

Controlled Substances User SOP 02: Commissioning and Decommissioning A CS Lockbox**1. Purpose**

This procedure for users describes the commissioning of a CS lockbox, the general laboratory operations for the use of Controlled Substances, and the decommissioning of a CS lockbox.

2. Regulatory References

Title 21 §1301.72

3. General Information**A. Abbreviations:**

- 1) Authorized Person (AP)
- 2) Central Controlled Substances Custodian (CCSC)
- 3) Controlled Substance (CS)
- 4) Controlled Substances Tracking System (CST)
- 5) Employee and Organizational Development (EOD)
- 6) Environmental Health and Safety (EHS)
- 7) Institute Point of Contact, Chief Research Policy Officer (IPOC)
- 8) Laboratory Controlled Substances Custodian (LCSC)
- 9) Office of Laboratory Animal Resources (OLAR)
- 10) Office of Research Compliance (ORC)
- 11) Principal Investigator (PI)
- 12) Uniform Distribution, Transfer, and Disposal Form (UDTD)

B. Caltech has two Drug Enforcement Administration (DEA) licenses and each license has its own CCSC, who is responsible for training personnel and managing CS inventory on their respective licenses.

4. Training Requirements

- A. The PI must complete all required documentation and training (CS SOP 2)
- B. All lab personnel using the CS must complete required training (CS SOP 2)

5. Commissioning a CS lockbox

- A. The PI will contact the IPOC to initiate the commissioning process. The IPOC will identify which Caltech license the lab will be assigned (an OLAR license or an EHS license).
- B. The lab should review the [Caltech Controlled Substances Policy](#) and complete all requirements for obtaining, storing and using CS at Caltech, as described in CS SOP 2. This includes completing applicable forms, background check, and CITI and/or in-person training: <https://researchcompliance.caltech.edu/compliance/controlled-substances-and-chemical-precursors>
- C. Prior to installation of any lockbox:

- 1) The laboratory must receive approval and necessary personnel (at a minimum the LCSC and PI) must complete training, as described in CS SOP 2. The training must be documented as stated in CS SOP 2.
- D. An approved lockbox location must be identified for installation:
- 1) The CS lockbox location should be large enough to accommodate a secure, double locked CS cabinet and should be in a lockable room with limited foot traffic. The key lockbox should be located in a room separate from the CS cabinet, unless otherwise approved by the CCSC.
 - 2) The CS lockbox location shall not be directly in the line of sight of an entryway to enhance security requirements.
 - 3) The proposed CS lockbox location must be approved by the CCSC prior to scheduling installation.
- E. When requirements provided in 5(A) through 5(D) are met, the CCSC from EHS or OLAR responsible for the laboratory will arrange to have a CS lockbox and key lockbox delivered. After delivery of this first lockbox, any subsequent lockboxes, safes or key lockboxes must be paid for by the laboratory.
- F. All CS lockboxes and key lockboxes will be assigned a corresponding identification number. The Carpentry Shop will install the lockbox in the lab.
- G. The CCSC will visit the lab to confirm the installation locations of the CS lockbox and key lockbox, =determine where/how CS documentation will be kept in the laboratory, and obtain either the combination number for the laboratories' key lockbox or an extra key.
- H. Prior to receipt of controlled substances in the lockbox, the lab must have a complete CS Binder. The CS Binder will be provided by the CCSC and must contain the following information.
- 1) Section 1: A copy of the Controlled Substances Authorization Form [Attachment A](#) with the IACUC Approval and Protocol Number and/or the Division Approval Form [Attachment A-1](#) Form with the completed Division Approval for the lab to use controlled substances in research.
 - 2) Section 2: A copy of the map showing the location of the controlled substances lockbox and the location of the controlled substances key lockbox. The key lockbox code SHOULD NOT be included on this map.
 - 3) Section 3: A list of all Authorized Persons in the laboratory who may use controlled substances in research.
 - 4) Section 4: This section should be reserved for all UDTD Forms.
 - 5) Section 5: This section should include copies of the completed [Attachment E](#): Self Inspection Forms for at least the previous 2 years
 - 6) Section 6: This section should include copies of the completed biennial inspection forms for at least the previous 2 years.
- 6. Request for decommissioning a CS lockbox**
- A. To end use of controlled substances in the lab, the PI or LCSC should submit a formal request for termination via email to the EHS or OLAR CCSC.

- B. The CCSC will organize a date and time to visit the lab to take physical possession of the CS, UDTD forms, logbook, and CS binder. The LCSC will sign the “Decommissioning Form” to verify that all CS units and dilutions, the CS binder and logbooks have been turned over to the CCSC.
- C. The CCSC may personally remove the box and take it into their possession, or will create an AIM workorder request to remove the lockboxes from the lab location by Carpentry Shop. The assigned lockbox number will be verified upon removal.
- D. Files related to the decommissioned lockbox must be maintained for a period consistent with DEA regulation (currently 2 years).

7. Revocation of Authorization and Decommissioning

- A. Notice: The Division Office, the IACUC, or the IPOC will notify the CCSC if a PI's authorization is revoked. Such notification will prompt the CCSC to take action to secure any inventory of CS related to the revoked authorization.
- B. Access Restricted/Surrender of Controlled Substances:
 - a. Once notified about a revocation, the CCSC will remove the PI and all authorized users from the list of Authorized Users.
 - b. The CCSC will contact the LCSC for the lab to request confirmation that the lockbox is secured and prepared for the LCSC to remove the CS.
 - i. A mutually convenient time will be arranged within 24 hours to remove the CS from the lab.
- C. If the revocation is for an individual, the CCSC will contact the LCSC to ensure that the person no longer has access to the CS- this may require changing the location of the lockbox keys, returning keys, changing the key lockbox code or revoking keycard access to a safe.