

Wayne State University

Office of Environmental
Health & Safety

Controlled Substances Program



Why is Wayne State doing this?

- In 2011, a survey of our laboratories revealed that some were not adhering to federal and state regulatory guidelines.



Source Material

- **Drug Enforcement Agency:**
<http://www.deadiversion.usdoj.gov/index.html>
- **Michigan Department of Community Health, Board of Pharmacy:**
<http://www.michigan.gov/healthlicense>
- **University of Michigan:**
<http://www.ucuca.umich.edu/csubs.htm>
- **Michigan State University:**
[http://www.orcbs.msu.edu/controlled_substances/controlled_substances_program/Controlled Substances_Program.pdf](http://www.orcbs.msu.edu/controlled_substances/controlled_substances_program/Controlled_Substances_Program.pdf)
- **Ohio State University:**
<http://orc.osu.edu/files/2011/01/Individual-Investigator-Use-of-Controlled-Substances-in-Research-Final-SMC-Approved-Policy-9-28-112.pdf>



Controlled Substances Program

Components of the Program:

- Licensing
- Ordering
- Storage
- Recordkeeping
- Disposal



CS Licensing – State of Michigan

- All WSU Researchers should have (or started the process to obtain):
 1. A State of Michigan Controlled Substance License, and;
 2. An individual DEA Research Registration
- The State license must be obtained before the DEA will issue a registration number.



CS Licensing – State of Michigan

The “***Application for Controlled Substance Research License***” is available from the Michigan Department of Community Health, Board of Pharmacy Website:

www.michigan.gov/documents/mdch_csresearchapp_147627_7.pdf



CS Licensing – State of Michigan

Applying for a State of Michigan Controlled Substance Research license is a two part process:

1. Completion of the application – \$85.00
2. Criminal background check – Free through WSU Police Dept.



CS Licensing – State of Michigan

- With your application, you must provide:
 - Credentials to conduct the proposed research
 - Protocol for the proposed research
 - List of controlled substances & doses to be used
 - Procedures for storage & security of drugs
 - List of other staff/persons involved
- * Note: A separate application must be submitted to conduct research with Schedule I Controlled Substances.
- Criminal background check: follow application instructions for the fingerprinting process.
- This licensing process typically takes 6-8 weeks.



CS Licensing – State of Michigan

For more information contact:

Michigan Department of Community Health
Bureau of Health Professions Investigation Division

PO Box 30545

Lansing MI 48909

517-373-1737

Email: bhpinfo@michigan.gov



CS Licensing – DEA Registration

- Obtaining a license is relatively easy but it can take some time. Start the DEA process as soon as you have submitted the State of Michigan application.
- The licensing process typically takes 6-8 weeks.
- Use the online DEA application system for the fastest turn-around time:

http://www.dea diversion.usdoj.gov/drugreg/reg_apps/index.html



CS Licensing – DEA Registration

- Complete Form 225. University employees qualify for exemption from the \$244 fee. Your department chair can serve as the certifying official.
- Note: This application is only for Schedules II-V Controlled Substances.
- Schedule I Controlled Substances require a separate application, as well as 3 copies of the protocol and a curriculum vitae.



CS Licensing – DEA Registration

For more information contact:

Detroit DEA Field Office

431 Howard Street

Detroit, MI 48226

313-234-4000

<http://www.deadiversion.usdoj.gov>



CS Authorized Use

- The registrant (PI) is responsible for managing the Controlled Substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions.
- The registrant's staff members may engage in approved activities under his/her direction.



CS Authorized Use

The registrant (PI) is required to screen employees prior to authorization of work with controlled substances and to include the following questions on a questionnaire as part of the screening process (21 CFR, 1301.90):

- 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?
- In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?



CS Authorized Use

- A completed questionnaire (Appendix A) for each employee who is authorized by the PI to handle DEA controlled substances under that PI's supervision.
- A completed questionnaire will be kept on file.



Ordering Controlled Substances

- Enter the purchase requisition into Banner using the Controlled Substance Account code 721H5.
- The director of the Office of Environmental Health & Safety (OEHS) will review and approve the request after checking the “approved faculty and staff” database.



Ordering Controlled Substances

- If approved, Purchasing will confirm that a copy of the researcher's DEA and State of Michigan Controlled Substance licenses are on file and the delivery address is correct.
- If the purchase requisition is not approved, please contact OEHS to resolve the issue.



CS Storage & Security

- Security depends greatly on the type, quantity, and form of controlled substances being used in a research project.
- Researchers must provide effective controls to guard against theft of controlled substances.



CS Storage & Security

- The number of keys and the number of employees who will have access to these keys is limited.
- Keys for locked cabinets should be kept in secure locations when not in use.
- A key accountability standard operating procedure 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 controlled substances.



CS Storage & Security

- Only authorized personnel should be allowed in a university laboratory where controlled substances are used or stored.
- Non-laboratory visitors entering these areas must be asked to provide identification and an explanation of why they are there.
- When maintenance work is done in the controlled substance storage area, the research staff must maintain adequate observation.



CS Recordkeeping

- Maintaining an accurate inventory is one of the most important aspects of DEA enforcement and the university's compliance program.
- Researchers must maintain an up-to-date inventory of controlled substances in their laboratories.
- In following best research practice, and to avoid OEH&S and DEA audit red flags, controlled substance inventories should only include the minimum amount necessary for research use.



CS Recordkeeping

- Researchers are required to maintain a Wayne State University Use of Controlled Substances in Research General Inventory Log for each controlled substance used in their laboratories.
- The form meets DEA documentation requirements for controlled substance inventory, administration, and use.
- DEA inventory requirements may be found here:

www.dea diversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm



CS Disposal

- To minimize waste, researchers should only purchase and store those quantities of controlled substances that they reasonably intend to use.
- Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations.
- There are two disposal options for expired or unwanted controlled substances, contact the supplier or reverse distribution. The Office of Environmental Health and Safety should be contacted to help determine the correct disposal method.



CS Disposal

- A Registrant's Inventory of Drugs Surrendered (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 and one copy must be retained by the investigator for at least 5 years.
- Disposal records must contain the following information:
 - The Investigator's DEA number, name, and address
 - If a reverse distribution (see below) is done, the reverse distributor's DEA number, name, and address
 - The number of units (in finished forms and/or commercial containers) disposed of in any manner, including the manner of disposal
- The disposal record must be dated to reflect when the products left the inventory and were sent for destruction.



Reporting Theft or Missing Controlled Substances

- Investigators must maintain complete accountability of all controlled substances stored or used in their laboratory.
- Theft or misuse of a controlled substance is a criminal act that must be immediately reported to the following agencies:
 - DEA Detroit Division: 313-226-7537
 - Wayne State University Police Department: 313-577-2222
 - Wayne State University OEH&S: 313-577-1200
- In addition to phone reporting, a “Report of Theft or Loss of controlled substances” Form (DEA Form 106) must be submitted to the DEA office.
- Investigators must keep one copy of any DEA Form 106 submitted to the DEA for at least 5 years.



Reporting Theft or Missing Controlled Substances

- On-line reporting to the DEA is also necessary if small quantities of controlled substances become unaccounted for on a recurring basis.

www.dea diversion.usdoj.gov/21cfr_reports/theft/index.html

- Researchers should keep one copy of any online DEA Form 106 submitted in their controlled substance inventory records.



Rules/Regulations

- The registrant /licensee (the person with an active State of Michigan license and DEA registration) is responsible for following all federal and state rules and regulations applicable to controlled substances.



Controlled Substances Program

- Effective February 13, 2012
- Covers of Wayne State researchers using controlled substances (CS) in their research
- Does not include human research



Questions?

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Detroit, MI 48202

313.577.1200

<http://www.oehs.wayne.edu>

