Title/Subject: **OVERSIGHT OF CONTROLLED SUBSTANCES IN RESEARCH**

Applies to: ☒ faculty ☒ staff ☒ students ☒ student employees ☒ visitors ☒ contractors

Effective Date of This Revision: December 15, 2016

Contact for More Information: Office of Research Compliance

☐ Board Policy ☒ Administrative Policy ☒ Procedure ☐ Guideline

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BACKGROUND:

The Vice President for Research and Dean of Graduate Studies has established this policy as part of the Central Michigan University'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, storage, record keeping, transfer, and disposal.

PURPOSE:

The purpose of this policy is to define the Central Michigan University program for oversight of controlled substances used in research. 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.

DEFINITIONS:

Controlled Substances: Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in **Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15**.

Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

Schedule I Controlled Substances

Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

Authority: George E. Ross, President
History: New Policy
Indexed as: Oversight of Controlled Substances in Research

Schedule II/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.

Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.

Schedule III/IIIN Controlled Substances (3/3N)

Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).

Examples of Schedule IIIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

POLICY:

Research activities that involve controlled substances are subject to federal and state drug enforcement laws as well as Central Michigan University policies and requirements. All Central Michigan University faculty, staff, students, agents, volunteers, or any individuals using University resources, facilities, or funds must comply with CMU policy and the following federal and state regulations relating to controlled substances:

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)

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PROCEDURE:

It is the responsibility of investigators and associated personnel who utilize controlled substances in a research setting to familiarize themselves with and comply with the regulations listed above and with all CMU requirements* pertaining to controlled substances. This includes the responsibility to:

1. Obtain a State of Michigan (SOM) researcher license and DEA researcher registration for the storage and administration of controlled substances in their laboratory or other research location.
2. Register with CMU's Controlled Substance Research Monitoring Program* by contacting the Office of Research Compliance and provide timely updates following any controlled substance SOM license and DEA registration renewal or change.
3. Successfully complete CMU training requirements* for conducting research with controlled substances.
4. Require that all authorized personnel complete an Authorized Agent Screening Form and maintain an Authorized Agent Log.
5. Store all controlled substances at secure authorized locations and restrict access to controlled substances to authorized personnel
6. Securely maintain all records, including acquisition (e.g., ordering and purchasing), formulating, inventory, usage/administration, and disposal records.
7. Properly dispose of controlled substances when they are no longer required for research, at their expiration, at project end, and before termination of the controlled substance license/registration.
8. Keep SOM licenses and DEA registrations up-to-date, including prior notification (and approval) of changes of address.
9. Immediately report any theft or significant loss to all of the following:
    a. CMU Police Department;
    b. CMU Office of Research Compliance (RESEARCHCONCERN@cmich.edu);
    c. U.S. Drug Enforcement Administration;
    d. Administrator of the Michigan Department of Licensing and Regulatory Affairs, via the Michigan Bureau of Health Professionals

*Forms and detailed information on all CMU requirements for the use of controlled substances in research can be found on the Office of Research Compliance web page.

COMPLIANCE:

The Vice President for Research and Dean of Graduate Studies 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 remediation, 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.

Central Michigan University reserves the right to make exceptions to, modify or eliminate this policy and or its content. This document supersedes all previous policies, procedures or guidelines relative to this subject.