University of Michigan Policy on Controlled Substances in Research and Education

Purpose

The Vice President for Research has established this policy to ensure the University of Michigan (U-M) maintains effective oversight of research and educational activities involving controlled substances. These substances are regulated due to their potential for diversion, misuse, or abuse, and are subject to extensive requirements concerning their manufacture, distribution, procurement, storage, recordkeeping, transfer, and disposal.

This policy aligns with the Controlled Substances Act of 1970 and addresses compliance with federal and state regulations, as well as internal U-M expectations. All University of Michigan activities that involve controlled substances are subject to federal and state drug enforcement laws as well as U-M policies and requirements. All University of Michigan faculty, staff, students, agents, volunteers, or any individuals using University resources, facilities, or funds must comply with all federal and state regulations and the applicable U-M policies relating to controlled substances. See “Federal and State Regulations” below.

Applicability

This policy applies to all U-M research and educational activities involving controlled substances, including:

- Animal research
- Administration to human subjects as part of a clinical research protocol, where controlled substances are the *object* of the study
- In vitro or analytical research

It covers all U-M faculty, staff, students, agents, volunteers, or any individuals using U-M resources, facilities, or funds.

Propofol

This policy **also applies to propofol** (also known as 2,6-diisopropylphenol), though some procedural requirements are modified. Exceptions are noted where applicable throughout the policy.

Clinical Care

This policy **does not apply** to controlled substances administered or dispensed to patients by licensed medical or dental practitioners during the course of clinical care. U-M faculty,

staff, and students involved in clinical care must refer to:

- **UMHS Policy on Management of Controlled Substances** (UMHS Policy #07-02-001)
- Related UMHS policies

Controlled Substances in Research Review Committee

The Controlled Substances in Research Review Committee (CSRRC) is a multidisciplinary oversight body charged with promoting the safe, ethical, and compliant use of controlled substances in research and educational activities at the U-M. This committee brings together subject matter experts in research administration, legal and regulatory affairs, environmental health and safety, laboratory operations, and animal and human research oversight. Its primary responsibilities include reviewing institutional policies and practices, advising on complex compliance matters, and supporting investigators in meeting federal, state, and institutional requirements.

Authorized by the Vice President for Research, the CSRRC is empowered to regulate and oversee all use of controlled substances in research and teaching at the University of Michigan. This authority includes suspending or restricting use in cases of noncompliance or safety concerns, and requiring corrective action plans when violations are identified. The committee may also set institutional standards for storage, documentation, and personnel authorization, as well as recommend disciplinary action or refer matters to regulatory authorities when warranted. These actions ensure legal compliance while upholding the University’s commitment to research integrity and public safety.

Policy

All use of controlled substances in research or teaching at the U-M must be registered through the Controlled Substances in Research Monitoring Program. This requirement applies to all individuals engaged in activities involving controlled substances under university auspices, regardless of funding source or the research setting.

Registration ensures appropriate oversight, promotes safe and responsible use, and aligns university practices with federal and state regulations. Investigators and associated personnel are expected to proactively engage with the program and uphold the highest standards of stewardship. By working collaboratively through this centralized process, the university can better safeguard research integrity, personnel safety, and institutional compliance.

Roles and Responsibilities

Investigators and authorized personnel must comply with applicable laws and U-M requirements. Responsibilities include:

1. **Review requirements:** OVPR Controlled Substances in Research Website
2. **Obtain appropriate licensing:**
    - State of Michigan (SOM) license
    - DEA registration
    - **Exception:** Not required for **propofol-only** research

Note: For the conduct of **non-clinical research activity** with controlled substances, a person with a **U-M faculty appointment** must be the one to obtain a State of Michigan Research License and DEA Research Registration for the procurement, storage, and administration of controlled substances in their laboratory or other research location. Exceptions to these requirements will be considered on a case-by-case basis.

3. **Register with CS Monitoring Program**:
    - Email: CS-monitors@med.umich.edu
    - **Exception**: Not required for **propofol-only** research
4. **Procurement:** Must **comply** with federal and state regulations, and U-M procedures
5. **Secure storage**:
    - Must match the address on the license/registration
    - **Propofol**: Must be stored securely as per the U-M controlled substance requirements.
6. **Access and personnel control:** Limit the number of personnel with access to the controlled substances and maintain an authorized personnel log.
7. **Recordkeeping:** Maintain records of procurement, inventory, administration, and disposal per the state and federal regulations, and U-M requirements.
8. **Disposal:**
    - Render substances irretrievable upon disposal
    - Required at project end, lab closure, or license/registration termination
9. **Maintain valid licenses:** Renew the state license and DEA registration at appropriate intervals and notify the CS Monitoring Program *in advance* of address or registration changes.

10. **Incident reporting (within U-M):**
    - Report immediately to CS Monitors (CS-monitors@med.umich.edu) or page*:
        1. Unresolved discrepancies
        2. Suspected loss, theft, or diversion
        3. Improper removal
        4. Signs of tampering
        5. Impairment of personnel
        6. Misplaced/unsecured substances
        7. Any deviation from policy

11. **Reporting to authorities (in case of significant loss or theft):**
    - Report in this order:
        1. U-M Department of Public Safety and Security
        2. OVPR CS Monitors (CS-monitors@med.umich.edu or page*)
        3. DEA (facilitated by U-M) – **Not required for propofol**
        4. State of Michigan LARA – Not required for propofol

***Emergency pager for CS Monitors:** 734-670-2286, enter callback number + '#'

Controlled Substances in Research Monitoring Program

The Vice President for Research has established the Controlled Substances in Research Monitoring Program to provide direct support and oversight to University registrants using controlled substances in research.

Monitoring visits by the CS Monitors are conducted on a regular, scheduled basis with registrants and their staff to review compliance with the controlled substance regulations and University internal policies.

Unscheduled monitoring visits conducted by the CS Monitors may occur on an as-needed basis to ensure continuing controlled substance compliance. During unscheduled monitoring visits, the CS Monitors may:

- Meet with the registrant and/or staff members, if available, to review the CS records and security.
- If the registrant and/or staff member(s) are unavailable, the CS Monitor may observe the research space and verify that the controlled substances are securely stored.
- If controlled substances are found to be stored in an unauthorized or noncompliant way, a witness will be obtained, the manner of storage will be documented, and the registrant and/or authorized personnel will be contacted immediately.
    - If the DEA registrant or authorized agent are unavailable to secure the controlled substances, U-M DPSS will be contacted to pick up and secure the controlled

substance(s). A receipt will be given to the CS Monitor to document the chain of custody. *U-M DPSS makes no guarantee that the controlled substance(s) will be returned to the DEA registrant.*

Compliance

Noncompliance may result in:

- Institutional discipline
- Suspension or termination of the use of controlled substances at U-M
- Misconduct referrals
- Reporting to law enforcement or licensing authorities

Violations of federal or state regulations may lead to:

- Administrative penalties
- Civil fines
- License/registration revocation
- DEA Registrant criminal prosecution

Controlled Substance Schedules

The Controlled Substances Act classifies substances into five schedules:

1. **Schedule I:**
    - No accepted medical use (e.g., certain illicit drugs)
    - Requires DEA Schedule I registration

2. **Schedule II-V:**
    - Accepted medical use
    - Varying levels of abuse potential
    - Require DEA Schedule II-V registration

Federal and State Regulations

Federal

- Controlled Substances Act of 1970 (21 USC)
- 21 CFR, Parts 1300–1399 (DEA regulations)

State (Michigan)

- Public Health Code Act 368 of 1978, Article 7

Version: October 23, 2025

- Board of Pharmacy – R 338.3101–338.3199

Questions and Additional Information

For help interpreting requirements, requesting monitoring visits, or reporting concerns:

- Email: CS-monitors@med.umich.edu
- Phone: 734-764-2003 / 734-615-3872
- Website: Controlled Substances in Research