Document Number: ANP029	Title: **HANDLING AND INVENTORY OF CONTROLLED SUBSTANCES**	Effective Date: JANUARY 2005
Section: Animal Research		Supersedes Date: N/A
Subsection: Facility	***CONFIDENTIAL INFORMATION*** **MOLECULAR MEDICINE RESEARCH INSTITUTE**	Page: 1 of 11

1.0 OBJECTIVE

1.1 The purpose of this Standard Operating Procedure (SOP) is to describe proper method of receiving, storing, tracking, and documenting the use of controlled substances at MMRI.

2.0 SCOPE

2.1 This procedure applies to controlled substances used in the Animal Research and Animal care facility of MMRI.

3.0 POLICY

3.1 It is the policy of Molecular Medicine Research Institute to establish written and approved procedures to ensure that these drugs are handled in responsible manner and according to the law.

4.0 RESPONSIBILITIES

4.1 It is the responsibility of the Manager of Animal Research:

4.1.1 ensure that substances are used properly

4.1.2 make certain that personnel utilizing controlled substances follow this SOP

4.1.3 maintain the accuracy of the Inventory Log book

4.1.4 maintain the security of the bulk controlled substance inventory

4.1.5 review this procedure annually and revise it as needed.

4.1.6 renewing the controlled substance license.

4.2 It is the responsibility of the investigators, utilizing the controlled substances in their work at MMRI to accurately record the purpose and the amount of compound used.

4.3 It is the responsibility of the Manager of the Animal Facility or designated alternate to implement this procedure and revise it whenever necessary.

5.0 REFERENCES

5.1 Code of Federal Regulations 21, Chapter II, Parts 1301-1308, April 1990.

6.0 PROCEDURE

6.1 Ordering

6.1.1 Anyone ordering controlled substances will obtain approval of the Manager of Animal Research Facility prior to placing the order. Screen all Research personnel according to CFR Section 1301.90 prior to approval for ordering and handling controlled substances.

6.1.2 To establish an account with a vendor of controlled substances, send a copy of the controlled substances license to the vendor for their records.

6.1.3 For established accounts, order substances from Category III by calling the veterinary supply vendor and requesting the specific item and the quantity needed. They will need to verify the company controlled substance license number and obtain the purchase order number.

6.1.4 For established accounts, order substances from Category II by itemizing the materials and quantity needed on DEA Form 222. Detailed instructions for filling out the purchasing form are on the back of each form. Read and follow these instructions carefully. Please refer to Figure 1 for a copy of the directions and a correctly filled out form. Keep DEA form 222 (both blank and completed) separate from all other DEA Registration information with in the animal facility.

6.1.5 Obtain more order forms from the DEA by reading the directions on DEA form number 222-a and filling in the required information.

6.2 Receiving of Ordered Items

6.2.1 Prior to arrival of controlled substances, inform the materials manager that controlled drugs have been ordered, and the seal on the package can only be broken by a designated employee or the Manager of the Animal Research Facility.

6.2.2 When the items ordered arrive at MMRI, the designated employee will break the seal on the box and check the box contents with the packing slip to ensure that all the items ordered are present.

6.3 Logging in of Ordered Items

6.3.1 Remove items from the box.

6.3.2 Assign and label each individual unit or vial with a MMRI Controlled Substance I.D. number.

6.3.2.1 The MMRI Controlled Substance I.D. number is a consecutive numbering system designed to individually identify each vial of substance that enters and exits the facility to provide a means of tracking each individual unit. Record the I.D. numbers in the Table of contents of the Controlled Substance Inventory Log. Do not record a page number until the bottle is opened.

6.3.2.2 For Schedule III materials, record the vial ID numbers on the packing slip and file a copy of the slip in the file labeled "Controlled Substance Packing Slips" in the Animal Facility Archives. Forward the original packing slip to the Accounting Department.

6.3.2.3 For Schedule II materials, retrieve the Purchaser's copy of the DEA Form 222, the Schedule II order form, from the appropriate file. On the blank space of the form, write the date of receipt, quantity received, lot number and initials of person opening the package.

6.3.3 Weigh each vial of Schedule II controlled substance. Record the initial weight in permanent black ink on the vial and on the Controlled Substance Inventory Log page for that vial. Vials of ketamine do not need to be weighed. Ketamine comes in a 10 ml vial that is typically used in its entirety during the course of a procedure. Logging the ketamine out by the vial is acceptable.

6.3.4 Begin a controlled substance Inventory Log page for the first vial to be used.

6.3.4.1 At the top of the page, record the following information:

6.3.4.1.1 Date Received

6.3.4.1.2 Name of the substance and finished form (i.e. Pentobarbital, 10 milligrams/mL)

6.3.4.1.3 Vendor

6.3.4.1.4 Received and Logged in By

6.3.4.1.5 Witnessed

6.3.4.1.6 MMRI Controlled Substance I.D. number.

6.3.4.1.7 Lot number and expiration date

6.3.4.1.8 Initial Weight of the bottle

6.3.4.2 Below this information, divide the page into six columns and label them left to right with the following information

6.3.4.2.1 Date

6.3.4.2.2 Pre Use Weight

6.3.4.2.3 Post use Weight

6.3.4.2.4 Quantity Used

6.3.4.2.5 Purpose

6.3.4.2.6 Protocol Number

6.3.4.2.7 Initials of person removing substance

6.3.5 For the vials of ketamine, set up the log book page as follows: (Please refer to Figure 2.)

6.3.5.1 At the top of the page, record the following information:

6.3.5.1.2 Name of the substance and finished form (i.e. Ketamine HCl, 100 milligrams/mL)

6.3.5.1.3 Vendor

6.3.5.1.4 Received and Logged in By

6.3.5.1.5 Witnessed

6.3.5.2 Below this information, divide the page into seven columns and label them left to right with the following information:

6.3.5.2.1 Date Bottle was opened

6.3.5.2.2 MMRI Controlled Substance I.D. number.

6.3.5.2.3 Lot number and expiration date

6.3.5.2.4 Purpose

6.3.5.2.5 Protocol Number

6.3.5.2.6 Date the empty bottle was discarded

6.3.5.2.7 Initials of person removing substance

6.3.5.3 When logging in a new shipment of Ketamine, bottles from the same lot may entered as a group. To correctly log in a new shipment, make the following entry; <Date Rec'd>, <range of ID numbers>, <lot number>, <New shipment rec'd>, <n/a>, <n/a> <initials>:

6.3.6 Place the controlled substance and the Inventory Log into the fireproof safe. This safe should be in a secured area, and comply with the security requirements set forth by CFR 1301.71

6.3.7 Close and lock the cabinet.

6.4 Inventory

6.4.1 When a controlled substance is removed from the cabinet for use in a procedure, the following must be recorded on the Inventory Log page:

6.4.1.1 Date

6.4.1.2 Pre Use Weight

6.4.1.3 Post use Weight

6.4.1.4 Quantity Used

6.4.1.5 Purpose

6.4.1.6 Protocol Number

6.4.1.7 Initials of person removing substance

6.4.2 Reconcile the inventory every six months. Report any discrepancy with the inventory to the Animal Facility Manager.

6.4.3 To reconcile the inventory, weigh the bottle that is currently being used. The bottle should weigh the same as last recorded weight in the log page.

6.4.4 Record the reconciliation procedure on the Inventory page in the same manner as any other procedure.

6.4.5 Reconcile the ketamine inventory by noting the quantity of vials received in last shipment and comparing it to the number of the bottles used and logged out then adding those to the number s of the bottles remaining in the drawer.

6.4.5 Keep all inventory records for at least two years from date of posting.

6.5 Disposal

6.5.1 If the substance has reached it's expiration date prior to the contents of the bottle being entirely used up (or any other reason for disposal of a partially used bottle) then the remaining portion must be sent to the local DEA approved disposal site. The local site is EXP Pharmaceutical Waste Management, in Hayward, CA. Contact EXP for their instructions on how to properly inventory, pack and ship controlled substances. *Do not send expired controlled substances to the DEA!*

6.5.2 If the substance must be disposed of, prior to using the contents, then the following two sentences must be written on the inventory page.

"This substance was disposed of by sending the remaining portion to the EXP Pharmaceutical Waste Management on, <Date substance was sent> . The reason for the disposal was ... < give explanation>."

6.5.3 Clearly mark any bottle of expired substance with "EXPIRED: DO NOT USE!" if it is necessary to hold expired substances within the facility prior to sending them out for disposal. Keep the expired bottles separated from useable material.

6.6 Report of Theft

6.6.1 If for some reason a quantity of the controlled substance is stolen, inform the Associate Director of Pharmacology and Toxicology immediately. A report of the theft must be filed with DEA and to the CA board of Pharmacy.

6.6.2 To report the theft, complete the front and backsides of DEA Form-106, (Figure 3).

6.6.3 Make three copies of the completed form.

6.6.4 Send the original and one copy to the DEA at the address listed in section D of this SOP.

6.6.5 Send the second copy to the California Board of Pharmacy: 1020 N. First Street, Room 448, Sacramento, CA 95814.

6.6.6 File the third copy with other DEA related documents in the Animal Facility Manager's office.

6.7 License Information

6.7.1 Renewing the DEA license is not automatic. A new application must be requested and filed with the DEA annually. Request form 225A (1996).

6.7.2 The MMRI Director will be the applicant on the DEA form 225A and will be responsible for:

6.7.2.1 Adherence to this SOP

6.7.2.2 Renewing license.

Figures referenced in document

6.1.4 Figures 1, DEA Form 222, copy of a correctly filled out form and the back which includes instructions how to fill it out.

6.3.5 Figure 2, Table of contents of the Controlled Substance Inventory Log

6.6.1 Figure 3, DEA Form-106, report of theft to be filed with DEA and to the CA board of Pharmacy

Figure 1

SAMPLE DEA FORM 222

Place this sample with your blank DEA Form 222s for quick reference. Use this sample and the "7-Step Checklist" (below) to ensure your form is correct before mailing.

See Reverse of PURCHASER'S Copy for Instructions	No order form may be issued for Schedules I and II substances unless a completed application form has been received (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010
TO: *(Name of Supplier)* THE BUTLER COMPANY (1*)		STREET ADDRESS **3820 Twin Creeks Drive** New Address
CITY and STATE COLUMBUS, OH 43204	DATE (2*)	TO BE FILLED IN BY SUPPLIER SUPPLIER'S DEA REGISTRATION NO.

LINE No.	TO BE FILLED IN BY PURCHASER: No. of Package (3*)	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1		250 ML	Socumb, 6 Grain			
2		20 ML	Hydromorphone Inj 2 MG			
3		5x10ml	Morphine Sulfate 1MG			
etc.		100	Morphine Tabs, 30 MG			
.		20 ML	Morphine Sulfate, 15 MG			
.		25 X 50 ML	Fentanyl CIT, 0.05 MG			
.		20 ML	Demerol HCL, 100 MG			
.		30 ML	Demerol HCL, 50 MG			
.		100	Demerol Tabs, 50 MG			
.		5	Duragesic Patches *(see below)			
.		100ml	Sleepaway, 260 mg			

▲(4*) LAST LINE COMPLETED	SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT (5*)
Date Issued / DEA Registration No.	(Name and Address of Registrant) (NOTE: THE NAME AND ADDRESS APPEARING IN THIS BLOCK MUST BE EXACTLY THE SAME AS THE NAME AND ADDRESS ON THE DEA FORM 223 - CONTROLLED SUBSTANCE REGISTRATION)
Schedules	
Registered as a / Form No.	

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
SUPPLIER'S COPY 1
* Indicate Duragesic Patches as 25mcg, 50mcg, 75mcg, or 100mcg

"7-Step Checklist"

1. **Name of supplier, address, city and state are correct.**
2. **Form is dated.**
3. **Number of packages, size of package, and strength desired is correct.**
4. **The "NO. OF LINES COMPLETED" block is filled in.**
5. **Veterinarian has signed the form.**
6. **Form contains no erasures or alterations.**
7. **Remove the purchaser's copy (blue copy) and place in your records.**

Figure 2

DRUG LOG

DRUG:________________________ HOW SUPPLIED:__________________

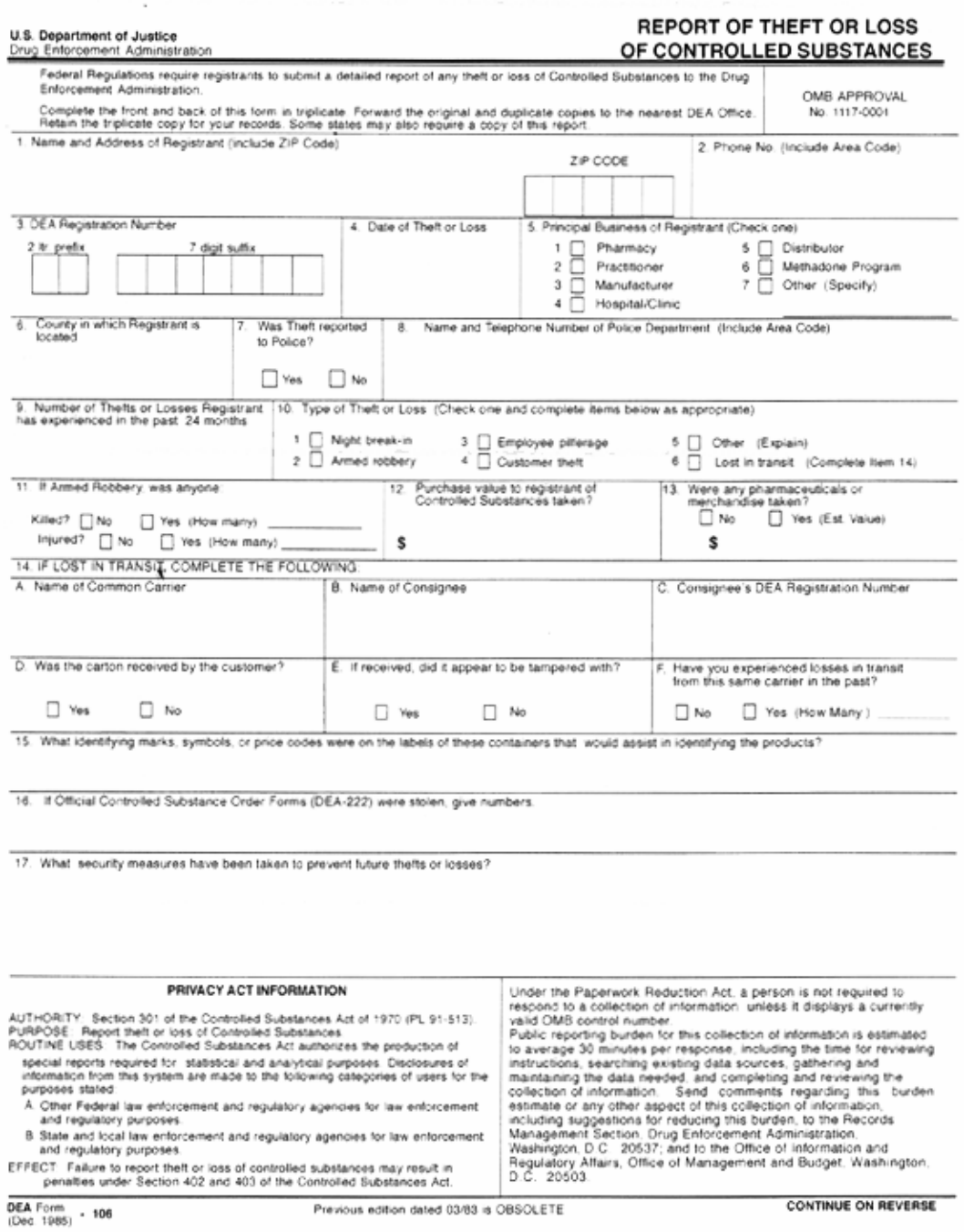
NO OF VIALS RECEIVED:________________ DATE RECEIVED:________________

LOT NUMBER:______________ EXPIRATION DATE:_____________

VIAL NUMBER:_________

DATE	AMOUNT USED	AMOUNT ON HAND	PROTOCOL NO.	INITIALS

Figure 3



U.S. Department of Justice
Drug Enforcement Administration

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL No. 1117-0001

1. Name and Address of Registrant (Include ZIP Code)

ZIP CODE

2. Phone No. (Include Area Code)

3. DEA Registration Number — 2 ltr. prefix — 7 digit suffix

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
1 ☐ Pharmacy
2 ☐ Practitioner
3 ☐ Manufacturer
4 ☐ Hospital/Clinic
5 ☐ Distributor
6 ☐ Methadone Program
7 ☐ Other (Specify)

6. County in which Registrant is located

7. Was Theft reported to Police?
☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has experienced in the past 24 months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 ☐ Night break-in
2 ☐ Armed robbery
3 ☐ Employee pilferage
4 ☐ Customer theft
5 ☐ Other (Explain)
6 ☐ Lost in transit (Complete item 14)

11. If Armed Robbery, was anyone
Killed? ☐ No ☐ Yes (How many) _____
Injured? ☐ No ☐ Yes (How many) _____

12. Purchase value to registrant of Controlled Substances taken?
$

13. Were any pharmaceuticals or merchandise taken?
☐ No ☐ Yes (Est. Value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer?
☐ Yes ☐ No

E. If received, did it appear to be tampered with?
☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past?
☐ No ☐ Yes (How Many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report theft or loss of Controlled Substances.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.
Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records Management Section, Drug Enforcement Administration, Washington, D.C. 20537; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

DEA Form 106 (Dec. 1985) — Previous edition dated 03/83 is OBSOLETE — CONTINUE ON REVERSE