

 California State University SAN MARCOS	Controlled Substances Procedures Manual	
	California State University San Marcos • Safety, Risk, & Sustainability Services 333 S. Twin Oaks Valley Road • San Marcos, CA 92096 • Craven Hall 4700 • (760) 750-4502	
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Scope The purpose of this document is to establish procedures for the authorization, procurement, receipt, security, storage, control, inventory and disposal of Controlled Substances and Listed Chemicals for research and teaching purposes. A controlled substance is a drug or chemical whose manufacture, possession, and use are regulated by the government and require a Drug Enforcement Agency (DEA) registration. The Director of Safety, Risk, & Sustainability (SR&S) or their designee is the program administrator who oversees the day-to-day activities of the Controlled Substances Program.

Definitions **Controlled Substance** – A drug or chemical whose possession and/or use is regulated under the [Resources - Title 21 United States Code \(USC\) Controlled Substances Act - Section 801-971](#) Title 21 United States Code Controlled Substances Act and the [California Uniform Controlled Substances Act](#).

Listed Chemical – Chemicals that are regulated by federal and/or state law that may be used to manufacture controlled substances and were established by [Public Law 103-200, The Domestic Chemical Diversion Control Act of 1993](#). See also [DEA Chemical Handler’s Manual](#).

Principal Investigator – A Principal Investigator (PI) includes Professors, Associate Professors, Assistant Professors, Instructors, and Veterinarians who are assigned space for research or teaching activities. A faculty member without assigned space may be considered a Principal Investigator with approval of their Department Chair.

Authorized Personnel – Authorized personnel are faculty, students, staff, or visiting scholars who have a need to handle or access controlled substances for department-approved projects at CSUSM. The number of Authorized Personnel shall be kept at a minimum in order to maintain security. To become an Authorized Personnel, the individual must have no prior history with controlled substances abuse or diversion, must complete and sign the [Personnel Screening Data Sheet](#), and obtain signature authorization from the Principal Investigator on the project.

UARSC - An auxiliary organization of California State University San Marcos, University Auxiliary and Research Services Corporation. The Office of Sponsored Projects provides professional and timely assistance to faculty and staff in their pursuit of externally funded research and sponsored programs.

Responsibility The SR&S Controlled Substances Program Administrator (or the administrator’s delegated authority) is responsible for the following processes and procedures as they pertain to management of the CSUSM Controlled Substances Program:

- 1) Maintenance of the Controlled Substances Program **Procedures Manual**
- 2) Review and approval of all controlled substances purchase requests
- 3) Annual (and as needed) audits of each PI’s controlled substances inventories (including required documentation) and controlled substances storage locations
- 4) Maintenance of the Controlled Substances Program **website**

- 5) Assist in the initial and annual renewal of Principal Investigator DEA registrations and any associated amendments
- 6) General administrative program management processes as defined in the manual

SR&S will maintain a controlled substances program file for each Principal Investigator (PI) who has been approved to order and research with controlled substances. Each file will contain the following:

- Controlled Substance Use Authorization (CSUA) for each research project.
- Personnel Screening Data Sheets for each authorized lab personnel
- Biennial Inventory logs
- Copies of controlled substances use logs
- Copies of purchase requests for all controlled substances
- Delivery and distribution logs for each controlled substance order
- Audit/inspection records or reports from SR&S or the DEA
- Other related correspondence

I. PROCEDURES

A. DEA Registrations

The Controlled Substances Program administrator (or delegated authority) shall assist the Principal Investigator in applying for an initial, renewal, and/or amendment(s) to their DEA registration. If the registration is no longer needed, the PI shall provide in writing to the DEA and the Controlled Substances Program Administrator a request to discontinue use of their registration.

The Principal Investigator must provide SR&S all applicable information that affects their DEA license. This includes, but is not limited to, changes in location, changes in research processes, changes in the type and/or amount of controlled substances and listed chemicals used, and changes in personnel allowed to have access to or use the material.

A copy of the PI's DEA registration shall be kept in the same location as the controlled substance locked cabinet, as well as in the PI's controlled substances program file located at SR&S.

SR&S must provide the DEA all information that can affect the registration requirements once it is received from the registrant. Once the changes are made to the registration, SR&S will provide confirmation to the PI to proceed.

B. Controlled Substances Use Authorization

A [Controlled Substance Use Authorization \(CSUA\) application](#) must be completed for each new research project involving a controlled substance or listed chemical. The [CSUA](#) application is available online on the [Controlled Substances Program](#) webpage.

This application identifies:

- Principal Investigator information (name, department, contact information)
- Controlled substance(s) or listed chemical(s) that will be utilized in the research project
- Storage location(s)
- All personnel authorized by the PI to receive controlled substances deliveries on their behalf

- All personnel authorized by the PI to conduct research utilizing the controlled substance

An updated CSUA form must be submitted if any changes occur in controlled substances storage location, research processes, personnel allowed to have access to or use the material, and any changes in the type and/or amount of controlled substances used after the initial CSUA has been submitted and approved by SR&S. If no changes occur, then the Controlled Substances Program administrator will work with the PI to update the CSUA annually. The CSUA will be terminated when the controlled substance is no longer necessary for the initial project for which it was approved.

II. PURCHASING

*** If you are ordering a controlled substance for a new research project, you must submit a new CSUA prior to making your purchase request.*

Steps for Ordering:

1. Prepare a purchase requisition or order form (see “Completing a Purchase Requisition” instructions below).
2. Complete the **Controlled Substances Purchase Requisition** online form on the Controlled Substances webpage.
3. Attach the requisition and back up documentation (if necessary) to the Controlled Substances Purchasing Request form.
4. The Controlled Substances Program administrator will review the purchase request and notify the PI of approval/denial, or request for more information if necessary. SR&S will also send a copy of the approved purchase request to the AVP for Research (Institutional Official), Procurement, or UARSC (depending on the funding source).
5. Once approved, the PI shall submit their purchase order form to Procurement to complete the purchasing process. **ProCards cannot be used to make controlled substances purchases.*
6. Procurement shall place the order, and delivery information shall be sent to the Controlled Substances Program administrator and the ordering PI.

Completing a Purchase Requisition:

1. Purchase requests for Schedules I and II must be on a separate purchase request form than Schedules III through V. Controlled substance purchase requests can only include multiple line items if items are either all in Schedules I and II, or all in Schedules III through V.
2. Controlled substances and non-controlled substances shall be ordered separately.
3. All items on one purchase request must be under the same DEA registration.
4. [DEA Form 222](#) needs to be completed for Schedule I and II purchases only.
5. Controlled substances for non-patient purposes cannot be purchased with a medical doctor’s clinical DEA registration.

The [Controlled Substances Purchasing Steps](#) (Short Form), is a quick guide to the purchasing process.

III. RECEIVING

- A. All shipments of controlled substances shall be delivered to the registered address (predetermined to be Distribution Services) established with the DEA. **A note should be included in the address line to contact SR&S for pick-up from Distribution Services.**

- B. Upon receipt, Distribution Services must immediately contact SR&S for pickup. **Distribution Services is advised to secure the package in their DEA approved locked cabinet without opening or disturbing the contents.** This process follows a specific Distribution Services administrative procedure that manages the package from this point.
- C. SR&S staff will arrange a pick-up of the package with Distribution Services, as well as a delivery time with the receiving PI (or their authorized delegate). SR&S will open the package in the presence of Distribution Services staff to verify accuracy of the package contents with the purchase order. If there is a discrepancy or damage to the package or product contained therein, SR&S will notify Procurement and the PI (or their authorized delegate), to arrange for order correction or product return.
- D. SR&S staff will sign for release of the package from Distribution Services into the custody of SR&S staff on both Distribution Services log as well as the SR&S controlled substances distribution form.

IV. DISTRIBUTION

- A. After the controlled substance package is received and logged by SR&S, distribution of the controlled substance package will be made to the requesting PI and/or authorized personnel listed on the CSUA.
- B. The PI or the authorized personnel will open the package in the presence of SR&S staff to determine its contents for accuracy, and sign the distribution form acknowledging receipt of the package and its confirmed contents.
- C. The PI or authorized personnel must immediately place the controlled substance in their DEA approved locked cabinet, thus assuming responsibility for storage and use in accordance with applicable regulations.

The [Controlled Substances Distribution Steps](#) (Short Form), is a quick guide to the purchasing process.

V. STORAGE

1. Each Principal Investigator shall have an appropriate locked storage and control measures as required by the DEA and pre-approved by SR&S. The methods for storing controlled substance shall be as follows:
 - A. Storage unit shall be secure enough to show forced entry.
 - B. Storage unit shall be bolted or cemented in place.
 - C. Storage unit shall be equipped with a padlock, pin-tumbler, or combination lock.
 - D. 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.
 - E. Hinges shall be installed so as to prevent access to mounting screws or bolts when the door is closed.
 - F. The combination or key shall at all times remain in the physical custody of the PI and the individual(s) listed by the PI on the approved CSUA as “Authorized Personnel”.
 - G. Storage unit shall contain only controlled substances and corresponding use logs. No other chemicals or supplies shall be store in the controlled substances storage area.

VI. DOCUMENTATION

- A. Controlled Substances [Use Logs](#) for Schedules I and II must be filed separately than those for Schedules III – V.
- B. The Controlled Substances [Use Log form](#) shall be kept in accordance with DEA regulations and SR&S standards. Controlled Substances Use Logs 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.
- C. All controlled substance dispensations from its original container shall be recorded on the Controlled Substance Use Log provided by SR&S.
- D. The actual amount of controlled substances remaining in the drawer must equal the documented remaining amount in the logbook at all times.
- E. Any breakage of containers shall be noted on the corresponding Controlled Substance Use Log, initialed by the individual responsible for the breakage, and co-signed by the Principal Investigator. A copy of this Controlled Substance Use Log shall then be forwarded to SR&S for inventory management and review.
- F. Receipts of controlled substances shall be noted on the Controlled Substance Use Log. Purchase order number and supplier name shall be shown.
- G. Departmental copies of Controlled Substance Purchase Requisition forms, Use Logs, and disposal documents shall be maintained by the Principal Investigator in the controlled substance lock-up and shall be made available upon request.

VII. SECURITY AND CONTROL

- A. Controlled substances shall not be transferred from the original containers for storage and/or inventory purposes.
- B. 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.
- C. 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 Administrator is responsible for notifying the DEA Regional Office and the University Police Department.
- D. Department Chairs are responsible for notifying SR&S prior to Principal Investigator arrival on campus with controlled substances. The Controlled Substances Program Administrator shall then contact the DEA to determine the appropriate action. A CSUA application shall be submitted as necessary. Additionally, the Department Chair must notify SR&S when a Principal Investigator authorized to experiment with controlled substances is deceased or intends to terminate employment. Controlled substances in possession at that time will be returned to SR&S for disposal.
- E. Controlled substances shall not be transferred, shipped, or removed from the registration location except for in cases of disposal, returned to supplier, or by prior agreement with the Controlled Substances Program Administrator and the DEA.

VIII. INVENTORY

- A. Upon notification by and under directions from SR&S, it is the responsibility of each Department Chair and Principal Investigator to conduct an inventory of all controlled substances.

- B. SR&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.

Biennial Inventory

The University and the DEA require an inventory be conducted and documented every 2 years. PI's must declare their inventory status even if there is zero controlled substances in stock when biennial inventory is taken.

- a) A Biennial Inventory shall be conducted utilizing the [Biennial Inventory form](#). Once complete, this form shall be submitted to SR&S for review and shall be placed in the PI's file. The PI shall keep the original copy of the form in their controlled substances lock-up.
- b) Instructions on how to conduct a Biennial Inventory are provided on the [Biennial Inventory form](#).
- c) SR&S will notify the PI by email with a specific date and instructions in advance when the biennial inventory is due. NOTE: If the biennial inventory is not received after three attempts, the CSUA can be suspended and Procurement can be notified to prevent future orders for controlled substances.

IX. DISPOSAL

To make arrangements for disposal of controlled substances in any manner other than the dispensation or use for which they were procured, contact SR&S. SR&S will receive the substances for disposal by making arrangements for pick-up with the PI and completing a Chain of Custody form. SR&S will indicate on the respective Controlled Substances Use Log that the substance has been received for disposal, and issue a copy of the Chain of Custody form to the laboratory as a receipt. SR&S will hold the substance(s), pending disposal by the DEA-approved reverse distributor vendor. The respective Controlled Substances Use Logs must be retained for a minimum of three (3) years by the PI and a copy is to be sent to SR&S. 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 Use Logs shall be sent to the Controlled Substances Program administrator 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 Use Logs, must be maintained in the department or forwarded to SR&S for record retention and shall be destroyed three (3) years after date of controlled substance disposal.

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Prepared by: Regina Frasca, Chemical Hygiene Officer

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Prepared by: Regina Frasca
Associate Director, SR&S

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Prepared by: Regina Frasca
Associate Director, SR&S

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Prepared by: Regina Frasca
Director, SR&S

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