SUBJECT: **Use of Controlled Substances SOP**

1. PURPOSE: To ensure the safe use, security, and accountability of controlled substances during ordering, storage, preparation, administration, and waste disposal; to minimize the potential for diversion; and to provide guidance for reporting incidents of suspicious loss or theft of controlled substances.

2. SCOPE: This SOP applies to all controlled substances used by any investigator or technician associated with the Research Service for human, animal and/or laboratory studies. [Note: For more detail related to animal studies, see MVAHCS-VMU-OPR-230 Current Revision entitled "The Use and Tracking of Controlled Substances."] The following list of controlled substances (Table 1) includes a few examples of those used within our Research Service. A complete list may be found at **https://www.deadiversion.usdoj.gov/schedules/index.html.**

TABLE 1

Schedule	Controlled Substance
I	none
II	sodium pentobarbital, morphine
III	buprenorphine, slow-release buprenorphine, ketamine, thiopental, Telazol®, Euthasol®
IV	butorphanol, diazepam, phenobarbital
V	none

3. RESPONSIBILITIES:

a) *MVAHCS Director* - Establishes a system for inspections, receives reviews, and acts on reports/findings.

b) *Controlled Substance Coordinator (CSC)* - Administers the inspection program, provides necessary training, and maintains a register of both inspections and report findings.

c) *Chief, Pharmacy* - Establishes and maintains a register of controlled substances received from vendors and communicates with the DEA, as appropriate.

d) *Research Service Staff (investigators and technicians)* - Understand and comply with the procedures described in this SOP; assist with controlled substance checks and help resolve any discrepancies found during the audit of records. An authorized user of controlled substances has the handling and administering of controlled substances on their Research Service Scope of Practice and trains on the use of controlled substances during annual safety training.

e) *VA Police* - Execute responsibilities as outlined under item 9 below.

f) *Subcommittee on Research Safety (SRS)* - Reviews, approves, and monitors human, animal, and lab studies with respect to Research Service staff and facility safety.

4. ORDERING/DISPENSING OF CONTROLLED SUBSTANCES:

a) *Ordering of Controlled Substances for Research* - These are ordered through Pharmacy and issued on request only to personnel authorized by the ACOS for Research. They must be part of an SRS-approved research protocol.

b) *Acceptance of Deliveries* - All orders for controlled substances received from a vendor are delivered directly to Pharmacy in unopened shipping cartons. Two designated employees (one from Pharmacy and one from the warehouse) annotate receipt on opening of the cartons.

c) *Dispensing of Controlled Substances* - Controlled substances, including IV solutions and patches, shall be dispensed by authorized Research staff or Pharmacy technicians. Should a nurse or technician remove and not use a controlled substance, they shall return the drug or dispose of the drug following the criteria for wasting (under item 7 below).

5. ACCOUNTABILITY AND STORAGE:

a) *All Research Areas:*

i) To verify receipt of controlled substances (after product inspection), the RN or authorized Research employee signs the "Controlled Substance Order Form" and an entry is made and signed on VAF 10-2721 for human studies; VAF 10-2721 and VAF 10-2638 (green form) for animal and lab studies. Entries are made when controlled drugs are administered, used, or wasted. Form VAF 10-2721 is returned to Pharmacy at the end of each month. Form VAF 10-2638 is returned to Pharmacy within 3 business days of a zero balance, either through administration or wasting.

ii) When using the green form (VAF 10-2638) for animal and lab studies, document amount of wasting/disposal with signatures (see item 7.a below) on this form by way of notes. This form does not include columns for these entries. For lab studies, enter protocol number and brief description of usage under "name of patient," for example, "1594000; cultured hepatocytes."

b) *Storage:*

i) Controlled substances are stored in double-locked secured areas or vaults.

iii) Only authorized staff should have access to controlled substance storage.

6. TURN-IN OF EXCESS CONTROLLED SUBSTANCES:

a) Only unopened controlled substance containers that were originally received through pharmacy will be accepted for turn-in. For other materials, see wasting/disposal under item 7.a below. The pharmacy-controlled substance technician will guide you through the turn-in process. Both the pharmacy technician and the PI or designee will sign the VAF 10-2638 and/or the VAF 10-2721 to document the transfer.

7. SPECIAL CIRCUMSTANCES:

a) *Wasting/Disposal:*

i) Wasting/disposal of complete or partial doses of controlled substances (including IV solutions and patches) will be performed by the user (or dispenser) and in the presence of knowledgeable witness.
iv) The wasting will be documented by both the disposer and witness in writing on the Controlled Substance Administration Record, i.e., VAF 10-2638 or VAF 10-2721.
v) Non-hazardous oral, IV and patch narcotics, including buprenorphine, buprenorphine SR, ketamine, morphine, butorphanol, diazepam, Telazol® and Euthasol® are wasted by sewering; document disposal on the drug's green sheet.
vi) For wasting of hazardous controlled substances, e.g., testosterone powder or Fenfluramine, notify the Controlled Substance Coordinator (CSC) at extension 31-7444 to arrange for disposal.
vii) If you do not know whether the controlled substance is hazardous, perform a Sewer Evaluation, and/or contact the GEMS Coordinator.

b) *Accidental Loss, Breakage, or Destruction:*

i) These situations require written explanation on the controlled substance dispensing form (either VAF 10-2721 or VAF 10-2638) by the responsible individual.
ii) For breakage/loss/destruction of a one dose unit, the substance must be wasted in the presence of a knowledgeable witness and the witness must document this on the controlled substance dispensing form.
iii) If the incident involves more than a one-dose unit, the incident will be brought to the immediate attention of the Principal Investigator (PI). If the explanation is not satisfactory, the PI or designee will alert Pharmacy, who will report the incident to the CSC and VA Police.

8. INSPECTIONS:

Inspections are the responsibility of the CSC. They are conducted unannounced monthly, include all controlled substance storage areas, and are conducted by reconciling records with the actual stock. The same inspector will not conduct consecutive inspections in the same area. See VHA Directive 1108.01 for additional information about controlled substance inspections and inspector responsibilities.

9. DISCREPANCIES:

When discrepancies (including losses) are identified that cannot be expeditiously resolved:

a) The Veterinary Medical Officer, PI, Research Nurse, or designee shall contact the VA Police, Pharmacy, ACOS for Research, and Chair of the SRS. [Note: The PI or designee will also submit an "Adverse Events Report" to the Chair of the SRS within 5 business days from the date the discrepancy was first discovered].

b) The ACOS for Research or VA Police will notify the CSC.

c) An Outlook email is generated by the CSC to the Controlled Substance Notification group. This message outlines the details of the discrepancy.

d) In collaboration with Controlled Substance Notification group, and/or the VA Police, the CSC determines if further review is necessary.

e) Further review may not be necessary if the loss is attributed to manufacturer shortage or mathematical error. These losses are logged and tracked on the Monthly Adjustment Report completed by Pharmacy Service.

f) In instances of potential theft or suspicious loss of controlled substance, the VA OIG is notified by VA Police, CSC or the MVAHCS Director's designee.

g) In such cases, following OIG review, either a focused review or board of investigation may be appointed as determined by the MVAHCS Director. Results of the review are communicated to executive leadership.

h) VA Police will provide information to the CSC including the Uniform Officer's Report number, name of the controlled substance, location, quantify and if reported to OIG.

i) Pharmacy will notify the DEA of reportable events through DEA Form 106 "Report of Controlled Substance or High Value Drug Loss." A copy will be forwarded to the CSC.

10. REFERENCES:

1. Facility Policy # TX-04I, "Medication Use," Attachment E: Regulatory Management of Controlled Substances and Alcohol, August 27, 2015.
2. MVAHCS-VMU-OPR-230 Standard Operating Procedure entitled, "The Use and Tracking of Controlled Substances", July 13, 2016.
3. VHA Directive 1108.01, Controlled Substances Management, May 1, 2019. Amended December 2, 2019. https://vaww.va.gov/vhapublications/publications.cfm?Pub=1
4. VHA Directive 1108.02(1), Inspection of Controlled Substances, November 28, 2016 and Amended April 18, 2022. https://vaww.va.gov/vhapublications/publications.cfm?Pub=1

11. Subcommittee on Research Safety (SRS) Approved: August 29, 2023

12. RESCISSIONS: Use of Controlled Substances SOP dated May 1, 2018.

13. EXPIRATION DATE: N/A

14. FOLLOW-UP RESPONSIBILITY: Subcommittee on Research Safety (SRS).

15. ATTACHMENTS:

A. VA Form 10-2638
B. VA Form 10-2721

Attachment A: VA Form 10-2638

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 1985 **10-2638** EXISTING STOCK OF VA FORM 10-2638, JAN 1978, WILL BE USED.

Attachment B: VA Form 10-2721

Department of Veterans Affairs | **Controlled Substance Administration Record**

IMPORTANT:
When new sheet is started & when shift changes:
1. Count controlled substances
2. Bring balance down
3. *Two nurses must sign*

DATE:
UNIT: Research
TEAM: VMU Bldg 49

NURSING REVIEWER:
DATE:
DATE:

DATE	TIME	NAME OF PATIENT	ADMINISTERED BY	DOSE Given	DOSE Wasted	WITNESS TO WASTE	Buprenorphine HCL 0.3mg/ml (1ml) inj	Pentobarbital 50mg/ml 20ml inj	Euthanasia SOLN 100ml	Tiletamine/Zolazepam 100mg/ml 5ml vial	Ketamine 100mg/ml 10ml inj	Diazepam 5mg/ml 2ml inj syr	Fentanyl 50mcg/ml 20ml inj		
		Balance forward													

Minneapolis VA Health Care System VAF 10-2721(618) R 05/2011