

Controlled Substances SOP 01: Commissioning A CS Lockbox**1. Purpose**

This procedure describes installing a controlled substances lockbox, a corresponding key lockbox, and establishment of initial inventory as a part of general laboratory operations for the Controlled Substances program.

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, Director of Research Compliance (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 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. Completion of all required documentation and training by the PI
- B. Training of LCSC

5. Personal PPE Requirements

None

6. Equipment

- A. Controlled Substances Lockboxes
- B. Key Lockboxes

7. Procedure

- A. Initiating a laboratory CS Program and Commissioning a CS Lockbox

- 1) Laboratories wanting to establish a laboratory CS program should contact the IPOC to identify which Caltech license to which they will be assigned. In general, labs with significant animal usage or using buprenorphine SR will be assigned to the OLAR license. Labs in CCE will usually be assigned to the EHS license.
 - 2) See the California Institute of Technology CS Procedure and complete all requirements for obtaining, storing and using CS at Caltech. This includes completing applicable forms, background check, and training:
http://www.safety.caltech.edu/services/controlled_substances
- B. Prior to installation of any lockbox:
- 1) All documentation must be completed and all background checks for laboratory personnel finalized, as confirmed by the CCSC, and
 - 2) the LCSC, CS authorized personnel, and the PI must complete training, which is documented. The LCSC and CS authorized personnel must complete CITI training, and the PI must complete in person training provided by ORC. (See [Training SOP 2](#))
- C. An approved lockbox location must be identified for installation:
- 1) The CS lockbox location should have adequate space 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.
- D. When requirements provided in (A) through (C) are met, the CCSC from the EHS or OLAR Office responsible for the laboratory will send an email to EHS to arrange to have a CS lockbox and key lockbox delivered to the CCSC EHS or OLAR Office.
- E. All CS lockboxes and key lockboxes will be assigned a corresponding control number. The CCSC will note the control numbers and campus location of the boxes on the SharePoint Excel sheet when assigning to the research lab.
- F. The CCSC will then enter an AIM workorder for the Carpentry Shop to arrange for installation of the lockboxes in the lab. The CCSC should provide the LCSC name and contact number in the notes section so the Carpentry Shop can contact the LCSC to determine a suitable time for installation.
- G. The CCSC will visit the lab to confirm the installation locations of the CS lockbox and key lockbox, as specified in [Attachment A](#) or [Attachment A-1](#), determine where/how CS documentation will be kept, and obtain the combination number for the LCSC key lockbox.
- H. The CCSC will generate a map that will then go into the Controlled Substances Lab Binder with a separate copy saved to the applicable EHS or OLAR Controlled Substances SharePoint folder. All maps are derived from the Caltech Meridian System, which is a space management software managed by the Design and Construction Department of the Facilities Group. The CCSC will note the combination for the key lockbox ONLY on the copy of the map going into the SharePoint folder.
- I. Before the lab is able to receive controlled substances for research, the CCSC must provide the lab with its CS Binder containing the following information.

- 1) Section 1: A copy of the Institute's *Controlled Substances Policy and Procedures*.
 - 2) Section 2: A copy of [Attachment A](#) with the IACUC Approval and Protocol Number or [Attachment A-1](#) Form with the completed Division Approval for the lab to use controlled substances in research.
 - 3) Section 3: A copy of the map showing the location of the controlled substances lockbox and the location of the controlled substances key lockbox (see G). The key lockbox code SHOULD NOT be included on this map.
 - 4) Section 4: A cover page with a listing of all Authorized Persons in the laboratory who may use controlled substances in research along with copies of corresponding [Attachment B](#).
 - 5) Section 5: This section should be reserved for all UDTD Forms.
 - 6) Section 6: This section should include 5 blank copies of the Attachment E: Self Inspection Forms. As forms are used, they should be stored here and new blank forms replenished.
- J. The CCSC will verify that the LCSC has a laboratory CS logbook prepared with a copy of [Attachment C](#) affixed to the inside cover of the book. The CCSC should document in his/her records how the lab intends to maintain its inventory documentation (logbook, electronic, etc.) to ensure compliance with recordkeeping requirements for the use of controlled substances in research.
- K. The CCSC should document in their records that all steps of this SOP have been completed and the lockboxes are in place. The documentation should include a date.