CHAPMAN UNIVERSITY | Environmental Health and Safety

CHAPMAN UNIVERSITY
Controlled Substances and Precursor Chemical Program

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INTRODUCTION

Research use of selected drugs is regulated by the Federal Drug Enforcement Administration (DEA) and California Department of Justice (CA-DOJ). To assist Chapman University personnel in compliance with these regulations and Chapman University policy, specific institutional requirements have been established for the management of controlled substances.

Scope of Program & Institutional Registration: This document applies to all Chapman University personnel working with controlled substances, and precursor chemicals. This Program covers Schedule III-V controlled substances regulated by the DEA (see Appendix A) used in research at all Chapman University campus locations. This document also outlines the procedures and responsibilities for the safe handling, storage, and disposal of precursor chemicals at Chapman.

The mission of the DEA's and the CA-DOJ's Precursor Chemicals (Appendix A) Control Programs are to disrupt the illicit production of controlled substances by preventing diversion of chemicals used to make drugs. The illegal production of drugs such as methamphetamine, cocaine, heroin, and MDMA (ecstasy) requires enormous quantities of precursor and essential chemicals. These federal and state programs seek to minimize the regulatory burden on the legitimate chemical industry while instituting effective anti-diversion policies.

DEFINITIONS:

Authorized Researcher - A Principal Investigator or laboratory member (e.g., staff, graduate students, undergraduate students, post-docs, visiting scholars and co-faculty) who are assigned by the Participating Faculty/Senior Research Staff to work with controlled substances within their laboratory.

Controlled Substances – Narcotic and non-narcotic drugs under the jurisdiction of the Federal Controlled Substances Act and the California Uniform Controlled Substances Act, including but not limited to those substances listed in 21 CFR §1308.11-1308.15

Controlled Substances Act (CSA) - Title 21 United States Code (USC) Controlled Substances Act (21 U.S.C. §801 et seq.)

Drug Enforcement Administration (DEA) – the agency responsible for enforcing the controlled substances laws and regulations of the United States.

Environment, Health and Safety (EH&S) – the administrative unit that manages Chapman's Environment, Health and Safety programs.

Precursor Chemical - substances used to manufacture illicit drugs. Most precursors also have legitimate commercial uses and are legally used in a wide variety of industrial processes and consumer products.

Program Administrator – person from Environment, Health and Safety charged with implementing and managing the Controlled Substances Program on a day-to-day basis. This person is also called Controlled Substance Officer.

Responsible Official – personnel with responsibility for oversight of the Controlled Substance Program. This is the EH&S Assistant Director.

REGULATIONS

Compliance with federal and state laws and university procedures governing controlled substances and precursor chemicals is required by all individuals and groups associated with Chapman University. These regulations include the following:

1. Code of Federal Regulations: Title 21, Chapter II (Parts 1300 to end) – These regulations implement the Controlled Substances Act of 1970, the Diversion Control Amendments of 1984, 1985, 1986, 2011 and subsequent amendments https://usc-cdn.house.gov/view.xhtml?path=/prelim@title21/chapter13&edition=prelim

2. Health and Safety Code Division 10: California Uniform Controlled Substances Act. (http://leginfo.legislature.ca.gov/faces/codes.xhtml).

CONTROLLED SUBSTANCES

Responsibilities

Environmental Health & Safety

Chapman University's Department of Environmental Health & Safety (EHS) provides oversight, including policy development for any use of controlled substances or precursor chemical for research purposes within the University. This includes:

1. Identifies need for new registrations, assesses current registration limitations, applies for, maintains and renews DEA institutional registrations. Liaison with DEA on registration issues.
2. Oversees initiation and maintenance of the institutional research registration for DEA Schedule III – V controlled substances.
3. With regard to any need by research personnel for the use of controlled substances not covered by the University Institutional Registration, collaborates with the researcher in a way to support the procurement and use of controlled substances by way of individual researcher-held DEA licensure. Activity under any individual license held by any University researcher will be coordinated with EHS, including approval for the purchase and use of controlled substances.
4. Coordinates research authorizations for use and transfer of controlled substances involving the University's DEA Registration.
5. Procures and dispenses orders for controlled substances used in research. Receives controlled substances and registered them in the inventory. Releases order to researchers who are listed as Authorized Recipients.
6. Maintains records of all controlled substance transactions.
7. Performs periodic compliance inspections.
8. Coordinates the biennial campus-wide inventories. This inventory must be conducted on a single day for all researchers covered under University registration.

9. Develops and promulgates compliance tools.
10. Authorizes purchase requisitions for acquisition of controlled substances and precursor chemicals from outside vendors.
11. Communicates with agencies on all compliance issues, including reports of lost or stolen controlled substances or precursor chemicals to the Department of Public Safety and the DEA within 24 hours.
12. Provides for appropriate disposal of controlled substances (Schedule III-V) obtained under CU's institutional DEA registration or researcher individual license.

Participating Faculty/Senior Research Staff

For the purpose of internal control, researchers whose work involves the use of Schedule III – V controlled substances shall enroll such work and secure EH&S's approval, which includes submittal of *the Controlled Substance - Authorized Researcher Application* (Form 1). The responsibilities of the participating faculty and Authorized Users are:

1. Comply with university, federal and state regulations pertaining to the possession of controlled substances via adherence to ***Chapman University's Controlled Substances and Precursor Chemical Program.***
2. Maintain strict control over inventory and security for controlled substances and precursor chemicals.
3. Ensure that controlled substances are not intermingled in any manner (usage, storage, etc.) with those controlled substances owned by other individual(s) or other sources. Any controlled substances held by research personnel under an individual DEA license must be maintained in separate storage and not intermingled with controlled substances held under institutional registration.
4. Ensure necessary researcher authorization for individuals in the laboratory who are assigned to work with controlled substances (e.g., staff, graduate students, post-docs, visiting scholars or co-faculty) and maintain documentation to verify currently authorized researchers.
5. Take the Controlled Substances Training available from the EHS Office and ensure that all Authorized Researchers under their supervision complete this training.
6. Provide training to Authorized Researchers on laboratory-specific operations involving controlled substances. Provide information on the health hazards of the substances, including local and systemic toxicity, and the conditions and situations that could result in exposure. Retain training records for at least one year.
7. Ensure Authorized Researchers receive, store, use, dispose of, and continually maintain usage log sheets and online chemical inventory management system for controlled substances per the University's Program. Maintain usage logs for 2 years after complete use or disposal of controlled substance, or for longer periods of time as may be required by EHS, the DEA or other regulatory agency.
8. Ensure that periodic self-inspections are conducted minimally on an annual basis, using *Controlled Substance Inventory and Inspection Form* (Form 5). Retain inspection records for at least one year. Submit a copy to EHS.
9. Biennially, complete the physical inventory, as required by regulations and directed by the institutional program.
10. Prior to moving, contact CU EHS to seek approval for moving storage location of Controlled

Substances.

11. Immediately report missing controlled substances to Environmental Health & Safety by calling (714) 532-7794 and emailing EHS@chapman.edu . EHS will forward cases of suspected theft or diversion to Chapman's Department of Public Safety. Any imminent safety threats are to be reported to Public Safety by calling 911 from any campus phone or local law authority if off-campus.
12. Ensure any delegated duties associated with this program are conducted in a timely manner.

Authorized Researcher

An Authorized Researcher is responsible for:

1. Submitting *Controlled Substance - Authorized Researcher Application* (Form 1) to EHS.
2. Take the online Controlled Substances Training available via EHS.
3. Complying with university, federal and state regulations pertaining to the possession of controlled substances via adherence to ***Chapman University's Controlled Substances and Precursor Chemical Program regarding***:
    - Authorization
    - Ordering
    - Training
    - Security, receiving, storing, using, maintenance of usage log sheets, disposing of controlled substances
    - Reporting theft or loss of controlled substances.
4. If delegated by Participating Faculty/Senior Research Staff, participating in or conducting program activities such as maintaining on-line inventory, periodic inspections, biennial campus-wide inventory, etc.

Use Authorization

Any university faculty or senior research staff member planning to use Schedule III – V controlled substances for research must first gain EHS approval. This is done by submitting the *CU Controlled Substance Authorized Researcher Application* (Form 1). This form fulfills the regulatory requirement to fairly assess the likelihood of personnel to commit a drug security breach. Authorization to access controlled substances will be denied to any personnel who has been convicted of a felony offense relating to controlled substances or who, at any time had an application for DEA registration denied or registration revoked—in accordance with Section 21 CFR 1301.90. Requestors agree to consent to a University requirement for a current background check. Names of all new Authorized Researchers are made available to the U.S. Drug Enforcement Administration (for screening of criminal history).

The form also communicates the Requestor's responsibility to:

- Take the Controlled Substances Training
- Obtain the requisite health and safety training on the hazards of working with the controlled substance from his/her supervisor.
- Follow listed work practices as further detailed in the Controlled Substances & Precursor Chemical Program.

Purchasing of Controlled Substances

Any University faculty or senior research staff member needing to purchase Schedule III – V controlled substances for research must gain EH&S use/ purchasing approval.

Step 1: For use/ purchasing approval, prior to any initial request to purchase Controlled Substances under the Chapman University DEA registration, submit to EHS *Chapman Controlled Substance Purchase Request Application* (Form 2). This Identifies the controlled substances requested, names of the authorized researchers, and provides proof of legitimate research use including approval from either the ICUC (for research that involves animals) or Department Chair. This will be approved by EHS.

Step 2: The authorized researcher will create a Purchase Requisition via University-standard PeopleSoft processes. The researcher will use a Vendor on this list of EHS Authorized Vendors. The researcher will attach the completed Form 2 to the online Purchase Requisition, which will be electronically routed to EHS for review and approval. The purchase of controlled substances under the Chapman University Institutional License cannot be advanced without EHS approval.

IMPORTANT: Under no circumstances can controlled substances be purchased using a P-Card, other credit card, or by any means other than through the University's established Purchasing System via PeopleSoft. The management of controlled substances under the Chapman University DEA Registration creates a significant obligation to researchers to follow all elements of this Controlled Substances and Precursor Chemical Program Manual. A failure to follow established policies and procedures can result in a discontinuance of researcher authority to purchase controlled substances and may jeopardize the Institutional Registration that is held in the name of the University. This could result in a loss of the authority granted by the DEA to purchase controlled substances, impacting the entire Chapman University science research community. This same notice applies to any controlled substances purchase under any EHS-approved individual license that may be held by a researcher.

Purchasing of Precursor Chemicals

A DEA registration (or California Department of Justice registration) is required for purchasing precursor chemicals from vendors outside of California. If precursor chemicals are bought from a vendor within California, use of the registration may not be required. Note that when purchasing precursor chemicals from California-based vendors, a minimum 21-day hold processing period is required for such purchases to be completed.

Central Receiving & Dispensing Process

All authorized controlled substance purchases are delivered to the Authorized Purchaser at the address shown on the DEA Institutional License and will be received in accordance with guidelines provided in this manual and with Chapman University EHS Policies and Procedures.

Inventory & Recordkeeping

Per the Code of Federal Regulations- Title 21, Section 1304, complete and accurate records shall be kept of all controlled substances purchased, manufactured, transferred, or wasted.

FOR AUTHORIZED RESEARCHERS: Controlled Substance Logbooks

Each authorized Faculty or Senior Research Staff Member in possession of controlled substances must maintain an up-to-date legible usage log of each controlled substance in possession using either the *Controlled Substances Usage Log* (Form 3) or the *Controlled Substance Dilution Usage Log* (Form 4). Records must be kept locally for a minimum of two years from final disposition of the controlled substance. Logbooks shall be made available for periodic audit by EHS and the DEA. DEA inspections are unannounced.

FOR AUTHORIZED RESEARCHERS: Annual Inventory Submission

Each Faculty or Senior Research Staff Member must perform an annual inventory and inspection of the controlled substance in their lab using the *Controlled Substances Inventory and Inspection Form* (Form 5). This is due on the 3rd Wednesday of January every year. Researchers will be provided notice 10 days in advance of the date.

Storage & Security

The University's overall security system involves a coordinated system of physical and administrative controls.

Public Safety: Chapman University's Department of Public Safety has officers who continuously patrol the University and enforce public safety and security.

Building Systems: Chapman University's buildings have card key or key systems to lock buildings after hours, with some facilities also having video cameras stationed at the entrances to buildings.

Access: Access within the laboratory must be limited to the smallest number of CU Controlled Substance Authorized Researchers necessary to perform related research activities to help assure complete accountability and reconciliation of any discrepancy that may result.

Screening of Authorized Researchers: All researchers intending to handle controlled substances, including faculty and senior research staff, are required to undergo background screening via submission of the *Controlled Substance - Authorized Researcher Application* (Form 1).

Work Practices: Controlled substances must never be left unattended at any time. Discovery of an unattended controlled substance, or an unsecured storage area, exposes the institution to losing its registration.

Containers/ Labeling: Controlled substances must not be transferred from the original containers for inventory purposes. Identifying labels must not be removed from the original containers. If the substance is converted or diluted, the new container must be labeled properly with at least the

name of the controlled substance and a unique number for tracking purposes. Dilutions and working solutions usage must be recorded on the *Controlled Substance Dilution Usage Log* (form 4).

Storage: Controlled substances shall be stored in a securely locked, substantially constructed cabinet, located where access is limited. When not in use all controlled substances must be stored there. The lockers in the vivarium 190T is the only approved location. There is a wall mounted locker with individual lockboxes for controlled substances that can be stored at room temperature. For those needing cooler storage there is a lock box in the -20°C refrigerator. The keys should not be stored near the lockbox.

Records and Disposing:

Loss or Theft: Any detected loss or theft of controlled substances must be reported immediately to Chapman University's Public Safety Office at 714-997-6763 and the EHS Office at (714) 532-7794.

Transfers

Intra-Campus Transfers:
Ownership of controlled substances may only be transferred to an individual covered under the University's Program, and such transfer may only occur upon specific written approval granted by EHS.

An intra-campus transfer of a controlled substance will be approved only if the following criteria are met:

1. The original inventory must have been acquired under the Chapman DEA registration.
2. The Faculty or Senior Research Staff Member receiving the substance(s) must submit a *Controlled Substance Purchase Request Application* (Form 2) to EH&S and receive approval from EH&S for such transfer.
3. Both parties maintain documentation of any approved transfer.

Precursor chemicals should be stored in a secure, locked area with restricted access.

Prohibition of Inter-Campus Transfers:
Under no circumstances can controlled substances or precursor chemicals falling under the Institutional Registration be transferred into or out of the location as identified on the DEA Registration. Faculty/Researchers with dual appointments at Chapman University and other universities and/or labs are prohibited from taking or transferring controlled substances into or out of those other laboratories. Also, faculty with on - and off - campus laboratories is prohibited from taking or transferring controlled substances into or out of on - campus laboratories.

Disposal

Controlled substances to be disposed of must be properly accounted for. A request for waste pickup must be made to EH&S's Hazardous Waste Program by submitting the *Controlled Substance Disposal Request Form (Form 6)*.

Categories of Waste:

1. **Wasted Controlled Substances -** These include items such as unused tablets, injections, oral liquid or preparations compounded in error, which contain controlled substances.
2. **Expired Controlled Substances** - These include controlled substances, which have exceeded their shelf life, unwanted Controlled Substances classified as non-formulary drugs or a drug that has fallen into disuse.

Destruction of properly submitted controlled substances is managed by EHS per the DEA's requirements: https://www.deadiversion.usdoj.gov/drug_disposal/drug-disposal.html

NOTE: EHS only manages the disposal of DEA controlled substances (Schedule III-V) obtained under CU's institutional DEA registration; individual registrants are responsible for managing the disposal of their controlled substances per DEA requirements. Any such disposal must be done under the direction and supervision of EHS.

APPENDIX A: SCHEDULES OF CONTROLLED SUBSTANCES and PRECURSOR CHEMICALS

The Federal Drug Enforcement Administration (DEA) lists controlled substances into 5 schedules. These drugs are listed in the Controlled Substance Act (CSA) of 1970. Section 812 of the Controlled Substances Act (21 U.S.C. §801 et seq.) (CSA) lists substances that were controlled in 1970 when the law was enacted. Since then, approximately 160 substances have been added, removed, or transferred from one schedule to another. The current official list of controlled substances can be found in section 1308 of the most recent issue of Title 21 Code of Federal Regulations (CFR) Part 1300 to end (21 CFR §1308) and the final rules which were published in the Federal Register subsequent to the issuance of the CFR.

Please note that a substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution. A controlled substance analogue is a substance that is intended for human consumption and is structurally or pharmacologically substantially similar to or is represented as being similar to a Schedule I or Schedule II substance and is not an approved medication in the United States. (See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21U.S.C. §813 for the schedule.)

Lists of Controlled Substances
https://www.dea.gov/drug-information/drug-scheduling

Precursor Chemicals, in addition to legitimate uses, have the potential to be used in the manufacture of controlled substances. State and federal laws require campus vendors to uphold stringent regulations regarding distribution of these chemical, therefore, researchers must order them through the Purchasing Department as a high value requisition and must have a Controlled Substance Use Authorization on file with EHS. (See Section 6a.)
The federal list (List I Chemicals) can be found at:
https://www.ecfr.gov/current/title-21/chapter-II/part-1310/section-1310.02
The state of California maintains a list of precursor chemicals which includes all federal List I Chemicals plus a few additional chemicals. The state of California precursor chemical list can be found at:
https://leginfo.legislature.ca.gov/

APPENDIX B: CHAPMAN UNIVERSITY LIST OF FORMS

Form 1 – CU Controlled Substances – Authorized Researcher Application

Form 2 – Chapman Controlled Substance Purchase Request Application

Form 3 – Chapman University – Controlled Substance Usage Log

Form 4 – Chapman University – Controlled Substance Dilution Usage Log

Form 5 –Controlled Substance Inventory Form

Form 6 – Controlled Substance Disposal Request Form

Form 7 – CU Signature Sheet for Controlled Substances

Form 8 – Transfer of Controlled Substances to Chapman University