University of Michigan
Policy on the Use of
Controlled Substances and Propofol in Research and Education

INTRODUCTION

The Vice President for Research has established this policy for the University of Michigan's oversight of research involving controlled substances. Due to the potential for diversion or abuse, controlled substances are subject to extensive regulation regarding their manufacture, distribution, procurement, storage, record keeping, transfer, and disposal. This policy applies to controlled substances as defined by the Controlled Substances Act of 1970.

PROPOFOL

This policy also applies to propofol (as known as 2,6-DIISOPROPYLPHENOL). Any exceptions to the controlled substance procedures for propofol researchers are indicated below.

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.

SCOPE OF U-M POLICY ON CONTROLLED SUBSTANCES IN RESEARCH AND EDUCATION

The scope of this policy is limited to oversight for research and education involving the use of controlled substances. This includes controlled substances associated with animal research, controlled substances administered to human subjects as part of a research protocol, and in vitro or analytical research with controlled substances.

This policy does not apply to controlled substances administered or dispensed to a patient by a licensed practitioner in the course of professional medical or dental practice. UMHS faculty, staff, and students involved in **clinical care** should refer to the UMHS Policy on Management of Controlled Substances (UMHS Policy #07-02-001) and associated UMHS policies. See "Applicability of the U-M Policy and the UMHS Policy" below.

INVESTIGATOR AND ASSOCIATED PERSONNEL ROLES AND RESPONSIBILITIES

It is the responsibility of investigators and associated personnel who utilize controlled substances in a research or education setting to familiarize themselves with and comply with the regulations (see "Federal and State Regulations" below), and with all U-M requirements pertaining to controlled substances. This includes the responsibility to:

1. Review the U-M Office of Research (UMOR) Controlled Substances in Research website for procedural requirements (http://research-compliance.umich.edu/controlled-substances-research).
2. Obtain a State of Michigan (SOM) license and a Drug Enforcement Administration (DEA) registration specifying the address for secure storage of the controlled substances to be used for research.

   *The University of Michigan requires that, for the conduct of **non-clinical research activity** with controlled substances, a person with a **U-M faculty appointment** be the one to obtain a SOM **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.*

   a. If using propofol ONLY, a SOM license and DEA registration is *not* required.

3. Register with the UMOR Controlled Substances Monitoring Program (CS-monitors@med.umich.edu) and provide timely updates following any SOM controlled substance license and DEA registration renewal or change. *Does not apply to propofol.*
4. Procure all controlled substances in a manner that complies with Federal and State regulations and U-M policies.
5. Store all controlled substances at a secure location matching the address listed on the State of Michigan license and DEA registration.
    a. If using propofol ONLY, securely store in a manner that complies with U-M storage requirements for controlled substances.
6. Restrict access to controlled substances to a limited number of authorized personnel and maintain an authorized personnel log.
7. Securely maintain all records, including procurement (e.g., ordering and purchasing), formulating/reconstituting, inventory, usage/administration, and disposal records. For assistance, set up an appointment with the UMOR Controlled Substance Monitors: (CS-monitors@med.umich.edu).
8. Properly dispose of controlled substances in an accountable manner that renders them irretrievable when they are no longer required for research, at their expiration, at project end, before decommissioning of laboratory, and before termination of the controlled substance license/registration.
9. Keep State of Michigan licenses and DEA registrations up-to-date, including prior notification (and approval) of changes of address.
10. Employees are required to report **immediately (upon discovery)** to the UMOR Controlled Substance Monitors (CS-monitors@med.umich.edu) any of the following events:
    a. All unresolved discrepancies in inventory relating to controlled substances;
    b. Possible significant loss or theft/diversion of controlled substances;
    c. Improper removal of controlled substances from U-M premises;
    d. Any signs that a controlled substance may have been interfered or tampered with (such as broken, empty or cracked containers, broken seals, or lack of efficacy*). *Testing services are available – contact CS-monitors@med.umich.edu.
    e. Signs that a co-worker may be impaired due to self-administration of controlled substances;
    f. Discovery of misplaced or unsecured controlled substances; and
    g. Any other situations where policies and procedures relating to controlled substances may not have been followed.
11. Any theft or significant loss of unknown origin must be reported **immediately (upon discovery)** to all of the following entities, in the order listed:
    a. U-M Department of Public Safety and Security;
    b. UMOR Controlled Substance Monitors (CS-monitors@med.umich.edu);
    c. U.S. Drug Enforcement Administration (this reporting to be facilitated by the UMOR Controlled Substance Monitor). *Does not apply to propofol*;
    d. Administrator of the Michigan Department of Licensing and Regulatory Affairs, via the Michigan Bureau of Health Professionals (this reporting to be facilitated by the UMOR Controlled Substance Monitor). *Does not apply to propofol*.

Emergency pager for the UMOR Controlled Substance Monitor: 734-936-6266, #31685

Detailed information on the above requirements is available on the UMOR Controlled Substances in Research web site, by email: CS-monitors@med.umich.edu, or by phone: 734-764-2003.

COMPLIANCE

The Vice President for Research oversees compliance with this policy. Failure to comply with this policy may be grounds for discipline by the University, suspension or termination of research, referral for non-compliance/misconduct proceedings, and/or reporting to external licensing or public safety authorities by the University. In addition, failure to comply with State of Michigan and federal controlled substances regulations may lead to administrative penalties, civil fines, revocation of state controlled substance license and/or DEA registration, as well as criminal prosecution sought against the research registrant.

SCHEDULES OF CONTROLLED SUBSTANCES

The drugs and substances covered under the Controlled Substance Act are organized into five schedules:

Schedule I: No accepted medical use.

- Schedule I compounds are classified as illicit drugs along with their chemical precursors.
- The DEA requires a Schedule I registration application for use of these substances.

Schedules II-V: Accepted medical uses.

- Schedule II substances have a high potential for abuse with severe psychological or physical dependence.
- Schedule III-V substances have a lower potential for abuse than substances in Schedules I or II.
- The DEA requires a Schedule II-V registration application for use of these substances.

FEDERAL AND STATE REGULATIONS

U.S. Department of Justice – Drug Enforcement Administration (DEA)

- Title 21 United States Code (USC) Controlled Substance Act (CSA)
- Title 21 Code of Federal Regulations, Part 1300-1399

State of Michigan – Public Health Code Act 368 of 1978

- Article 7: Controlled Substances

State of Michigan – Department of Licensing and Regulatory Affairs (LARA)

- Board of Pharmacy – Controlled Substances (R 338.3101-338.3199q)

APPLICABILITY OF THE U-M POLICY AND THE UMHS POLICY

For research uses in a research or education context, across U-M (except where superseded by the UMHS Policy #07-02-001), see:

- U-M Policy on Controlled Substances in Research and Education (this document)

For clinical uses in a clinical context, within the U-M Health System, see:

- UMHS Policy on Management of Controlled Substances (UMHS Policy #07-02-001), and associated UMHS policies

In a dual clinical/research context, within the U-M Health System (e.g., a specific research purpose in a clinical setting, or as part of clinical standard of care that is incidental to research), both policies apply:

- U-M Policy on Controlled Substances in Research and Education (this document)
- UMHS Policy on Management of Controlled Substances (UMHS Policy #07-02-001), and associated UMHS policies.