Controlled Substances SOP 02: Central Controlled Substances Custodian Training Requirements

1. Purpose
This procedure provides guidelines for the training responsibilities of a Central Controlled Substances Custodian (CCSC).

2. General Information
A. Abbreviations:
   1) Controlled Substance (CS)
   2) Controlled Substances Tracking System (CST)
   3) Employee and Organizational Development (EOD)
   4) Environmental Health and Safety (EHS)
   5) Institute Point of Contact, Director of Research Compliance (IPOC)
   6) Laboratory Controlled Substances Custodian (LCSC)
   7) Office of Laboratory Animal Resources (OLAR)
   8) Office of Research Compliance (ORC)
   9) Principal Investigator (PI)
   10) Uniform Distribution, Transfer, and Disposal Form (UDTD)

B. Caltech has two DEA licenses, one managed by EHS and one managed by OLAR. Each license has its own CCSC.

3. Coordination of Training and Approval for CS Users
A. Upon receipt of an Attachment A from a new laboratory, the CCSC should confirm and document that the laboratory has IACUC and/or Divisional approval. IACUC approval can be confirmed using the Protocol Application System (PAS).
   1) The Division Chair must keep records of all Attachment A approvals per the Caltech Controlled Substances Procedures. The CCSC should ensure that an electronic copy is sent to the Assistant to the Chair or Division Operations Officer (DOO) for each Division.
   2) Upon receipt of an Attachment B from a new laboratory CS user (including the PI), the CCSC should send a scanned copy of the form to both the user and EOD.
   3) EOD will contact the user directly to initiate the background check process and will e-mail the CCSC if/when new users are cleared.
   4) All CS users (with exception of the PIs) must complete the CS CITI training prior to being authorized to use CSs. The CCSC should confirm that the user has completed the CITI training for CS. If not completed, the CCSC should email the user and provide instructions for the user to access the CS Training on CITI and request that the user provide their certificate of completion as soon as possible.
   5) The ORC will provide in-person training sessions for PIs as required. ORC will document that PI training is complete in Sharepoint and the CCSC will enter this training into MyLearn (Controlled Substances-Faculty) upon confirmation.
   6) The CCSC should meet the new and backup LCSCs to review the paperwork requirements in person. The review should include providing the LCSCs with information regarding responsibilities
as outlined in the training handout (SharePoint: Training/Lab Training/CS Program Handout). The CCSC should enter this training into MyLearn.

7) Once the background check and training are complete, the CCSC will email the user and cc the LCSC to confirm that the lab is approved to use CS. The CCSC should include an electronic copy of the applicable training handout (SharePoint: Training/Lab Training/CS Program Handout). The CCSC should enter the Authorized User and/or LCSC training in MyLearn.

   o The CCSC should maintain a copy of the Attachment B in the CCSC files in as well as on SharePoint in the appropriate Lab’s folder (SharePoint: OLAR or EHS License/Authorization Forms/Lab). The CCSC should add any new user onto the “OLAR or EHS CS labs and authorized users” Excel spreadsheet (SharePoint: OLAR vs. EHS license).

4. Establishing CST Records and Authorization for Procurement

   A. The CCSC should enter the new LCSCs into the CST system. (Note: non-LCSC authorized users are not entered into the CST). To do this:

   B. Log onto access.caltech.edu and go into the CST system.

   C. Click on the “setup” tab.

   D. Select “LCSCs” under the setup option located on the right side of the screen and click “create”.

   E. Click on the search button (magnifying glass icon) next to “LCSC name” and type in the name of the new LCSC and click “search.”

   F. Select the name of the person.

   G. Select the corresponding lab name from the drop down menu and click “create”. Email Procurement to request access for the new LCSC to the TechMart CS form. If the new LCSC is replacing a former LCSC, request removal of access for the former LCSC.

       o Ensure TechMart access was already requested. If not, have the lab fill out and email the “Access Request for TechMart E-Procurement Application” form.

5. Transferring CS

   B. As necessary, the CCSC may need to transfer all CSs from a former LCSC to a new LCSC. To do this:

       1) Stay on the “Setup-LCSC” tab and scroll to the bottom of the page to where there is an option for “Mass LCSC transfer.”

       2) Type in the name of the former LCSC and the new LCSC in their respective boxes and click “transfer.”

           a. This will move all of the CSs in a lab from the former LCSC to a new LCSC. CSs can only be transferred to LCSC’s within a single lab using this function. This function cannot be used to transfer CSs to a new lab.

           b. This transfer will allow you to edit and “de-activate” the former LCSC creating an end date. An LCSC cannot be deleted.

   C. CS may only be transferred between separate labs on the same license using the UDTD. The CCSC should coordinate such a transfer and ensure all transactional activity is documented.
D. CS should not be transferred between licenses. If there is an emergency situation requiring such a transfer, the transfer needs to be justified, documented and carefully coordinated between the IPOC, the CCSCs, and the LCSCs.
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