharmacy (119)

6. RESCISSIONS: Pharmacy Service Policy Memorandum 119P-08-35, Research Service SOP for Handling of Investigational Drugs Obtained from a VA Affiliate dated October 7, 2011

7. RECERTIFICATION: December of 2019

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Attachment (2)