Wayne State University
Office of Environmental Health & Safety
Controlled Substances Program Description

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I. Purpose

The purpose of this policy is to facilitate a general understanding of the steps necessary to comply with federal and state laws and regulations governing controlled substances in Wayne State University (WSU) animal or *in-vitro* research and to ensure safe handling and security of controlled substances.

II. Scope

This Controlled Substance Policy applies to all Wayne State University faculty and research staff using controlled substances (CS) in human, animal, or *in-vitro* research. The policy *does not* apply to WSU faculty and research staff members' use of CS in clinical treatment associated with human subject research.

III. Overview

Controlled substances are drugs regulated by the federal Drug Enforcement Administration (DEA) and the State of Michigan because of their potential for abuse. The purpose of this document is to describe the processes and responsibilities required for WSU employees who wish to conduct research involving CS. It describes the responsibilities of Wayne State University faculty and research staff members who use CS with respect to compliance with the DEA and State of Michigan regulations regarding usage, handling, storage, recordkeeping, and disposal and/or transfer of CS. Appendix 2 and Appendix 5 refer to the state and federal rules and regulations that apply to the use of CS under their program. Forms and suggested procedures for compliance are also provided.

To legally obtain and use CS in IACUC approved animal or *in vitro* research in the State of Michigan, investigators must either: 1) hold a State of Michigan controlled substance research license **and** a current individual federal research registration, *or* 2) conduct the research as an "authorized agent" (as defined herein and in Appendix 3) of a university faculty researcher who holds a current federal research registration and state license. The address on both the license (State of Michigan) and the registration (DEA) must be the same as the laboratory address where CS are stored and less than 1000ft (less than a five-minute walk) from where the substances are administered.

Practitioners can use their license/registration (non-research license) for ordering, storing, and administering controlled substances at their laboratory for research purposes provided the following conditions are met:

- The address on the registration (DEA) are the same as the laboratory address where CS are stored and less than 1000ft (less than a five-minute walk) from where the substances are administered.
- The research is within the scope of the State of Michigan license and the DEA registration in regard to coincidental activities

Contact OEHS if you are uncertain if your current license and registration can be used in a new location.

IV. Controlled Substance Definitions

Controlled substances are drugs or other chemicals that have the potential to be abused. The Drug Enforcement Administration (DEA) divides CS into five schedules based on their potential to be habit forming, and usefulness in medicine as a drug. For a more comprehensive listing, refer to the DEA Office of Diversion Control website:

Schedule I Drugs, or other substances that have a high potential for abuse, no currently accepted medical use in the United States, and are accepted as unsafe even under medical supervision.

Schedule II Drugs or other substances that have a high potential for abuse, currently have an accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

Schedule III Drugs or other substances that have a potential for abuse that is less than Schedule I or II CS, with currently accepted medical use in treatment in the United States. Schedule III drugs may lead to moderate or low physical dependence and high psychological dependence.

Schedule IV Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III. These drugs have a currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule III.

Schedule V Drugs or other substances that have a low potential for abuse relative to Schedule IV. These drugs have a currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule IV.

V. Responsibilities

A. Office of Environmental Health and Safety

- Provide guidance to campus units for registering with state and federal agencies
- Provide advice on storage of CS
- Dispose of CS
- Annual audits

B. Registered Controlled Substance User

- Ensure DEA registration and State of Michigan controlled substance license remain current while in possession of CS
- CS disposal must be confirmed prior to allowing license and registration to expire
- Ensure compliance of the physical facilities with Federal, State, and University regulations and policies governing the proper use of CS
- Ensure compliance of laboratory personnel with Federal and State and University regulations and policies governing the proper use of CS
- Provide and employ proper storage for CS
- Maintain accurate CS records

- Report theft or loss of CS
- Ensure proper disposal of CS

VI. Wayne State University Registration Requirements

Wayne State University faculty and research staff members holding current individual federal research or practitioner registrations as well as state licenses for human, animal, or *in-vitro* research must notify the Office of Environmental Health and Safety (OEHS) of their registration and license. The OEHS shall serve as the primary point of contact for Wayne State University faculty and research staff members who hold or intend to hold an individual federal research registration or a state license. The DEA requires that faculty and staff obtain a state license before the agency will issue a federal research registration.

VII. Controlled Substances Licensing and Registration

A. Michigan Board of Pharmacy

Applicants in the State of Michigan must first submit an online application for a State of Michigan Controlled Substance Research License. A license is required for every person who manufactures, distributes, prescribes, dispenses, or conducts research with CS. Additional instructions for obtaining a Michigan CS license can be found on the OEHS Controlled Substances website.

B. Federal Drug Enforcement Administration

Following receipt of the State of Michigan Controlled Substance Research License, persons conducting research involving CS must register with the DEA. The type of registration required varies according to the nature of the activity involving CS.

The DEA application for registration can be found online. DEA form #225 should be completed to obtain a researcher registration. Additional instructions for obtaining a DEA CS registration can be found on the OEHS Controlled Substances website.

VIII. Authorized Use

Authorized agents of the registrant/licensee may engage in approved activities under the direction of the registrant/licensee. The activities must be delegated by the licensee/registrant to the authorized agent in writing. Authorized agents who use CS under an investigator's Research Registration must be documented on the Wayne State University *Controlled Substances Authorized Agent List*, which must be retained with the controlled substance inventory.

- Authorized agents must follow all state and federal regulations governing controlled substances.
- The number of authorized agents with access to controlled substances should be kept to a minimum.
- A current list of authorized agents with access to controlled substances should be maintained on the Wayne State University *Controlled Substances Authorized Agent List*.

- Only the registrant/licensee and authorized agents are allowed access to the storage cabinet or safe where controlled substances are stored.

The registrant /licensee is responsible for managing the CS in accordance with the requirements of the regulations (21 CFR 1300 to 1321) including inventory, record keeping and security provisions. Lab employees can be considered authorized agents of the person with an active state license and federal research registration if they are acting in the usual course of their business or employment and with proper screening and authorization by the registrant/licensee. The registrant/licensee must also screen all authorized agents.

IX. Employee Questionnaire

The DEA requires all authorized agents who have access to CS be documented (Appendix 1: Controlled Substances Authorized Agent List addressing the two questions below (21 CFR, 1301.90):

1) Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or are you presently charged with committing a criminal offense?
2) In the past three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

The completed form(s) must be retained with the Controlled Substances Inventory.

X. Recordkeeping Requirements: An Overview

Individuals holding federal research registrations and state licenses are responsible for maintaining appropriate records and inventories of all CS used. Faculty and research staff members who obtain and use CS as Agents under federal research registrations are also responsible for maintaining appropriate records and inventories of CS used in their research at the university. The term "Agent" refers to an authorized person who acts on behalf of, or at the direction of, a licensed researcher.

Controlled substance records must conform to the record keeping requirements of federal law and the procedures described below. Controlled substance records include all purchasing records, use and destruction records, controlled substance ordering forms (DEA Form 222), usage logs, and inventory records. Faculty and research staff members who purchase CS from outside pharmacy vendors/suppliers and use their own federal research registration are responsible for maintaining the DEA Form 222s and individual purchase invoices (and/or purchase/receipt logs) associated with such purchases. All licensed and required faculty and research staff members are responsible for maintaining the CS records.

All CS records must be available upon request by Federal or University inspectors and stored separately from the registrant's ordinary business records. Schedules I and II CS records must also be maintained separately from records for Schedule III, IV, and V CS.

Federal law requires all controlled substance records be maintained for at least two years from their creation. If the records are copied for an inspection, they must be kept for an additional two years from the date of copying (21 CFR 1304.04, 1304.11, 1304.21 and 1304.22). These records include, but are not limited to, purchasing, usage, inventory, and disposal records.

Wayne State University requires registered/licensed investigators to retain controlled substance records for five years following the date of such inventory or other CS records.

XI. Purchasing Controlled Substances: Procedures and Record Keeping

Wayne State University faculty (registrant) and research staff (authorized users) must use the controlled substance account code 721H5 when purchasing CS through the WayneBuy system. The request is automatically routed to OEHS who will confirm that the purchaser holds a current federal research registration, state license, and that the delivery address is correct. A purchase order will then be generated and sent to the vendor with a scanned copy of the original DEA order Form 222 (for Schedule I and II only).

A. Schedule I or II

Any person licensed and registered to conduct research with controlled substances in Schedules I or II must send a prepared and executed DEA order form # 222. OEHS does not have copies of this form. This form can only be obtained through the DEA. Researchers must contact the DEA directly at 1-800-882-9539 or submit a Request Order Forms through the DEA Diversion Control website. Schedule I and II controlled substances can only be ordered by the licensee/registrant.

B. Schedule I CS that is not commercially available

Requests to obtain Schedule I CS that are not commercially available must be made to the National Institute on Drug Abuse.

C. Schedule III-V

DEA Form 222 is not required to purchase Schedule III-V CS. These CS may be purchased from commercial suppliers

D. Maintaining Purchase Records

Wayne State University faculty and research staff members are responsible for obtaining and maintaining the following information for all CS purchased from pharmacies or distributors:

- The name of the controlled substance purchased
- The size and strength of the controlled substance purchased, i.e., bottle size and concentration
- The amount purchased (which should match the amount received), i.e., quantity received
- The name, address, and DEA number of the company from which the controlled substance was purchased
- A copy of the invoice, i.e., payment order
- A copy of the purchase order
- A copy of the shipping document, i.e., Fed Ex air bill, UPS bill, etc.
- A copy of the packing slip, i.e., itemized list of contents

The purchasing record (purchase order, invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt.

There are additional recordkeeping requirements for investigators purchasing Schedule II CS. Investigators purchasing Schedule II CS from pharmacies or distributors are required to retain a copy of the invoice and individual DEA Form 222 for each purchase. Investigators purchasing Schedule II CS from non-university sources must also complete a Record of DEA Form 222. Use to maintain accountability for all DEA Form 222s used. The entries for the date and the quantity received that are on the form should then match the date and quantity received entries on the Controlled Substances Record for each drug purchased.

XII. Storage and Security

Security depends greatly on the type, quantity, and form of CS being used in a research project. Schedule I, II, III, IV, and V CS must be stored in a locked steel cabinet or a locked substantially constructed cabinet. For examples, see SelectLocks.com.

Controlled substances should not be located near a glass panel where they can be visible from the outside. Researchers must provide effective controls to guard against theft. This includes limiting the number of keys and the number of employees who will have access to the keys. Keys for locked cabinets must be kept in secure locations when not in use. Developing a key accountability standard operating procedure (SOP) is recommended. If combination locks are used, combinations must be changed whenever there is turnover of any employee who has knowledge of the combination and access to the CS. Non-laboratory visitors entering areas where CS are used or stored should always be asked to provide identification and the purpose of their visit. When maintenance work is done in the controlled substance storage area, the research staff must maintain adequate observation.

XIII. Inventory Records

Maintaining an accurate inventory for CS is one of the most important aspects of the DEA enforcement programs and the university's compliance program. In following best research practices and to avoid OEHS and DEA audit red flags, investigator-controlled substance inventories should not exceed the amount necessary for research. Faculty and research staff members must maintain an up-to-date inventory of the CS in their laboratories.

A separate inventory for each location must be performed on the date the registrant/licensee first engages in any activity covered by their state license and DEA registration. Initial inventories are usually zero. Thereafter, a physical inventory of all controlled substances to be conducted on an annual basis. The annual inventory must be performed between April 1 and June 30 of each year per Michigan Public Health Code, Section 333.732. The DEA requires a physical inventory every two (2) years. The annual State inventory satisfies this request. It is recommended that registrants use the Annual Inventory Form found on the OEHS website.

XIV. Controlled Substance Usage: Recordkeeping

Controlled substances must be tracked from acquisition to administration/disposal. A separate Usage Log should be used for each unique vial or container. Registrants/licensees may develop their own forms or use the following:

- WSU Usage Log – Animal
- WSU Dilution and Usage Log

- WSU Usage Log – Non-animal

A continuous General Inventory Log is required to track acquisitions, current on-hand stocks, administration, transfers to usage logs, transfers to other registrants/licensees, and transfers of substances for disposal. A separate General Inventory log should be created for each stock of drug and its associated strength or container size. Registrants may develop their own General Inventory Log or use the WSU General Inventory Log.

XV. Controlled Substance Disposal: Permitted Methods and Record Keeping

To minimize waste, faculty and research staff members with research registrations/licenses should only purchase and store quantities of CS that they reasonably intend to use. The preferred method of disposal of controlled substances is complete use of the substance such that there is none left to dispose of.

Damaged, expired, unwanted, unusable, or non-returnable CS must be accounted for, retained, and disposed of in accordance with applicable state and federal regulations (21 CFR 1304.11).

There are two disposal options for expired or unwanted CS. The Office of Environmental Health and Safety should be contacted to help determine the correct disposal method.

A. Contact the Supplier

Some suppliers will take back unused pharmaceuticals for credit. If possible, this is the best means of controlled substance disposal. The CS should be unused and in resalable form.

B. Reverse Distribution

This option involves transfer of ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. Reverse distribution requires completion of DEA Form 222 and DEA Form 41 for Schedule I and II. Reverse distribution requires completion of DEA Form 222 for Schedule III-V. Those interested in reverse distribution of CS should first contact OEHS.

A Registrant's Inventory of Drugs Surrendered form (DEA Form 41), must be completed prior to disposing of any DEA controlled substance. Two copies of the form must be sent to the local DEA branch by OEHS, and one copy must be retained by the investigator for at least five years.

Investigators must maintain disposal records with the following information:

- The investigator's DEA number, name, and address
- If a reverse distributor is used, the reverse distributor's DEA number, name, and address
- The number of units (in finished forms and/or commercial containers) disposed of, and the manner of disposal

The disposal record must be dated to reflect when the products were sent for destruction and left the inventory.

XVI. Separation of Investigators from the Institution

Controlled substances purchased by investigators conducting research are the property of Wayne State University. Faculty and research staff members holding individual federal research

registrations and investigators holding CS as agents who plan to leave the university (e.g., accept a position at another university, company, or retire) must contact the Office of Environmental Health and Safety prior to their departure to arrange appropriate disposal of the CS.

XVII. Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported. This type of loss, however, must be documented by the registrant and witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g., tablets), must be placed in the disposal/destruction waste stream as described in **"Disposal Options"** above. If the spilled controlled substance is not recoverable (e.g., liquids), the registrant must document the circumstances in their inventory records and the witnesses must sign.

XVIII. Theft of or Missing Controlled Substances Reporting

Investigators must maintain complete accountability of all CS stored or used in their laboratory. Keeping good records is essential for the detection of shortages or missing CS. Theft or misuse of a controlled substance is a criminal act that must be reported by phone to the following agencies:

- DEA Detroit Division: (313) 234-4000
- WSU Police Department Emergency Number: (313) 577-2222
- OEHS number: (313) 577-1200

In addition to reporting theft or misuse of CS by phone, a Report of Theft or Loss of Controlled Substances form (DEA Form 106) must be completed and submitted through the DEA's online system. Investigators must retain one copy of any DEA Form 106 submitted to the DEA for at least five years. Online reporting to the DEA is also necessary if small quantities of CS are unaccounted for on a recurring basis. Investigators should print and email a copy of the DEA 106 form to the State of Michigan at bpldata@michigan.gov.

XIX. Monitoring and Inspection

The Office of Environmental Health and Safety (OEHS) will annually audit the recordkeeping, inventory, security, and disposal of CS used in research by Wayne State University faculty and research staff members. Reviews will be conducted to assure the university's compliance with DEA and State of Michigan regulations and this program. If deficiencies are identified during an audit, subsequent audits may be performed more frequently to assist with adherence to regulatory compliance.

XX. Corrective Measures

Failure of investigators and agents to follow the requirements of this Controlled Substances Program may result in personal, civil, and criminal liability under state and federal law and disciplinary action under applicable faculty and staff policies, including loss or limitation of an investigator's privilege to conduct animal research.

Appendix 1: Controlled Substances Authorized Agent List

(Note: For security purposes, the number of individuals who have access to controlled substances should be limited)

DEA Registrants Name:	
Location Name:	
Location Address:	

- Authorized Agents cannot:
  - Have been convicted of a felony in the last five years or a misdemeanor in the past two years
  - Have knowingly used narcotics, amphetamines, or barbiturates (other than those prescribed to you by a physician) in the past three years.
- Keep a completed copy of this list with your controlled substances records. Update any changes in listed personnel immediately.

Below is a current list of all persons designated by me, the DEA Research Registration Holder, to access controlled substances at the above location.

Name (Print or Type**)**	**Signature** (Legal Signature)	**WSU Access ID Number**	**Registrant Initials**

I hereby certify that I have designated the persons listed above as Authorized Agents for this location.

Registrant's Signature: _____ Date: _____

Appendix 2: Controlled Substance Regulations and Agencies

State of Michigan

- Michigan Regulations and Administrative Rules – Controlled Substances
    - Michigan Act 368 of 1978 Public Health Code: Article 7

      Controlled Substances
    - Michigan Board of Pharmacy – Administrative Rules: Controlled Substances
    - State License Michigan Department of Community Health (MDCH)
    - Licensing and Regulatory Affairs (LARA) – Licensing for Health Care Professionals
    - State of Michigan Board of Pharmacy – Controlled Substance Licensing Information

For questions regarding controlled substance licensing contact: Bureau of Professional Licensing:

PO Box 30545, Lansing MI 48909

Phone: (517) 241-0199

Fax: (517) 241-9416

Email: BPLHelp@mighigan.gov

Federal Government

- Federal Regulations
    - Title 21 United States Code – Controlled Substance Act
    - Title 21 Code of Federal Regulations, Part 1300-1399
    - federal research registration Drug Enforcement Agency (DEA)
    - DEA Office of Diversion Control – Controlled Substance Registration
        - DEA Support
        - Registration Categories and Fees
        - Questions and Answer

For questions regarding federal research registration contact:

Detroit DEA Field Office

431 Howard Street, Detroit, MI 48226

Phone: (313) 234-4000

Fax: (313) 234-4149

URL: www.deadiversion.usdoj.gov

Appendix 3: Definitions

- **Drug Enforcement Administration (DEA):** a part of the Department of Justice.
- **Controlled Substance:** a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
- **Authorized Agent:** an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.
- **Practitione**r: a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.
- **Readily Retrievable:** certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.
- **Chemical Mixture:** a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.
- **Net Disposal:** for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a non-controlled substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a non-controlled substance or in the manufacture of dosage forms of that basic class.
- **Reverse Distributor:** a registrant who receives controlled substances acquired from another DEA registrant for the purpose of-
- returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or
- where necessary, processing such substances or arranging for processing such substances for disposal.
- **Registrant:** include entities such as controlled substance and listed chemical manufacturers, importers, exporters, distributors, and pharmacies, hospitals, physicians, nurse practitioners, and physician’s assistants and researchers who have a controlled substance license and registration.

Appendix 4: Frequently Asked Questions

U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control
https://www.deadiversion.usdoj.gov/index.html

1. Where can I find the DEA Registration Application forms and tools?

The following DEA website contains helpful online application links and additional tools: https://www.deadiversion.usdoj.gov/online_forms_apps.html

2. What is the processing time for a new or renewal application?

New online Researcher Applications (DEA Form 225) are processed within 4 to 6 weeks. Renewal Applications (DEA Form 225a) are processed within approximately 4 weeks.

3. Has my application been processed?

You can check the status of your application through the "CSA, Check Registration Status" webpage, or call the nearest DEA Field Office.

4. Can you verify a DEA number?

A current DEA registrant can check the validity of another DEA registrant and download the Registrant dataset via an online application through the DEA website.

5. Where can I find the DEA Regulations Governing Controlled Substances?

The DEA regulations governing controlled substances are covered in Title 21, Code of Federal Regulations

6. How does a Schedule I researcher apply for a DEA registration?

A Schedule I research applicant should submit an online DEA Form 225 and must include the following information:

- Investigator:
- Name, address, DEA registration number (if any)
- Institutional or company affiliation
- Qualifications, including *curriculum vitae* (CV) with a list of publications
- Research Project
- Title of project
- Statement of the purpose
- Name of controlled substances (CS) involved, amount (with justification) of each needed and source.

- Research protocol (detailed description of procedures), including number and species of research subjects, dosage to be administered, route and method of administration, and duration of project.
- Location where research will be conducted.
- Statement of security provisions for storing and dispensing the CS(s) in order to prevent diversion.
- If investigator plans to manufacture or import the CS(s), statement of quantity to be manufactured or imported and sources of chemicals to be used or substance to be imported.
- Authority (if applicable):
- Institutional approval
- Approval of a Human Research Committee for human studies.
- Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number).
- If applicable, Indication of an approved funded grant (number).