Controlled Substance Policy
Research & Development Service

1. Introduction

Due to their abuse potential, scientists using items identified by the US Department of Justice, Drug Enforcement Administration (DEA) or the Department of Veterans Affairs Health Administration (VHA) as controlled substances must adhere to extensive licensing, registration, storage, security, use, and disposal regulations.

2. "Controlled Substance" Defined

Materials containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and having the tendency to promote abuse or physiological or psychological dependence, as designated in federal controlled substance schedules and policies.

3. Applicability

Principal Investigators (PIs) using controlled substances in their laboratory research (including research animals) are subject to federal regulatory requirements, as outlined in this Policy. Please note that these requirements (including licensing/registration with regulatory agencies) are separate from and in addition to any that apply to medical practitioners (i.e., MDs and MD/PhDs conducting laboratory research must also obtain licensure/registration for laboratory use of controlled substances).

4. Schedules

Controlled substances are divided into five categories, known as Schedules. Schedules I drugs are the most highly regulated. They have a high potential for abuse, have no accepted medical use in the US and/or have a lack of accepted safety for human use. These include many widely known street drugs, including heroin and hallucinogenic drugs such as LSD and marijuana. Schedule II drugs also have a high potential for abuse but have an accepted medical use in the US and have an accepted safety profile. Examples of Schedule II drugs include morphine, methadone, cocaine and oxycodone. Schedule III compounds include many stimulants and depressants, pain-killers and cough suppressants, the veterinary anesthetic ketamine, and anabolic steroids. Schedule IV substances cover the balance of lower abuse potential stimulants and depressants, while Schedule V includes therapeutic drug mixtures containing very limited quantities of controlled substances. Attachment A contains examples of controlled substances in schedules I through V that are used in research at this medical center.

Researchers planning work with controlled substances must be aware of and comply with federal statutes and regulations for these materials.

5. Responsibilities

a. Medical Center Director

The Medical Center Director is charged with the authorization of Principal Investigators to conduct research with controlled substances. Every Principal Investigator seeking to use a controlled substance in a research study must be authorized by the Medical Center Director. The Administrative Officer for Research & Development (R&D) Service will assist in aquiring authorization (see below).

Controlled Substance Policy
Research & Development Service

b. ACOS Research or the Administrative Officer Research (designee)

The ACOS for Research is responsible for:

1) Establishing policies and procedures for the use of controlled substances in research.
2) Authorizing DEA licenses for Principal Investigators by signing DEA form 225 to obtain a DEA license for research purposes(Attachment B). The form can be obtained on line at http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm.
3) Serving as the primary contact for the Controlled Substance Program Coordinator for the monitoring and reporting of the Controlled Substance Program within R&D
4) Preparing the authorization for the Medical Center Director's concurrence
5) Reporting any loss, theft, unauthorized use or other violation of federal law pertaining to controlled substances within Research to the Director

c. Principal Investigator

1) Since R&D Service cannot, by law, maintain "blanket" registration for controlled substances, it is the responsibility of individual Principal Investigators (PI) to obtain appropriate licenses and registration, and to adhere to federal regulatory requirements when working with controlled substances. Every Principal Investigator must be authorized by the Medical Center Director to conduct research with controlled substances. When a PI indicates that controlled substances will be used on a research project that is being reviewed by the Subcommittee on Research Safety (Attachment C), a memo of authorization must be prepared by the Administrative Officer for R&D Service and sent to the Director for concurrence.
2) Federal Registration: Principal Investigators are responsible for preparing a research laboratory registration Form DEA-225 (Attachment B), obtaining the signature of the ACOS for R&D Service, and sending a copy of the registration certificate DEA 223 (Attachment D) to the Administrative Officer for R&D Service who will provide a copy to the Research Phamacist. If you work with both Schedule I substances and Schedule II through V substances you will need to send in two applications of Form DEA 225 to receive two registration certificates, Form DEA 223.

   For schedule 1 substances, you will need a separate application for a DEA registration. A protocol outline must accompany the application form. See http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm#refer for a description of protocol requirements. Principal Investigators will receive a registration certificate, known as Form DEA-223 directly from the DEA. A copy must be forwarded to the Administrative Officer of R&D Service. DEA registrations for researchers remain active for a 1-year period, at which time a renewal notice will be mailed to you.

   For schedule 2-5 substances, you are required to submit another application for a DEA registration (Form DEA-225). Principal Investigators will receive a registration certificate, known as Form DEA-223 directly from the DEA. A copy must be forwarded to the Administrative Officer of R&D Service. DEA registrations remain active for a 1-year period, at which time a renewal notice will be mailed to you.

Controlled Substance Policy
Research & Development Service

Renewals: Renewals notices will be mailed to you by the DEA and will be processed in the same way as the initial registration. If registration lapses, controlled substances may not be used until the Form DEA 223 is received.

3) Authorized Users: Principal Investigators may authorize members of their laboratory staff to work with controlled substances under their license/registration, provided staff have been listed on the Grant Approval Request form (Attachment C) and have passed the required background checks that are initiated by the Research administrative office and sent to Human Resource Management Service. Principal Investigators are responsible for submitting a list of authorized users in each lab to the Administrative Officer of R&D Service for verification of the background check. A copy will be sent to the Research Phamacist.

Principal Investigators, Research Assistants, Lab Technicians and any other person previously convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, revoked, or surrendered may not be authorized for work with these materials. New employees will be screened and checked for offenses prior to being authorized access to controlled substances. Authorized staff must follow all of the rules and regulations outlined here, and are also obliged by law to immediately report any loss or diversion of controlled substances to their PI and ACOSResearch.

Registrants seeking to modify, transfer, or terminate their research laboratory use license and/or registration must submit a written request to the Administrative Officer, R&D Service for processing with the regulatory agencies.

d. Controlled Substance Program Coordinator

The Medical Center Controlled Substance Program coordinator will review monthly inspections of the controlled substances. Entries from the QM Service on VA Form 10-2638 (Attachment E) will confirm compliance with the program and regulatory requirements. The ACOS Research or his/her representative will be immediately notified if discrepencies are found in controlled substance inventory. After one working day, unresolved discrepencies will be reported per medical center policy.

e. Research Pharmacist

The Research Pharmacist serves as a consultant to the ACOS/R&D Service for establishing policies and procedures for controlled substance usage that conforms to federal regulations and policy to ensure the licensure, purchasing, storage, security, use, recordkeeping and disposal of controlled substances meet federal and VHA requirements. The Research Pharmacist will order, receive, distribute and arrange for destruction all Schedule I– V controlled substances used in Research. The Research Pharmacist will maintain records for five years as required by law. An inventory of the pharmacy stock will be completed at least every 72 hours within Pharmacy Service. The ACOS, Research & Development Service or his/her representative will be immediately notified if discrepencies are found in the controlled substance inventory of the pharmacy stock. After one working day, unresolved discrepencies will be reported per medical center policy.

Controlled Substance Policy
Research & Development Service

6. Purchasing/Ordering Controlled Substances

a. All Controlled substances used in the Portland VA Medical Center must be coordinated by the Pharmacy Service.

b. The Research Pharmacy will be responsible for ordering and purchasing all Schedule I through V controlled substances using standard Pharmacy purchasing procedures.

c. The investigator or authorized designee will email a request for ordering to the Research Pharmacy. Using the Order form on the following website which will be transmitted directly to the Research Phamacist: web site: http://www.va.gov/portlandrd. (Attachment F). The request will include: date, laboratory, building and room, title of the grant to be charged and administrator of the grant, i.e. VA, PVARF or OHSU, manufacturer, drug, dosage form, strength and quantity requested, and the person requesting the order and a contact telephone number. The VMU may order drugs for the clinical care of animals by noting "Clinical Care" rather than the title of the grant.

d. The Research Pharmacy will order the drug by the close of business on the next business day after receipt of order request.

e. Controlled substances in Schedules I through V will be delivered to the Research Pharmacy. The Research Pharmacy will notify the investigator when the controlled substances arrive and arrange for the investigator or authorized user to pick up the item. The Research Pharmacy will send a copy of the invoice for each item dispensed to the Budget Analyst in R&D Service who will arrange for payment.

7. Scope of Use

Controlled substances may only be used for duly authorized, legitimate medical or scientific research purposes, to the extent permitted by a registrant's license and registration, and in conformity with federal statutes and regulations.

8. Storage and Security Controls

Controlled substances possessed, kept, or otherwise stored in a manner or location not in compliance with state or federal law are subject to seizure and forfeiture. Failure to comply with applicable requirements may also result in a suspension of purchasing privileges and a ban on the use of controlled substances in future experiments conducted at the Portland VA.

In order to guard against theft or diversion, all controlled substances - regardless of schedule - must be kept under double lock, and accessible only to authorized personnel. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stocks of controlled substances to the smallest quantity needed.

All controlled substances must be stored in a refrigerator or locked cabinet that has been approved by the Research Pharmacist. Regardless of schedule, all controlled substances must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

Controlled Substance Policy
Research & Development Service

9. Recordkeeping

PIs must maintain complete and accurate inventory records for all controlled substances on VA form 10-2638 For Research (Attachment E). These records must be kept separate from all other records and documents, in or near the primary work area, and available for inspection during regular work hours. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited. In the event that any controlled substances are lost, destroyed, or stolen, the kind and quantity of the material and the date of discovery of such loss must be recorded in detail. **A loss of VA form 10-2638 is considered a loss of a controlled substance**. After use is completed, VA form 10-2638 must be returned to Research Pharmacy for review. All records will be maintained by Research Pharmacy for a period of at least five years from the date of return of the form.

A. Receipt of Controlled Substance: Only those staff listed on the Grant Approval Request form may receive controlled substances from the Research pharmacy. The name of the PI, pharmacy dispensing number, location of the safe, aubstance & amount, lot number and weight of the vial released by pharmacy (i.e., the weight of the container plus contents) will be noted by the Research Pharmacy on VA Form 10-2638. Upon the receipt of controlled substances the investigator or other Authorized User will sign and date the bottom of VA Form 10-2638 and VA Form 10-2321 (the Narcotic Dispensing/Receiving Form) which is Attachment G.

B. Use of Controlled Substances: All use of controlled substances will be noted on VA Form 10-2638 For Research as a perpetual inventory of each dispensed item. Each time an aliquot of a controlled substance is removed for an experiment, the PI must record the date, time, describe the use, and the weight or volume removed. Most importantly, the PI should then weigh the vial and enter the weight of the vial plus contents in the last column of form 10-2638. During the monthly controlled substance inspections, the surveyors will weigh each vial and comper it to the weight recorded on 10-2638.

C. Inventory of Controlled Substances: A complete and accurate inventory of the stock of controlled substances within each registrant's laboratory must be maintained in the controlled substance notebook. The Medical Center Controlled Substance Program coordinator, will perform monthly unannounced inspections of the controlled substances. If the investigator or designee is unavailable for the inspecton the Medical Center Controlled Substance Program Coordinator will contact the Administrative Officer of R&D Service to arrange for the inspection. Entries on Form 10-2638 will confirm compliance with the program and regulatory requirements. The ACOS Research or his/her designee will be immediately notified if descrepancies are found in the controlled substance inventory. After one working day, unresolved discrepencies will be reported per medical center policy.

10. Disposal

Expired material, unused product, **or neat waste** for all Schedules I through V must be returned to the Research Pharmacy along with a signed VA Form 10-2638 (Attachment F). The Principal Investigator or authorized designee will contact the Research Pharmacy when drug is expired, there is product that must be wasted or when the drug is no longer needed. The controlled substances submitted for disposal must contain the following information to be received for processing and disposal: all units must be appropriately labeled with contents, strength, quantity, Principal Investigator, laboratory name and location. The Research Pharmacy will prepare a return receipt for signature by the authorized person (Lab Technician, Research Assistant) submitting the material. A copy of this form will be given to the person returning the material. This form should be kept until after the next Medical Center Controlled Substance Inspection for documentation of return. The Research Pharmacy will keep the original form for 5 years. The Research Pharmacy will use a certified contractor to dispose of Schedule I through V controlled substances. Drugs provided through the Pharmacy will use the Pharmacy DEA number to return the drug, Schedule I drugs will

Controlled Substance Policy
Research & Development Service

use the Investigator's DEA number. A copy of the disposal/return form will be provided to the investigator for their records.

11. Reporting of Loss, Destruction, Theft, or Unauthorized Use

Thefts, suspected thefts, unauthorized uses, or other losses of any controlled substance must be reported to the ACOS Research immediately upon discovery. Principal Investigators must also document the incident in writing for submittal to the DEA within 72 hours. The written statement must describe the kinds and quantities of controlled substances, and the specific circumstances involved. Where the controlled substances are stolen, lost, or destroyed in transit, the consignee will also be required to prepare a similar report and include documentary evidence that local authorities were notified. The registrant should retain a copy of the statement.

12. Accepting Controlled Substances from Collaborators

Investigators wishing to accept controlled substances from collaborators must coordinate the transfer with the Research Pharmacist at the PVAMC. Advance notice of the transfer must be given. The controlled substances may not be delivered to the PIs laboratory. It must be delivered to the Research Pharmacist who will generate a VA form 10-2638 and call the PI's laboratory for pick up. All other aspects of the policy described here will apply.

13. Resources and References

R&D Service Controlled Substance Coordinator	Beverly Jefferson Administrative Officer, R&D	Ext. 55125
Controlled Substance Coordinator	Cathy Fowler Quality & Performance	Ext. 55267
Research Pharmacy	Vickie Vonderohe, Pharm.D. Program Manager	Ext. 55543
Police Service	Officer on Duty	Ext. 56982

Manual M-2, Part VII, Chapter 5, Controlled Substances in Research Areas
Manual M-2, Part VII, Chapter 10 Inspection of Controlled Substances
Controlled Substance Handbook 1108.2
Code of Federal Regulations, Title 21, Part 1300-1399, Drug Enforcement Administration (DEA)

14. Approved Date: March 17th, 2004

15. Review Date: March 17th, 2005

Michael P. Davey, M.D., Ph.D
ACOS, Research & Development Service

Edward Jai, R.Ph
Chief, Pharmacy Service

Attachment A
Schedules of Various Controlled Substances

Drug	Schedule
222-Tribromoethanol	Schedule III
a-Endorphin	Schedule II
Alprazolam	Schedule IV
Amphetamine	Schedule II
β-CFT Naphthalenesulfonate	Schedule II
Buprenorphine	Schedule III
c-5776 (cocaine solution)	Schedule II
Chloral Hydrate	Schedule IV
Clonazepam	Schedule IV
Cocaine	Schedule II
D-Amphetamine Sulfate	Schedule II
Diazepam	Schedule IV
Ethchlorvynol-USP (placidyl)	Schedule IV
Euthasol (Phenytoin/Phenobarbital)	Schedule III
Fenfluramine	Schedule IV
Fentanyl-2ml amp; 100ug/amp	Schedule II
Fentanyl-2ml amp; 50ug/amp	Schedule II
Flunitrazepam (Rohypnol)	Schedule I
GHB -Gamma Hydroxybutyric Acid	Schedule I
Ketamine	Schedule III
Levorphanol Tartrate	Schedule II
Lorazepam	Schedule IV
Mazindol	Schedule IV
Mazindol-Sigma	Schedule IV
Methamphetamine	Schedule II
Methylenedioxy-Methylamphetamine	Schedule I
Methylphedidate	Schedule II
Methyprylon	Schedule III
Midazolam HCl	Schedule IV
Morphine sulfate	Schedule II
Morphine-10ml vial; 10mg/ul	Schedule II
Mouse cocktail (ketamine)	Schedule III
Oxymorphone	Schedule II
Oxymorphone-10mg bottle, powder	Schedule II
Pentobarbital	Schedule II
Phencyclidine	Schedule II
Phenobarbital	Schedule IV
Rat cocktail (ketamine)	Schedule III
Remifentanil-2mg amp	Schedule II
Epistestosterone	Schedule III
Testosterone	Schedule III
Dihydrotestrosterone	Schedule III
Etiocholan (Dehydroepiandrosterone)	Schedule III
Thiobutabarbital	Schedule III
Thiopental Sodium	Schedule IV
Triazolam	Schedule IV

Attachment B
FORM 225

READ INSTRUCTIONS BEFORE COMPLETING
USE BLACK INK

APPLICATION FOR REGISTRATION
UNDER CONTROLLED SUBSTANCES ACT OF 1970

APPROVED OMB NO. 1117-0012
FORM DEA-225 (11-00)
Previous editions are obsolete

NAME: APPLICANT OR BUSINESS(LAST) (First, MI)

No registration will be issued unless a completed application form has been received (21 CFR 1301.13).

TAX IDENTIFYING NUMBER and/or SOCIAL SECURITY NUMBER

The Debt Collection Improvement Act of 1996 (PL 104-134) requires that you furnish your Taxpayer Identifying Number and/or Social Security Number to DEA. This number is required for debt collection procedures should your fee become uncollectable.

PROPOSED BUSINESS ADDRESS *(When using a P.O. Box you must also provide a street address)*

CITY STATE ZIP CODE

APPLICANT'S BUSINESS PHONE NUMBER APPLICANT'S FAX NUMBER

FOR DEA USE ONLY

1. BUSINESS ACTIVITY: (Fill-in Circle)
E. ○ MANUFACTURER F. ○ DISTRIBUTOR G. ○ RESEARCHER
H. ○ ANALYTICAL LAB J. ○ IMPORTER K. ○ EXPORTER

2. DRUG SCHEDULES: *(Fill-in all circles that apply)*
○ SCHEDULE I ○ SCHEDULE III ○ SCHEDULE IV
○ SCHEDULE II ○ SCHEDULE III NON NARCOTIC ○ SCHEDULE V

3. INDICATE HERE IF YOU REQUIRE ORDERFORM BOOKS ○

4. SUPPLY ANY OTHER DEA REGISTRATION NUMBERS FOR ANY CLASS OF BUSINESS AT THE ADDRESS SHOWN ON THIS APPLICATION

5. MANUFACTURERS ONLY
Mark category and Schedules applicable in the circles to the right
(Definitions on reverse of instruction sheet)

MANUFACTURES CATEGORIES	SCHEDULES I	II	III	IIINon IV	V
A ○ Bulk, Synthesizer - Extractor	○	○	○	○	○
B ○ Dosage Form	○	○	○	○	○
C ○ Repacker - Relabeler	○	○	○	○	○
D ○ Non-Human Consumption	○	○	○	○	○

6. ALL APPLICANTS MUST ANSWER THE FOLLOWING:

(a) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate?

○ YES - State License No. ○ PENDING ○ N/A

○ YES - State Controlled Substance No. ○ PENDING ○ N/A

ATTENTION ▶ Researcher, LAB $130; Dist., Importer, Exporter $813; Manuf $1,625: For 1 YR Continue on Reverse ▶

Attachment B
FORM 225

6. CONTINUED

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law? ○ YES ○ NO

(c) Has the applicant ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied? ○ YES ○ NO

(d) Has the applicant ever surrendered or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? Is any such action pending? ○ YES ○ NO

(e) If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under state or federal law, or ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied,or ever had a state professional license or controlled substance registrationrevoked, suspended, denied, restricted, or placed on probation? ○ YES ○ NO ○ N/A

7. EXPLANATION FOR ANSWERING "YES" TO ITEM(S) 6(b), (c), (d), OR (e). Applicants who have answered "yes" to item(s) 6(b), (c), (d), or (e) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use a separate sheet and return with application.

8. DRUG CODE NUMBERS must coincide with the schedules requested. Listed below are the Drug Code requirements for each business activity:

Analytical Lab - Not required to list drug codes
Distributor - Schedule I
Importer - Schedule I thru V
Exporter - Schedule I thru V
Researcher - Schedule I an II (See Item I, Researcher on Instruction Sheet)
Manufacturer - Schedule I, II, III, IIIN in addition to codes furnished, bulk manufacturer (synthesizer/extractor) applicants MUST Circle Below those "Basic Classes" of controlled substances in Schedule I and II which you propose to Manufacture in Bulk **"If additional space is required, use a separate sheet and return with application.**

9. PAYMENT METHOD (Fill-in only one circle)

○ VISA ○ MASTER CARD ○ CHECK

FEES ARE NOT REFUNDABLE

CREDIT CARD DATE

EXPIRATION DATE ___ — ___

SIGNATURE OF CARD HOLDER

10. CERTIFICATION FOR FEE EXEMPTION (Fill-in Circle)

○ FILL-IN CIRCLE IF APPLICANT NAMED HEREON IS A FEDERAL, STATE, OR LOCAL GOVERNMENT OPERATED HOSPITAL, INSTITUTION, OR OFFICIAL. The undersigned hereby certifies that the applicant named hereon is a federal, state, or local government operated analytical lab or researcher, and is exempt from payment of the application fee.

SIGNATURE OF CERTIFYING OFFICIAL **(Other than applicant)** | DATE

PRINT OR TYPE NAME OF CERTIFYING OFFICIAL | PRINT OR TYPE TITLE OF CERTIFYING OFFICIAL

11. APPLICANT SIGNATURE ***(must be an original signature in ink)*** ► **Remove form from package before signing**

SIGNATURE | DATE

I hereby certify that the foregoing information furnished on this application is true and correct.

Print or Type Name

Print or Type Title (e.g., President, Dean, Procurement Officer, etc...)

MAKE A COPY FOR YOUR RECORDS.

RETURN COMPLETED APPLICATION WITH FEE IN ATTACHED ENVELOPE

MAKE CHECK PAYABLE TO:

DRUG ENFORCEMENT ADMINISTRATION

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
CENTRAL STATION
P.O. BOX 28083
WASHINGTON, D.C. 20038-8083

For information, call 1 (800) 882-9539
See "Privacy Act" Information on last page of application.

Attachment C
Subcommittee for Research Safety Approval Form

Subcommittee on Research Safety
Department of Veterans Affairs Medical Center
Portland, Oregon

Grant Approval Request

PRINCIPAL INVESTIGATOR (PI):

VA RESPONSIBLE INVESTIGATOR:

Service: **Lab Location:**

Phone ext.: **Pager:** **Mail Code:**

Project Title:

Funding Source (VA, NIH, etc.):

Personnel: List the names of all personnel, co-investigators and collaborators who will work with the PI on this research proposal.

Does your proposal involve the use of any of the following items?

Hazardous Chemicals (Refer to the Research Service Chemical Hygiene Plan or Master List Spreadsheet of Chemical Hazards; **list any hazardous chemicals** that were **not** provided on your most recent semiannual chemical inventory submitted to FMS)

- Toxic Chemicals (including heavy metals) yes ☐ no ☐
- Flammable, explosive, or corrosive chemicals yes ☐ no ☐
- Carcinogenic, mutagenic, or teratogenic chemicals yes ☐ no ☐
- Toxic compressed gases yes ☐ no ☐
- Acetylcholinesterase inhibitors or neurotoxins yes ☐ no ☐

Cell or tissue culture yes ☐ no ☐

Human Tissues or fluids yes ☐ no ☐

BSL2 or BSL3 microbiological or viral agents, pathogens, or toxins. List: yes ☐ no ☐

Poisonous, toxic or venomous plants or animals yes ☐ no ☐
List:

Controlled Substances yes ☐ no ☐
PI has research DEA number: yes ☐ no ☐
List Substances:
List Authorized Users in Lab:

Recombinant DNA yes ☐ no ☐

Radioactive Materials yes ☐ no ☐
List:

***** Attach the abstract for your proposal. Avoid use of acronyms (unless defined) and provide sufficient detail to describe the use of any of the materials or methods indicated above.**

Has your use of the items indicated above been reviewed and approved by the Subcommittee on Research Safety, the Research and Development Committee, and the Facility Safety Office? yes ☐ no ☐

If **NO**, please revise your SRS Annual Self-Inspection Form to include the required additional information, and submit this form to the Subcommittee on Research Safety for review.

Subcommittee on Research Safety (SRS) Review

Acknowledgement of Responsibility

I certify that my protocol will be conducted in compliance with Federal, State, and local policies and regulations governing the use of chemical, radioactive and biohazardous materials. I further certify that all technical and incidental workers involved in this project will be aware of the potential hazards and will receive instructions and training on the proper handling and use of chemical, physical, radioactive and biohazardous materials.

_____ _____
Principal Investigator's Signature **Date**

Certification of Proposal Approval

D. ___ The safety information for this proposal has been reviewed and found in compliance with Federal, State, and local policies and regulations governing the use of chemical, physical, radioactive and biohazardous materials. Resources necessary for the performance of these proposed studies are available and adequate.

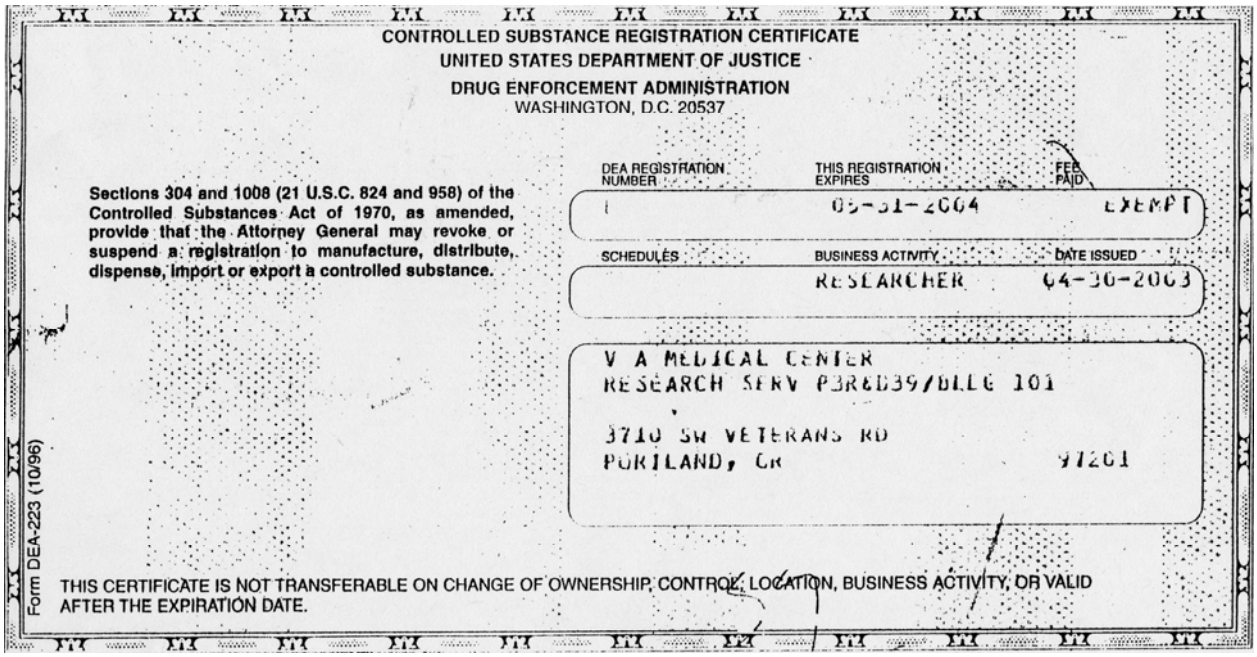
_____ _____
Radiation Safety Officer (if applicable) **Date**

_____ _____
Chair, Subcommittee on Research Safety **Date**

_____ _____
Chair, Research & Development Committee **Date**

_____ _____
Facility Safety Officer, VAMC, Portland, OR **Date**

Attachment D
FORM 223



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[illegible]	05-31-2004	EXEMPT

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
	RESEARCHER	04-30-2003

V A MEDICAL CENTER
RESEARCH SERV P3R&D39/BLLG 101
3710 SW VETERANS RD
PORTLAND, OR 97201

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (10/96)

Attachment E

Form 10-2638 for Research

CONTROLLED SUBSTANCE USE RECORD Pharmacy Dispensing #: _____

Principal Investigator: Location of Safe (bldg/rm #): _____

Substance and amount: _____ Quantity: _____ Expiration: _____

Lot# _____ Ordered by:_____ Disp by: _____ Date: _____

Final weight of vial released from pharmacy: _____ (grams)

Date	Time	Use[1]	Removed by	Quantity removed[2]	New weight[3]
Initial weight of vial					

Received by_____ Date_____
Signature of PI or designee that green sheet is ready for return to Pharmacy _____
Completeness checked by_____ Date_____
Reviewed by Pharmacist_____ Date_____

[1] For *in vivo* study, state species receiving substance; for *in vitro* studies, give a general description of use (for example, name of assay or cell culture system).
[2] Enter weight or volume of amount taken from vial
[3] Of entire vial + contents after removing aliquot portion for current experiment

Attachment F

Controlled Substances for Research
Order Form

Date Requested:

Principal Investigator:

Building & Room:

Title of Grant to be Charged:

Administrator of Grant: PVARF

Drug:

Dosage Form:

Strength:

Manufacturer:

Quantity Requested:

Requestor's Name:

Requestor's Phone Number:

Submit Reset

Attachment G
VA Form 10-2321, Narcotic Dispensing/Receiving Form

VA FORM 10-2321 Narcotic Dispensing/Receiving Report for RESEARCH
JAN 27,2004@12:42

DISP #	DATE DISPENSED	QTY	DRUG	DATE ORD ORDERED BY
210069	01/27/2004	2	FENTANYL 50MCG/ML 50ML	01/27/2004 VONDEROHE, VICKIE

Mfg/Lot#/Exp Date: ELKINS/XXX/3/2006

Disp by RPh:_____ Rec'd by PI or designee:_____
(Full Name) (Full Name)

COMMENTS: For Research lab