

# CALTECH PROCEDURE REGARDING CONTROLLED SUBSTANCES



## **INTRODUCTION**

It is the policy of the California Institute of Technology to comply fully with all applicable laws and regulations concerning the registration, procurement, inventory, storage, record keeping, use, and disposal of controlled substances. Caltech has two Institute licenses from the Drug Enforcement Administration (DEA), which are each managed by a Central Controlled Substances Custodian (CCSC). The Caltech Veterinarian holds a Practitioners license.

Members of the Caltech community requiring use of controlled substances for research must comply with all applicable laws and regulations. Principal Investigators, staff, students, and authorized visiting researchers (Caltech Authorized Researcher) who require access to controlled substances for research must be knowledgeable about and follow all applicable procedures before they will be authorized to handle controlled substances.

Failure to comply with laws or procedures may result in the loss of privileges to use controlled substances in research, or in disciplinary action up to and including separation from the Institute. Penalties for violations of applicable laws and regulations may result in the imposition of heavy fines, imprisonment of those responsible, and in the rescission of Caltech's registration and a loss of use for the Principal Investigator (PI).

## **Controlled Substances**

Controlled substances, as used in this document, are those drugs and other substances included in Schedules II – V of the Controlled Substances Act, 21 U.S.C. sec. 801 et seq., and those listed under California Health and Safety Code sections 11054 to 11058 (including California Schedule III hormones as defined in section 11056). It is the responsibility of each Principal Investigator (PI) and any Caltech Authorized Researcher who detects a theft, loss, or unexplained disappearance of controlled substances to immediately notify the CCSC, the Security and Parking Services Office (Security), and the Institute Point of Contact (POC) of that theft, loss, or unexplained disappearance.

Caltech does not have a license to use Schedule I controlled substances. If your research requires the use of a Schedule I controlled substance, please contact the Director of Research Compliance.

References linking to the appropriate schedules have been included at the end of this document.

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## **RESPONSIBILITIES**

### **Division Chair**

The Division Chair is responsible for approving each PI's use of a controlled substance, and will indicate approval in the Controlled Substances Authorization Form ([Attachment A](#)).

If a protocol is not within the scope of IACUC approval, a Divisional Approval Form ([Attachment A-1](#)) shall be completed and approved by the Division Chair and submitted with the Controlled Substances Authorization Form.

The Division Chair is also responsible for ensuring that each PI maintains (1) a complete and accurate inventory of all controlled substances in their lab, and (2) a list of those individuals within their labs authorized to handle controlled substances.

### **Principal Investigator**

PIs who require the use of controlled substances in their research shall submit a Controlled Substances Authorization Form ([Attachment A](#)) for each instance of a controlled substance to the designated CCSC after approval from their Division Chair. Each PI will:

1. Identify by name all persons in their lab who are authorized to handle controlled substances and provide those names to the CCSC.
2. Require each Caltech Authorized Researcher needing to fill out the Controlled Substances Authorized Personnel Registration Form ([Attachment B](#)).
3. Designate, by name, one person to be the Lab Controlled Substance Custodian (LCSC) who is authorized by the PI to request the purchase of controlled substances, and who will receive controlled substances. An alternate person may be named to request and receive controlled substances in the event that the designated LCSC is unavailable.
4. Update the list of Caltech Authorized Researchers given to the designated Central Controlled Substances Custodian as personnel change on a semi-annual basis.
5. Ensure a Log Book is maintained for all controlled substances used in the lab, with a separate log book for Schedule II substances, and another log book for Schedule III-V substances ([Attachment C](#)).
6. Ensure that periodic self-inspections are conducted no less than twice a year, using the Controlled Substances Self-Inspection checklist form ([Attachment E](#)) and keep custody of all inspection checklists in the lab.
7. Ensure that all storage and security requirements are met.
8. Immediately notify the designated CCSC, the POC, and Security immediately of any theft, loss or unexplained disappearance of controlled substances.

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## **Central Controlled Substances Custodian**

Caltech's controlled substances program is managed by two CCSCs. The CCSCs are administratively responsible for overall coordination of these procedures and have the following responsibilities for the labs designated under the DEA license they manage:

1. Maintain the list of Controlled Substances Authorization Forms for the designated under their license that have been approved by the respective Division Chair or IACUC as indicated in [Attachment A](#).
2. Maintain completed Attachment B forms.
3. Approve procurement and distribution of controlled substance used in research;
4. Perform periodic compliance inspections;
5. Coordinate the biennial campus-wide inventories;
6. Provide for appropriate disposal of controlled substances;
7. Approve all storage locations and procedures;
8. Report any theft, loss or unexplained disappearance of controlled substances of which the CCSC is aware to Security and the POC.
9. Maintain hard copies or readily retrievable electronic copies of initial inventory, biennial inventory, DEA 222 Forms, and Certificates of Destruction (DEA Form 41 equivalent) as well as the electronic procurement Controlled Substances Tracking System.

## **Institute Point of Contact**

The Director of Research Compliance is the formal POC to the DEA. As such, the POC will be the primary interface with the DEA on all Institute matters in relation to the DEA, including:

1. Initiating and maintaining the Institute Licenses, and performing revisions for the license.
2. Requesting the DEA 222 forms on behalf of the Institute.
3. Completing and filing the DEA 106 forms in the event of a verified diversion event.

## **Security**

Security is responsible for investigating any suspected theft, loss or unexplained disappearance of controlled substances.

## **Human Resources**

Human Resources is responsible for providing security background checks and clearances to all Caltech Authorized Researchers who will be utilizing controlled substances in their research.

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## **PROCEDURES**

### **Registration and Purchase**

Authority to utilize controlled substances in research shall be in accordance with Caltech's DEA licenses.

A record of all PIs authorized to use controlled substances in research shall be maintained by the CCSC, with a copy provided to the Division on request. Division Offices must notify the CCSC if PI authorizations are revoked. Such notification will prompt the CCSC to take action to secure any inventory of controlled substances related to the revoked authorization.

### **Off-Campus Sites**

If any research activities will require the use of controlled substances at a geographic site other than the Caltech campus in Pasadena, CA, a separate DEA License will be required for that geographic site. The CCSC or the POC may be contacted for further information.

### **Requesting Controlled Substances**

Prior to requesting the purchase of controlled substances, the PI must submit the Controlled Substances Authorization Form ([Attachment A](#)) to the CCSC which (1) describes the purpose of the research, (2) identifies the specific storage location and the key lockbox location for the controlled substances which has been approved by the CCSC, and (3) provides that all individuals in the lab who will have access to controlled substances have submitted a Controlled Substances Authorized Personnel Registration Form.

Purchase orders for controlled substances must follow a specific submittal procedure in Techmart by the PI or their designated LCSC.

Specified controlled substances require the PI to obtain a prescription. Please contact the veterinarian to request a prescription.

### **Caltech Authorized Researchers**

Potential Caltech Authorized Researchers must complete a Controlled Substances Authorized Personnel Registration Form ([Attachment B](#)) signed by both the applicant for the Authorized Person and the PI. All personnel, when approved to handle controlled substances, must be cleared by Human Resources, and trained by the CCSC before beginning any work with controlled substances.

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### **Delivery**

Vendors will ship controlled substances to the CCSC. The CCSC will arrange for the LCSC to receive the controlled substance in the lab. The CCSC will issue a Unified Distribution, Transfer, and Disposal Form (UDTD, [Attachment D](#)) that will be associated to the container of the controlled substance.

This document will accompany the controlled substance and its container for the life of the material, and activities, including transfers and final disposal of Controlled Substances, will require this form.

Upon distribution of the controlled substance container, the form will be signed by the authorized LCSC. A copy of the form will be returned to the designated CCSC for recordkeeping.

### **Security & Storage**

Each PI with controlled substances must provide effective controls and procedures to guard against diversion. This includes having adequate security for storage and control as inspected and approved by the designated CCSC in accordance with the following standards:

1. Controlled substances must be stored in a safe or in a securely-locked, substantially constructed cabinet.
2. Access to controlled substances must be limited to the minimum number Caltech Authorized Researchers necessary.
3. The keys to the safe or cabinet should be stored in a separate locked location.

If a researcher must reconstitute and aliquot or aliquot a controlled substance for storage and future use, each aliquot must be labeled with the name and control number (from the UDTD) for the controlled substance, the concentration, and the date of expiration. Each aliquot recorded and tracked in the appropriate Log Book as UDTD-1, UDTD-2, etc.

If dilution is required, the new container must be labeled with the name and control number for the controlled substance, the concentration and the date of expiration. The initial stock removed from the primary container must be documented in the Log Book.

### **Logbooks/Recordkeeping**

Each Principal Investigator using controlled substances in research must ensure that the current Log Book(s) of all controlled substances are maintained in their lab. All Schedule II materials must have their own separate logbook from Schedule III-V controlled substances. All Schedule III-V materials can be in the same logbook.

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The log book must use the Controlled Substances Inventory Logbook template ([Attachment C](#)). Log Books shall be readily available and retrievable for audit by the CCSC, Caltech Audit Services and Institute Compliance and the DEA. All inventory records will be kept for the duration of the use of controlled substances in the laboratory plus 2 years.

Any discrepancy shall be noted in the Log Book, initialed by the individual user and immediately reported to the CCSC.

All self-inspection reports ([Attachment E](#)) performed on the semi-annual basis should be kept for at least two years from the date that the report was created. Self-inspection reports, when completed, should be kept in a readily accessible area inside the lab.

### **Inventories**

Each PI will ensure the complete and accurate inventory of controlled substances used in their labs.

### **Biennial Inventory**

The DEA requires a biennial inventory that all labs must perform on the same day. On the day designated in advance by the designated CCSC, the LCSC will provide a complete and accurate inventory of all the controlled substances on hand to the designated CCSC. All inventory records will be maintained, and be available for inspection, for at least 2 years from the date the record is created.

Biennial inventory must contain the following information:

1. The name of the substance
2. Each finished form of the substance (e.g. 10-milligram tablet or 10 mg/oz or 10 mg/ml concentration)
3. The number of units or volume of each controlled substance in each commercial container (e.g. 100-tablet bottle or 3-milliliter vial)
4. The number of commercial containers (e.g. four 100-tablet bottles or six 3- milliliter vials)

Controlled substances will not be transferred from the original containers for inventory purposes; comparison with the log books is appropriate. Identifying labels shall not be removed from the original containers.

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### **Transfers**

When one lab wishes to transfer a container of controlled substances to another lab, the LCSC of the transferring lab will contact the designated CCSC to obtain authorization.

If approved, the LCSC of the transferring lab will fill out the appropriate information on the UDTD Document associated with the container of controlled substances and both Laboratory Controlled Substances Custodians will sign the form.

A copy of this form should then be sent to the designated CCSC for recordkeeping.

### **Disposal**

Contact the designated CCSC for disposal of controlled substances. The CCSC shall receive the substance for disposal and the LCSC will indicate in their Log Book that it has been received by CCSC for disposal. Only the LCSC can release material to the CCSC for disposal.

Disposal must be arranged when:

1. When the container is empty after all controlled substances have been used for the intended research work.
2. A project has been closed or terminated and any controlled substances are still in supply.
3. The PI determines that the controlled substances are no longer required.
4. The controlled substance has expired.

The original UDTD will be requested and retrieved from the lab at the time disposal pickup.

### **Attachments:**

- A. [Controlled Substances Authorization Form](#) A-1. [Divisional Approval Form](#)
- B. [Controlled Substances Authorized Personnel Registration Form](#)
- C. [Controlled Substances Inventory Logbook](#)
- D. [Unified Distribution, Transfer, and Disposal Form](#)
- E. [Controlled Substances Self Inspection Form](#)

### **References:**

- A. [DEA Schedules of Controlled Substances](#)
- B. California Schedules of Controlled Substances (California HSC §11054 to 11058)
  1. [HSC Section 11054](#)
  2. [HSC Section 11055](#)
  3. [HSC Section 11056](#) (Includes Schedule III Hormones)
  4. [HSC Section 11057](#)
  5. [HSC Section 11058](#)