

# Use and Maintenance of Controlled Substances in Research

May, 2025

In response to the June 2023 internal audit of controlled substances in research at the Universities of Wisconsin System Administration and seven UW universities, the Office of Compliance and Risk Management (OCRM) and Office of Academic Affairs issues the following guidance and recommendations related to this activity based on federal and state statutes and regulations, as well as best practices. This document provides general guidance only and should not be interpreted as a UW policy or procedure or replace any existing UWSA or other written policy or protocol.

## Proposed Actions and Recommendations

1. **Eliminate the use of controlled substances if prudent.** As highlighted by the audit, the majority of our universities have two or fewer controlled substance users. If this research is no longer deemed advantageous by the university, disposing of this material and surrendering any related licenses would eliminate the cost and administrative burden tied to ongoing compliance.
2. **Create and require an approval process for potential registrants to complete prior to submitting any application.** Licenses are an agreement between the state, DEA, and the registrant, rather than the university. As a result, unless a registrant informs a university of their intention to work with controlled substances, the university could be unaware of the presence of these materials and their related compliance issues.

The following entities could be part of any approval process at a university:

- a. Department Chair – Reviews materials to ensure the department is well informed of the nature of these materials, their costs, and the compliance requirements.
- b. Risk Management/Compliance – Identifies any associated risks and reviews compliance issues at the university level.
- c. Environmental, Health and Safety – Reviews protocols and equipment to ensure occupational safety.
- d. Facilities Management – Ensures that the secure storage installation requirements are met and will function properly in the designated location.

- e. Hazardous Waste Management – Ensures that any waste generated can be properly disposed of.
  - f. University Police Department – Reviews security solutions for high target materials.
3. **Require that registrants review the DEA Researchers' Manual, federal and state law, and any regulations prior to submitting any application. The university should document this training/review.**

Registrants are responsible for reviewing the DEA Researcher's Manual, which provides comprehensive guidance on regulatory requirements. The manual outlines procedures for applying and maintaining registration, ordering controlled substances, recordkeeping, inventory management, security measures, and proper disposal protocols.

It is the registrant's responsibility to ensure compliance with the following regulations:

- a. Controlled Substance Licensing and Registration 21 CFR 1301
- b. Inventory and Usage Records 21 CFR 1304
- c. Invoice and Purchase Records 21 CFR 1305
- d. Disposal 21 CFR 1317
- e. Loss or Theft 21 CFR 1301.76
- f. Security 21 CFR 1301.71-1301.93

The university should document that this training/review has taken place. This could be accomplished by providing these materials to the registrant and having them attest in writing that they have reviewed them, or it could be accomplished through a more formal training program.

4. **Require registrants to register with federal and state authorities and submit proof to the university.** Completed applications and approved licenses should be shared with the universities.
- a. Registrants must submit the application for a Controlled Substances Special Use Authorization (SUA) with the [Wisconsin Department of Professional Services \(DSPS\)](#).
    - 1. [DSPS Physical Security Requirements for Controlled Substances](#)
    - 2. [DSPS Special Use Authorization Application Instructions](#)
    - 3. [DSPS Special Use Authorization Checklist for Research](#)
    - 4. When completing the DSPS application the registrant must complete the field labeled "*Institution, Research Lab, or Business Facility Represented*"

*by or Employing Applicant.*” A copy of the application will be submitted to the university for recordkeeping.

- b. Registrants must submit an application to the DEA Office of Diversion Control. 21 CFR 1301.13(e)(1)(v), (vi). Typically, the certificate is valid for 12 months.

It should be noted that the local DEA office may complete an onsite inspection to ensure that storage and security are satisfactory prior to the approval of any registration. The local office may be contacted for additional information regarding storage and security.

Registration is also based on a specific location, if a controlled substance will be utilized in more than one location, there would need to be a separate registration submitted for each location. 21 CFR 1301.12(a).

5. **Authorized users.** Registrants should notify the university of all authorized users. Registrants are responsible for ensuring the authorized users are listed on any controlled substance protocol submitted with the license application. Registrants must work with the university to ensure that all authorized users are properly screened and comply with use, handling, storage, documentation and reporting requirements.
6. **Complete required training.** All registrants and any authorized users must complete all required training to work with controlled substances. Proof of this completed training should be submitted to the university.
7. **Ensure proper procurement.** The purchase of controlled substances is the responsibility of the registrants. The university should require the purchase of materials through a vendor that is authorized as a reverse distributor if prudent. This can help cut the costs of shipping out hazardous waste for disposal. Registrants should follow the university’s policies and procedures related to procurement.
8. **Unit Registrants.** For any university that uses larger amounts and multiple researchers utilizing controlled substances, it may make more sense for there to be a Unit Registrant. This type of license is held by a unit (or department) at the university and there is a designated individual for ensuring compliance. This individual is responsible for managing and meeting all controlled substance regulatory requirements.

Additional Resources:

- [DEA DCD Controlled Substance Schedules](#)
- [DEA DCD Researcher’s Manual](#)
- [Wisconsin administrative code and statutes pertaining to controlled substances.](#)
- [WI DSPS Controlled Substances Special Use Authorization](#)

*This document is intended solely as guidance and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. This guidance does not establish or affect legal rights or obligations and is not finally determinative of any of the issues addressed. This guidance does not create any rights enforceable by any party in litigation with the State of Wisconsin or the Board of Regents. Any decisions made by the Board of Regents in any matter addressed by this guidance will be made by applying the governing statutes and administrative rules to the relevant facts.*