1. **Introduction**
Controlled substances and precursor chemicals that can be used to create controlled substances are regulated by the Federal Drug Enforcement Administration (DEA) and the California Department of Justice (CA-DOJ). These regulations establish specific requirements and restrictions on registration, acquisition, usage, record keeping, transfer, storage and disposal. The purpose of this program document, developed by Environmental Health and Safety (EH&S) in consultation with the Office of Ethics and Compliance (OEC), is to assist USC personnel in complying with these regulations if they use these substances for research purposes.

This program document applies to all controlled substances and precursor chemicals that are used in performing research at USC, regardless of location, and regardless of whether the research is sponsored or not. This program document does not cover any non-research uses of either controlled substances or precursor chemicals.

2. **Definitions**

2.1 **Controlled Substances:** A controlled substance is a narcotic or non-narcotic drug regulated by the Federal Controlled Substances Act and the California Uniform Controlled Substances Act. Examples include pentobarbital, ketamine, oxycodone, morphine, codeine, Xanax, and Vicodin. (See Appendix “A” for a list of controlled substances).

2.2 **Precursor Chemicals:** A precursor chemical is one that has the potential to be used in the illegal production of controlled substances, such as methamphetamine, cocaine, heroin, and MDMA (ecstasy), and is designated as such by the California Department of Justice. (See Appendix “B” for a list of Precursor Chemicals).

2.3 **Drug Enforcement Administration (DEA):** The DEA is the federal agency responsible for enforcing the controlled substances laws and regulations of the United States.

2.4 **Environmental Health & Safety:** The USC Office of Environmental Health and Safety (EH&S) is responsible for providing a safe and environmentally healthy workplace and atmosphere for students, employees, and the surrounding community. EH&S' responsibilities include oversight of USC’s Controlled Substances Program.

2.5 **Authorized Investigator:** An Authorized Investigator is a principal investigator who possesses a DEA registration and is permitted to order, receive, and use controlled substances or precursor chemicals for research purposes at USC.

2.6 **Authorized User:** An Authorized User is any faculty (other than faculty who qualify as Authorized Investigators) or research personnel designated by an Authorized Investigator to use or purchase controlled substances or precursor chemicals for research purposes at USC.

3. **Controlled Substances Management**

3.1 **DEA Registration Requirements**
3.1.1 Principal Investigators seeking to perform research with Schedule II-V controlled substances must obtain an **individual registration with the DEA**.

3.1.2 Principal Investigators seeking to perform research with Schedule II controlled substances must also obtain and submit **DEA Form 222** to place an order of such controlled substances. To obtain a copy of Form 222, please visit the DEA web site.

3.1.3 Principal Investigators and co-investigators seeking to perform research with Schedule I controlled substances must obtain a separate individual registration with the DEA, even if they already maintain an individual registration for use of Schedule II-V controlled substances. As described in Section 3.4, below, Principal Investigators and co-investigators seeking to perform research with Schedule I controlled substances must also obtain written approval from the Research Advisory Panel of California (RAPC) before doing so.

3.2 **USC Controlled Substance Program Enrollment Requirements**

3.2.1 Principal Investigators seeking to become Authorized Investigators permitted to order, receive, and use controlled substances for research purposes at USC shall:

3.2.1 (a) Obtain an individual DEA registration for research involving use of Schedules II-V controlled substances, and a separate DEA registration for each research project involving the use of Schedule I controlled substances (See Section 3.1, above).

3.2.1 (b) Submit a **Controlled Substances Use Authorization (CSUA) Application Form** to EH&S. All fillable forms are available on the EH&S website.

3.2.1 (c) Complete USC’s **Controlled Substance Safety Training**, administered by EH&S.

3.2.2 Any faculty or research personnel seeking to become Authorized Users permitted to use or purchase controlled substances under the supervision of an Authorized Investigator shall:

3.2.2 (a) Review the Controlled Substance Use Authorization Form that they will be listed on.

3.2.2 (b) Complete USC’s Controlled Substance Safety Training, administered by EH&S.

3.2.3 EH&S will review all applications for Authorized Investigator and Authorized User status, and issue CSUA’s as appropriate. This review may include verifying an approved IACUC or IRB protocol, as applicable.

3.3 **Requirements Applicable to Authorized Investigators and Authorized Users**

Authorized Investigators and Authorized Users are responsible for:

3.3.1 Appropriately tracking, utilizing, securing, and disposing of controlled substances procured for research purposes.
3.3.2 Keeping an updated inventory of controlled substances at all times, and submitting an Initial and Annual Physical Inventory Form to EH&S. Failure to comply with the annual inventory requirement may result in EH&S terminating the applicable CSUA and suspending any further orders for controlled substances.

3.3.3 Disclosing to EH&S as soon as practicable any modifications in authorized use locations, security location and/or method, Authorized Users and authorized controlled substances.

3.3.4 Maintaining all required records, including usage logs, inventories, and disposal requests for controlled substances, for a period of two years post-disposal.

3.3.5 Timely reporting to EH&S verbally, and in writing, any loss or theft of controlled substances.

3.3.6 Obtaining EH&S’ approval for all transfer and disposal of controlled substances.

3.3.7 Obtaining explicit authorization from the DEA before importing or exporting controlled substances.

3.4 Research Advisory Panel of California (RAPC)

3.4.1 Certain types of research with controlled substances must be reviewed and authorized by the Research Advisory Panel of California (RAPC) in the Attorney General’s office. This includes:

3.4.1 (a) All research involving Schedule I controlled substances

3.4.1 (b) Human subjects research involving Schedule II controlled substances; and

3.4.1 (c) Research for the treatment of drug abuse using any drug, controlled or not.

3.4.2 Authorized Investigators are responsible for preparing necessary applications to the RAPC. EH&S is available to provide guidance upon request.

3.4.3 Authorized Investigators must comply with all measures required by the RAPC in connection with an application and must ensure that EH&S receives a copy of all application materials submitted to the RAPC as well as all materials received from the RAPC including, but not limited to, the RAPC’s decision on any application submitted by an Authorized Investigator.

3.5 Receipt and Record-Keeping

3.5.1 Authorized Investigators shall retain receipts, packing slips and other shipping paperwork for purchased controlled substances.
3.5.2 Authorized Investigators shall maintain an appropriate usage and disposal log to track usage of controlled substances under their DEA registration and USC CSUA. Logs shall be kept up-to-date at all times. (Please see USC’s Controlled Substances Usage and Disposal Log for an appropriate example).

3.5.3 Authorized Investigators shall keep all records relating to Schedule I and II controlled substances separate from all records relating to Schedule III through V controlled substances.

3.5.4 Authorized Investigators shall ensure that all records (i.e. usage logs) relating to controlled substances that are obtained under separate DEA authorizations are not intermingled in any manner.

3.5.5 Records (i.e. receipts, packing slips, logs) shall be maintained for a minimum of 2 years following disposal.

3.6 Transfer

3.6.1 Authorized Investigators shall complete and submit EH&S’ Controlled Substance Transfer Form for all transfers of controlled substances from one lab to another at USC.

3.6.2 Transfer of controlled substances between Authorized Investigators at USC will only be allowed if:

3.6.2 (a) The intended recipient is an Authorized Investigator with a current DEA registration and CSUA.

3.6.2 (b) The controlled substance is approved in the recipient’s CSUA.

3.6.2 (c) Appropriate security measures are in place, as determined by EH&S.

3.6.3 Documentation related to any transfer of controlled substances shall be maintained by each lab and a copy provided to EH&S.

3.7 Security

Physical security shall be appropriate for the schedules and quantity of controlled substances in a particular lab or facility, as follows:

3.7.1 Schedule I and Schedule II controlled substances shall be stored in a drug safe, vault, or steel cabinet under lock and key.

3.7.2 Schedule III through Schedule V controlled substances must be stored in a substantially constructed cabinet (without wheels) under lock and key and in a room that has limited access during work hours and is locked during non-working hours.
3.7.3 EH&S has authority to require incorporation of any additional physical security measures, if deemed appropriate.

3.7.4 Access to controlled substances shall be restricted to the absolute minimum number of individuals needed and authorized to handle daily transactions with such items, namely Authorized Investigators, Authorized Users, and EH&S. Access to key or combination must be restricted to the aforementioned personnel.

3.7.5 Controlled substances shall never be left unattended at any time.

3.7.6 Controlled substances shall not be transferred from their original containers, and identifying labels shall not be removed from original containers. If the Controlled Substance is converted or diluted, the new container shall be labeled appropriately.

3.7.7 Any detected loss or theft of controlled substances must be reported to EH&S within 24 hours of discovery using EH&S’ Controlled Substances Incident Report. EH&S will file all necessary reports with the police and/or the DEA, as required.

3.8 Disposal: EH&S coordinates all disposal of controlled substances procured for research purposes at USC. Authorized Investigators seeking to have EH&S dispose of controlled substances must submit EH&S’ Controlled Substances Waste Disposal Request Form. Thereafter, EH&S will provide and request further information on how to dispose of controlled substances.

3.9 Oversight and Non-Compliance: EH&S conducts controlled substance inspections, at least annually, for all Authorized Investigators. Inspection findings are subject to remediation within five (5) or twenty (20) business days depending on the severity of the findings. The CS Inspection Process Flow Chart depicts how findings that are not corrected may be progressively escalated to higher authority levels.

4. Precursor Chemical Management

4.1 Principal Investigators seeking to purchase and use precursor chemicals for research purposes shall inform EH&S.

4.2 Principal Investigators should endeavor to procure precursor chemicals from a vendor located within the State of California (e.g. Spectrum Chemical). When procuring precursor chemicals in this fashion, the registration requirements outlined below with respect to procurement from out of state vendors do not apply.

4.3 A minimum 21-day processing period will be required for purchases made from an in-state supplier in order to fulfill DEA and California state regulations.

4.4 In-state suppliers are required to obtain purchaser identification and a Letter of Intended Use for all purchases of precursor chemicals.
4.4.1 The required purchaser identification and a Letter of Intended Use shall be submitted for each precursor chemical purchased (e.g. separate paperwork for anthranilic acid and hydriodic acid).

4.4.2 The Letter of Intended Use shall be displayed on departmental letterhead and shall be dated with a signature written in ink.

4.5 If a Principal Investigator chooses to procure precursor chemicals from an out of state vendor, the PI shall either:

4.5.1 Obtain a California Precursor Permit specific regulated item, as defined in the California Health and Safety Code Sections 11100-11107.1; or

4.5.2 Obtain a DEA Registration for an “Analytical Lab”.

4.6 Principal Investigators are responsible for maintaining appropriate purchase records for precursor chemicals (DEA List I & II; California List) used in their research at the University. All records shall be kept for 2 years post-disposal.

4.7 All precursor chemicals shall be input and maintained in the lab’s chemical inventory; inventory shall be updated in EHSA, Bruno or other system approved by EH&S.

Related Policy and Additional References

Department of Environmental Health and Safety- (323) 442-2200

Controlled Substances (Federal)

Controlled Substances (California)

Precursor Chemicals (Federal)

Precursor Chemicals (California)

Research Advisory Panel of California

Federal Controlled Substances Act

California Uniform Controlled Substances Act

Responsible Office: Office of Environmental Health and Safety
Controlled substance or precursor chemical related messages and questions for EH&S should be sent to ehs-cs@usc.edu.

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1 To obtain a California Precursor Permit, contact the California Controlled Substances group at 916-210-4313 or email CCSP@DOJ.CA.GOV.
Appendix A: Schedules of Controlled Substances

Controlled substances include, but are not limited to, the following:

1. **Schedule I Controlled Substances**
   Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse—heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

2. **Schedule II Controlled Substances**
   Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence—combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

3. **Schedule III Controlled Substances**
   Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence—products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, and testosterone.

4. **Schedule IV Controlled Substances**
   Substances in this schedule have a low potential for abuse relative to substances in Schedule III—Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

5. **Schedule V Controlled Substances**
   Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics—cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

Consult the federal [Controlled Substances Act](https://www.deadal survival.org) and the [California Health and Safety Code](https://www.ca.gov) to obtain a current list of controlled substances.
Appendix B: Precursor Chemicals

Precursor chemicals are chemicals governed by both federal and California law used in the course of legitimate research, and that can potentially be used in the illicit production of controlled substances such as methamphetamine, cocaine, heroin, and MDMA. DEA registration, recordkeeping and suspicious order reporting requirements apply to importers, exporters, manufacturers, distributors and certain retailers of listed chemicals. Consult the federal Chemical Control Program and the California Health and Safety Code to obtain a current list of precursor chemicals.