



OP 79.06: CONTROLLED SUBSTANCES USED IN RESEARCH

PURPOSE

The purpose of this policy is to ensure that controlled substances in research activities at Mississippi State University are purchased, stored, used, and disposed in a manner consistent with the requirements of United States Drug Enforcement Administration (DEA). University personnel subject to this policy should consult the full DEA regulations for detailed requirements.

POLICY

Any researcher who plans to use controlled substances in a university non-clinical setting must obtain and keep current DEA registration, unless exempted by law (Ref: 21 CFR 1301)

Registrants are responsible for full compliance with DEA regulations (Ref: 21 CFR 1300 – 1317, as applicable) governing:

1. Initial registration and yearly renewal
2. Procurement of Controlled Substances
3. Training
4. Use of Controlled Substances
5. Maintaining secure storage of Controlled Substances
6. Recordkeeping
7. Disposal of Controlled Substances

No person(s) that is required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by DEA.

To be university compliant, all research activities utilizing controlled substances for which DEA registration is required must be registered by the researcher with MSU's Office of Research Compliance (ORC). ORC will monitor all DEA-registered research projects to ensure continued compliance with registration requirements.

DEFINITIONS

Clinical Setting – A setting where a Controlled Substance is used in a medical or veterinary application.

Controlled Substance – A drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of Part B of U.S.C. Title 21 Subchapter I. The current official schedule of

controlled substances can be found in Section 1308 of the most recent issue of Title 21 Code of Federal Regulations Part 1308 (21 CFR 1308).

Non-Clinical Setting – A setting where a Controlled Substance is used in research, teaching, or testing, which is not a clinical usage of the Controlled Substance.

PROCEDURE

1. The researcher must register their research project with MSU's Office of Research Compliance prior to initiating research and prior to registering with DEA to conduct research which utilizes a controlled substance.
2. Prior to registration with DEA, the researcher must register with the Mississippi Board of Pharmacy. Just as with DEA registration, registration with the Board is researcher specific; i.e., registration will be in the researcher's name. The registration form can be found on their website at <https://www.mbp.ms.gov/Pages/App-and-Fees.aspx>. For "Business Name" use Mississippi State University and your department. If this is your initial registration, leave "DEA #" blank. Once DEA registration is complete, you will be required to update your registration with the Board to include your DEA registration number. Note registration with the Board requires a \$50 fee which must be submitted with your registration.

Board regulations pertaining to controlled substances licensure and license renewal can be found on the Board's website at <https://www.mbp.ms.gov/Pages/Regulations.aspx>.

3. DEA registration (Ref: 21 CFR 1301)

Once you have received your registration number with the Mississippi Board of Pharmacy, you must complete your DEA registration.

Researchers registering to use Schedule I controlled substances must apply in writing including registration form (DEA Form 225) and research protocol. Requirements for research protocol submittal are given in 21 CFR 1301.18. DEA Form 225 and instructions may be downloaded from the following link:

https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm.

Researchers registering to use Schedule II – V controlled substances and analytical laboratories registering to use any schedule may register on-line via the following link:

<https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>.

All researchers and analytical laboratories may renew registration on-line via the following link: <https://www.deadiversion.usdoj.gov/drugreg/>.

Researchers who are employees of any State are exempt from the registration fee. (Ref: 21 CFR 1301.21) However, in order to claim exemption, the registrant's superior must certify to the status and address of the registrant and to the authority of the registrant to acquire,

possess, or handle controlled substances. Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirement or duties prescribed by law.

4. Registration Renewal

Both the Mississippi Board of Pharmacy and DEA require annual license renewal. The researcher is responsible for ensuring that annual renewal is completed. Annual renewals must also be reported to MSU's Office of Research Compliance.

Board regulations for license renewal can be found on the Board's website at <https://www.mbp.ms.gov/Pages/Regulations.aspx>.

DEA registration renewal can be accomplished on-line at <https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp>.

5. Inspections

ORC will monitor all DEA-registered research projects to ensure continued compliance with registration requirements. Likewise, DEA-registered research projects are subject to announced and unannounced inspections by either or both Mississippi Board of Pharmacy and DEA. ORC must be notified of any such inspections and a copy of the inspection results must be filed with ORC.

REVIEW

The university Director of the Office of Research Compliance, Vice President for Research and Economic Development, and Provost and Executive Vice President will review this operating policy every four years or when circumstances require an earlier review.

This policy has been superseded.

REVIEWED BY:

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07/23/2019

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07/29/2019

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08/07/2019

APPROVED:

/s/ Mark Keenum
President

08/22/2019

This policy has been superseded.