

October 7, 2011

**RESEARCH 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 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 (Appendix 1).

3. ACTION: The procedures described below will be followed for all study protocols involving investigational drugs obtained from 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 to a study participant at STVHCS, 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 and ACOS for Research will then sign approval of each form which are to be filed in the Research Pharmacy.
- (3) If drugs being tested or evaluated in a study protocol are antineoplastics, then written orders will be requested at the administrative review meeting. The orders will be reviewed by an Oncology Pharmacy Specialist, and any modifications or questions will be addressed to the study coordinator by the Oncology Pharmacy Specialist. Finalized orders 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.
- (4) 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, 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.

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b. Orders

- (1) Initial orders written by an authorized prescriber will be sent to the Affiliate by nursing staff or Oncology 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.
- (2) 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.
- (3) 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 nursing staff for administration after both forms have been scanned.*

c. Transport

- (1) The Affiliate will reliably transport the drug to ensure care is taken to maintain the stability of the drug product during delivery, to provide adequate packaging for products, to prevent possible compromise of product integrity, and to make certain that patient confidentiality during transport is not compromised.

d. Receipt

- (1) 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.
- (2) 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.
- (3) 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.
- (4) 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.

e. Dispensing

- (1) The medication will be dispensed to Nursing staff, and the respective nurse accepting the investigational drug will sign the investigational medication pick-up log.

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- (2) The Research Pharmacist will document the 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.

f. **Record retention**

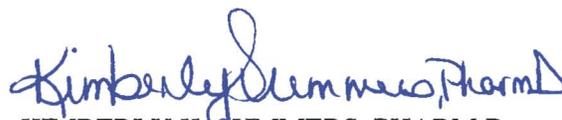
- (1) The Affiliate will maintain drug accountability records of all drugs that were dispensed to STVHCS.
- (2) An electronic drug accountability log (as previously described in the section entitled Receipt of investigational agent) will be maintained in the Research Pharmacy electronic folder within the Research Serviceline under the appropriate protocol.
- (3) 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.

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

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

6. RESCISSIONS: Pharmacy Service Policy Memorandum 119P-08-35

7. RECERTIFICATION: October 2016


KIMBERLY K. SUMMERS, PHARM.D.
ACOS for Research and Development

Attachment (1)

RESEARCH SERVICE MEMORANDUM 11-68
LETTER OF UNDERSTANDING

Medical Center Name: South Texas Veteran Health Care System

Medical Center Number: 671

“Protocol Title”

This letter reflects the understanding between VA Affiliate (hereinafter referred to as “Department of Veterans Affairs (VA) Affiliate”) and the VA Medical Center at San Antonio regarding the circumstances under which the VA Affiliate agrees to provide Investigational Drug to the VA Medical Center for the following research study, “Protocol Title” (STUDY).

The VA Medical Center Research Pharmacy will serve as the liaison between VA Affiliate and the VA investigator and will act as the central control and distribution center for donated drugs for the STUDY. The Research Pharmacy will provide guidance and information regarding Investigational Drugs as well as serving as a conduit for communications between the VA Affiliate and the Food and Drug Administration (FDA) or any other regulatory body when appropriate.

The VA Affiliate will provide Investigational Drug at a dose per protocol (hereafter referred to as “Investigational Drug”) for the STUDY in accordance with the following provisions.

The VA Medical Center at San Antonio and the VA Affiliate have agreed upon the following operating procedures in connection with the STUDY and this Letter of Understanding:

1. **Conduct of the STUDY.** The VA Medical Center at San Antonio will conduct the STUDY in accordance with the terms of Protocol and within VA guidelines with the participation of the VA Affiliate.

2. **Drug Supply, Distribution, and Accountability.** The VA Affiliate will supply Investigational Drug for the duration of the STUDY, free of charge, and will include in planning allowances for wastage that may unavoidably occur during dispensing. The VA Affiliate will provide shipment of Investigational Drug directly to the Research Pharmacy in accordance with the schedule agreed to by both parties. The VA Affiliate will be responsible for procuring, preparing and dispensing of the Investigational Drug in accordance with the Food, Drug and Cosmetic Act and maintaining drug accountability records. The Research Pharmacy will receive and dispense Investigational Drug and keep all records of drug disposition. The Research Pharmacy warrants that in its processes the Investigational Drug shall not be adulterated or misbranded, in accordance with the Food, Drug and Cosmetic Act. The Research Pharmacy agrees to use the Investigational Drug supplied by VA Affiliate only for the investigational purposes authorized under the Protocol; no other use of the drug will be permitted by the Research Pharmacy. In the event that the Research Pharmacy has unused Investigational Drug at the time the STUDY is completed or terminated, the Research Pharmacy will dispose of Investigational Drug in accordance with operating procedures outlined by the VA Affiliate.

3. **Safety Information Reporting.** The local investigator is responsible for reporting adverse events with respect to Investigational Drug to the IRB at UTHSCSA and/or FDA in conformance with all applicable laws, rules, and regulations in effect (Appendix A). It is understood and agreed that these adverse events reporting requirement provisions are based upon the IRB at UTHSCSA’s respective policies and procedures and regulatory reporting requirements. Accordingly, in the event of changes to the IRB at UTHSCSA’s policies and procedures for adverse events reporting, the local investigator agrees to comply with such revised notification