

January 24, 2013

**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 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 investigational 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 and ACOS for Research will then sign approval of each form which are to be filed in the Research Pharmacy.

b. Procedures involving 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 Pharmacy Specialist, and any modifications or questions will be addressed to the study coordinator by the Oncology 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, drug

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- 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 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

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- (12) The medication will be dispensed to the patient, authorized agent of the patient, study personnel 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 investigational 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.

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**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, Research Service SOP for Handling of Investigational Drugs Obtained from a VA Affiliate dated October 7, 2011

**7. RECERTIFICATION:** October 2016

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

Attachment (2)

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

requirements as reasonably requested in writing by the IRB at UTHSCSA. This is provided that the scope and extent of activity and undertakings are not materially increased.

4. **Early Study Termination.** The STUDY may be terminated at any time by the Investigational Review Board or the STVHCS institutional office for safety or efficacy reasons if it is thought to be in the best interests of the patients. Either the VA or the VA Affiliate may withdraw support from the STUDY with 90 days written notice only if this agreement has been violated.

5. **Patient Confidentiality.** Patient confidentiality will be maintained at all times in accordance with applicable law and VA policy. Reports issued for public distribution will contain only aggregate data with all patient identifiers removed.

6. **Selection of Participants.** The principle investigator will be responsible for all decisions concerning the selection and/or discontinuation of participants in the STUDY.

7. **Record Retention.** The VA Medical Center at San Antonio shall retain all records related to the STUDY for a minimum period of 3 years from the date of the last patient follow-up. At that point the STUDY records will be evaluated for archiving.

8. **Term of Agreement.** This agreement shall be effective as of the date last signed below and shall expire upon completion of all activities related to the STUDY as defined by the submission of the final STUDY report to the VA Affiliate and the primary publication of the STUDY results.

9. **Modification to Agreement.** This agreement can only be modified in writing and would require signatures by the VA Medical Center at San Antonio and VA Affiliate representatives.

10. **Approval.** The following signatures indicate approval of the terms of this letter of understanding.

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PI  
VA Affiliate

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Date

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Acting ACOS for Research at STVHCS

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Date

LETTER OF UNDERSTANDING

Medical Center Name: South Texas Veteran Health Care System

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“Protocol Title”

This letter reflects the understanding between the 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 Medical Center agrees to provide the Investigational Drug or Device to the VA Affiliate for the following research study, “Protocol Title” (hereinafter referred to as “STUDY”).

The VA Medical Center Research Pharmacy will serve as a liaison between Investigational Drug or Device Supplier and the VA Affiliate and will act as the central control and distribution center for donated drugs or devices for the STUDY. The Research Pharmacy will provide guidance and information regarding Investigational Drugs and Devices 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 Research Pharmacy will provide the Investigational Drug or Device per protocol (hereafter referred to as “Investigational Drug or Device”) 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 Affiliate will conduct the STUDY in accordance with the terms of Protocol and within VA Affiliate guidelines with the participation of the VA Medical Center at San Antonio.

**2. Drug Supply, Distribution, and Accountability.** The Investigational Drug or Device will be provided by Investigational Drug or Device Supplier to the Research Pharmacy for the duration of the STUDY, free of charge, and will include in planning allowances for wastage that may unavoidably occur during dispensing. The Research Pharmacy will provide the Investigational Drug or Device directly to the VA Affiliate in accordance with the schedule agreed to by both parties. The Research Pharmacy will be responsible for procuring, preparing and providing the Investigational Drug or Device in accordance with the Food, Drug and Cosmetic Act and maintaining drug or device accountability records. The VA Affiliate will receive and provide the Investigational Drug or Device. Each Investigational Drug or Device provided by the Research Pharmacy to the VA Affiliate will be signed for by the designee picking up the Investigational Drug or Device in the appropriate tracking log located within the Research Pharmacy. The VA Affiliate will ensure signed consent forms for each patient are appropriately documented prior to dispensing the Investigational Drug or Device. The VA Affiliate warrants that in its processes the Investigational Drug or Device shall not be adulterated or misbranded, in accordance with the Food, Drug and Cosmetic Act. The VA Affiliate agrees to use the Investigational Drug or Device supplied by the Research Pharmacy only for the investigational purposes authorized under the Protocol; no other use of the drug or device will be permitted by the VA Affiliate. In the event that the VA Affiliate has any unused Investigational Drugs or Devices at the time the STUDY is completed or terminated, the Investigational Drug or Device will be returned to the Research Pharmacy for disposal in accordance with operating procedures outlined by the Protocol.

**3. Safety Information Reporting.** The local investigator is responsible for reporting adverse events with respect to the Investigational Drug or Device to the IRB at UTHSCSA and/or FDA in conformance with all

applicable laws, rules, and regulations in effect. 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 requirements as reasonably requested in writing by the IRB at UTHSCSA. This is provided that the scope and extent of activity and undertakings are not materially increased.

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Date