

CALTECH PROCEDURE REGARDING CONTROLLED SUBSTANCES

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Abbreviations:

- AP - Authorized Person
- CA-DOJ – California Department of Justice
- CCSC - Central Controlled Substances Custodian
- CS - Controlled Substance
- CST - Controlled Substances Tracking System
- DEA - Drug Enforcement Administration, part of the U.S. Department of Justice
- EHS - Environmental Health and Safety
- IACUC - Institute Animal Care and Use Committee
- IPOC - Institute Point of Contact, Chief Research Policy Officer
- LCSC - Laboratory Controlled Substances Custodian
- OLAR - Office of Laboratory Animal Resources
- ORC - Office of Research Compliance
- PI - Principal Investigator
- SOP - Standard Operating Procedure (See section --- for a detailed list)
- UDTD - Uniform Distribution, Transfer, and Disposal Form

INTRODUCTION

It is the policy of the California Institute of Technology (Caltech) to comply fully with all applicable laws and regulations concerning the registration, procurement, inventory, storage, record keeping, use and disposal of controlled substances. Caltech maintains two (2) DEA Controlled Substances licenses to support research, one in the Office of Laboratory Animal Resources and one on the Environmental Health and Safety Office. The licenses are renewed annually.

Members of the Caltech community requiring use of controlled substances for research must comply with all applicable laws and regulations. Principal investigators, staff, and students who require access to controlled substances for research must be trained to, be knowledgeable about, and be prepared to follow the procedures outlined in this document and provided in all Caltech Controlled Substances Standard Operating Procedures ([CS-SOPs](#)), before being authorized to work with controlled substances.

Failure to comply with these procedures and CS-SOPs may result in the loss of privileges to use controlled substances in research or in disciplinary action, up to and including, separation from Caltech. Penalties for violations of applicable laws and regulations may also 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 and/or all of Caltech.

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

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Investigator (PI), Caltech employee, and student who detects a theft, loss, or unexplained disappearance of controlled substances to immediately notify (1) the Central Controlled Substances Custodian and (2) the Institute Point of Contact (IPOC) of that theft, loss, or unexplained disappearance.

Reference websites linking to the appropriate controlled substance schedules have been appended to this document.

RESPONSIBILITIES**Division Chair**

The Division Chair is responsible for approving all use of controlled substances by faculty and staff within the Division, and will indicate approval in the Controlled Substances Authorization Form ([Attachment A](#)). Approval will be either for animal use or other research.

Use of controlled substances in animal research must be approved in an Institute Animal Care and Use Committee (IACUC) approved protocol. If use of controlled substances is not within the scope of IACUC approval (i.e. use in non-vertebrate animals, cells, plants, or in vitro), a Divisional Approval Form ([Attachment A-1](#)) shall be completed and approved by the Division Chair and submitted with the Controlled Substances Authorization Form to the Central Controlled Substances Custodian (CCSC) for EHS.

The Division Chair is also responsible for ensuring that each PI authorized to use controlled substances 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 (PI)

PIs who require the use of controlled substances in their research shall submit a Controlled Substances Authorization Form ([Attachment A](#)) to the appropriate CCSC to establish a controlled substance program in their laboratory. Attachment A should be signed by the PI and approved and signed by the Division Chair prior to submission. PIs should contact the IPOC to determine which of Caltech's two licenses is appropriate. Each PI will:

1. Provide the name of each person in their lab who will be authorized to handle controlled substances (Authorized Personnel) to the CCSC. A list of such Authorized Personnel must be maintained in the laboratory and updates/changes conveyed to the CCSC in a timely manner, but not less than semi-annually.
2. Require Authorized Personnel to complete the Controlled Substances Authorized Personnel Registration Form ([Attachment B](#)). Each Authorized Personnel must pass a required background check.
3. Complete PI training provided by the IPOC.

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4. Require all Authorized Personnel to complete controlled substances training. (CS-SOP 2, “Training Authorized Users of Controlled Substances”)
5. 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. If no LCSC is designated, the PI is responsible for purchase and receipt.
6. Ensure that Logbook(s) are maintained for all controlled substances used in the lab. Schedule II substances must be tracked in a single Logbook and Schedule III-V substances ([Attachment C](#)) can be tracked together in a single Logbook. All Logbooks must be kept in the laboratory as long as a lockbox is maintained in the lab, regardless of whether or not there are controlled substances are present in the lab.
7. Ensure that all controlled substances present in the laboratory have a corresponding UDTD form, which is readily accessible in the lab.
8. Ensure that periodic self-inspections are conducted no less than twice a year, completing the Controlled Substances Self-Inspection checklist form ([Attachment E](#)), even when there are no controlled substances in the lab. Current self-inspection documentation must be kept in the laboratory for the current and past 2 years, as long as a lockbox is maintained in the lab, regardless of whether or not controlled substances are present in the lockbox.
9. Ensure that all storage and security requirements are met. All lockbox locations and key storage must be approved by the CCSC.
10. Notify the CCSC and the IPOC immediately of any theft, loss, or unexplained disappearance of controlled substances. An investigation will be organized including the IPOC, the relevant CCSC, and, as necessary, an individual from Caltech Security.
11. Notify the CCSC and the IPOC as soon as practicable regarding a discrepancy in inventory, as this could possibly be evidence of a diversion. An investigation will be organized including the IPOC, the relevant CCSC, and, as necessary, an individual from Caltech Security.

Central Controlled Substances Custodian (CCSC)

Caltech’s controlled substances program is managed by the Central Controlled Substances Custodian (CCSC). The CCSC is administratively responsible for overall coordination of these procedures and has the following responsibilities:

1. Follows CS-SOPs and participates in annual review and revision of the CS-SOPs with the IPOC.
2. Maintains the Controlled Substances Authorization Forms that have been approved by the respective Division Chair or IACUC ([Attachments A](#) and [A-1](#)).

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3. Maintains a copy of completed Authorized Personnel Registrations ([Attachment B](#)).
4. Approves all storage locations.
5. Approves procurement and distribution of controlled substances used in research.
6. Is responsible for executing DEA 222 order forms and delivering controlled substances to the laboratories.
7. Performs and documents periodic compliance inspections, at least semi-annually.
8. Works with the Office of Research Compliance to coordinate biennial campus-wide inventories with the laboratories.
9. Responsible for: the removal of unused or expired controlled substances from the laboratories; documentation, maintenance and storage of the waste-controlled substances inventory; arranging for and execution of removal of waste controlled substances inventory from Caltech.
10. Reports any theft, loss or unexplained disappearance of controlled substances of which the CCSC is aware to Caltech Security and the IPOC.
11. Maintains hard copies or readily retrievable electronic copies of initial inventory, biennial inventory, DEA 222 forms, DEA Forms 41, disposal inventory and certificates of destruction.
12. Maintains the electronic CS Tracking System, including changes/updates to the DEA or California controlled substances list.

Institute Point of Contact

The Chief Research Policy Officer is the formal Institute Point of Contact (IPOC) to the DEA. As such, the IPOC will be the primary interface with the DEA on all Institute matters in relation to the DEA, including:

1. Initiates and maintains the Caltech Licenses, and performs revisions of the licensure, as necessary.
2. Requests the DEA 222 forms on behalf of the Institute.
3. Completes and files the DEA 106 forms, “Report of Theft or Loss of Controlled Substances,” in the event of a verified loss, theft, or diversion.
4. Serves as the institute point of contact in the event of a DEA inspection.
5. Reviews the CS-SOPs and this procedure on an annual basis and amends, as necessary.

Caltech Campus Security

Caltech Campus Security is responsible for assisting in the investigation of any suspected loss, theft, or unexplained disappearance of controlled substances.

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Human Resources

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

PROCEDURES

Registration and Purchase

Authority to utilize controlled substances in research and/or teaching activities 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 Division, with a copy provided to and maintained by the CCSC. Division Offices must notify the CCSC if PI authorizations for in vitro uses of controlled substances are revoked. The CS Tracking System will flag purchases of controlled substances intended for use in vertebrate animals that do not have an IACUC approval. Such notification will prompt the CCSC to take action to immediately secure any inventory of controlled substances related to the revoked authorization.

Off-Campus Sites

If any research and/or teaching activities that require the use of controlled substances take place at a geographic site other than the Caltech campus in Pasadena, CA, a separate registration shall be obtained for that geographic site. The CCSC or the IPOC may be contacted for further information.

Requesting Controlled Substances

Prior to requesting the purchase of controlled substances and participation in this program, the PI must submit a Division approved Controlled Substances Authorization Form ([Attachment A](#)) to the CCSC which (1) describes the purpose of the research, (2) certifies that the specific storage location and the key lockbox location for the controlled substances has been approved by the CCSC, and (3) certifies that all individuals in the lab who will have access to controlled substances have submitted a Controlled Substances Authorized Personnel Registration Form. The CCSC will proceed to follow CS-SOP 1, "Commissioning a Lockbox."

Once the lab is fully commissioned and personnel are trained as participants in the controlled substances program, the PI or their designated Laboratory Controlled Substances Custodian (LCSC) may submit purchase orders for controlled substances in Techmart, taking care to follow specific procedures.

Authorized Personnel

Each faculty member, staff member, and student who requires use of Controlled Substances in any form or concentration must be authorized pursuant to these procedures. Authorized

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personnel must complete a Controlled Substances Authorized Personnel Registration Form ([Attachment B](#)) which must be signed by both the applicant (Authorized Person) and the PI. All Authorized Personnel must undergo a background check, be cleared by Human Resources, and trained by the CCSC and/or the IPOC (PIs) before ordering or beginning any work with controlled substances. This form will be kept by the CCSC.

Delivery

All vendors must ship controlled substances to the CCSC, who will arrange receipt with the requesting LCSC. The CCSC will issue a Unified Distribution, Transfer, and Disposal (UDTD) Form ([Attachment D](#)) that will be associated with the container of the controlled substance via a Control Number.

Upon receipt of the controlled substance in the laboratory, the UDTD will be signed by the authorized LCSC and copy of the UDTD will be returned to the CCSC for recordkeeping. The UDTD shall accompany the controlled substance and its container for the life of the material, including through transfers and the final disposal of controlled substance. With each transfer of the controlled substance, the UDTD shall be updated.

Security & Storage

Each laboratory with controlled substances must maintain effective controls and procedures to guard against diversion. The lockbox and key storage and security must be approved by the CCSC. Effective controls must meet 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 Authorized Personnel necessary.

Unless dilution is required, controlled substances shall not be transferred from the original container for storage purposes, nor shall the labels identifying the substances be removed. If dilution is required, the new container must be labeled with the name and control number for the controlled substance, the concentration, volume and the date of expiration.

Logbooks/Inspections/Recordkeeping

Each PI using controlled substances in research must ensure that the current Logbook(s) of all controlled substances are maintained in his or her lab. All Schedule II materials must have their own Logbook, separate from Schedule III-V controlled substances. All Schedule III-V materials can be in the same Logbook.

The Logbook must conform to the Controlled Substances Inventory Logbook template ([Attachment C](#)). Logbooks shall be readily available and retrievable for audit by the Central Controlled Substance Custodian, Caltech Audit Services and Institute Compliance, and the DEA. All inventory records will be kept for the duration of the use of CS in the laboratory plus 2 years.

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Any discrepancy shall be noted in the Logbook, initialed by the individual user and immediately reported to the Central Controlled Substance Custodian.

All self-inspection reports ([Attachment E](#)) performed on a 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. (CS-SOP 6, “Semiannual Controlled Substances Inspections”).

All records, including Logbooks and inventory records must be maintained in the laboratory, and be readily accessible, as long as the laboratory has a lockbox, even if the lockbox has no controlled substances in inventory.

Inventories

Each PI will ensure the complete and accurate inventory of controlled substances used in his or her lab.

Biennial Inventory

The DEA requires that a campus-wide biennial inventory be conducted for each license. All labs under that license must perform the inventory on the same day, and the individual lab inventories must be combined into a single license inventory. On the day designated in advance by the CCSC, the LCSC will provide a complete and accurate inventory of all the controlled substances on hand to the CCSC. All inventory records will be maintained, and be available for inspection, for at least 3 years from the date the record is created.

For each substance in a lab lockbox, the biennial inventory must contain the following information:

- Name of the Controlled Substance,
- CS Schedule (e.g. I-V),
- Caltech Control Number,
- Container Type (e.g. 5g bottle, 1ml bottle),
- Form (e.g. liquid, powder, tablet),
- Units of Measure (e.g. mg, mg/ml, 10 mg tablet),
- Weight/Volume in Container (e.g. 1mg, 2ml, 2tablets),
- Current Status (e.g. in lab, empty, etc.), indicate whether the Logbook entry is consistent, and any comments.

Controlled substances will not be transferred from the original containers for inventory purposes (i.e. to weigh contents or measure volume). Rather, visual comparison of the container contents with the Logbook entry is appropriate. Identifying labels shall not be removed from the original containers.

See CS SOP-8, “Biennial Inventory”

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

If approved, the LCSC from the Transferring Lab will complete the appropriate information on the UDTD associated with the container of controlled substances and both LCSCs will sign the form.

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

Disposal

The LCSC should contact the CCSC for disposal of controlled substances. The CCSC shall receive the substance for disposal and the LCSC will indicate in the appropriate laboratory Logbook that the controlled substance has been transferred to CCSC for disposal. Only the LCSC can release material to the CCSC for disposal.

Disposal should be arranged when:

1. The controlled substances 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 completed and the CCSC will remove the UDTD along with the controlled substance from the lab at the time of disposal pickup.

See:

CS-SOP 3, "Receipt of Controlled Substances for Disposal"

CS-SOP 4, "Removal of Controlled Substances from Caltech"

Decommissioning a Lockbox/Key Lockbox

The LCSC or PI should contact the CCSC to request decommissioning. At the time of decommissioning, the LCSC and CCSC shall perform an inventory, document all remaining controlled substances, and update all remaining UDTDs. The CCSC shall remove all remaining controlled substances in accordance with CS-SOP 5, "Decommissioning a Lockbox," and take custody of all lab documentation. The CCSC shall arrange for facilities personnel to remove the lockbox and key lockbox.

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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](#)

Caltech Controlled Substances Standard Operating Procedures (CS-SOP):

- 1. [CS-SOP 1 COMMISSIONING A LOCKBOX](#)
- 2. [CS-SOP 2 TRAINING AUTHORIZED USERS OF CONTROLLED SUBSTANCES](#)
- 3. [CS-SOP 3 RECEIPT OF CONTROLLED SUBSTANCES FOR DISPOSAL](#)
- 4. [CS-SOP 4 REMOVAL OF CONTROLLED SUBSTANCES FROM CALTECH](#)
- 5. [CS-SOP 5 DECOMMISSIONING A LOCKBOX](#)
- 6. [CS-SOP 6 SEMIANNUAL CONTROLLED SUBSTANCES INSPECTIONS](#)
- 7. [CS-SOP 7 DEA 222 FORMS MANAGEMENT AND USE](#)
- 8. [CS-SOP 8 BIENNIAL INVENTORY](#)
- 9. [CS-SOP 9 DEA LICENSE RENEWAL AND ORDERING DEA 222 FORMS](#)