
Controlled Substance Program

Procedure Overview

Purpose and Scope

- This procedure is to provide guidance and resource information for University faculty and staff who utilize controlled substances (CS) in teaching and research laboratories at the University.
- It outlines compliance requirements with U.S. Drug Enforcement Administration (DEA) and the Indiana Board of Pharmacy (IBOP).

Training Requirements

- All licensees and persons working under the licensee shall be familiar with and adhere to all federal and state CS rules and regulations.
- Licensees, or their designees, shall provide appropriate training to all Authorized Users working under the license.
- This training shall include a review of this procedure and safety information specific to the substance and application.

Responsibilities

- PIs registered to use CS are responsible for:
 - Ensuring CS are licensed and registered for use in their labs and properly maintained.
 - Working within scope of the current license/registration.
 - Restricting access only to authorized users.
 - Proper record keeping in accordance with this procedure.
 - Proper disposal of CS in accordance with this procedure.
 - Reporting any theft or loss of CS.
 - Notifying RMS of scheduled DEA or Indiana Board of Pharmacy (IBOP) inspections.
 - Complying with all federal and state laws.

Registration and Licensing

- Any person engaged in research with CS shall acquire a IBOP CS license and a DEA registration to receive, distribute, store, and administer CS for research purposes.
- No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued and received by IBOP and DEA.
- The activities and CS used shall be limited to those described in the protocol(s) approved in the Indiana Board of Pharmacy CS Registration and DEA Registration.

Registration and Licensing

- Initial Application
 - Any person considering obtaining a IBOP and DEA registration shall first contact RMS for guidance.
 - Once each application is approved, the licensee shall retain the license certificate and provide a copy to RMS.
- License Renewal
 - IBOP and DEA registrations shall be renewed prior to expiration date.
 - Once renewed, licensee shall retain license certificate and provide a copy to RMS.

Registration and Licensing

- Registration Modification
 - After notification to RMS, any licensee may apply to modify his/her registration to authorize the handling of additional CS or to change the name or address.
 - Copies of all documentation submitted to IBOP and DEA, as well as copies of new certificates of registration shall be provided to RMS.
- Registration Termination
 - Any licensee desiring to discontinue business activities altogether or with respect to CS shall first notify RMS.
 - The licensee shall notify the DEA in writing.
 - Any controlled substances in his/her possession shall be properly disposed of.

Purchasing and Receiving

- Only researchers with a current IBOP license and DEA registration shall purchase CS.
- Purchases shall be accompanied by registration and license information and delivered solely to the address on the DEA registration.
- Ordering CS for research shall be done only through approved distributors or manufacturers.

Purchasing and Receiving

- Schedule I or II Substances shall only be ordered by the licensee using DEA Form 222 and invoices maintained separately from Schedule III-V.
- Schedule III-IV Substances shall only be ordered by the licensee or an authorized agent of the licensee.
- Purchasing records shall contain the following:
 - A handwritten date and signature of receipt on the invoice
 - Name, address, and DEA number of the company from which CS was purchased
 - The name, size strength & amount of the CS purchased

Storage, Security and Access

- Licensees shall provide effective physical security controls & operating procedures to guard against theft & diversion.
- Access to CS shall be restricted to minimum number of employees who shall be documented & maintained with the licensee's CS records.
- All CS shall be kept under lock and key, in a substantially constructed cabinet, safe, or vault and accessible only to authorized personnel.
- CS shall be kept locked in their storage locations except for the time required for authorized staff to remove, work with, and replace them.

Storage, Security and Access

- The room in which the storage container is located shall have limited access during working hours and provide security (e.g., locked door or locked door and alarm) after hours.
- An overall evaluation of the security measures will be made by the IBOP and DEA.
- A licensee shall not employ an individual who has had his or her application for registration with DEA denied or revoked at any time, and who, as a result of employment, will have access to CS.

Theft, Loss or Unauthorized Use

- Thefts, suspected thefts or any significant loss of any CS shall be reported immediately to NDSP and RMS.
- Any unauthorized person who gains access to a CS for the purpose of diversion or theft shall be reported to NDSP and be subject to university discipline policies.
- Upon discovery, the licensee shall notify in writing the IBOP and DEA within one business day of any theft or significant loss of any CS.

Theft, Loss or Unauthorized Use

- The licensee shall also complete and submit DEA Form 106, "Report of Theft or Loss of Controlled Substances".
- Thefts must be reported whether or not the CS are subsequently recovered and/or the responsible parties are identified and action taken against them.
- When a diversion has occurred, an inspection from the DEA is likely to occur.

Abandoned Substances

- CS left by a licensee are still legally the licensee's responsibility.
- When abandoned CS are discovered, RMS shall be notified immediately upon discovery.
- The licensee's department shall make every effort to contact the licensee. If unsuccessful, RMS shall provide guidance to the department on how to handle disposal.

Destruction of Controlled Substances

- Expired, unused, or contaminated substances shall be stored under lock and key until ready for disposal.
- When ready for disposal, the licensee shall notify RMS and prepare DEA Form 41 for RMS review omitting the names of witnesses. Upon RMS approval, Form 41 shall be submitted by licensee to DEA.
- RMS shall perform the physical destruction process with witnesses who shall print, sign and date DEA Form 41.
- The licensee shall fax the 41 Form to the DEA, placing one copy with the licensee's CS records and providing one to RMS.

Inventorying of Controlled Substances

- Every licensee shall maintain complete and accurate accounting of all CS for at least 2 years from the date of such inventory or records.
- Inventories and records shall be kept at the premises where the licensed activity is conducted, and be readily available.
- Inventories and records of Schedules I and II CS shall be maintained separately from all of the records for Schedules III-V.
- Inventory records shall include:
 - Initial inventory
 - Perpetual inventory
 - Biennial inventory

Internal Auditing

- RMS shall conduct semi-annual audits of laboratories that use CS to evaluate and assess the laboratory's compliance with state and federal requirements.
- The audits shall include one paperwork audit and one field audit per year for each applicable laboratory.
- Participation from the licensee or designee shall only be required during field audits.
- Audits shall be documented providing details of inspection results, including corrective action recommendations.
- Audit reports shall be distributed to the licensee, Associate Director of Research Safety, and the Office of Research.