

Policy on Controlled Substances and Chemical Precursors

I. POLICY

It is the policy of the California Institute of Technology to comply fully with all applicable federal and state laws and regulations concerning the registration, procurement, inventory, storage, record keeping, use and disposal of controlled substances and chemical precursors.

Members of the Caltech community requiring use of controlled substances and/or chemical precursors for research or teaching must comply with this policy and with all applicable federal and state laws and regulations. Principal investigators, staff, and students who require access to controlled substances and/or chemical precursors for research and/or teaching must be knowledgeable about the requirements of this policy, and follow all applicable procedures, before they will be authorized to handle controlled substances or chemical precursors.

Failure to comply with this policy may result in disciplinary action up to and including separation from the Institute. Penalties for violations of applicable federal and state regulations may result in the imposition of heavy fines, imprisonment of those responsible, and in the rescission of Caltech's registrations.

Controlled Substances and Chemical Precursors

Controlled substances, as used in this policy, are those drugs and other substances included in Schedules II – V of the Controlled Substances Act, 21 U.S.C. sec. 801 et seq. Chemical precursors, as used in this policy, are any substance listed under California Health and Safety Code sec. 11100 et seq.

II. RESPONSIBILITIES

Division Chair

The Division Chair shall be responsible for approving Principal Investigators whose projects involve the use of controlled substances and for appointing the Registrant (see definitions and duties below) to purchase, receive and dispose of controlled substances and chemical precursors. The Division Chair shall be responsible for ensuring that an appropriate inventory of all controlled substances and chemical precursors in the Division is maintained, and that a list is maintained of those individuals authorized to handle controlled substances and/or precursors.

Principal Investigator

Each Principal Investigator who requires the use of controlled substances and/or chemical precursors for laboratory use shall be responsible for determining the need for and signing all authorizations for purchase of controlled substances and chemical precursors in his or her lab. Use of controlled substances by research groups shall be restricted to protocols submitted to IACUC which describe the intended use of the controlled substances and which list the authorized personnel. The Principal Investigator shall maintain a Log Book for all controlled substances used in his or her lab, and shall ensure that an inventory of all controlled substances used in his or her lab is performed quarterly. The Principal Investigator shall also meet all security requirements and shall notify the Division Registrant immediately of any theft, loss or mysterious disappearance of controlled substances or chemical precursors.

Division Registrant

The Division Registrant (currently one in Biology and one in Chemistry) shall be administratively responsible for overall coordination of this policy, and shall have specific responsibility for the purchase, receipt, and delivery of substances to authorized division staff and students, disposal of controlled substances, and for taking a biennial inventory of all controlled substances and chemical precursors in the Division. The Division Registrant shall be responsible for maintaining central storage and pickup areas for incoming shipments of controlled substances and chemical precursors, and for obtaining appropriate signatures of persons authorized to use controlled substances and chemical precursors in conjunction with research and teaching activities. The Division Registrant shall also be responsible for keeping and maintaining acquisition and disposition records of transfers he or she authorizes.

Environmental, Health & Safety (EH&S) Office

The EH&S Office shall be responsible for approving all storage locations and procedures, conducting periodic audits of Log Books, inventory and disposal records, and reviewing handling procedures for controlled substances or chemical precursors.

Security Services Office

The Security Services Office shall be responsible for investigating any suspected diversion of controlled substances and chemical precursors.

III. PROCEDURES CONCERNING CONTROLLED SUBSTANCES

Registration and Purchase

Authority to dispense controlled substances for use in conjunction with research and teaching activities shall be in accordance with a registration requested by the Registrant from the U.S. Department of Justice, Drug Enforcement Administration (DEA).

Each Division using controlled substances shall register with the DEA. The registration shall be obtained by submitting DEA Form 225 (DEA Form 225a for renewal). The Division Chair shall appoint a Division Registrant, who shall be responsible for registering with the DEA. Purchase requests for controlled substances must be made to the Division Registrant, according to the terms of the registration with the DEA. The Division Registrant is the only individual in the Division authorized to purchase controlled substances. Division employees or students other than the Registrant may not place orders directly with vendors by telephone, purchase order, or any other means.

If any research or teaching activity requiring the use of controlled substances is to be conducted at a geographic site other than the Caltech campus in Pasadena, CA, a separate registration shall be required for that geographic site.

If approval of any other federal or state agency is required for the use of any controlled substance, application for such approval shall be filed by the Principal Investigator with evidence of approval submitted to the Division Chair and Division Registrant.

A registration record, listing of all registrants and authorized persons, shall be maintained by the Division Chair, with a copy provided, upon request to the EH&S Office. A copy of the list of all authorized persons shall also be maintained by the Division Registrant.

Campus Authorization Requirements

Before the Division Registrant can honor any purchase request for controlled substances, the Division Registrant must be notified by means of a *Controlled Substances Authorization Form, Exhibit A* that the individual(s) requesting the purchase are authorized to do so. A copy of the completed *Controlled Substances Authorization Form, Exhibit A* must be forwarded to the Division Registrant.

Purchasing Controlled Substances

The *Controlled Substances Authorization Form, Exhibit A*, must be placed on file by the Division Registrant and the specific storage location must be approved by EH&S before orders may be placed via purchase orders submitted by those named on the *Controlled Substances Authorization Form, Exhibit A*. Orders submitted for controlled substances must be signed by the responsible Principal Investigator and the Division Chair, and submitted to the Division Registrant for processing.

All faculty, staff and students who are provided access to and/or handle controlled substances must answer the following questions:

- (1) In the last five years, have you been convicted of a felony, or within the past 2 years, of any misdemeanor, or are you presently formally charged with committing a criminal offense (i.e., not presently out on bail or on your own recognizance pending trial) (not including traffic violations, juvenile offenses, or military convictions, except by general court martial); and
- (2) In the past three years have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed by a physician?

If the answer is "yes" to any of these questions, please furnish details to Gregg Henderson, Chief of Security Operations, Caltech Security Office.

Delivery

All shipments of controlled substances shall be sent to the Division Registrant, who, in turn, shall notify the requestor for pickup. The Division Registrant shall maintain a file that identifies all controlled substances purchased, including (1) a full description of the item purchased, including the name, quantity, size of the package, potency, name of the substance, and if applicable, the Federal Schedule of Controlled Substances to which it is assigned; (2) the date of receipt; (3) the name, address, and registration number of the source from which the controlled substance was received; (4) the reason the controlled substance is distributed, dispensed, or transferred; and (5) the expiration date and lot numbers of the containers received.

To pick up controlled substances, an authorized recipient must identify him or herself as a Caltech employee or student with a current Caltech identification card. As set forth above, authorized recipients shall be designated by each Principal Investigator.

Storage

Each laboratory requesting controlled substances shall have adequate security for storage and control as inspected and approved by EH&S in accordance with the following standards:

- 1) Controlled substances must be stored in a securely locked, substantially constructed, cabinet or safe;
- 2) Access to controlled substances must be limited to the minimum number of people necessary;
- 3) To the extent necessary, an alarm system or electronic detection device may be installed;

Whenever possible controlled substances shall not be transferred from the original container for storage purposes, nor shall the labels identifying the substances be removed.

Log Book/Recordkeeping

Each Principal Investigator using controlled substances in research and/or teaching activities must maintain a current Log Book of all controlled substances. Log Books shall be available for periodic audit by the Division Registrant, EH&S, and/or DEA. The following information must be included in the Log Book for controlled substances:

- (1) Name of substance;
- (2) The date received;
- (3) The date the controlled substance will expire;
- (4) The individual lot number or serial number on bottle/package;
- (5) The number of units or total volume in each commercial container handled (e.g. 5 ml, 10 mg, 10 ampoules x 1 ml);
- (6) The number of units or volume dispensed;
- (7) The date of dispensing, the number of units dispensed, and the name or initials of the individual who dispensed or administered the substance;
- (8) The purpose for which the controlled substance was dispensed.

Any discrepancy shall be noted in the Log Book and initialed by the individual user and co-signed by the Principal Investigator.

Inventory

Each Principal Investigator shall ensure that an inventory of controlled substances used in his or her lab is taken each quarter. In addition, the Division Registrant shall take a complete and accurate inventory of all the controlled substances on hand in the Division at least every two years. All inventory records shall be maintained, and be available for inspection, for at least 2 years from the date the record is created. Inventory records 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 shall not be transferred from the original containers for inventory purposes. Identifying labels shall not be removed from the original containers.

Security

It is the responsibility of each Principal Investigator or anyone who detects a theft, loss, or mysterious disappearance of controlled substances to immediately notify the Division Registrant of that theft, loss, or mysterious disappearance. The Division Registrant has the responsibility to notify the Security Services Office and the appropriate authorities.

Disposal

To make arrangement for disposal of controlled substances in any manner other than the dispensation or use for which they were procured, the Division Registrant must be contacted for instructions. The Division Registrant shall receive the substance for disposal and indicate in the Log Book that it has been received for disposal.

Disposal must be arranged when:

- (1) A project has been closed or terminated and any controlled substances are still in supply;
- (2) The Principal Investigator determines that the controlled substances is no longer required; or
- (3) The controlled substance has expired.

IV. PROCEDURES CONCERNING CHEMICAL PRECURSORS

Registration and Purchase

Authority to dispense chemical precursors for use in research or teaching activities purchased from a source outside the state of California shall be requested from the California Department of Justice (CA DOJ). Registration with the CA DOJ must be accomplished by timely filing of Form BNE 010. Authority to purchase chemical

precursors purchased within the state of California does not require registration with the CA DOJ.

Each Division using chemical precursors purchased from an out of state source shall register with the CA DOJ. The Division Registrant shall be responsible for registering with the CA DOJ. All out of state purchases of chemical precursors shall be covered under an applicable Division registration. Purchase requests for chemical precursors must be made to the Division Registrant, according to the terms of the registration with the CA DOJ. The Division Registrant is the only individual in each Division authorized to purchase chemical precursors. Division personnel other than the Registrant may not directly place orders with vendors by telephone, purchase orders, or any other means.

When chemical precursors are to be purchased from an out of state source, the Division Registrant is required to submit a report of that transaction to the CA DOJ 21 days in advance of obtaining the substance, unless CA DOJ determines that the registrant has established a record of utilization of the substance for lawful purposes, in which case CA DOJ may authorize submission of reports within 72 hours (or other acceptable time frame) of receipt of the substance.

Campus Authorization Requirements

Before the Division Registrant can honor any purchase request for chemical precursors, the Division Registrant must be notified by means of a *Chemical Precursors Registration Form, Exhibit B*.

A copy of the *Chemical Precursors Registration Form, Exhibit B* must be forwarded to the Division Chair.

The Division Registrant shall maintain a list of individuals authorized to receive chemical precursors.

Purchasing Chemical Precursors

All orders for chemical precursors must be signed by the responsible Principal Investigator and submitted to the Division Registrant for processing. Once the *Chemical Precursors Registration Form, Exhibit B*, is placed on file by the Division Registrant, orders may be submitted by those named on a *Chemical Precursors Registration Form, Exhibit B*.

Delivery

All shipments of chemical precursors shall be sent to the Division Registrant, who in turn shall notify the requestor for pickup. The Division Registrant shall maintain a file that identifies all chemical precursors purchased.

To pick up chemical precursors, an individual must identify him or herself with a current Caltech identification card and must be listed on the current *Chemical Precursors Registration Form, Exhibit B*. Authorized recipients shall be designated by each Principal Investigator.

Inventory

The Division Registrant shall keep a detailed record documenting the following:

- (1) The place to which the chemical precursor was transferred;
- (2) The amount of precursor that was transferred;
- (3) The recipient of the precursor chemical;
- (4) The date upon which the transfer occurred.

This inventory of records may be kept on a computer or by hand in a notebook. The CA DOJ may spot check this inventory of records when it visits the campus for yearly audits.

Chemical precursors shall not be transferred from the original containers for inventory purposes. Identifying labels shall not be removed from the original containers.

Security

It is the responsibility of each Principal Investigator to notify the Division Registrant immediately of any theft, loss, or mysterious disappearance of chemical precursors. The Division Registrant has the responsibility of notifying the Security Services Office and the CA DOJ, if applicable.

Disposal

To make arrangements for disposal of chemical precursors in any manner other than the dispensation or use for which they were procured, the Division Registrant may be contacted for instructions. Disposal of chemical precursors is handled by the Environment, Health and Safety Services Office.

