

Controlled Substance Compliance Program: Guidelines for DEA Inspection Preparation

This document serves as a guideline for the preparation for periodic **unannounced** inspections by the U.S. Department of Justice Drug Enforcement Administration (DEA). In compliance with the [Controlled Substance Act](#) the DEA is authorized to audit any registered controlled substance storage location and laboratories where they are used. The registrant and all authorized personnel must be knowledgeable about federal regulations, CU policies, and laboratory policies and procedures regarding the security, ordering, storage, disposal and administration of controlled substances used in research.

The DEA investigators may audit select controlled substances to track usage from the last biennial inventory or purchase invoices to the present. This may include asking the registrant or authorized agents to physically count, weigh, or otherwise inventory the substances. It also may involve reviewing the IACUC protocols and laboratory notebooks to compare usage of the substances that were approved for use to the inventory and usage logs. Be prepared to walk through/explain the typical daily use of controlled substances, from the point of retrieving an aliquot and completing the inventory log to its transport and use in a surgery suite, for example.

Controlled Substances in Research policies and procedures are found at:

<https://www.colorado.edu/researchinnovation/controlled-substances/policies-guidelines>.

Do's & Don'ts During the Inspection:

- Be sure to have an action plan to immediately retrieve records during a DEA inspection.
- Answer the DEA investigator's questions as truthfully and as concisely as possible.
- If you do not know the answer to a question, DO NOT speculate on the answer. Acknowledge that you do not know at the moment but will get the answer as soon as possible.
- Do not argue or debate with the DEA investigator.
- Take notes of all recommendations and observations made by the DEA Investigators.
- Ask any questions you might have regarding the DEA findings so corrective actions can be implemented.
- Copy any records required by the DEA and obtain a receipt (DEA Form 12) for any original records and/or controlled substances taken off-site.

Inspection Procedure

1. Review the DEA investigators' credentials, photo identification, and their contact information (business card)
2. Inquire about the reason for the inspection.
3. Contact the registrant and request they immediately come to the inspection site. If they are not available and neither are any authorized agents, arrange a time for the DEA agents to return later that day or as soon as possible.
4. Reserve a conference room for the investigators to use.
5. Sign the Notice of Consent to Inspection (DEA Form 82), which acts as informed consent (*registrant only*) and obtain a copy for your records.
6. Upon request, provide access to the controlled substance storage cabinet or safe (*registrant or authorized agent only*)
7. Upon request, be prepared to provide any of the following:
 - DEA Certificate of Registration
 - Authorized agent log, with screening statements similar to those attested to on Form 225 for the registrant
 - Laboratory policies and procedures regarding security, ordering, storage, disposal and administration of controlled substances
 - Access to controlled substance storage cabinet or safe
 - Purchasing records: invoices for Schedules III – V and Form 222 for Schedules I – II. (Note: Be prepared to show the inspectors that Schedule I – II records are stored separately from Schedules III – V and that none of these records are stored within the cabinet or safe.)
 - Most recent inventory (e.g., initial, biennial)
 - Current usage logs and dilution logs
 - Disposal records (NOTE: Frequently, expired or unused substances are required to be stored in the cabinet prior to pick up by EHS. Be sure these are clearly labeled and segregated from other substances. Be prepared to explain the time delay.)
 - Waste or breakage-spillage reports, if applicable (DEA Form 41)
 - Theft/significant loss reports, if applicable (DEA Form 106)