

UCSB Controlled Substances Program Procedures

I. DEA Registration

Prior to any controlled substance related activity, a UCSB researcher must first obtain a DEA Registration. If research involves any Schedule I controlled substance or Schedule II on human subjects, the researcher will also require project approval of the [Research Advisory Panel of California](#) (RAPC).

- 1.) At least 8 weeks before controlled substances are to be ordered, a complete written Research Application must be submitted by the researcher to the State of California Research Advisory Panel.
- 2.) The Registration Holder of each approved project must submit an annual progress report to the RAPC.
- 3.) Upon completion or discontinuation of project, a final report must be submitted to the RAPC and a copy sent to the CSPA.

If the project involves vertebrate animals, the researcher must also obtain a Protocol Approval from the [Institutional Animal Care & Use Committee](#) (IACUC). The application for animal projects is found [here](#).

The Controlled Substances Program Administrator (CSPA) shall assist researchers in applying for a DEA Registration. The DEA Registration application for Researcher Schedule II-V can be found [here](#). Research to be done at different locations require their own separate Registrations.

DEA Registrations must be renewed annually. If a researcher chooses to cancel or allow a Registration expire, they must first dispose of all controlled substances in their inventory.

II. Required Documentation

Prior to obtaining any inventory, a Registration Holder must complete and/or submit the following to the CSPA:

- 1.) [PI/Registration Holder Screening Form](#)
- 2.) [UCSB Controlled Substances Program Project Registration Form](#)
- 3.) Successful completion of Controlled Substances Training module.
 - a.) Log on at the [UCSB LMS](#) and search for “controlled substances”.
- 4.) Roster of Authorized Users

III. Authorized Users

Only Authorized Users are permitted to take part in any controlled substance activities including:

- 1.) Purchasing/ordering/receiving controlled substances
- 2.) Handling or otherwise using controlled substances for research
- 3.) Conducting biennial inventory
- 4.) Disposing controlled substances

To become an Authorized User, a lab member must:

- 1.) Complete and submit to the CSPA a [Non PI Screening Form](#). This screening form must be refreshed every three years
- 2.) Attend an online training module which must be re-taken every three years as a refresher.

IV. Regular Inspections

DEA Registration Holders are subject to inspection at any time. Inspectors can be from the DEA, IACUC, or the UCSB CSPA. Registration Holders can expect to be inspected by the campus CSPA at least once every year. CSPA inspections can be announced or unannounced. The CSPA will look at the following during routine inspections:

- 1.) Current Authorized Users along with their training and screening form status
- 2.) Secure storage area
- 3.) Inventory
- 4.) Controlled substance record keeping

V. Purchasing Controlled Substances

- 1.) The CSPA must be notified of and approve all controlled substance acquisitions. This includes drugs purchased through vendors as well as drugs obtained through the National Institute on Drug Abuse.
- 2.) Controlled substance purchase requisitions can only be prepared and placed by Authorized Users.
- 3.) Controlled Substance Purchase Requisitions may only include multiple line items if items are either all in Schedule 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 pharmaceuticals shall be ordered separately.
- 4.) Registration information and DEA 222 forms (for Schedule I & II purchases only) will be forwarded to the purchasing department for order placement and processing
- 5.) EH&S will monitor for inappropriately acquired controlled substances during audits.

VI. Receiving Controlled Substance Shipments

- 1.) Packages containing controlled substances must always be received and signed for by Authorized Users.
- 2.) Controlled substances must be delivered to the location listed on the purchaser's DEA Registration.
- 3.) A Controlled [Substance Delivery Record](#) must be filled out and signed for each drug purchase. One copy of the delivery record shall be kept with all other controlled substance documents and another copy must be sent to the CSPA.
- 4.) Any damage to controlled substance items or inconsistencies between the items received and items listed on the PO must be immediately reported to the CSPA.

VII. Transfers of Controlled Substances

- 1.) The CSPA must be notified prior to any transfer of controlled substances.
- 2.) Controlled substances may only be transferred from one DEA Registrant to another DEA Registrant.
- 3.) The receiving DEA Registrant's registration must cover the schedule of the drug being transferred.
- 4.) All controlled substance transfers must be documented on a [Transfer of Controlled Substances](#) form.
- 5.) One copy of the completed form must be kept in the transferors records, another copy in the transferees records, and a third copy must be sent to the CSPA.

VIII. Storage, Control, Documentation, Biennial Inventory

- 1.) Each DEA Registrant shall have adequate security for storage and control of controlled substances in their inventory. The storage arrangement for each registrant must be approved by the DEA prior to issuance of registration. Controlled substance storage areas must adhere to the following standards:
 - a.) Storage unit shall contain ONLY controlled substances and their associated logbooks and documents. No other chemicals or supplies can be stored with your controlled substance inventory.
 - b.) Expired drugs may be kept in the same area, but must be in a separate box/container marked as expired.
 - c.) Storage unit shall be secure enough to show signs of forced entry.
 - d.) Schedules I and II must be stored in a safe, Schedule III-V can be stored in a locked cabinet or drawer.
 - e.) Cabinets or drawers must be equipped with a padlock, pin or wafer tumbler lock, or a combination lock.
 - f.) The number of keys shall be kept to an absolute minimum and be kept on an Authorized User's person.

- g.) All mounting hardware for the locking mechanism and hinges must be inaccessible when the unit is closed and locked.
- 2.) The controlled substances logbook shall be kept in the approved controlled substances storage unit. Controlled substance log sheets for Schedules I and II must be kept in separate logbooks than those used for Schedules III-V.
 - 3.) Each and every controlled substance dispensation from its original container must be recorded on the Controlled Substance Usage Log. The actual amount of controlled substances remaining in your storage unit must equal the amount documented in the logbook at all times.
 - 3.) Any breakage or spilling of controlled substances shall be noted on the Controlled Substance Usage Log, initialed by the responsible individual, and co-signed by the Registration Holder. A copy of this Controlled Substance Usage Log must then be sent to the CSPA for inventory management and review.
 - 4.) Receipts for controlled substance purchases must be kept in the logbook and shall include the PO number and supplier name.
 - 5.) Controlled substances shall not be transferred from the original containers for the purpose of storage and/or inventory.
 - 6.) 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 Registration Holder shall maintain a current list of all Authorized Users.
 - 7.) It is the responsibility of each Authorized User to notify UCSB Police and the CSPA immediately of any theft, loss, or disappearance of any controlled substance. The Registration Holder is responsible for reporting such incidents to the DEA Regional Office.
 - 8.) Department Chairs are responsible for notifying the CSPA prior to any Registration Holder's arrival on campus with controlled substances already in their possession. In addition, Department Chairs are required to notify the CSPA when a Registration Holder terminates employment or cancels their Registration. Controlled substances in that Registration Holder's inventory must be disposed prior to departure.
 - 9.) Upon notification and with instructions from the CSPA, it is the responsibility of Registration Holders to conduct a biennial inventory of all controlled substances as required by the DEA.
 - 10.) Controlled substances shall not be transferred, shipped, or removed from the registration location except in cases of disposal, return to supplier, or by prior agreement with the CSPA.

IX. Returns to Suppliers/Vendors

To make arrangements to return controlled substances to the supplier/vendor, the Registration Holder must contact the Procurements Department and the CSPA. Procurements will contact the supplier/vendor, identify the required documentation,

and advise the appropriate individuals of the procedure necessary to facilitate the return. Once the return is complete, the CSPA will remove the returned items from the inventory.

X. Disposal

- 1.) Registration holders seeking to dispose of expired or otherwise unwanted controlled substances shall contact the CSPA for instructions. All CS disposal is handled by shipping to INMAR RX Solutions. A user account must be created for each lab prior to shipment
- 2.) Registration Holders planning to cease controlled substance activities must first contact the CSPA to make arrangements for disposal of remaining controlled substance inventory.
- 3.) Registration Holder shall request documentation as to final disposal from reverse distributor following disposal. This document must be retained in the controlled substance logbook along with the original Usage Log for three years following disposal. The Usage Log must reflect disposal in the quantity remaining field.