Controlled Substances Program Procedures

UC Merced
Environmental Health and Safety
August 2015

I. Introduction

The procedures set forth the University of California, Merced (UCM) Controlled Substance Program (CSP) and are intended to implement UC BUS-50. The CSP provide campus personnel, including researchers with the knowledge needed to comply with applicable laws and regulations associated with the use of controlled substances, and precursor chemicals in their research hand instruction. Compliance with these procedures is mandatory. To the extent there is any conflict between these UCM CSP procedures and BUS-50, the provisions of BUS-50 shall control.

Federal and state law regulates the manufacture, distribution, use, storage and disposition of controlled substances, and precursor chemicals. Controlled substances generally include narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. The federal Drug Enforcement Administration (DEA) regulates the lawful use of controlled substances and List I chemicals Title 21 Chapter 13 Code of Federal Regulations (CFR) Part 1300 to end. The California Bureau of Narcotic Enforcement and the California State Board of Pharmacy regulate controlled substances and prescription drugs, respectively, under California law.

The University of California (University or UC) has established policies and procedures covering the acquisition and use of controlled substances for research purposes in compliance with both state and federal laws. The UC policies and procedures are found in Business and Finance Bulletin BUS-50 http://www.ucop.edu/ucophome/policies/bfb/bus50.html.

The UCM Controlled Substance Program covers five main areas involved in the use of controlled substances, and precursor chemicals in research: acquisition, storage, use, recordkeeping, and disposal. The UCM CSP procedures apply to all individuals authorized to conduct chemical analysis, instructional activities, or research using controlled substances or precursor chemicals at the University of California, Merced. The CSP Procedures do not apply to the use of controlled substances by licensed healthcare personnel for non-research, clinical purposes.

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.E.

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 It is a substance that has a stimulant, depressant, or hallucinogenic effect on the nervous system. Controlled substances include prescription drugs that are further classified as Schedule I-V drugs. The Controlled Substances Act (1970) listed substances that were controlled when the law was enacted. Since then, approximately 160 substances have been added, removed, or transferred from one schedule to another. A general reference list of controlled substances in alphabetical order can be found at: http://www.deadiversion.usdoj.gov/schedules/alpha/alphabetical.htm.

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 – 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.

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. 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.

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 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.

Schedules of Controlled Substances:

Schedule I: No currently accepted medical use. Highest potential for abuse. (e.g., GHB, heroin, marijuana).

Schedule II: Currently accepted medical use with restrictions. High potential for abuse with severe psychological or physical dependence. (e.g., amphetamine, methamphetamine, cocaine, codeine, morphine, meperidine, methylphenidate, pentobarbital (Nembutal)).

Schedule III: Currently accepted medical use. Abuse of drug may lead to moderate to low physical dependence or high psychological dependence. (e.g., Ketamine, Telazol, testosterone, pentothal. Euthasol is a Schedule III due to pentobarbital/phenytoin mix).

Schedule IV: Currently accepted medical use. Low potential for abuse relative to Schedule III. (e.g., barbital, butorphanol, chloral hydrate, diazepam).

Schedule V: Currently accepted medical use. Low potential for abuse relative to Schedule IV (e.g., buprenorphine and Zolpidem).

Complete **schedules of controlled substances** can be found in section 1308 of CFR Title 21 (21 CFR §1308).

Controlled substances can only be purchased, handled and stored by individuals and/or entities holding a valid DEA registration. *See* Section 3b below

Precursor Chemicals:

Precursor chemicals (state-listed chemicals) and List I Chemicals, are chemicals that have the potential to be used in the manufacture of controlled substances, in addition to legitimate uses. The State of California maintains a list of precursor chemicals that includes all federal List I Chemicals and additional state-listed chemicals. State and federal law require campus vendors to enforce stringent controls regarding distribution of these chemicals, therefor orders are required to be placed through the Campus Procurement Services as a high value requisition.

A complete list of List I Chemicals can be found at:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm.

The state of California precursor chemical list can be found at: http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=5761393734+5+0+0&WAISaction=retrieve.

The term "precursor chemical" is used in these UCM CSP Procedures to include both List 1 Chemicals (federal list) and precursor chemicals (state list).

Note: Precursor chemicals have a 21 day hold from the vendor at the time of order. Precursors cannot be ordered from vendors outside of California.

III. Controlled Substance Registrations

A. UCM Institutional DEA Research Registration

The DEA registration program identifies and validates individuals and institutions that have been authorized by the DEA to purchase, possess, distribute or prescribe controlled substances. UCM has an institutional DEA research registration. Controlled substances acquired through drug companies or any other outside institutions and that are intended for research purposes must be obtained under UC

Merced's institutional DEA research registration.

An individual's DEA registration (such as a registration held by a licensed health care professional) cannot be used to acquire controlled substances intended for research, instruction and/or chemical analysis purposes at UC Merced.

In addition to UCM's institutional DEA research registration, an individual DEA registration is required for each UCM location that will store controlled substances.
Vendors and suppliers may only deliver controlled substances and precursor chemicals to the address listed on UC Merced's institutional DEA research registration. Once received at the authorized location, the controlled substance will be transferred to the individual DEA registered location. At UC Merced, all deliveries of controlled substances and precursor chemicals must be made to:

UC Merced Central Receiving
University of California, Merced
5200 North Lake Road
Merced, CA 95343

Once received and logged in, the controlled substance will be transferred to the individual DEA registered location using the required chain of custody forms. *See* Section VII below, form is exhibit 2.

B. Additional Individual DEA Registrations for UCM Locations

UCM's DEA research registration provides for use of controlled substances in Schedules II through V for non-human research at the UC Merced campus. If controlled substances are required for research that is not covered by UCM's institutional DEA research registration, additional registrations may be required.

The Controlled Substances Program Manager will assist the Principal Investigator in applying for any additional DEA registrations required to conduct their research. Individual DEA registrations must be renewed with the DEA on an annual basis. If the registration is no longer needed to conduct the subject research, it shall be terminated by the Principal Investigator in writing to both the DEA and Controlled Substances Program Manager after all controlled substances have either been fully used or properly disposed of. See section VIII below.

Additional registrations are required for 1) the use or possession of Schedule I controlled substances at any location for each project, 2) human research requiring Schedule I or II controlled substances, 3) use or possession of controlled substances at locations other than the UC Merced campus 4) the manufacture of controlled substances intended for sale, and 5) the use of controlled substances for teaching/instructional purposes.

1. Projects requiring Schedule I controlled substances and human research requiring Schedule I or II controlled substances:

   At least 8 weeks before the date the controlled substances are to be ordered, the Principal Investigator must complete and submit a written Research Application to both the Controlled

Substances Program Manager and to the State of California Research Advisory Panel. Research Application forms are available at: http://caag.state.ca.us/research/research.htm. In addition, if required, the Principal Investigator is responsible for ensuring that the project is reviewed by UC Merced's Institutional Review Board or IACUC. A controlled substance will not be ordered until this review is complete and the project has been approved.

2. Except as provided above, use of Schedule II-V controlled substances at locations other than the UC Merced Campus:

   Requests to use Schedule II through V controlled substances, for non-clinical research at locations other than the UC Merced Campus must be made by the Principal Investigator to the Controlled Substances Program Manager at least one month in advance of ordering the controlled substance.

3. Manufacturing of Controlled Substances:

   A separate registration is required from the DEA to manufacture controlled for sale. The Principal Investigator must file a Manufacturing Registration and corresponding project protocol with DEA following consultation with the Controlled Substance Program Manager. The project protocol should define the items being manufactured and the reason(s) for and/or need to manufacture controlled substances.

4. Teaching/Instructional Purposes:

   A separate registration is required for controlled substance use for instructional purposes. Any relevant animal, human, or in-vitro experimental protocols must also be provided.

IV. Controlled Substance Authorization

A Controlled Substances Use Authorization (CSUA) must be obtained prior to acquiring access to controlled substances. Authorizations will be granted annually to a specific Principal Investigator by the Controlled Substances Program Manager and are subject to annual review of laboratory security and other authorization information. Separate authorization is required for each location where controlled substances are used in the UC Merced facilities. The CSUA form is used to update the usage and location information for licensing and EH&S Controlled Substances Program management purposes.

The CSUA form and instructions are available at https://ehs.ucmerced.edu/researchers-labs/chemical-safety/controlled-substances. Requests for CSUA renewal must be submitted for each subsequent years of a project. A renewal request should be submitted one month before the current CSUA expires. The Departmental Dean, Controlled Substances Manager, and local DEA office authorizes CSUA applications. A Departmental Dean cannot authorize his or her own CSUA application.

All CSUA applicants and parties authorized to work with controlled substances must complete a personnel screening data sheet identifying any 1) felony convictions in connection with controlled

substances, 2) surrender of previous registrations or revocation, suspension, or denial of a previous registration, and 3) use of narcotics, amphetamines, or barbiturates other than those prescribed to the applicant by a physician. All persons with access to controlled substances will be Live Scanned through the UC Merced police department. Hours are posted at http://police.ucmerced.edu/programs-services/live-scan. Persons with access to precursor chemicals may be live scanned depending on quantities or other chemicals ordered.

The CSUA shall be terminated when controlled substances are no longer necessary for project(s).

A CSUA may remain active during a PI's sabbatical leave as long as an acting PI is named in writing and approved by the Department's Dean or Vice Chancellor of Research and the Controlled Substances Program Manager. The acting PI must file a Personnel Screening Data Sheet with EH&S if one is not already on file. Alternatively, if live scanned, the Department Dean may serve as the acting PI.

In case of sabbatical, a CSUA may be extended for up to 3 months beyond the one-year renewal date if, due to extenuating circumstances the PI is not available, *e.g.*, temporarily out of the country. The renewal shall be processed at the PI's earliest opportunity upon recommencing work on the project.

V. Training

All persons handing controlled substances must have completed "Controlled Substances" training by EH&S prior to access to or authorization to use controlled substances..

VI. Purchasing Controlled Substances

A. All requests to obtain controlled substances, including those provided at no charge to the University, shall be submitted to EH&S as a Purchase Requisition for review by the Controlled Substances Program Manager. CONTROLLED SUBSTANCES MAY NOT BE PURCHASED ON A LOW VALUE OR DEPARTMENTAL PURCHASE ORDER.
B. The PI must submit a Purchase Requisition through the appropriate administrative office for their department and provide the following information 1) name of researcher/PI holding the CSUA, 2) the name of the custodian and end-user/researcher, 3) a full item description of the controlled substance, including name, strength, size of package, quantity, and Schedule number (for Controlled Substances only), 4) the requested delivery date, and 6) a detailed statement of the purpose for which the controlled substance is needed and 6) the final delivery and storage location.
C. Purchase Requisitions may only include multiple line items if all items are either in Schedules I and II, or Schedules III through V. Additionally, all items ordered on a single Purchase Requisition must be obtained under the same DEA Registration. Controlled substances and non-controlled substances must be ordered separately.
D. All Purchase Requisitions must be signed by the Principal Investigator. Controlled substances for non-patient purposes must be purchased with the institutional UCM registration and cannot be purchased with a medical doctor's clinical DEA Registration.
E. The Controlled Substances Program Manager will review each Purchase Requisition before it is submitted to the Procurement Services. Purchase Requisitions that are determined to match the research needs as described in the CSUA, in kind and quantity, and that are authorized by

Principal Investigator on a Purchase Requisition shall be forwarded to the Procurement Services for order processing.

F. Registration information and DEA 222 forms (for Schedule I & II purchases only) will be forwarded to the Procurement Services for order placement and processing.

G. The designated Procurement Services Buyer shall place the order, forward procurement and delivery information to the PI and Central Receiving, and maintain a file identifying the name, address, and registration number of the vendor from which the controlled substance(s) were ordered and received. All shipments of controlled substances shall be sent to the registered address on the institutional license. Procurement shall use the carrier and method as requested by Central Receiving in order to comply with the procedure. Procurement shall provide Central Receiving with delivery information at least one business day before delivery, i.e., carrier, method, purchase order contract, tracking number, and scheduled time of delivery. Procurement Services

H. The Procurement Services of the Business and Financial Services Division is charged with monitoring the procurement process to identify any inappropriately procured substances that may have been procured under a departmental purchase order or otherwise obtained in violation of the law or UC policy. EH&S is also charged with monitoring for the presence of inappropriately acquired substances during site visits and inspections.

VII. Receiving

All shipments of controlled substances shall be sent to the registered address on the institutional license. The PI that signed the Purchase Requisition is responsible for receiving all controlled substances obtained through a UCM registration, until such time as a registration for UCM's Central Receiving is approved by the DEA for the receipt of controlled substances.

If received by Central Receiving (after DEA registration and approval of this location):

Procurement shall provide Central Receiving with delivery information at least 1 business day before delivery, i.e., carrier, method, purchase order contract, tracking number and scheduled time of delivery.

Only Central Receiving personnel that have received EH&S authorization shall take receipt of the controlled substance as identified by Procurement; authorized personnel shall be trained and hold DEA registration

If there is a discrepancy or damage to the material, Central Receiving shall contact Purchasing to arrange for the return of product to the vendor. Purchasing shall work with the Controlled Substances Program Manager and the vendor to ensure that appropriate action is taken.

Upon receipt, Central Receiving shall verify and sign for the controlled substance package. The controlled substance package shall be placed in the designated controlled substances safe, as identified by procurement. The safe needs to be opened and verified with at least two individuals present. Central Receiving shall initiate a Chain of Custody form, Exhibit 2. The PI shall be notified of the controlled substance delivery and will take receipt directly from Central Receiving. Upon the transfer of the controlled substance to the PI, the Chain of Custody form, Exhibit 2, will be signed by Central Receiving and the PI. Chain of Custody forms will be

provided to the Program Administrator.

Until such time as a registration for UCM's Central Receiving is approved by the DEA, the PI that signed the Purchase Requisition is responsible for receiving all controlled substances obtained through a UCM registration. As soon as a PI receives and logs a shipment of controlled substances, the shipment material must be carried directly to the PI's DEA approved storage location and properly stored immediately.

VIII. Storage

A. Each PI shall have adequate security for storage and control of controlled substances. All controlled substance storage facilities must be inspected and approved by EH&S, and the DEA if housing Schedules I and II, in accordance with the following standards:

1. Storage units shall only contain controlled substances and corresponding logbooks. No other chemicals or supplies shall be stored in the controlled substances storage area.
2. Storage units shall be secured in a manner that will provide evidence of any attempt at forced entry.
3. For DEA controlled substances only (i.e. Schedules I-V), storage unit shall be bolted or cemented in place or weigh in excess of 750 pounds and be DEA approved.
4. Controlled substances may not be stored in corridors.
5. The storage unit shall be equipped with a padlock, pin-tumbler, or combination lock.
6. The storage unit shall have at least three points of contact for the locking mechanism.
7. If a padlock, pin-tumbler, or combination lock is used, a hasp shall be installed so that there is no access to the mounting screws or bolts when the door is closed and the lock is fastened.
8. Hinges shall be installed in such a manner as to prevent access to mounting screws or bolts when the door is closed.
9. The key shall at all times remain in the physical custody of the individual(s) listed by the Principal Investigator on the approved CSUA as Authorized Personnel.
10. The combination (if any) shall be changed upon termination of the Authorized Personnel status of any individual. This change shall be documented in the controlled substance logbook.
11. Key(s) must be retrieved from Authorized Personnel upon termination of Authorized Status.
12. Storage units cannot be shared by multiple Principal Investigators.

B. Storage locations for Schedule I and II controlled substances will be inspected and approved by EH&S and the DEA.

IX. Inventory

A. It is the responsibility of each PI to ensure that a current inventory of all controlled substances under his/her control is maintained on a separate Controlled Substances Log Sheet, in a separate book that is available for periodic audit by EH&S, the IUCAC and/or the DEA. A log sheet can be found in Exhibit #1.

B. EH&S shall maintain a record of all new controlled substances purchased for each Principal Investigator and incorporate these controlled substances into the next inventory cycle.
Upon notification by EH&S, each Principal Investigator shall conduct a physical inventory of all controlled substances. At a minimum, controlled substances must be inventoried every two years.

X. Documentation

A. All documentation must be retained for 2 years.

1. The controlled substances logbook shall be kept in accordance with the EH&S standards specified below. Controlled substance logbooks must be kept in a secure location either inside the approved controlled substances storage area or in close proximity with its location noted inside the storage area. Controlled Substance Log Sheets for Schedules I and II must be filed in separate logbooks than those for Schedules III-V.
2. Any dispensation of a controlled substance from its original container shall be recorded on the Controlled Substance Log Sheet for that material found in exhibit #1. The amount of controlled substances remaining in the bottle must equal the amount of controlled substances documented in the logbook at all times.
3. Any breakage of containers shall be noted on the Controlled Substance Log Sheet, initialed by the individual responsible for the breakage and co-signed by the Principal Investigator. A copy of this Controlled Substance Log Sheet shall then be forwarded to EH&S for inventory management and review.
4. Any receipts of controlled substances shall be noted on the Controlled Substance Log Sheet. Purchase order numbers and supplier names shall be shown. Departmental copy of the purchase order, receipt, and disposal documents shall be maintained by the Principal Investigator in the controlled substance logbook and shall be available for inspection upon request.
5. Packing slips for orders of controlled substances will be forwarded to the Controlled Substances Program Manager.

XI. Control

A. A transfer of controlled substances in Schedules II-V to other Principal Investigators at the same registration location is only allowed when a transfer of a project to that PI has occurred. The transfer must be approved and coordinated by EH&S. Prior to any transfer, a CSUA must be on file with EH&S for the individual requesting the transferred controlled substance(s) (*i.e.,* the PI receiving the controlled substance). The Controlled Substances Program Manager should be contacted four weeks before the transfer to arrange for the transfer.

B. Controlled substances shall not be transferred from the original containers in which the controlled substance was received for storage and/or inventory purposes.
C. Access to controlled substances shall be denied to any individual who has had a personal application for registration with the DEA denied or revoked due to pending charges or a specific crime among other issues. The Principal Investigator shall maintain a list in the laboratory of those individuals handling controlled substances and shall is ensure that each listed individual has completed the personnel screening process and has been authorized to handle the controlled substance.
D. It is the responsibility of each individual authorized to handle controlled substances to notify the Controlled Substances Program Manager immediately of any theft, loss, or disappearance of controlled substances. The Controlled Substances Program Manager is responsible for notifying the University of California Police Department. The UC Police will notify the DEA Regional Office.
E. Department Deans are responsible for notifying EH&S prior to the arrival at UC Merced of any Principal Investigator who proposes to work with controlled substances at any UC Merced location. The Controlled Substances Program Manager shall then contact the DEA to determine the appropriate process for authorizing the PI to handle controlled substances at the UCM location. If controlled substances are brought from another institution, a chain of custody form must be completed. A CSUA application shall be submitted at least one month before the PI proposed to use any controlled substance. Additionally, the Department Dean must notify EH&S when a Principal Investigator authorized to experiment with controlled substances is separated from the University by death or termination of UC Merced employment. Controlled substances in the PI's possession at that time will be disposed of as specified in this manual.
F. Controlled Substances shall not be imported, exported, transferred, shipped, or removed from the registration location except for in cases of proper disposal pursuant to these procedures, return to supplier, or by prior agreement with the DEA.

XII. Returns to Suppliers/Vendors

To arrangement for the return of controlled substances to the supplier/vendor, the PI must contact the Purchasing Division and EH&S for specific instructions regarding the proper procedure for the return. The Purchasing Division will contact the supplier/vendor, identify the documentation required to process the return, and advise the appropriate individuals of the proper return. Once the return is complete, EH&S will remove the items from their inventory records.

XIII. Disposal

To arrange for disposal of controlled substances in any manner other than the dispensation or use for which they were procured, the PI must contact EH&S. EH&S will collect the controlled substances for disposal and will complete a Chain of Custody form, document on the respective Controlled Substances Log Sheet that the controlled substances have been received for disposal, and issue a copy of the Chain of Custody form to the PI as a receipt. EH&S will hold the controlled substances in an authorized location, pending disposal by the DEA or DEA-approved vendor. Once the disposal has been completed, the respective Controlled Substances Log Sheets must be retained for a minimum of two (2) years by the Principal Investigator.

Empty vials can be disposed by authorized personnel in the same manner as any other chemical bottle of similar construction. A copy of the Controlled Substances Log Sheets for the controlled substance previously contained in the empty vial, updated to reflect the use of the all of the substance, shall be sent to the Controlled Substances Program Manager for inventory control.

A. The PI must arrange for disposal of all remaining controlled substances when:

1. A project has been closed or terminated and controlled substances are still in supply.
2. A Controlled Substance Use Authorization has expired and a renewal has not been submitted.
3. A Principal Investigator determines that the controlled substance is no longer required.
4. A Principal Investigator maintaining controlled substances separates from University by terminating employment or death.

Following termination of employment or death of a Principal Investigator, in addition to the requirement to dispose of any remaining controlled substances, all inventory records, including Controlled Substance Log Sheets, must be maintained in the department or forwarded to EH&S for record retention and shall be destroyed 3 years after date of controlled substance disposal.

XIV. Research Advisory Panel

In addition to the authorizations and approvals required under University Policy and procedures, including BUS 50 and these procedures, the State Research Advisory Panel (established under Sec. 11480 of the State Health and Safety Code, website: http://ag.ca.gov/research/index.php) meets periodically to consider new research protocols in California. The following types of activities that may be conducted by university researchers requires approval of the Panel:

1. Research of any nature involving use of controlled substances listed in Schedule I (See Section VI.A.1.).
2. Human research using any Schedule I or Schedule II controlled substance
3. Research for the treatment of drug abuse using any drug, scheduled or not.

The Principal Investigator of each approved program subject to Research Advisory Panel approval must submit an annual progress report to the Panel each year, or if the program has been completed or discontinued, a final project report. A copy of each report shall also be sent to the Controlled Substances Program Manager.

XV. Exemption of certain chemical preparations

In rare cases, a chemical preparation or mixture containing one or more controlled substances may be declared exempt by the Drug Enforcement Administrator from all or any part of the Controlled Substance Act if preparation or mixture is intended for laboratory, educational, or special research purposes and is not for general administration to a human being. Application for exemption shall be filed by the Principal Investigator. Application requirements can be obtained from the Controlled Substances Program Manager, or from 21CFR1308.23 at http://www.ecfr.gov/cgi-bin/text-idx?SID=77d228cfb9bc2dd1bcbf55c192a10223&node=21:9.0.1.1.9.0.28.11&rgn=div8. A list of

exempt chemical preparations is located in 21CFR1308.24 or at
http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf

XVI. Escalation Procedures

Failure to follow this procedure or BUS-50 policy will result in the following action:

First Offense- Supervisor or Dean will be notified.

Second Offense – Vice Chancellor will be notified in addition to Supervisor or Department Chair.

Third Offense – Suspension of authorization to work with controlled substances and notification of the above.

EXHIBIT 1

Controlled Substance Usage Log

Environment, Health & Safety,
University of California, Merced

Complete one log sheet 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.

Drug name: _____ Schedule#: _____ (I-V) CS storage location: _____

Finished form: _____ (eg: tablet, powder, liquid) Strength: _____ (eg:10mg/mL) Container type: _____ (glass, plastic)

Principal Investigator name: _____ Acquired under Reg #: _____ PO#: _____

CSUA#: _____ Date added to PI inventory: _____ Department: _____ Container ID#: _____

Date	Amount Received	Amount Used	Balance (unit)	Dispenser's Printed Name	Reason for Use/ Animal Protocol #/ Species
		-	-		
	-				
	-				
	-				
	-				
	-				
	-				
	-				
	-				
	-				
	-				
	-				

CS transferred to EH&S for disposal? Y ☐ N ☐ If Yes: EH&S Initials _____ Date _____ Disposal #: _____

CS is completely used up? Y ☐ N ☐ If Yes, copy of log sheet sent to EH&S and empty bottle disposed by: _____ Date _____

- This log must be kept in the controlled substance storage drawer or safe. The log balance must match the physical balance of CS at all times.
- This log must be retained in the lab for 3 years from either the date of disposal or date of complete use: **Retain until:** _____
- Any log discrepancies, suspected mis-use, or theft of controlled substance must be reported to EH&S Controlled Substances Program Manager immediately.
- When this controlled substance is no longer needed, call EH&S at 209 228-7864 for disposal instructions.
- When this controlled substance is completely used up, send a copy of the log sheet to EH&S; then deface label and throw away in regular trash.
- Any breakage of containers must be initialed by the individual responsible for breakage and co-signed by the PI.

Exhibit 2 – Chain of Custody Form

Chemical	Amount	Released by	Date	Time	Received by	Date	Time	Signature

References

BUS-50 Contrtolled Substance Policy http://www1.ucop.edu/ucophome/policies/bfb/bus50.pdf

Code of Federal Regulations Title 21 Part 1308 http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=77d228cfb9bc2dd1bcbf55c192a10223&n=21y9.0.1.1.9&r=PART&ty=HTML

Controlled Substances Program Manager: 228-7864