DEA Site Investigation Guide

As part of the application review process, the DEA typically conducts an on-site investigation of your anticipated controlled substance storage and use locations. Prior to this visit, the DEA often requests detailed information about your lab, research, and controlled substance procedures.

Most procedures are covered in UC's Controlled Substance SOP, but you should be prepared to explain how they apply to your lab's specific locations, personnel, substances and research. **This guide outlines commonly requested information and materials by the DEA prior to your on-site visit.**

Beyond what is covered in this guide, the DEA may ask you to submit additional documents or written statements as part of your application. Failure to provide these within a reasonable time is considered a waiver of your opportunity to present these materials for DEA consideration during application.

Personnel & Business (Lab) History

- Name, title, college, and department of Principal Investigator (applicant)
- Name(s) and title(s) of lab personnel (authorized agents)
- Employee screening procedures
- Number of employees (including contracted or temporary employees) and status (part or full time)
- Lab details (e.g. management structure, year established, day/hours of operation, address and building/room of primary lab location, building description, previous locations of operation)
- Any other DEA registrations the researcher currently holds, previously held, or applied for
- Historical experience with controlled substances or listed chemicals
- Known subsidiaries, parent companies, or related companies doing business as (dba)
- Name, location and total number of research partners (e.g. other companies or entities) you are conducting researcher on behalf of (if applicable)

Substance Information

- Name, DEA schedule, product size, and National Drug Code (NDC) number per substance
- Estimated quantity you plan to use per calendar year per substance
- Anticipated vendors/supplier name(s), address(es), and DEA registration number(s)
- Identify measuring/aliquoting equipment (e.g. scales, measuring devices, calibration pumps), how frequently they are calibrated, and who is responsible for maintaining them

Research Project

- Research protocol (e.g. IACUC or IBC protocol) and approval letter
- Type of research (e.g. animals, culture systems, *in vitro*)
- Associated research grants and/or funding
- OBP TDDD license (and any other licensure acquired for this project, e.g. EPA, USDA)
- Chemical analysis procedures (if applicable)

Ordering & Receipt

- Ordering, receipt, verification and/or reconciliation procedures (including incorrect order receipt)
- Names of personnel who will receive, verify, and/or reconcile controlled substances orders (including those completing the receiving portion of DEA 222 Form or Controlled Substance Ordering System record)

- Duration and location where substances are quarantined after receipt
- Assay (i.e. purity) test procedures on received materials (including assay test failure procedures)

Storage, Inventory & Security

- Storage location (postal address and building/room) and floor map of the storage room
- Describe how access to controlled substance storage areas is limited (e.g. card readers, keys, restricted spaces, visitor access denied or supervised)
- Name, DOB, title(s), and position(s) of all individuals who will have physical access to controlled substances and/or access to the keys/alarms that secure controlled substances
- A securely locked, substantially constructed storage cabinet in alignment with 21 CFR 1301.75
- How often inventory (physical count) is performed

Destruction, Theft/Loss & Recordkeeping

- Destruction and/or return procedures
- Theft and/or loss procedures
- Name and title of individual(s) responsible for recordkeeping
- Recordkeeping method and location (e.g. manual/paper records in a room, substance management software, Excel spreadsheet on a shared lab drive)