BFB-BUS-50: Controlled Substances

Responsible Officer:	Chief Risk Officer
Responsible Office:	RK - Risk / EH&S
Issuance Date:	5/5/2009
Effective Date:	5/5/2009
Scope:	This policy does not apply to University clinical activities. Clinical care activities performed by a University Medical Center, veterinary teaching hospital, pharmacy, or clinic are governed by federal and state accrediting and regulatory agencies and are subject to review and audit by those agencies. Medical practitioners in University facilities are required to maintain appropriate state and federal licensure with respect to dispensing controlled substances. Except as cited in the preceding paragraph, this policy applies to all authorized campus research and teaching activities which involve dangerous drugs, including controlled substances, listed and/or precursor chemicals, and dangerous devices. Based on feedback and the need for continuous improvement, this policy will evolve to incorporate updates that are identified to support scientific research or to address the needs of clinical activities**.**

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I. POLICY SUMMARY

The purpose of this document is to define the roles and responsibilities for establishing and maintaining a Controlled Substances Program. This document allows University locations to tailor their programs to meet local expectations based on the various state

jurisdictions of the Drug Enforcement Administration (DEA). The policy establishes the minimum regulatory requirements and provides a Best Practices Guide to aid in program implementation. University locations are expected to implement the program using the Best Practices Guide or equally effective procedures. University locations are also expected to develop detailed written procedures to implement this policy and to demonstrate compliance with federal and state regulations (US Department of Justice, DEA (CFR Title 21, Food and Drug Act §1300-1316) and California regulations (California Health and Safety Code §11100-11700)) on acquiring, maintaining, storing, using, and disposing of controlled substances.

II. DEFINITIONS

Authorized University Activities – University approved research, veterinary care associated with research, and teaching uses of Dangerous Drugs and Devices, including Controlled Substances, and Precursor and Listed Chemicals.

Authorized Individual – A Principal Investigator or laboratory member who is authorized to possess or use Controlled Substances by the University or Laboratory. (See Section IV)

Clinical Setting – A setting where a controlled substance or dangerous drug is used in a human or animal patient care application not associated with research.

Controlled Substances – Narcotic and non-narcotic drugs under the jurisdiction of the federal Controlled Substances Act and the California Uniform Controlled Substances Act, including but not limited to those substances listed in 21 CFR §1308.11-1308.15.

Drug Enforcement Administration (DEA) – the agency responsible for enforcing the controlled substances laws and regulations of the United States.

Dangerous Drug or Device – The terms “Dangerous Drug” and “Dangerous Device” are defined in California Business and Professions Code Chapter 9, Division 2, Article 2 §4022 and includes the following:

(a) Any drug that bears the legend “Caution: federal law restricts this device to sale by or on the order of a physician, pharmacist, veterinarian, etc.” “Rx only” or words of similar import.

(b) Any device that bears the statement “Caution: federal law restricts this device to sale by or on the order of a physician, pharmacist, veterinarian, etc.” “Rx only” or words of similar import.

(c) Any other drug or device by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 (of the California Business and Professions Code).

University investigators engaged in Authorized University Activities are permitted to purchase dangerous devices without a prescription as defined by California Business and Professions Code Chapter 9 Division 2 Article 3 §4059 and §4059.5.

Environment, Health and Safety (EHS) Department – The administrative unit that manages the location's Environment, Health and Safety programs.

Investigational New Drug (IND) – A drug that has not been approved for general use by the Food and Drug Administration but is under investigation in clinical trials regarding its safety and efficacy first by clinical investigators and then by practicing physicians using subjects who have given informed consent to participate.

Institutional Review Board (IRB) – The respective location's Committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.

Listed Chemicals – Under federal law, any List I or List II chemical including a List I chemical specifically designated by the DEA Administrator in 21 CFR §1310.02(a), that in addition to legitimate uses, can be used in manufacturing a controlled substance in violation of the federal Controlled Substances Act, and any List II chemical specifically designated by the DEA Administrator in 21 CFR §1310.02(b), that in addition to legitimate uses is used in manufacturing a controlled substance in violation of the Act.

Materiel Manager – See Section IV

Non-Clinical Setting – A setting where a controlled substance or dangerous drug is used in a teaching, research, or veterinary care associated with research. This includes human subject research protocols.

Precursor Chemical – Under California pharmacy law, a precursor chemical is any chemical that may be used to create controlled substances, including but not limited to catalysts, direct precursors or crucial ingredients used in the production of controlled substances (see also California Health and Safety Code §11100).

Program Administrator – The position with operational responsibility for the location's Controlled Substance Program (Section IV)

Research Advisory Panel of California – A function of the California Attorney General's office which, pursuant to California Health & Safety Code §11480 & 11481, must review and authorize proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances.

Responsible Official – The position with responsibility for oversight of the location's Controlled Substance Program. See Section IV

III. POLICY TEXT

Each University location is responsible for complying with the following general requirements.

A. DEA Registration

1. Obtaining and maintaining the appropriate types of DEA Controlled Substance Registrations. 21 CFR §1301.13 lists the scope of activities authorized within each category; DEA registration categories, applications for registration, and instructions are available online at http://www.deadiversion.usdoj.gov/drugreg/index.html.

2. Establishing written procedures for:

   a. Filing of new applications;

   b. Application management;

   c. How University research personnel shall individually maintain separate registrations with the DEA (such as licensed healthcare professionals);

   d. How University employees engaged in an Authorized University Activity with Schedule I Controlled Substances shall obtain an individual DEA registration for each such project.

B. Authorization Process and Training

Each location must develop an authorization process and establish a training program for those who require access to Controlled Substances. Training shall occur prior to authorizing an individual and at a minimum, must include:

1. Storage site controls and security;
2. Ordering, delivery, and receipt;
3. Usage logs and biennial inventory requirements;
4. Transfers of Controlled Substances;
5. Import and export policies;
6. Disposal of Controlled Substances;
7. Diversion and loss reporting; and
8. Illicit activities and repercussions.

C. Power of Attorney

Each Responsible Official may designate additional individuals to sign official Controlled Substances order forms and to procure Controlled Substances for Authorized University Activities. A sample Power of Attorney form and Notice of Revocation is available at CFR Title 21 §1305.05.

D. Complying with Import, Export, Interstate and Intrastate Use Requirements

1. Imports

   It is unlawful to import Dangerous Drugs, including Controlled Substances, into the United States unless: (i) the DEA grants an import permit to the University; or (ii) in the case of other Dangerous Drugs that are not Controlled Substances, the drug is subject to FDA regulation and may require an Investigational New Drug Permit (IND) issued by the FDA.

2. Exports

   The University does not permit the export of Dangerous Drugs including Controlled Substances, federal List I and II chemicals, or California-listed chemicals acquired under a University DEA registration or using University funds without first obtaining explicit permission from the DEA Office of Diversion Control Import/Export Unit and institution's Responsible Official.

3. Interstate and Intrastate Use

   A DEA registration may need to be obtained in the State or location within California that the research is being conducted. Transfers between DEA registrants may be permitted with the permission of the Program Administrator.

E. Documentation of Local Controlled Substances Program Compliance

Each campus must develop and publish written procedures that address the following federal or state requirements:

1. Controls with regard to ordering, procurement and distribution of Controlled Substances for Research Purposes. Minimally, these must address:

   a. Prohibits any individual the ability to order, receive, distribute, and dispose of controlled substances;

   b. General requisition, procurement, and distribution requirements and approval processes; this includes identification of orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency;

   c. The approval process and requisition information for Investigational New Drugs;

   d. orders for Schedule I and II drugs using DEA Form 222;

   e. Orders for Schedules III, IV, and V and other Dangerous Drugs;

f. Orders for Federal List I Chemicals/Precursor Chemicals

g. Orders for California Listed Chemicals/Precursor Chemicals;

h. Orders for Dangerous Drugs and Devices (Material requiring a Prescription).

2. Controls, Storage, and Security safeguards to prevent unauthorized acquisition, access, use, theft, or a diversion of Controlled Substances, List I chemicals, California Precursor Chemicals, and other Dangerous Drugs and Devices.

3. Personnel Screening Requirements to ensure that no individual has access to controlled substances who has been convicted of a felony offense relating to controlled substances or whose application for registration with the DEA has been denied, or whose registration was revoked or surrendered for cause. See 21 CFR §1301.76 and 1301.90.

4. Record-Keeping and Inventory Requirements, including:

   a. Power of Attorney forms;
   b. Purchasing and associated records;
   c. Distribution and chain-of-custody records;
   d. Proper retention schedules for acquisition, use, and disposition records;
   e. Adequate recordkeeping by investigators or authorized personnel:

      i. Usage log and inventory and biennial inventories;
      ii. Separation of records by location;
      iii. Purchase records for Dangerous drugs and Devices. (See 21 CFR §1304.04, 1304.11, 1310)

5. Diversion, Loss, or Theft Reporting of Controlled Substances, Precursors, and List I chemicals. Location-specific procedures must include details on which campus office should be notified of and report to DEA within 24 hours about each theft or significant loss of controlled substances. See 21 CFR §1301.91.

6. Disposal or Destruction of any controlled substance must be in accordance with DEA policies, procedures, and regulations. See 21 CFR §1307.21.

7. California Research Advisory Panel Requirements for Principal Investigators to obtain and submit applications to the Research Advisory Panel.

California law requires that certain studies involving Schedule I and II Controlled Substances be submitted and approved by the Research Advisory Panel of California. Principal Investigators must follow the guidance on the Research Advisory Panel webite (http://ag.ca.gov/research/index.php)

F. Required Auditing and Monitoring

Each location must develop and implement a routine auditing and monitoring program that includes unannounced inspections of investigator-maintained substances and records for compliance with state and federal laws governing the use of dangerous drugs and controlled substances in Authorized University Activities.

G. Illicit Activities

The University complies with federal and state law which makes it a criminal activity for employees to illegally possess, sell, use, or divert controlled substances, but shall also immediately become the subject of independent action regarding their continued employment. Any member of the University community who suspects another member of such illicit activities should follow campus or laboratory reporting policy.

H. Complying with State Licensure Requirements for Research Involving Human Subjects

Only California licensed medical personnel and investigators engaged in Authorized University Activities and acting within the scope of their authorized professional practice and consent of all applicable Institutional Review Boards (IRB) may prescribe, furnish, dispense or administer Dangerous Devices and Dangerous Drugs, including Controlled Substances, to human research subjects. .

IV. COMPLIANCE / RESPONSIBILITIES

A. Chancellor or Laboratory Director

Each Chancellor or Laboratory Director is responsible for providing resources to effectively administer a Controlled Substances program and for designating, in writing, a Responsible Official to establish and oversee the program.

B. Responsible Official

As designated by the Chancellor or Laboratory director, the Responsible Official shall:

1. Establish and oversee the Controlled Substances Program in accordance with DEA regulations and best practices;
2. Sign all DEA registrations on behalf of the UC Regents; and
3. As appropriate, grant a Power of Attorney to managers to enable them to obtain and execute order forms for controlled substances. The Responsible Official may designate one or more individuals to implement and manage the program.

C. Program Administrator

The Responsible Official's designee (such as personnel from Environment, Health and Safety) charged with implementing and managing the Controlled Substances Program on a day-to-day basis. The Program Administrator shall be either (i) a California licensed pharmacist or California licensed medical professional who is legally authorized by California and federal law to order, prescribe, or dispense dangerous drugs and devices, including Controlled Substances; or (ii) a person with training and experience in California and federal laws governing dangerous drugs, including Controlled Substances, and dangerous devices.

D. Materiel Management

The Materiel Manager or designee is responsible for procuring Controlled Substances, Listed and Precursor chemicals for Authorized University Activities in compliance with DEA registrations, the location's Controlled Substances Program, and University/Laboratory policies.

E. Authorized Individuals

A Principal Investigator or laboratory member (e.g. staff and/or students) who are authorized to possess or use Controlled Substances by the University or Laboratory. Authorized Individuals are responsible for understanding their responsibilities within the program and complying with DEA regulations, program requirements, and University/Laboratory policy governing the acquisition, use, storage, and disposition of controlled substances.

V. PROCEDURES

See Appendix A, Best Practices Guide

VI. RELATED INFORMATION

Food and Drug Act of 1906 (as amended) (21 USC §§1300-1316)
Controlled Substances Act of 1970
California Uniform Controlled Substances Act, Health and Safety Code §§11100-11700
California Research Advisory Panel (http://ag.ca.gov/research/index.php)
California Business & Professions Code Chapter 9, Division 2, Article 2 §4022+-

VII. FREQUENTLY ASKED QUESTIONS

Not applicable

VIII. REVISION HISTORY

This policy was reformatted into the standard University of Califonria policygtemplate effective June 1, 2012.

Appendix A
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II. PURPOSE

The purpose of this document is to provide examples of best practices to assist University locations in establishing and maintaining a Controlled Substances Program that is fully compliant with federal and state regulations. This non-mandatory appendix contains portions from several University programs which may be used while developing detailed procedures in accordance with the BUS 50 Policy.

- EXPECTATIONS

Each location must develop a Controlled Substances Policy and Program that meets the minimum requirements of BUS 50 and addresses the expectations of the local DEA office. Each location should collaborate with affected campus organizations (e.g. researchers, materiel management, EH&S, internal audit, and risk management) to work with and gain approval of their Policy and Procedures from their local DEA office. The preferred office of record for the Policy and home of the Program is the campus Environment, Health & Safety Department.

III. RESPONSIBILITIES

Each campus Chancellor or Laboratory Director is responsible for providing resources to effectively administer a Controlled Substance program and for delegating authority to a Responsible Official in order to establish and oversee the program.

The Responsible Official should be a direct report to the Chancellor or Laboratory Director and an individual who is authorized to legally commit on the behalf of the campus or National Laboratory that it will meet the federal and state requirements. The Responsible Official should designate the program's management team as follows:

A. Program Administrator - personnel from Environment, Health and Safety charged with implementing and managing the Controlled Substances Program on a day-to-day basis. The Program Administrator should provide an annual report to the Responsible Official describing the status of the program.

B. Materiel Manager - responsible for procuring controlled substances and listed and precursor chemicals for Authorized University Activities in compliance with DEA registrations, the location's Controlled Substances Program, and University/Laboratory policies.

IV. GENERAL PROGRAM REQUIREMENTS

A. DEA Registration

The Responsible Official must assign responsibility to either the Program Administrator or Materiel Manager for obtaining and maintaining the appropriate types of DEA Controlled Substance Registrations in order to

cover the Authorized University Activities at each principal place of business where Controlled Substances are manufactured, distributed, imported, exported, or dispensed by authorized University personnel.

B. Authorization Process and Training

Each location must develop an authorization process and establish a training program for those who require access to Controlled Substances.

1. Authorization Process

Each location's Controlled Substances Program shall have an authorization process for initial request to store controlled substances in a facility/laboratory and for those individuals who require access to Controlled Substances for Authorized University Activities.

a. Facility Evaluations

Each location must have written procedures for the evaluation of a proposed storage site for controlled substances with the Principal Investigator. This evaluation should include the control and security requirements, inventory and usage log requirements, and participation in the personnel screening program. The Principal Investigator must successfully complete the location's training and personnel screening programs prior to the approval of the storage site. Attachment A provides an example form for the initial storage site evaluation.

b. Individual Authorization

Each location must establish standard operating procedures to authorize individuals for access and use of controlled substances. This must include successfully completing the location's training and personnel screening programs.

2. Training Program

Each location must provide training with respect to compliance with applicable laws and program requirements prior to authorizing an individual's ability to requisition or use controlled substances. At a minimum, the training program must include:

a. Storage site controls and security;
b. Ordering, delivery, and receipt;
c. Usage logs and biennial inventory requirements;
d. Transfers of Controlled Substances;
e. Import, export, and intra, interstate policies;
f. Disposal of Controlled Substances;
g. Diversion and loss reporting; and

h. Illicit activities and repercussions.

The actual format of the training can be any type of method deemed appropriate for the campus culture. These methods may include the traditional instructor-based classes, web-based tutorials, a reference guide approach with certification of understanding, or a combination of training methods. Each training program should include a method to measure effectiveness and understanding. This may include a short exam after the training session or an assessment during the routine audits.

Finally, each training program should have a re-training component for the authorized individuals at an established frequency that is no longer than four years. The re-training program should also be developed with the campus culture in mind and can take the form of an on-line tutorial, exam, or instructor-based class. The re-training material should cover the program requirements and any new policies and procedures that were instituted during the established re-training frequency.

C. Power of Attorney

Each Responsible Official may designate additional individuals to sign official Controlled Substances order forms and to procure Controlled Substances for Authorized University Activities.

If a location deems it necessary to designate an alternate to sign order forms for Controlled Substances, the location must execute and have on file a fully executed Power of Attorney. The Responsible Official may grant this Power of Attorney based on specific University needs. The Power of Attorney remains in effect as long as the designated individuals remain in these roles. To revoke the Power of Attorney, the location must execute a Notice of Revocation and maintained with the original Power of Attorney. A Sample Power of Attorney and a Notice of Revocation Form is provided in DEA regulations (CFR Title 21, Food and Drug Act §1305.05) are provided in Attachments B and C.

Power of Attorney forms must be kept readily available for inspection upon request by the DEA or State Board of Pharmacy inspectors.

D. Import, Export, Interstate and Intrastate Use Requirements

The location's policy must comply with the requirements stated in the BUS 50 policy. Each location must establish procedures for individuals who conduct research outside the State of California that require transport or use of controlled substances. This may include having the Program Administrator act as the liaison between the Principal Investigator and the

DEA office in the State that the research is being performed in order to assist the researcher in obtaining a registration in that State. Similarly, procedures must be established for investigators to notify the Program Administrator prior to any intrastate transport and/or transfer of controlled substances.

E. Documentation of Local Controlled Substances Program Compliance

Each location must develop and publish written procedures that address the following federal or state requirements. Example procedures and forms are provided for each required program element:

1. Processes and controls with regard to ordering, procurement and distribution of Controlled Substances for Research Purposes. Minimally, these must address:
    a. Determine if a drug is a controlled substance through one of the following references:
        i. Refer to the Drug Enforcement Administration website for a searchable list of controlled substances.
        ii. Use the Physicians' Desk Reference, Red Book, or Veterinary Pharmaceuticals and Biologicals.
        iii. Contact the Program Administrator or a member of the Purchasing Department.
    b. Ordering controlled substances:
        i. All orders for controlled substances must be placed and/or approved by the Responsible Official or those individuals delegated by Power of Attorney, regardless of whether the controlled substance is purchased or obtained free of charge from the supplier. Departments must complete a Purchase Requisition (PR). No order for controlled substances may be placed by any other means.
        ii. Schedule I and II controlled substances may be included on one PR, but must not be included on a PR with substances from any other schedules or any other products. Controlled substances on Schedules III, IV, and V may be combined on a separate PR with no other products.
        iii. Information on the PR must include:
            1) A statement that the substance requested is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
            2) A full description of the item requested, including vendor, catalog number, quantity, size of package, name of drug, and the number of the Federal Schedule of Controlled

Substances to which it is assigned.

3) A detailed statement of the purpose and/or manner of use that is planned and if it is to be used for teaching and research.

4) The name of the Principal Investigator.

5) The name of the authorized recipient, even if the same as the Principal Investigator (contact person at point of delivery).

6) The final delivery and storage location.

7) The appropriate study approvals from the location's Institutional Review Board (IRB), Animal Care and Use Committee, Radiation Safety Committee, and/or Chemical Safety Committee (i.e., Animal Care and Use Protocol Number). If the location does not have a committee to cover the specific research (specifically in cases where plants, non-regulated species are involved in research) the Program Administrator may review the research protocol.

Information on the PR must be very specific. Example language is provided as Attachment D.

iv. The PR must be ad hoc routed to the approving department head or one authorized designee for approval. The PRs will also be routed to the Program Administrator, Office of Environmental Health and Safety (EH&S) or designee for approval.

v. Purchasing will monitor for inappropriately procured substances that may have been procured under a departmental purchase delegation or through use of an incorrect commodity code. Purchasing and EH&S will follow approved escalation procedures if substances were purchased inappropriately. Attachment J provides an example escalation procedure. EH&S will also monitor for inappropriately acquired substances during the routine audits.

c. Receiving

i. Controlled substances may only be received at the addresses currently registered with the DEA.

1) With the exception of pharmacies and a very few remote locations, all controlled substances are delivered to Central Receiving area who takes possession of the drug and initiates a Controlled Substance Delivery Record, which will follow the shipment to the authorized storage site.

2) All controlled substances received require that a record of chain-of-custody be kept on a Controlled Substance

Delivery Record. Each shipment received shall be opened and the contents verified, under dual custody, every time it changes hands. Authorized recipients shall sign and note any discrepancy or damage on the Controlled Substance Delivery Record each time the drug changes hands.

ii. The ordering department will receive a photocopy of the purchase order from Purchasing. The authorized recipient designated on the Purchase Requisition must, as the ultimate receiver of the substance, sign the photocopy and be the last to sign the Controlled Substance Delivery Record.

iii. Both of the signed documents must be returned to Purchasing within 15 days of receipt of the controlled substance. If the required documentation is not returned to Purchasing within 15 days, a notice of negligence will be sent to the authorized individual with a copy to the department head and EH&S. If the information is not returned within 15 additional days, the Purchasing department will no longer place orders for the authorized individual in question and will send another letter to the authorized individual, department head, the appropriate Deans' office, and EH&S. The Purchasing Controlled Substance Database will be annotated, and all controlled substance buyers and managers will be notified.

iv. Purchasing will provide information to EH&S about the details of the delivery, including whether a partial delivery or complete delivery was made.

v. If the supplier delivers a controlled substance directly to a department (other than approved remote locations), the department must immediately contact Central Receiving to notify them that the delivery bypassed them and add a note to the photocopy of the purchase order stating that the delivery bypassed Central Receiving and was made directly to the department.

vi. Under no circumstances must a controlled substance be left unsecured and unattended, unless in a location approved by EH&S.

d. The approval process and requisition information for Investigational New Drugs:

   See CFR Title 21, Food and Drug Act Chapter 1, Subchapter D, Part 312, Subpart B, Section 312 for federal approval process and requisition information relating to Investigational New Drugs.

e. Orders for Schedule I and II drugs using DEA Form 222:

The Purchasing Department must use the DEA 222 form for all orders of Schedules I and II controlled substances. Specific instructions (if needed) are available on the back of every 222 form.

Each research project using a Schedule I substance will need a separate DEA registration, approval by the State Research Advisory Panel of California (RAPC), and approval of the Office of Research (OR), and IRB.

Proposals requiring use of Schedule II substances (except stimulants) that will be used in human research must also be reviewed and approved by the RAPC prior to procurement.

f. Orders for Schedules III, IV, and V and other Dangerous Drugs:

Orders for Controlled Substances listed in Schedules III, IV and V, and other Dangerous Drugs may be secured by issuance of a standard University purchase order. No controlled substance may be purchased through a blanket order. Each request requires a new order.

g. Orders for Federal List I Chemicals/Precursor Chemicals:;

A site-specific DEA registration must be used to purchase List I chemicals.

h. Orders for California Listed Chemicals/Precursor Chemicals:

California Listed Chemicals do not require a license or registration to purchase. The exemption for laboratory use of these materials is covered under California Business and Professions California Business and Professions Code Chapter 9 Division 2 Article 2 §§ 4059 and 4059.5

i. Orders for Dangerous Drugs and Devices (Material requiring a Prescription):

University and National Laboratory Investigators engaged in Authorized University Activities are permitted to purchase and use dangerous drugs and devices without a prescription as exempted by California Business and Professions Code Chapter 9, Division 2, Article 2 §§4059 and 4059.5.

Purchase records which identify the date, name, and address of the supplier, drug or device, and quantity must be readily retrievable.

3. Controls, Storage, and Security safeguards to prevent unauthorized acquisition, access, use, theft, or diversion of Controlled Substances,

List I chemicals, California Precursor Chemicals, and other Dangerous Drugs and Devices. Attachment A provides an example of an evaluation of the storage site and Attachment E provides guidance on appropriate controls, storage, and security.

3. Each University location must establish a Personnel Screening Program to ensure that no individual has access to controlled substances who has been convicted of a felony offense relating to controlled substances or whose application for registration with the DEA has been denied, or whose registration was revoked or surrendered for cause. Attachment F provides an example screening form. The program can be implemented and managed at the Principal Investigator level and reviewed during the routine audits or centralized and managed by EH&S. See 21 CFR §1301.76 and 1301.90.

4. Record-Keeping and Inventory Requirements, including:

   f. Power of Attorney forms:

   See section IV.C. for policy description and attachments B and C for example forms.

   g. Purchasing and associated records:

   All purchase records must be maintained for at least three years.

   h. Distribution and chain-of-custody records:

   Documentation of the chain-of-custody must accompany each receipt of controlled substances. Attachment G provides example documentation for receipt and chain-of-custody.

   i. Proper retention schedules for acquisition, use, and disposition records;

   All records must be maintained for at least three years.

   j. Adequate recordkeeping by authorized individuals:

   iv. Usage log, inventory, and biennial inventories;

   Investigators must maintain a current inventory and usage log for all controlled substances. Attachment H provides an example usage log for controlled substances.

   Every two years following the date of the registration's initial inventory the Program Administrator shall secure from each Department Chair or Principal Investigator an inventory of all stocks of Controlled Substances on hand. The biennial inventory shall be performed:

   1. on the same day and month on which the initial inventory was taken; or

2. on a regular general physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply; the DEA shall be notified of the date; or
3. on any other fixed date which does not vary by more than six months from the biennial date that would otherwise apply; the local DEA Office may require notification of the date.

Attachment I provides an example inventory form for reporting the biennial inventory.

v. Separation of records by location;

a. A separate inventory shall be made for each registration and stored at the location.

The inventory may be taken either as of opening of business or as of the close of business on the inventory date, and it must be indicated on the inventory.

vi. Purchase records for Dangerous drugs and Devices.

Purchase records of all pharmaceutical drugs and devices (California Business and Professions Code Chapter 9, Division 2, Article 2, § 4031) must be readily retrievable.

(See 21 CFR §1304.04, 1304.11, 1310)

5. Diversion, Loss, or Theft Reporting of Controlled Substances, Precursors, and List I chemicals.

Location-specific procedures must include details on which campus office should be notified of and report to DEA within 24 hours about each theft or significant loss of controlled substances. See 21 CFR §1301.91. However, all authorized individuals are expected to report missing controlled substances to their supervisor, Program Administrator, and the location's law enforcement unit (e.g., the University of California Police Department) as soon as the loss is discovered. The Program Administrator and local law enforcement will investigate the diversion, loss, or theft of Controlled Substances, Precursors, and List I chemicals. Reports will be kept confidential to the extent permitted by law and other University policies.

The Program Administrator must promptly (within 24 hours) submit DEA Form 106 to the local DEA office for each theft and any significant loss of Controlled Substances. According to DEA guidance:

"Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage

or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process.

If the breakage or spillage is not recoverable, the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41, Registrants Inventory of Drugs Surrendered is not required for non-recoverable controlled substances."

6. Disposal or Destruction of any controlled substance must be in accordance with DEA policies, procedures, and regulations. See 21 CFR §1307.21.

   Authorized Individuals must inform the Program Administrator or the authorized waste management team of the need to dispose of Controlled Substances or Dangerous Drugs that are expired or no longer needed for Authorized University activities. The Program Administrator or authorized waste management team member will coordinate disposal of any controlled substance with a reverse distributor or campus on site pharmacy.

   The reverse distributor, or on site pharmacy, must provide documentation as to final disposition of disposed/destroyed/returned drugs to the Program Administrator or authorized waste management team. If applicable, the final disposition of such substances must be documented by receipt of one of the following:
   a. A Certificate of Destruction and corresponding Form 222 for each Schedule I and II controlled substance covered by that certificate or a DEA Form 41;
   b. A completed copy of the waste manifest from the Treatment Storage and Disposal Facility;
   c. A certificate of return to manufacturer.
7. California Research Advisory Panel Requirements for Principal Investigators to obtain and submit applications to the Research Advisory Panel.

   California law requires that certain studies involving Schedule I and II Controlled Substances be submitted and approved by the Research Advisory Panel of California. Principal Investigators must follow the guidance on the Research Advisory Panel (http://ag.ca.gov/research/index.php) website and provide documentation to the Program Administrator.

F. Required Auditing and Monitoring

Each location must develop and implement a routine auditing and monitoring program that includes unannounced inspections of investigator-maintained substances and records for compliance with state and federal laws governing the use of dangerous drugs and controlled substances in Authorized University Activities.

G. Illicit Activities

The University complies with federal and state law which makes it a criminal activity for employees to possess, sell, use, or divert controlled substances , but shall also immediately become the subject of independent action regarding their continued employment. Any member of the University community who suspects another member of such illicit activities should follow campus or laboratory reporting policy.

H. Complying with State Licensure Requirements for Research Involving Human Subjects

Only California licensed medical personnel and investigators engaged in Authorized University Activities and acting within the scope of their authorized professional practice and consent of all applicable Institutional Review Boards (IRB) may prescribe, furnish, dispense or administer Dangerous Devices and Dangerous Drugs, including Controlled Substances, to human research subjects. Questions regarding scope of practice should be referred to the Office of the General Counsel, Health Law Section.

References:
Food and Drug Act of 1906 (as amended) (21 USC §§1300-1316)
Controlled Substances Act of 1970
California Uniform Controlled Substances Act, Health and Safety Code §§11100-11700
California Research Advisory Panel (http://ag.ca.gov/research/index.php)
California Business & Professions Code Chapter 9, Division 2, Article 2 §4022+-

Attachment A

CONTROLLED SUBSTANCE PROGRAM
INITIAL STORAGE SITE EVALUATION FORM

Date: _____

Principal Investigator_____ **Location**_____ _____
Department:_____ **Phone:** _____
E-mail: _____

A. Requirement ***Satisfactory*** ***Unsatisfactory***

IX. STORAGE AREA

Key Control (2 keys)		
Hinges inaccessible from outside		
Hasp inaccessible from outside when closed		
Tumbler/Padlock		

Training Program Completion		
Personnel Screening Program Completion		
A. Review Usage Log		
Review Biennial Inventories		
Review Disposal Procedures		

B. Comments

_____
_____
Principal Investigator Program Administrator

Attachment B

POWER OF ATTORNEY FOR DEA ORDER FORMS

(Enables the signed individual to obtain and execute order forms on the Responsible Official's behalf)

Name of registrant

Address of registrant

DEA registration number

I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____(name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, solely for the purpose of executing applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S. C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____

(Signature of person granting power)

I, _____, (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____

(Signature of attorney-in-fact)

Witnesses:

1.

2.

Signed and dated on the _____ day of _____(month) _____ (year),

at_____.

Attachment C

NOTICE OF REVOCATION

(Name of registrant)

(Address of registrant)

(DEA registration number)

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ _____ this same day.

_____(Signature of person revoking power)

Witnesses:

1._____

2._____

Signed and dated on the _____ day of_____, 2007, at_____.

Attachment D

SAMPLE GUIDANCE DOCUMENT FOR INVESTIGATORS

Ordering & Receiving Controlled Substances

The United States Drug Enforcement Administration and the State of California Board of Pharmacy strictly regulate controlled substances. UC Davis has a specific procedure for ordering, delivery, and receipt of controlled substances on campus for clinical, research, and teaching needs.

Determining if a Drug is a Controlled Substance

The Drug Enforcement Administration provides searchable online controlled substance schedules . You can also refer to medical reference manuals, such as:

- The Physicians' Desk Reference
- Red Book
- Veterinary Pharmaceuticals and Biologicals

If you are unable to use any of the above to determine if a substance is controlled, contact a member of the Purchasing Agricultural & Scientific Team.

Ordering Controlled Substances

All orders for controlled substances must be processed on a Requisition (PR) and cite an appropriate commodity code. Include the following information on the PR:

- A statement that the substance requested is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
- A full description of the item requested: quantity, size of package, name of drug, and the number of the Federal Schedule of Controlled Substances to which it is assigned.
- A detailed statement of the purpose and/or manner of planned use and if it is to be used for teaching, research or clinical applications.
- The name of the authorized custodian.
- The name of the end user, even if the same as the authorized custodian.
- The final delivery and storage location.
- The appropriate study approvals from the location's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Radiation Safety Committee, and/or Chemical Safety Committee. If the location does not have a committee to cover the specific research (specifically in cases where plants, non-regulated species are involved in research) the Program Administrator may approve the research protocol.

Note: Schedule III, IV, and V substances may be included on a single PR; Schedules I & II may be included on a single PR, but must be separate from the other schedules.

A sample statement satisfying the above conditions would resemble the following:

"This material is subject to the Comprehensive Drug Abuse Prevention & Control Act of 1970 (Controlled Substances Act) and is a Schedule II substance. The authorized

custodian is Jonathan Doe. The substance will be used by Dr. Jane Deer to anesthetize dogs in research on heart disease. The approved storage site is Building Y, Room X."

Ad hoc route the PR to the approving department head or authorized designee for approval. If the department head/designee is not a DaFIS user, a hard copy signature must be sent to Purchasing. PRs citing controlled substance commodity codes will special conditions route to Environmental Health and Safety (EH&S) for approval.

Procedure for Receiving

All controlled substances are to be delivered to Central Receiving area. They will take possession of the drugs and initiate a Controlled Substance Delivery Record, which will follow the shipment to the authorized storage site. Every time the shipment is transferred to another person it must be opened and the contents verified by both parties. In addition, an authorized recipient must sign and note any discrepancy or damage on the Controlled Substance Delivery Record each time the drug changes hands. An authorized recipient is the individual authorized to use or dispense the drug or someone who is listed on the Controlled Substances Receipt Authorization list (CSRA). Contact Purchasing to add or delete names from the CSRA list.

The ordering department will receive a photocopy of the purchase order from Purchasing and must complete the area stamped in red.

The end user designated in the description area of the Requisition must, as the ultimate receiver of the substance, sign the photocopy and will be the last to sign the Controlled Substance Delivery Record. Both of the signed documents must be returned to Purchasing within fifteen days of receipt of the controlled substance.

Please note that if the required documentation is not returned to Purchasing within fifteen (15) days of delivery of the controlled substance, a notice of negligence will be sent to the authorized end user with a copy to the department head and EH&S. If the information is not returned within fifteen additional days, the Purchasing department will no longer place orders for the authorized end user in question and will send another letter to the authorized end user, department head, the appropriate Deans' office, and EH&S. The Purchasing Controlled Substance Database will be annotated, and all authorized controlled substance buyers and managers will be notified.

If a controlled substance is delivered directly to your department by the supplier, contact Central Receiving to notify them that the delivery bypassed them. Also, add a note to your photocopy of the **Purchase Order** that the delivery bypassed Central Receiving and was made directly to your department.

Delivery Troubleshooting

All controlled substance deliveries are opened and verified for accuracy at the Central Receiving department. If there is a discrepancy or damage, Central Receiving will contact Purchasing for product return arrangements. Purchasing will work with the department and the vendor to ensure that the most appropriate action is taken.

Questions regarding controlled substance purchasing procedures? You may contact any member of the _____.

Attachment E

STORAGE REQUIREMENTS AND ACCESS RESTRICTIONS

Summary: Find out how to securely store controlled substances (CS) according to Environment, Health & Safety (EH&S) standards. **Before purchasing or installing a storage container** for your CS inventory, contact the Program Administrator (phone) to develop a storage plan.

Storage requirements Notify EH&S immediately of missing controlled substances: (XXX) XXX-XXXX.	Principal investigators are responsible for providing and maintaining secure storage for their CS inventory that meets these criteria: **Store CS according to schedule number:** • Schedule I: Store in a safe or steel cabinet equivalent. • Schedule II-V: Store in a locked drawer or cabinet that is inaccessible from above or below. **Install the following equipment according to these standards:** o Padlocks and hinges: Must have the mounting screws or bolts of the hasp inaccessible when the door is closed and the lock is fastened • Safes and steel cabinet equivalents: o Must be cemented or bolted to the floor or wall, or weigh more than 750 pounds o Storage units: Must be secure enough to show forced entry o Drawers: Must be inaccessible from the upper or lower drawers in the stack. Assign the top drawer of the stack to use as the storage facility, if possible. • Use CS storage units only for CS and their inventory logs.. • Storage restrictions: o Do not share CS storage facilities. o Do not transfer CS from its original container for storage purposes. o Do not store other chemicals or supplies in a CS storage unit. o Do not store CS in a corridor.
Access restrictions	**Restrict access only to authorized personnel** on your Controlled Substances Use Authorization (CSUA) and follow these precautions: • Keep storage key(s) in the physical custody of authorized personnel at all times. • You can make multiple key copies and assign them to authorized personnel. • Do not store keys in a drawer or on the wall. • When authorized personnel leave their position in the lab. • Change combinations or retrieve the individual's keys. • Document authorized personnel security changes in the inventory log. • Remove the authorized individuals from the CSUA.
Moving or closing your lab	Relocation of CS during lab moves or closures is strictly regulated and must be approved by EH&S. • Notify EH&S with the online Lab Relocation or Closure Notification form 3 weeks before your intended move or lab closure. • **Moving within UCXX:** Contact the Program Administrator [phone] to have your new storage location approved **prior** to moving. Your CS inventory can be temporarily stored at a secure EH&S facility during your move. o Note: Moving Services must not transport CS. • **Moving off campus or closing the lab:** Follow steps to terminate your CSUA.

Attachment F

PERSONNEL SCREENING PROGRAM

Principal investigators: Use this form to add an Authorized Personnel to your Controlled Substance Usage Authorization (CSUA). The following is to be filled out by all proposed handlers of controlled substances (CS) (21CFR1301.90). Return the completed form to the Program Administrator at Mail Code 0089 or fax ( ) or scanned & emailed to _____.

APPLICANT INFORMATION:

☐ **Add to CSUA as an Authorized Personnel**

☐ **Designate as CS Lab Contact**
(Circle one: Primary / Secondary)

☐ **Authorized Recipient (OK to Pick up Controlled Substance Shipments)**

Name: _____ Employee/Student/Passport #: _____

Lab/Office location: _____ Phone: _____

E-mail address: _____ Mail Code: _____CSUA#:_____

Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date, and sentence on additional page. ☐ Yes ☐ No

In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details on additional page. ☐ Yes ☐ No

Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended, or denied? ☐ Yes ☐ No

By signing below, I authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions. I understand that any false information, omission of information, or misuse of controlled substances will jeopardize my position with the University. Information included herein will not preclude me from utilizing controlled substances in non-human research at ____, but will be considered as part of the overall evaluation of qualifications in the application.

The DEA requires that an employee who has knowledge of drug diversion from his/her employer by a fellow employee is obligated to report such information to a responsible security official of the employer. At ____, all such reports can be made confidentially to the Controlled Substances Program Manager who will inform the appropriate officials and initiate an investigation on the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries.

Applicant signature: _____ Date:_____

PI authorization for the person (identified above) to handle controlled substances issued to the PI:

Principal Investigator signature: _____ Date: _____

Principal Investigator name: _____

Attachment G

CONTROLLED SUBSTANCE DELIVERY FORM

PO#: 102000000

Vendor: MWI

PO Date: 04/30/2007

PI: John Smith

Received at:

Quantity	Concentration	Amt per Container	Substance Name	Schedule	Qty Rec'd
12 bottles	50.00 mg/mL	50.00 mL	Pentobarbital	II N	10
2 bottles	4.00 percent	43.00 Patches	Nalorphine	III	2

Accepted at Mail Services by:	Distributed from Mail Services by:	Accepted from Mail Services by:
Sign: M .Green	Sign: .M. Green	Sign: JeffreySmith
Print: M. Green	Print: M. Green	Print: Jeffery Smith
Date: 5/1/2007	Date: 5/3/2007	Date: 5/3/2007

Lab Contacts			Notified on:	
Primary:	Jeffrey Smith	@ucop.edu	**5/1/07**	
Secondary:	Jada Wang	@ucop.edu	**5/1/07**	

Mark receiving party	Authorized Recipients	
XXX	Jeffrey Smith	@ucop.edu
	Jada Wang	@ucop.edu
	Dominic Del Re	@ucop.edu
	Chris Means	@ucop.edu
	Shigeki Miyamoto	@ucop.edu
	PI: John Smith	@ucop.edu

Comments:

Attachment H

CONTROLLED SUBSTANCE USAGE LOG

One log sheet is to be completed for each container of controlled substance. Controlled substance usage must be tracked on a per dose (use) basis. Record total quantity of the substance to the nearest metric unit weight or the total number of units finished form. “Received” includes drugs imported, manufactured, purchased or delivered. “Use” includes exported, disposed, sold, transferred or otherwise utilized.

Principal Investigator: _____

Date	Amount Received	Amount Dispensed	Balance	Name (print) Dispensed To:	Initials Dispensed To:	Initials Dispensed By:	Purpose

Attachment I

CONTROLLED SUBSTANCES BIENNIAL INVENTORY FORM

The Biennial Inventory is a requirement of the Federal Drug Enforcement Administration (21 CFR 1304.11). Please return this form to the Program Administrator at EH&S by mail ( ) or fax ( ).

Principal Investigator Name: _____ Department: _____
Controlled Substances storage location: ☐ La Jolla ☐ Hillcrest ☐ Elliot Field Station

Instructions: List all Controlled Substances in possession as of the close of business on February 8th. List open containers as separate line items. Unopened containers of same substance, manufacturer, volume, and concentration can be listed together on same line. Fill out separate forms for each storage location.

Line Item	Unopened Containers		Opened Containers			Controlled Substance Name	Drug Code & Schedule+	Finished Form‡
	Qty	Container size	Qty	Remaining amount*	Container size			
1								
2								
3								
4								
5								

Number of completed line items in table: (write “Zero” if none)

By signing below, I agree the information listed here represents the actual amount of controlled substances existing in inventory as of the close of business on February 9th, 2007 (Biennial Inventory Date).

Principal Investigator signature: _____ **Date:** _____

For a list of Controlled Substances visit:
http://www.deadiversion.usdoj.gov/schedules/alpha/alphabetical.htm

* Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules). For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact count must be made.

+ For DEA Drug Code and Schedule number, refer to DEA Controlled Substances website (above). DEA Drug Code is a 4-digit number. Controlled Substance Schedule number is expressed in Roman numerals, I through V; N denotes the item is non-narcotic and only applies to schedules II and III.

‡ Finished Form refers to the strength and form of the item as commercially prepared.

Attachment J

CONTROLLED SUBSTANCE PROGRAM ESCALATION PROCEDURE

I. Purpose:

The purpose of this escalation procedure for the Controlled Substance Program is to ensure compliance with the U.S. Department of Justice, Drug Enforcement Administration regulations (21 CFR) in regards to purchasing and transfers of controlled substances.

II. Procedure:

The following escalation procedure will be used for all inappropriate purchases and transfers between departments or authorized individuals of controlled substances:

An unauthorized purchase of controlled substance can occur in the following manners:

1. DEPARTMENTAL PURCHASE ORDER (DPO);

a. Use of a procurement card;
b. By telephone;
c. By a vendor automated ordering system.

Once information has been obtained by the Purchasing Department that one of the above purchase types has occurred, the following escalation procedure will be implemented and tracked:

1. The Purchasing Department will immediately notify the authorized custodian and department office that inappropriate purchase has occurred. In all cases, the vendor will also be contacted regarding the appropriate purchasing procedures.

2. Escalation Procedure:

    a. First Occurrence
    A follow-up letter will be immediately faxed to the authorized custodian and department head stating the inappropriate purchase, actions to be taken, and consequences if this type of purchase of controlled substance continues. A copy of the existing policy will also be provided to the authorized custodian.
    b. Second Occurrence
    A follow-up letter will be immediately faxed to the authorized custodian, department head, and Dean or Vice Chancellor stating the inappropriate purchase, actions to be taken, and consequences if this type of purchase of controlled substance occurs again.
    c. Third Occurrence
    In the event that an authorized custodian attempts three (3) inappropriate purchases in any one calendar year, the purchasing privileges for controlled substances will be suspended for twelve (12) months by the Purchasing Department. A follow-up letter will be immediately faxed to the authorized custodian, department head, and Dean or Vice Chancellor stating that suspension has occurred.

Transfers of Controlled Substances must be incompliance with the approved procedures. This includes appropriate documentation by the transferee, recipient, and a copy of the transfer record to the Office of Environmental Health and Safety (EH&S).

When EH&S becomes aware of an inappropriate transfer, the escalation procedure as stated in section A.2.a-c in this document will be followed by EH&S staff.