

**CALTECH PROCEDURE REGARDING CONTROLLED SUBSTANCES
(INCLUDES PROCEDURES ON CHEMICAL PRECURSORS, CA 11107.1
CHEMICALS AND REGULATED LABORATORY ITEMS)**

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.

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 knowledgeable about and follow these procedures, and follow all applicable procedures, before they will be authorized to handle controlled substances.

Failure to comply with these 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.

Controlled Substances

Controlled substances, as used in this document, are those drugs and other substances included in Schedules I – V of the Controlled Substances Act, 21 U.S.C. sec. 801 et seq., listed under [21 CFR sections 1308.11 to 1308.15](#), and those drugs and other substances included in Schedules I – V of the California Health and Safety Code and 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) or any Institute employee who detects a theft, loss, or unexplained disappearance of controlled substances to immediately notify the Central Controlled Substances Custodian, the Security and Parking Services Office (Security) and the Institute Point of Contact of that theft, loss, or unexplained disappearance.

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

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](#)).

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If a protocol is not within the scope of IACUC approval (i.e. non-vertebrate, cells, plants, or non-biologicals), 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 (PI)

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 Central Controlled Substances Custodian (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 Central Controlled Substances Custodian.
2. Require each authorized lab person 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 who is authorized by the PI to request the purchase of controlled substances, and who will receive controlled substances.
4. Update the list of names given to the 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 Central Controlled Substances Custodian, the Institute Point of Contact, and the Security Services Office immediately of any theft, loss or unexplained disappearance of controlled substances.
9. As soon as practicable, notify the Institute Point of Contact and Central Controlled Substances Custodian of an intent to use a [Schedule I](#) substance in research.

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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. Maintains the list of Controlled Substances Authorization Forms that have been approved by the respective Division Chair or IACUC as indicated in [Attachment A](#).
2. Maintains completed Attachment B forms.
3. Approves procurement and distribution of controlled substance used in research;
4. Performs periodic compliance inspections;
5. Coordinates the biennial campus-wide inventories;
6. Provides for appropriate disposal of controlled substances;
7. Approves all storage locations and procedures;
8. Reports any theft, loss or unexplained disappearance of controlled substances of which the CCSC is aware to Security and the Institute Point of Contact.
9. Maintains hard copies or readily retrievable electronic copies of initial inventory, biennial inventory, DEA222 forms and DEA Forms 41 as well as the electronic CS Tracking System.

Institute Point of Contact

The Director of Research Compliance is the formal Institute Point of Contact (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. Initiates and maintains the Institute License, and performing revisions for the license.
2. Requests the DEA 222 forms on behalf of the Institute.
3. Completes and files 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 Authorized Personnel who will be utilizing Controlled Substances in their research.

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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 the CCSC. 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 and/or teaching activities require the use of controlled substances are 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 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) that the specific storage location and the key lockbox location for the controlled substances has been approved by the CCSC, and (3) 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 Laboratory Controlled Substances Custodian (LCSC).

Schedule I Substances: Caltech does not hold a registration for Schedule I substances. A registration to use Schedule I substances in research requires permission both from the State of California and the DEA. Such permissions are only issued on a project-by-project basis. If possible, PIs should limit research use to drugs from Schedules II-V. If a PI desires or has a requirement to use a Schedule I substance in research at Caltech, then he or she shall contact the Institute Point of Contact and their Central Controlled Substances Custodian as soon as possible so that they may assist in the process of obtaining a registration.

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Authorized Personnel

All faculty, staff and students who are assigned to research that have authorized use of Controlled Substances 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 trained and cleared by Human Resources before beginning any work with controlled substances.

Delivery

Vendors must ship controlled substances to the CCSC, who will arrange for the lab to obtain the controlled substance with the requesting LCSC. The Central Controlled Substances Custodian will issue a Unified Distribution, Transfer, and Disposal Form ([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 CCSC for recordkeeping.

Security & Storage

Each laboratory 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 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 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 and the date of expiration.

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 his or her 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 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.

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

All self-inspection reports ([Attachment E](#)) performed on the semi-annual basis shall 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 Principal Investigator 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 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 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 CCSC to obtain authorization.

If approved, the LCSC of the Transferring Lab will fill out the appropriate information on the Unified Distribution, Transfer and Disposal 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 CCSC for recordkeeping.

Disposal

Contact the 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 Principal Investigator determines that the controlled substances are no longer required.
4. The controlled substance has expired.

The original Unified Distribution, Transfer, and Disposal Document 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](#)

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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](#)

CHEMICAL PRECURSORS, CA 11107.1 (a) CHEMICALS AND LABORATORY ITEMS

INTRODUCTION

Members of the Caltech community requiring use of chemical precursors and CA Health and Safety Code 11107.1 (a) Chemicals for research must comply with all applicable laws and regulations, as well as Caltech's policies and procedures. Principal Investigators, staff and students who use these chemicals for research must be knowledgeable about and follow all applicable procedures, before ordering or using them.

Failure to comply with these procedures may result in the loss of privileges to use these chemicals in research and/or discipline up to and including separation from the Institute. Violations of applicable law and regulations may result in penalties including but not limited to the imposition of fines and/or penalties.

Chemical Precursors

Chemical precursors are chemicals used in the course of legitimate research that can potentially be used in the manufacture of controlled substances, such as methamphetamine, cocaine, heroin and MDMA (ecstasy). Chemical precursors, as used in this document, are those regulated by the State of California Department of Justice, Office of the Attorney General (CA-DOJ) and the Drug Enforcement Administration (DEA). The substances considered by CA-DOJ and DEA to be chemical precursors can be found at these weblinks: [DEA Lists I and II](#) and [California Precursor Chemicals](#), respectively. Chemical precursors may not be purchased by anyone under the age of 18.

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CA 11107.1 (a) Chemicals

California Health and Safety Code 11107.1(a) lists chemicals that can be used to facilitate the manufacture of controlled substances.

Responsibilities

Principal Investigators – Principal Investigators (PIs) who require the use of chemical precursors or 11107.1 (a) chemicals in their research are responsible for ensuring the proper procurement, storage, use, and disposal of these chemicals. PIs are also responsible for ensuring that their lab personnel understand and comply with required procedures for purchasing, storage, use, and disposal of these chemicals.

Lab personnel -- Lab personnel using chemical precursors or 11107.1 (a) chemicals in their research are responsible for properly storing, using, and disposing of these chemicals.

Environment, Health and Safety Office (EHS) – EHS coordinates with the Office of Research Compliance for reviewing and updating this program as needed. EHS provides training and technical assistance to Division Administrators, faculty and staff on implementation of this program, monitoring chemical precursors and 11107.1 (a) chemical purchases, as required, managing disposal of unused or expired chemical precursors consistent with the Caltech Chemical Hygiene Plan, and assisting Division Administrators, faculty and staff in identifying, evaluating and updating processes as needed.

Office of Research Compliance – Maintains DEA license(s), coordinates with EHS regarding all aspects of this program, and, together with Security, is responsible for investigating any theft or loss of chemical precursors or 11107.1 (a) chemicals, as necessary.

Security – Security, together with the Office of Research Compliance, is responsible for investigating any suspected theft or loss of chemical precursors or 11107.1 chemicals, as necessary.

Procedures

Purchasing of Chemical Precursors and 11107.1 (a) Chemicals

Chemical precursors must be ordered from vendors within the state of California. A minimum 21 day processing period may be required for such purchases to be completed.

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All chemical precursors ordered from campus, including the VWR stockroom, must be purchased through the Division of Chemistry and Chemical Engineering (CCE). Contact the EHS Central Controlled Substances Custodian at x 6727 or the CCE Purchasing Assistant at x6033 for more information. All purchasers will be asked to complete a Caltech Report of Sale or Transfer of Controlled Chemical Substance within California Form ([Attachment F](#)). Please contact the Central Controlled Substance Custodian at x 6727 if you receive a different Declaration Form, Management Approval Form, or another form entitled, "Report of Sale or Transfer of Controlled Substance within California" from a vendor. When you retrieve the chemical precursor, you will be asked to provide appropriate identification and sign a document.

All 11107.1(a) chemicals ordered from campus, including the VWR stockroom should be purchased through CCE or through TechMart.

Manufacturing of Controlled Substances

If any research or other use of chemical precursors or 11107.1 (a) chemicals, incidentally or by design, generates one or more [controlled substances](#), please contact the Central Controlled Substances Custodian (CCSC) at x 6727 immediately. If controlled substances are generated, the [Controlled Substances Procedure](#), above, must be followed.

Storage & Security

Storage of chemical precursors and 11107.1(a) chemicals must follow Caltech's chemical storage requirements for the hazard class of the chemical (e.g., flammable, toxic). Also, labs must provide effective controls and procedures to guard against theft or loss of chemical precursors.

Theft or Loss

Theft or loss of any chemical precursors or 11107.1 chemicals must be reported immediately to Security and/or the Office of Research Compliance.

Recordkeeping

The CCE Purchasing Assistant will keep copies of all Caltech Report of Sale or Transfer of Controlled Chemical Substance within California Forms for three years.

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A report will be run, periodically, but not less than every two years at the time of the Controlled biennial inventory. This report will be kept on file and will include a list of 11107.1(a) chemicals purchased in the last three years by Caltech, as well as date of purchase, description and quantity of the item purchased, the name of the vendor, date of purchase, cost and invoice number.

Disposal

Contact EHS for disposal of any unused and/or expired chemical precursors or 11107.1 chemicals.

Sale of Laboratory Items

As part of the CA-DOJ effort to prevent diversion of chemical precursors, there are specific requirements associated with the sale of any laboratory glassware or apparatus, any chemical reagent or solvent, or combination thereof, where the value of the goods sold (per sale) exceeds \$100. Therefore, no sales (or transfer) of these items may be made without notifying and seeking the assistance of your Division Administrator and the Central Controlled Substance Custodian at x6727.

Attachments:

- F. Caltech Report of Sale or Transfer of Controlled Chemical Substance within California Form

References:

- A. [DEA Lists I and II Chemical Precursors](#)
- B. [California Chemical Precursors](#)
- C. [California Health and Safety Code 11107.1\(a\) List Chemicals](#)