UC San Diego
Controlled Substances Program
Procedures

I. PROCEDURE

A. Controlled Substance Use Authorization Requirements

A Controlled Substance Use Authorization (CSUA) must be completed prior to acquiring controlled substances. The CSUA form is used to update and keep current the above information for DEA licensing and EH&S Controlled Substances Program management purposes.

The online form and instructions are available at http://blink.ucsd.edu/go/cs.

Authorizations will be issued annually by project to a specific Principal Investigator (PI) by the Controlled Substances Program Manager pending review of laboratory security and authorization information. Each CSUA must be renewed by the Principal Investigator annually for subsequent years of a project. Separate authorization is required for each location of use (e.g. the La Jolla campus (including Scripps Institution of Oceanography), the Medical Center, or Elliott Field).

All applicants must answer questions concerning 1) felony convictions in connection with controlled substances, 2) surrendering previous registrations or having a registration revoked, suspended, or denied, and 3) any use of narcotics, amphetamines, or barbiturates other than those prescribed to the applicant by a physician. A Department Chair cannot authorize his or her own CSUA application. The CSUA shall be terminated when controlled substances are no longer necessary for corresponding project(s).

A CSUA may remain active during sabbatical leave of the PI as long as an acting PI is named in writing and approved by the Department Chair and Controlled Substances Program Manager. The acting PI must file a Personnel Screening Data Sheet with EH&S. Alternatively, the Department Chair may serve as the acting PI.

In case of a sabbatical, a CSUA may be extended for up to 3 months beyond the one-year renewal 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 first opportunity upon returning to the project.

B. Registrations

University registrations with the DEA provide for use of controlled substances in Schedules II through V for non-human research at the La Jolla Campus, UC San Diego Medical Center, Scripps Institution of Oceanography, and Elliot Field. Additional registrations may be required as detailed here.

The Controlled Substances Program Manager shall assist the Principal Investigator in applying for any additional DEA registrations. Additional registrations shall be in the name of the Principal Investigator. However, registrations for alternate locations shall be in the name of the academic department. These shall be renewed with the DEA on a yearly basis. If the registration is no longer necessary, it shall be discontinued by the Principal Investigator in writing to the DEA and Controlled Substances Program Manager. This shall be done after all controlled substances have been used or disposed.

Additional registrations are required for 1) use or possession of Schedule I controlled substances at any location for each project and human research requiring Schedule I or II controlled substances 2) use or possession of controlled substances at locations other than the La Jolla Campus, UC San Diego Medical Center, Scripps Institution of Oceanography, and Elliot Field 3) the manufacture of controlled substances, and 4) 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 controlled substances are to be ordered, a complete written Research Application must be submitted simultaneously by the Principal Investigator to 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.

2. Use or possession of controlled substances at locations other than the La Jolla Campus, UC San Diego Medical Center, Scripps Institution of Oceanography, and Elliot Field

   Requests to use Schedule II through V controlled substances for non-clinical research at locations other than the La Jolla Campus, UC San Diego Medical Center, Scripps Institution of Oceanography, or Elliot Field must be made by the Principal Investigator to the Controlled Substances Program Manager in EH&S. Appropriate DEA registrations will be filed accordingly.

3. Manufacturing Controlled Substances

   A separate registration is required from the DEA to manufacture controlled substances. The requisite project protocol should define the items being manufactured and the reason(s) for and/or need to manufacture controlled substances and shall be approved by the

Department Chair. The Manufacturing Registration and corresponding project protocol will be filed with the DEA by the Principal Investigator.

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.

C. Purchasing Controlled Substances

1. All requests for controlled substances, including those provided at no charge to the University, shall be submitted to EH&S via a Controlled Substance Purchase Requisition and a Controlled Substance Requisition Supplemental Form signed by the Principal Investigator (PI) for review by the Controlled Substances Program Manager. Controlled Substances are **not** to be purchased on a low value purchase order.

2. Controlled Substance Purchase Requisitions may only include multiple line items if items are either all in Schedules I and II, or all in Schedules III through V. Additionally, all items on one Purchase Requisition must be obtained under the same DEA Registration. Controlled substances and non-controlled substances shall be ordered separately. The CSUA order requisition module ensures this separation.

3. The Controlled Substance Requisition Supplemental Form must be signed by the Principal Investigator or Department Chair. The Controlled Substance Requisition will not be reviewed until the PI-signed supplemental form has been sent to EH&S. Controlled substances for non-patient purposes cannot be purchased with a medical doctor's clinical DEA Registration.

4. The Controlled Substances Program Manager will review each purchase requisition. Purchase requisitions, which match the research needs as described in the CSUA in kind and quantity and are authorized by Principal Investigator's signature, shall be forwarded to the Procurement and Contracts Department for order processing.

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

6. The Purchasing Division shall place the order, forward procurement and delivery information to the Controlled Substances Program Manager, and maintain a file identifying: the name, address, and registration number of the person (vendor) from whom the controlled substance(s) were ordered or received.

The Procurement and Contracts Department of the Business and Financial Services Department will monitor for inappropriately procured substances that may have been procured under a departmental purchase order or through use of an incorrect commodity code. EH&S will also monitor for inappropriately acquired substances during site visits.

D. Receiving

All shipments of controlled substances shall be sent to the registered address, which shall be predetermined by the appropriate registration and established with the DEA. EH&S is responsible for receiving controlled substances obtained through University registration except in off-campus locations where EH&S cannot physically be present. In case of this exception, a responsible individual will be assigned to handle incoming packages at each registered location according to methods established by the Controlled Substances Program Manager. Each shipment shall be logged and stored according to established EH&S standards.

All controlled substance deliveries are opened and verified for accuracy. It is best practice to open the sealed packages in the presence of two or more persons. If there is a discrepancy or damage to the product, EH&S will contact Purchasing to arrange for order correction or return of product. Purchasing will work with the Controlled Substances Program Manager and the vendor to ensure that the most appropriate action is taken.

E. Distribution

After the controlled substance is received and logged at EH&S, the Principal Investigator, Primary and Secondary Lab Contacts as indicated on Controlled Substance Use Authorization (CSUA) in section 2 will be notified. Only Authorized Personnel as listed on the CSUA with an Authorized Recipient demarcation can accept a shipment. Distributions will be logged by EH&S by recording the Authorized Recipient's signature at the point of pickup and verifying the person by a government-issued photo ID. The signature of each individual through whose hands a controlled substance passes shall be recorded, including the Authorized Recipient, whose signature serves as acknowledgement of delivery and assumption of responsibility for ensuring storage and use in accordance with applicable regulations. EH&S shall maintain a file to identify all controlled substances distributed.

Once the Authorized Recipient receives the shipment, the shipment must be carried directly to the Principal Investigator's EH&S-approved storage location and stored immediately.

F. Storage, Control, Documentation, and Biennial Inventory

1. Each Principal Investigator shall have adequate security for storage and control as inspected and approved by EH&S in accordance with the following standards:
    a. Storage unit shall contain ***only*** controlled substances and corresponding logbooks. No other chemicals or supplies shall be stored in the controlled substances storage area.
    b. Storage unit shall be secure enough to show forced entry.
    c. Storage unit shall be bolted or cemented in place or in excess of 750 pounds.
    d. Corridor Storage of controlled substances is prohibited.
    e. The cabinet shall be equipped with a padlock, pin-tumbler, or combination lock.
    f. 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.
    g. Hinges shall be installed in such a manner as to prevent access to mounting screws or bolts when the door is closed.
    h. The combination or key (if any) 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. When a key or combination code is issued to or retrieved from the Authorized Personnel update section 3 of the CSUA, "Storage Key/Code" accordingly.
2. Storage locations for Schedule I controlled substances will be inspected and approved by EH&S and the DEA.
3. It is the responsibility of each Department Chair to ensure that a current inventory of all controlled substances under his/her control is maintained by the Principal Investigator on the Controlled Substances Log Sheet, in a separate book for periodic audit by EH&S and/or the DEA.
4. The controlled substances logbook shall be kept in accordance with EH&S standards. Controlled substance logbooks must be kept in a secure location either inside the approved controlled substances storage area or in close proximity and its location noted inside the storage area. Controlled Substance Log Sheets for Schedules I & II must be filed in separate logbooks than those for Schedules III-V.
5. All controlled substance dispensations from its original container shall be recorded on the Controlled Substance Usage Log provided by EH&S. The actual

amount of controlled substances remaining in the drawer must equal the documented remaining amount in the logbook at all times.

6. Any breakage of containers shall be noted on the corresponding Controlled Substance Usage Log, initialed by the individual responsible for the breakage, and co-signed by the Principal Investigator. A copy of this Controlled Substance Usage Log shall then be forwarded to EH&S for inventory management and review.
7. Receipts of controlled substances shall be noted on the Controlled Substance Usage Log. Purchase order number and supplier name shall be shown. Departmental copy of Controlled Substance Requisition Supplemental forms, Usage Logs, and disposal documents shall be maintained by the Principal Investigator in the controlled substance logbook and shall be available upon request.
8. Controlled substances shall not be transferred from the original containers for storage and/or inventory purposes.
9. Access to controlled substances shall be denied to any individual who has had a personal application for registration with the DEA denied or revoked. The Principal Investigator shall maintain a current list in the laboratory of those individuals handling controlled substances.
10. It is the responsibility of each Authorized Personnel 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 DEA Regional Office and the University of California Police Department.
11. Department Chairs are responsible for notifying EH&S prior to Principal Investigator arrival on campus with controlled substances. The Controlled Substances Program Manager shall then contact the DEA to determine the appropriate action. A CSUA application shall be submitted as necessary. Additionally, the Department Chair must notify EH&S when a Principal Investigator authorized to experiment with controlled substances dies or intends to terminate employment. Controlled substances in possession at that time will be returned to EH&S for disposal (see Procedures section I.H).
12. EH&S shall maintain a file of all new controlled substances purchased for each Principal Investigator and incorporate these controlled substances into the next inventory cycle.
13. Upon notification by and with directions from EH&S, it is the responsibility of each Department Chair and Principal Investigator to conduct an inventory of all controlled substances.

14. Controlled substances shall not be transferred, shipped, or removed from the registration location except for in cases of disposal, return to supplier, or by prior agreement with the Controlled Substances Program and the DEA.

G. Returns to Suppliers/Vendors

To make arrangements to return controlled substances to the supplier/vendor, the Procurements and Contracts Department and EH&S must be contacted for instructions. The Procurement and Contracts Department will contact the supplier/vendor, identify the documentation needed, and advise the appropriate individuals of the procedure necessary to facilitate the return. Once the return is complete, EH&S will remove the items from its inventory records.

H. Disposal

To make arrangements for disposal of controlled substances in any manner other than the dispensation or use for which they were procured, contact EH&S. EH&S will receive the substances for disposal by completing a Chain of Custody form, indicate on the respective Controlled Substances Usage Log that they have been received for disposal, and issue a copy of the Chain of Custody form to the laboratory as a receipt. EH&S will hold the substances, pending disposal by the DEA or DEA-approved vendor. Once the disposal has been completed, the respective Controlled Substances Usage Logs must be retained for a minimum of three (3) years by the Principal Investigator. Empty vials can be disposed of by Authorized Personnel in the same manner as any other chemical bottle of similar construction. A copy of the corresponding empty vials' Controlled Substances Usage Logs shall be sent to the Controlled Substances Program Manager for inventory control.

Disposal must be arranged when:

1. A project has been closed or terminated and controlled substances are still in supply.
2. A Controlled Substance Use Authorization (CSUA) 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 employment.
5. A Principal Investigator maintaining controlled substances dies.

In the instances of terminating employment or death of a Principal Investigator, and in addition to the requirement to dispose of any remaining controlled substances, all inventory records, including Log Sheets, must be maintained in the department or

forwarded to EH&S for record retention and shall be destroyed three (3) years after date of controlled substance disposal.

I. Research Advisory Panel

The Research Advisory Panel (established under Sec. 11480 of the State Health and Safety Code, website: http://ag.ca.gov/research/index.php) meets to consider new research protocols in California. The following types of activities require approval of the Panel:

1. Research of any nature involving use of controlled substances listed in Schedule I (See Policy and Procedure Manual 516-7 Section IV.C).
2. Human research using any Schedule I or Schedule II controlled substances
3. Research for the treatment of drug abuse using any drug, scheduled or not.

The Principal Investigator of each approved program must submit an annual progress report each year to the Research Advisory Panel. If the project has been completed or discontinued, then a final project report shall be submitted to the Research Advisory Panel. A copy of each report shall also be sent to the Controlled Substances Program Manager at EH&S and the CSUA amended to reflect project completion.

J. Exemption of certain chemical preparations

In rare cases, a chemical preparation or mixture containing one or more controlled substances may be declared exempt from any or all parts of the Controlled Substance Act by the Drug Enforcement Administration. Such a preparation or mixture is intended for laboratory, educational or special research purposes and **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.

View Controlled Substances Program Policy PPM 516-7