Chapter 290, Health and Safety Services
Section 70, Controlled Substances
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Exhibit A, Controlled Substance Transfer
Exhibit B, Personnel Screening Program, Authorization Form

I. Purpose

A. This section describes the requirements and procedures applicable to the procurement, storage, use, transfer, disposal, and inspections of controlled substances used for research and teaching activities at all locations that are the responsibility of UC Davis.

B. This policy does not apply to clinical activities performed at UCDHS, VMTH, pharmacies, or clinics, which are governed by federal and state accrediting and regulatory agencies and are subject to review and audit by those agencies.

II. Definitions

A. Authorized custodian—the Principal Investigator (PI) or approved designee within the requesting department who is authorized by the Program Administrator or designee to receive and store controlled substances.

B. Authorized end user—person approved by the authorized custodian to use the controlled substance.

C. 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.

D. 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 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title21/21cfr1308_main_02.tpl).

E. Program Administrator – the Responsible Official's designee charged with implementing and managing the Controlled Substances Program on a day-to-day basis. Research Safety Unit Manager within Administrative Resource Management is the designated Program Administrator.

F. Responsible Official – the Vice Chancellor—Administrative and Resource Management is the designated Responsible Official.

G. Temporary receiver—individual physically located at the department's designated delivery stop that has been identified in advance to Central Receiving to receive controlled substance shipments prior to final delivery to the authorized custodian.

III. Policy

A. The University shall comply with all applicable Federal and States laws and regulations governing controlled substances.

B. Procurement and use of controlled substances must be under a registration granted to UC Davis by the Drug Enforcement Administration (DEA)

1. Registrations cover controlled substances in Schedules II through V.
2. Additional registrations must be obtained for Schedule I controlled substances or for controlled substances that will be used at a remote site (i.e., location away from the Davis campus or UCDMC, such as a field station).
3. The use of personal DEA numbers for teaching and research activities is prohibited.

C. Separation of duties prohibits a single individual the ability to order, receive, distribute, and dispose of controlled substances.

D. Violation of University policies and procedures, or DEA regulations may result in revocation of a department's privilege to obtain and use controlled substances, rescission of campus registrations, and imposition of fines or imprisonment of individuals responsible for the violations.

IV. Authorities

A. Authority to sign purchase orders for controlled substances is restricted to authorized persons in the Purchasing Department.

B. Authority to requisition controlled substances through the Purchasing Department is limited to the department head and one designee, who must be identified through completion of a DaFIS Approval Authorization or Cancellation form (http://accounting,ucdavis.edu).

C. Authority to receive controlled substances from Central Receiving or UCDHS Pharmacy stores is limited to the department's temporary receiver or Authorized Custodian.

V. Roles and Responsibilities

A. Responsible Official

1. Provides oversight of the controlled substance program.
2. Applies for all DEA registrations granted to UC Davis.
3. Grants Power of Attorney, as appropriate, to managers for them to obtain and execute order forms for controlled substances.

B. Program Administrator

1. Implements and manages the controlled substance program on a day-to-day basis.
2. Reviews departmental handling procedures for controlled substances.
3. Provides consultation to investigators to assure compliance with DEA regulations.
4. Authorizes storage facilities for controlled substances.
5. Conducts site inspections, including unannounced inspections of investigator-maintained substances and records.
6. Requests and reviews biennial inventories.
7. Ensures that proper disposal procedures are in place and implemented for all unused, expired, or waste-controlled substances.
8. Provides a controlled substance training program for all individuals who need access to or use controlled substances.

C. Materiel Manager

1. Oversees procurement and delivery of controlled substances for authorized University activities.
2. Develops applicable procedures to administer the terms of DEA regulations relating to procurement and delivery.

D. Department heads

1. Determine the need for controlled substances by department members and authorized DaFIS Purchase Requisitions.
2. Designate up to three temporary receivers (see http://purchasing.ucdavis.edu/geninfo/controlledsubs.cfm).
3. Assure that the storage, use, inventories, transfers, and disposal of controlled substances by department members comply with applicable laws, regulations and University policies.

E. Authorized custodians

1. Oversee all operations, activities, materials, and personnel in their assigned laboratories or work areas.
2. Maintain the daily usage logs and submission of a biennial inventory.
3. Conduct a visual inventory verification every six months to ensure all controlled substance containers and an associated usage log are present.
4. Ensure that all authorized end users and temporary receivers successfully complete the controlled substances training program prior to accessing or using controlled substances.
5. Comply with DEA regulations, program requirements (including training, background check, and personnel screening programs), and University policy governing acquisition, use, storage, and disposition of controlled substances.

F. Authorized end users

1. Must participate in the training and personnel screening programs.
2. Annotate the daily usage log when checking out controlled substances.
3. Return any unused portions of controlled substances to the authorized custodian.

G. Environmental Health and Safety (EH&S) Hazardous Waste Manager develops and implements pick-up and disposal procedures that meet DEA regulations.

H. Temporary receivers

1. Assure that shipments are securely stored and transferred to the authorized custodian in accordance with policy.
2. Participate in training and personnel screening programs.

I. University Police Department investigates all suspected thefts or misuse of controlled substances.

J. The Purchasing Department monitors for inappropriately procured controlled substances that may have been procured under a departmental purchase delegation or through use of an incorrect commodity code.

VI. Procedures

A. Filing new registration applications

1. Research projects using Schedule I controlled substances, or using Schedule II controlled substances in human subjects require separate DEA registrations.

   a. The authorized custodian shall contact Office of Research to secure the approval of the Institutional Review Board (IRB) and State Research Advisory Panel of California (RAPC).

   b. The authorized custodian submits the RAPC approval to the Purchasing Department to initiate a new DEA registration application.

   c. The Purchasing Department assists the authorized custodian with the application process.

2. Remote locations using controlled substances require separate DEA registration

   a. The authorized custodian submits a description of the research requiring use of the controlled substance to the Program Administrator 3-6 months in advance of the order.

   b. The Program Administrator evaluates the storage site, proposal for security and safety procedures, and provides program requirements and training.

   c. The Program Administrator transmits approval to the Purchasing Department to submit the application for registration to the DEA.

3. Departments should anticipate that the process for obtaining a new DEA registration will take several months.

B. Procurement

1. The department determines if the drug is a controlled substance through one of the following references:

   a. The list available on the DEA Website (http://www.justice.gov/dea/pubs/scheduling.html).

   b. The Physicians' Desk Reference, Red Book, or Veterinary Pharmaceuticals and Biologics.

   c. Contacting a member of the Purchasing Department.

2. The department completes a Purchase Requisition (PR), citing an appropriate controlled substance commodity code.

   a. 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.

   b. Controlled substances on Schedules III, IV, and V may be combined on a separate PR with no other products.

3. The following information must be included in the item description area of the PR:

   a. A statement that the substance requested is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 (http://www.fda.gov/RegulatoryInformation/Legislation/ucm148726.htm).

b. A full description of the item requested, including quantity, size of package, name of drug, and the number of the Federal Schedule of Controlled Substances to which it is assigned.

c. A detailed statement of the purpose or manner of use that is planned, and if it is to be used for teaching, research, or clinical operations.

If the substance is for animal use, the statement must include whether or not the substance is pharmaceutical grade.

d. The name of the authorized custodian.

e. The final delivery and approved storage location.

4. The PR must be ad hoc routed to the department head for review and approval to ensure the statement describes an authorized University activity and that the quantities ordered are consistent with the proposed use.

a. The department head may designate an individual who is knowledgeable regarding whether a particular substance and quantity is appropriate for the intended use to review the PR.

b. If the department head/designee does not use DaFIS, a signed hard copy of the PR must be sent to the Purchasing Department as an attachment to the PR.

C. Receiving and Delivery

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

a. Controlled substances used for teaching and research on the Davis campus shall be delivered to Central Receiving.

b. Controlled substances used for teaching and research at UCDHS shall be delivered to the UCDHS Pharmacy stores.

c. Departments (other than approved remote locations) who receive a controlled substance directly from a supplier must immediately contact Central Receiving.

1) The department shall notify Central Receiving and note on a photocopy of the purchase order that the delivery bypassed Central Receiving and was made directly to the department.

2) Central Receiving will verify the errant shipment with the authorized custodian and complete a Controlled Substance Delivery Record.

2. Each shipment shall be opened and the contents verified, under dual custody, each time it changes hands.

a. The chain of custody shall be documented on a Controlled Substance Delivery Record.

b. Any discrepancy or damage that occurs when the shipment changes hands shall be noted on the Controlled Substance Delivery Record and the department should contact Purchasing and Central Receiving or UCDHS Pharmacy stores regarding appropriate action.

c. The controlled substance may never be left unattended, unless in a location approved by the Program Administrator.

3. The department will receive a photocopy of the purchase order from Central Receiving with delivery of the product.
    a. The department shall complete the area stamped in red on the photocopy.
    b. The authorized custodian on the PR must, as the ultimate receiver of the substance, sign the photocopy and be the last individual to sign the Controlled Substance Delivery Record.
4. The signed documents must be returned to the Purchasing Department within 15 business days of receipt of the controlled substance.
    a. If the documents are not returned, a notice of negligence will be sent to the authorized custodian with a copy to the department head and Program Administrator.
    b. If the documents are not returned within an additional 15 business days, the Purchasing Department will send another letter to the authorized custodian, department head, dean's office, and Program Administrator; and will no longer place orders for the authorized custodian, annotating the Purchasing Controlled Substance Database and notifying all controlled substance buyers and managers.
5. The Purchasing Department will provide information regarding the delivery, including whether a partial or complete delivery was made, to the Program Administrator.

D. Cancellations, Returns, and Replacements

Detailed information on how to handle cancellation, returns, and replacements can be obtained at http://purchasing.ucdavis.edu/geninfo/controlledsubs.cfm.

E. Transfers

1. Controlled substances may be transferred from one authorized custodian to another within UC Davis.
    a. The transferor shall confirm with the Program Administrator that the recipient is an authorized custodian with an approved storage site.
    b. The parties complete the transfer form (Exhibit A).
        1) Each party retains a copy of the transfer form for three years.
        2) The completed transfer record is faxed to EH&S (530-752-4527) within 24 hours of the transfer.
    c. Both parties document the transfer in their Controlled Substance Usage Logs.
2. Controlled substances can be used only for the same purpose for which they were originally acquired as noted in the statement on the PR.

F. Personnel screening and background checks

1. Faculty

    Faculty needing access to controlled substances must complete the Personnel Screening Program Authorization form (Exhibit B).

2. Staff

    Staff requiring access to controlled substances must have a background check performed in accordance with Personnel Policies for Staff Members Section 21 and the UC Davis

Background Check Program (http://www.hr.ucdavis.edu/salary/comp/background-check/background-check).

G. Storage and Use

1. Controlled substances must be stored in a location approved by the Program Administrator.
2. Storage facilities must meet the following minimum requirements:
   a. Storage cabinet must have inaccessible hinges when the door is closed, and a lockable hasp that does not allow access to the mounting hardware when the door is closed and locked.
   b. The cabinet should be securely affixed to the building structure (e.g., wall or floor) or otherwise be incapable of being moved.
   c. The cabinet must have either a built-in tumbler-type lock or a padlock.
      1) If a keyed lock is used, a maximum of 2 keys must be available and each key must be kept in the physical custody of the authorized custodian at all times.
      2) Key assignments must be documented.
      3) Locks must be rekeyed if the storage cabinet is not functioning properly or if a key is misplaced or lost.
   d. Metal cabinets, rather than wood, should be used to secure controlled substances.
   e. There cannot be any sign or other indication that the cabinet is used for storage of controlled substances.
3. Etorphine hydrochloride and diprenorphine must be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.
4. All records of withdrawals of controlled substances from storage must be signed by the authorized end user making the withdrawal.
   a. The use must be tracked on a per dose (use) basis and must be recorded to the nearest metric unit weight or the total number of units finished form.
   b. The authorized custodian must maintain all controlled substance use logs for three years.
5. Departments that require controlled substances for the health maintenance of animals may keep those substances in the approved storage site, but they must be separated from the teaching and research substances and documents must be available to demonstrate the substances were purchased or prescribed for health maintenance.

H. Semi-annual inventory verifications

1. The Program Administrator informs the authorized custodians of the inventory due date at least one month in advance.
2. The authorized custodian or designee assesses the security of the controlled substances and conduct a visual inventory of all existing stocks of controlled substances and associated usage logs in the authorized custodian's possession.
3. The authorized custodian acknowledges that the inventory and security verification has been completed within 30 days of the due date.

I. Biennial inventory

1. The Program Administrator will inform authorized custodians of the inventory due date at least one month in advance.
2. Both the authorized custodian and an individual other than the authorized custodian will conduct an inventory of all existing stocks of controlled substances in the authorized custodian's possession.
3. The inventory must include the following information for each controlled substance in finished form:
   a. The name of the controlled substance.
   b. The purpose the controlled substance is being maintained by the authorized custodian.
   c. The total quantity of the controlled substance to the nearest metric unit weight or total number of units of finished form. The number of units of each finished form of a controlled substance in a commercial container that has been opened shall be determined as follows:
      1) For Schedule II controlled substances, an exact count or measure of the contents.
      2) For Schedule III, IV, or V controlled substances, an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact measure of the contents must be made.
4. The authorized custodian completes the Controlled Substance Inventory form, obtains the signatures of the person performing the inventory and the department head, and returns the completed form to the Program Administrator.

J. Disposal

1. The authorized custodian, authorized end user, or department having custody of the controlled substance must request disposal from EH&S (530-752-1493).
2. The authorized custodian officially transfers the controlled substance to the EH&S representative.
3. EH&S secures permission for disposal from the DEA, complying with the DEA disposal regulation and procedures.

K. Termination of Use

The authorized custodian or department must contact the Program Administrator to officially close out a storage location and dispose of any controlled substances when the storage and use of controlled substances is no longer needed (e.g., research project has ended, retirement or termination of the authorized custodian).

L. Diversion, Loss, Theft, or Illicit Activities

1. Diversion, loss, or theft of a controlled substance must be reported to the University Police Department and Program Administrator immediately upon discovery.
   a. The Program Administrator will complete DEA Form 106 and submit it to the Responsible Official and DEA within 24 hours.
   b. The police department will investigate and prepare a police report of the circumstances surrounding the diversion, loss, or theft, for the Responsible Official.

2. Illegal possession, sale, use, or diversion of controlled substances must be reported to the Locally Designated Official (see Section 380-17) and to the University Police Department.

M. Import, Export, Interstate, and Intrastate Use

Transport of controlled substances off campus is highly regulated. Contact the Program Administrator for assistance with all imports, exports, and interstate and intrastate transport and use to ensure compliance with FDA and DEA regulations and restrictions.

N. Research Involving Human Subjects

Only investigators engaged in authorized university activities approved by the IRB may furnish, dispense, or administer controlled substances to human research subjects.

VII. Further Information

A. University pharmacies (UCDHS pharmacy and satellites, VMTH pharmacy, student health center pharmacy) operating under the supervision of a licensed pharmacist and dispensing controlled substances for clinical use maintain internal policies consistent to licensing requirements and applicable laws and regulations.

B. Example language for information to be included on the PR is available at http://purchasing.ucdavis.edu/geninfo/controlledsubs.cfm.

C. Additional information is available from the Program Administrator in Safety Services.

VIII. References and Related Policies

A. 21 CFR, Chapter II, Drug Enforcement Administration, Department Of Justice, §§1300-1316 (http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html).

B. Controlled Substances Act of 1970 (http://uscode.house.gov/download/pls/21C13.txt).

C. California Uniform Controlled Substances Act, Health and Safety Code §§11100-11700 (http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11100-11107.1).

D. California Research Advisory Panel (http://ag.ca.gov/research/index.php).

E. UC Office of the President:

1. Business & Finance Bulletin BUS-50, Controlled Substances Program (http://www.ucop.edu/ucophome/policies/bfb/bus50.pdf).

2. Personnel Policies for Staff Members 21, Appointment (http://atyourservice.ucop.edu/employees/policies_employee_labor_relations/personnel_policies/spp21e.html

F. UC Davis Policy and Procedure Manual (http://manuals.ucdavis.edu/PPM/about.htm):

1. Section 240-50, Principles and Policies.

2. Section 350-21, Departmental Purchase Delegations.

3. Section 350-25, Procurement through the Purchasing Department.

4. Section 350-35, Receipt and Delivery of Goods.

5. Section 380-17, Improper Governmental Activities.

G. UC Davis Background Check Program (http://www.hr.ucdavis.edu/salary/comp/background-check/background-check)