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

Research Service Policy Memorandum 11-66

October 14, 2011

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Controlled Substances Utilized in Animal Research

1. PURPOSE: To establish a standard operating procedure for the handling of controlled substances utilized in animal research at the South Texas Veterans Health Care System (STVHCS).

2. POLICY: It is STVHCS policy that the Research Pharmacy will handle controlled substances utilized in animal research in accordance with local Pharmacy Service Policy Memorandum *Controlled Substances* which complies with the Department of Veterans Affairs (VA) and Federal regulations regarding controlled substances.

3. ACTION:

a. **Responsibilities**

(1) **The Director** is responsible for:

(a) Authorizing in the animal research area, also known as the Veterinary Medical Unit (VMU), a designated provider to be responsible for ensuring the appropriate security, handling, and storage of all controlled substances.

(b) All responsibilities as described in Pharmacy Service Policy Memorandum *Controlled Substances*.

(2) **ACOS for Research** is responsible for:

(a) Ensuring all requirements for receipt, handling, storage, security, administration, waste, and destruction or return of controlled substances used in animal research are followed in accordance with Controlled Substances and this SOP.

(b) Ensuring documentation of receipt, administration, and the wasting of controlled substances used in the VMU.

(c) Ensuring all required inventory verification is performed, security of controlled substances is maintained and the room is appropriately secured in the VMU.

(d) Ensuring principal investigators are appropriately educated on this Research Standard Operating Procedures (SOP) Controlled Substances Utilized in Animal Research.

(3) **The Chief, Pharmacy Service** is responsible for:

(a) Ensuring the medical facility Director is notified of the need to authorize a Designated Provider to ensure security, handling, and storage of the controlled substances in the VMU.

(b) All responsibilities as described in Pharmacy Service Policy Memorandum *Controlled Substances*.

(4) **The Principal Investigators** are responsible for:

(a) Ensuring appropriate implementation of this policy and procedure on handling of controlled substances utilized in animal research.

(b) Ensuring laboratory technicians and all other study staff are in compliance with all local policies and procedures related to controlled substances.

(c) Notifying the ACOS for Research of requests for controlled substances to be utilized in animal research pursuant to a study protocol.

(5) **The Research Pharmacist** is responsible for:

(a) Stocking the Automated Dispensing System (ADS) as described within this standard operating procedure.

(b) Ensuring the VistA Controlled Substances Package is the primary storage mechanism for controlled substances forms and transactions. VA Forms 10-2321 and 10-2638 will be completed in ink and signed by the principal investigator, laboratory technician, VMU designated provider and/or research pharmacist and filed separately in the research pharmacy in a numerical file once completed.

(c) Resuming custody of controlled substances returned by the VMU ADS once notified to do so by the VMU designated provider.

(d) Reviewing expended VA Forms 10-2638 for errors, losses and/or waste upon receipt from the VMU designated provider.

(e) Ensuring all controlled substances returned to the research pharmacy are posted on the Controlled Substance Destruction menu in VistA and held for destruction.

(6) **The Animal Research Designated Provider** is responsible for:

(a) Appropriately securing, handling, storing, wasting, issuing and inventorying all controlled substances within the VMU ADS.

(b) Ensuring laboratory technicians' or Principal Investigators' (PI) documentation of receipt, administration, and the wasting of controlled substances used in animal research is appropriate.

(c) Performing inventory verification and discrepancy resolution as required in *Automated Dispensing System Policy for Pharmacy Automated Dispensing System Machines.*

(d) Returning controlled substances to the research pharmacy as described in the section titled disposition.

b. **Procedures**

(1) Ordering

(a) The Research Pharmacist, with the concurrence of the ACOS for Research, will place a request to the Pharmacy Procurement Supervisor for the purchase of a controlled substance to be utilized in animal research pursuant to a principal investigator's study protocol.

(b) The Chief of Pharmacy will initiate the order of all purchase requests through the Pharmacy Procurement Supervisor.

(2) Opening shipments, Receiving and Verification of Posting in VistA

(a) All procedures described in *Controlled Substances* are to be followed as written.

(b) All controlled substances being tested or evaluated in study protocols will be received by the Pharmacy Procurement Supervisor as authorized by the Chief of Pharmacy.

(c) The source of controlled substances may be from a prime vendor, a non-prime vendor, or directly from a study sponsor. In all instances, pharmacy procurement personnel or designee will receive, open, count the contents of the shipment, and sign and date the invoice or packing/shipping documentation for that shipment in the presence of the Accountable Officer (AO).

1. In the instance of a prime vendor receipt, pharmacy procurement personnel or designee will process the received items in the drug accountability package in VistA, and Research Pharmacist will verify the invoice in the drug accountability package in

VistA and perform an invoice review in Receipts into Pharmacy in the Controlled Substances package in VistA. The Research Pharmacist will print the invoice review and sign with a witness.

2. In the instance of a non-prime vendor receipt, pharmacy procurement personnel or designee will receive the controlled substances as described above (excluding the drug accountability package invoice procesing), and the Research Pharmacist will receive the Purchase Order Number in the Receipts into Pharmacy option of the Controlled Substance package in VistA. Then the Research Pharmacist will perform a Purchase Order Review in Receipts into Pharmacy menu in the Controlled Substances package in VistA. The Research Pharmacist will print the purchase order history and sign with a witness.

3. In the instance of a controlled substance receipt directly from a Study Sponsor, pharmacy procurement personnel will receive the controlled substances as described above (excluding the drug accountability package invoice processing), and the Research Pharmacist will perform a Balance Adjustment entry using the Supervisor menu in the Controlled Substances package in VistA. The balance adjustment will cite the source and the invoice or packing/shipping documentation number of the received items in the comments field. The Research Pharmacist will print the balance adjustment sheet and sign with a witness.

(3) Veterinary Medical Unit (VMU) procedures

(a) All controlled substances will be dispensed from the Research Pharmacy to the VMU via VA Form 10-2321 (Attachment 1). All controlled substances issued by the VMU designated provider to laboratory technicians will be dispensed via VA Form 10-2638 (Attachment 2). All records for controlled substance dispensing activities will be maintained electronically in the VistA package and manually on VA Form 10-2638 signed by the principal investigator, laboratory technician, VMU designated provider and/or research pharmacist.

(b) Controlled substances will be dispensed to the VMU ADS on a recurring basis at predetermined time intervals (i.e. every 30 days) or otherwise based on the needs of the animal protocols. The amount prepared and dispensed, however, may be subject to changes in study protocols.

1. The research pharmacist will dispense controlled substances to the VMU and physically load them into the VMU ADS in the respective drawer for that controlled substance. VA Form 10-2321 will document the quantities received, date, and serial number and will be signed by the research pharmacist and receiving VMU designated provider. VA Form 10-2321 will be filed in the research pharmacy.

2. When laboratory technicians or PIs request controlled substances for administration to research animals, the VMU designated provider will remove the controlled substances from the ADS assigning it to patient - Animal Research. Within the comments field in the ADS at the time of drug removal, The VMU designated provider will enter the assigned VA-Form 10-2638 sequential number and the Investigator's name and protocol number. The VMU designated provider will document on the header of VA Form 10-2638 (Attachment 1) the following information:

   a. Under Pharmacy Dispensing number, enter sequential dispensing number
   b. Enter the page number
   c. Drug name, size, and strength
   d. Drug Expiration Date
   e. Drug dosage form and quantity
   f. Lot number and manufacturer
   g. Under ordered by, printed name of Principal Investigator
   h. Under dispensed by, printed name of VMU designated provider and initials
   i. Under ward number, lab number
   j. Date dispensed

3. The VMU designated provider will provide this VA Form 10-2638 to the principal investigator or laboratory technician to be utilized as a controlled substance administration record. The individual receiving the drug must date and sign at the bottom of the form confirming the drug has been received. The principal investigator or laboratory technician will maintain a secure record of drug accountability to include the following information on VA Form 10-2638:

   a. Date and time administered
   b. Under Name of Patient, enter the Protocol number, Cage#
   c. Under dose, enter the quantity of drug administered
   d. Balance remaining after quantity administered
   e. Signature of individual administering drug
   f. If any wasting occurs, under Name of Patient, enter "Waste" and under dose, enter the amount wasted. The VMU designated provider must sign in addition to the individual wasting the drug as a witness to the wasting.

   ***Note**: The first line item entry will be the issuance of drug from the VMU designated provider to the principal investigator or laboratory technician. Therefore, the entry under name of patient will be "Issued to Lab", the dose will be "N/A" and the VMU designated provider will sign under administered by.*

4. Expended VA Forms 10-2638 will be returned to the VMU designated provider. The individual returning the form must date and sign at the bottom of the form confirming the drug has been administered. The designated provider must review the completed

form for errors, losses and/or waste upon receipt from the laboratory technician. After review, these forms will be returned to the research pharmacy. The research pharmacist will also review the completed form for errors, losses and/or waste and will date and sign at the bottom of the form confirming the review of entries. If any drug issued remains at the time of return of VA Form 10-2638, the drug will also be returned to the VMU designated provider and appropriately wasted as described in the final disposition section below.

(c) ADS/Omnicell Monitoring

1. All Omnicell Monitoring procedures described in *Controlled Substances* and Pharmacy Service Policy Memorandum *Automated Dispensing System Policy for Pharmacy Omnicell Machines* are to be followed as written

(d) ADS/Omnicell Inventories and Discrepancies

1. The VMU designated provider will conduct weekly cycle counts and daily discrepancy resolution reports of the controlled substances within the ADS in the VMU as described in *Automated Dispensing System Policy for Pharmacy Automated Dispensing System Machines.*

(e) Final Disposition

1. Opened or breached containers or syringes will be disposed of by the VMU designated provider. Wasting of these medications will be documented using the automated dispensing system. In all cases, the wastage or disposal will be verified by a witness, to be reflected in the record. In order to reduce the risk of diversion, partially administered controlled substances and their residue will be destroyed as "Regulated Medical Waste" using the following procedures:

   a. Injectable controlled substances will be drained into a locked sharps container and any associated empty vial and syringe placed into the locked sharps container.

   b. Wasting of these medications will be documented using the automated dispensing system. In all cases, the wastage or disposal will be verified by a witness, to be reflected in the record.

2. No partial parenteral containers will be accepted by the research pharmacy.

   a. Injectable controlled substances including ampoules and vials removed from the ADS machines and which have no evidence of having been tampered-with must be returned to the research pharmacy.

   b. Expired or unopened containers will be returned to the research pharmacy (not wasted).

c. The VMU designated provider will contact the research pharmacist when any controlled substances require return to the research pharmacy within 1 business day.

(f) Expired or excess controlled substances

1. All controlled substances returned from the VMU (determined unusable) to the research pharmacy will be posted with all appropriate information on the Controlled Substance Destruction menu in VistA and will be destroyed via a third party reverse distributor authorized to destroy controlled substances. The Controlled Substances Coordinator will ensure that the "Drugs on Hold for Destruction" report in VistA and sealed bags of the unusable controlled substances are inspected monthly. The inspector will also verify the accountability of the sealed bags. The contents will be verified at the time of transfer to a DEA-licensed destruction company.

2. Once excess controlled substances are returned to the research pharmacy all procedures outlined in the VistA Controlled Substance Package will be followed, including:

a. The research pharmacist will check the controlled substances in the presence of witness, then:

(1) Place each item returned into an evidence bag;

(2) Write in ink on the evidence bag the date, name and quantity of the controlled substance (believed or purported to be returned);

(3) Seal the bag; and

(4) Store the sealed medications in the research pharmacy vault, apart from other drugs or current stocks.

3. The research pharmacist and witness will follow all procedures outlined in the VistA Controlled Substance Package, including:

a. Completion of the "Hold for Destruction" report in VistA (attaching the document to the bag for future reference); and

b. Posting the unusable controlled substance in the database.

4. The Accountable Officer (AO) will be involved in the controlled substances turn-in to the destruction company. The AO will verify that the destruction company actually received the drugs identified for destruction.

4. REFERENCES: VHA Handbook 1108.01, VHA Handbook 1108.04, Research Service Standard Operating Procedure (SOP) Handling of Investigational Drugs and Devices, Pharmacy Service Policy

Memorandums Automated Dispensing System Policy for Pharmacy Omnicell Machines and Controlled Substances.

5. RESPONSIBILITY: ACOS for Research and Development (151) and Chief, Pharmacy Service (119)

6. RESCISSIONS: None

7. RECERTIFICATION: October 2016

Kimberly Summers, Pharm.D.

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

GEORGE A. CRAWFORD, RPH
Acting Chief, Pharmacy Service

Attachments (2)

CONTROLLED SUBSTANCE ORDER

ISSUE TO *(Ward or Clinic)*	PHARMACY FILE NUMBER

DRUG NAME: *(Order by generic name and metric system only)*

STRENGTH:

PHARMACY DISPENSING RECORD	MANUFACTURER	EXPIRATION DATE	PREPACKAGE OR CONTROL NO.
SIGNATURE AND TITLE OF MD, DDS, OR RN			DATE ORDERED
SIGNATURE OF DISPENSING PHARMACIST			DATE DISPENSED
RECEIVED BY *(Signature and Title)*			DATE RECEIVED

VA FORM NOV 1997 **10-2321**

EXISTING STOCK OF VA FORM 10-2321, NOV 1974, WILL BE USED.

SAMPLE ONLY

ORDER THROUGH NORMAL SUPPLY CHANNELS

CONTROLLED SUBSTANCE ADMINISTRATION RECORD

PHARMACY DISPENSING NO.	PAGE NO.

DRUG NOMENCLATURE - SIZE AND STRENGTH IN METRIC	DRUG EXPIRATION DATE	DOSAGE FORM	QUANTITY DISPENSED

LOT OR MFG. NO.	ORDERED BY: R.N.	DISPENSED BY: R.PH.	WARD NO.	DATE

DATE	TIME	NAME OF PATIENT	DOSE	BALANCE	ADMINISTERED BY

The above drug has been received		*The above drug has been administered*		*The above entries have been reviewed*	
DATE	SIGNATURE OF NURSE R.N.	DATE	SIGNATURE OF NURSE R.N.	DATE	SIGNATURE OF PHARMACIST R.PH.

DRUG NOMENCLATURE	SIZE AND STRENGTH IN METRIC	DOSAGE FORM	PHARMACY DISPENSING NO.

VA FORM MAY 1965 10-2638 EXISTING STOCK OF VA FORM 10-2638, JAN 1976, WILL BE USED.

★U.S.GPO:1987-0-181-822/63459