Name of Policy: The Use of Controlled Substances andDangerous Drugs in Animal and In-Vitro Research **Policy Number**: 3364-70-27 **Approving Officer**: President **Responsible Agent**: Vice President for Research **Scope**: All University Research			**Revision Date:** May 27, 2022 **Original Effective date**:July 16 2018
	New policy proposal	X	Minor/technical revision of existing policy
	Major revision of existing policy		Reaffirmation of existing policy

(A) Policy statement

The United States Drug Enforcement Administration (DEA) and the State of Ohio Board of Pharmacy regulate the use of controlled substances and dangerous drugs. The University of Toledo (UToledo) and its employees will comply with the federal and state laws and regulationsthat pertain but are not limited to ordering, storing, dispensing, recording and destruction of controlled substances and dangerous drugs used in animal and in-vitro research.

To obtain, synthesize, and use controlled substances in UToledo Institutional Animal Care and Use Committee (IACUC)-approved animal or in-vitro research, an Investigator must be either aRegistrant or Authorized Agent.

(B) Purpose of policy

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 and dangerous drugs in UToledo animal or in-vitro research and to ensure safe handling and securityof controlled substances and dangerous drugs.

(C) Scope

This policy applies to all UToledo faculty, students and staff using controlled substances ordangerous drugs in animal and in-vitro research.

(D) Definitions

1. “Registrant” UToledo employee who holds both a current DEA registration and a Stateof Ohio Board of Pharmacy Terminal Distributor of Dangerous Drugs (TDDD) License

2. "Authorized Agent" UToledo employee or student who is authorized to act on behalf ofor at the direction of the Registrant with respect to controlled drug access, use, receipt, and disposal.
3. "Controlled Substances" Drugs regulated by U.S. government including illegal andprescription drugs. List of controlled substances found here.
4. "Controlled Substance Schedules" Classification of controlled substances used by theDEA. An updated list of schedules may be found online.
5. "Dangerous Drugs" As defined by Ohio Administrative Code (§ 4729.01); any drug with a label prohibiting dispensing or use without a prescription or by order of a licensedveterinarian, and drugs that may be dispensed only upon a prescription; Any drug intended for administration by injection into the human body other than through a naturalorifice of the human body. These are also known as "pharmaceutical grade" drugs. Thisdoes not include substances known as "chemical grade" or "reagent grade".
6. "DEA" U.S. Drug Enforcement administration, the U.S. Department of Justice lawenforcement agency. https://www.deadiversion.usdoj.gov/
7. "IACUC" The UToledo IACUC or an IACUC authorized in writing by the UToledoOffice of Research and Sponsored Programs (RSP).
8. "List I and List II Chemicals" Chemicals specifically designated by the DEA and used in manufacturing a controlled substance.
9. "TDDD" Terminal Distributer of Dangerous Drugs is a person (individual, association, corporation, or government agency) who either is engaged in the sale of dangerous drugs for retail or any person who, other than a pharmacist, has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.

(E) Management of Use and Disposal

Controlled substances and/or dangerous drugs obtained or manufactured pursuant to this policy may only be used for UToledo-authorized scientific research purposes. When using controlled substances and/or dangerous drugs in research on animals, UToledo Registrants may do so only pursuant to an IACUC-approved research protocol, which defines the specific agent(s), dosage(s), and method(s) of administration of controlled substances and/ordangerous drugs used in the research protocol.

Registrants, TDDDs and Authorized Agents are responsible for compliance with all applicable laws, rules and regulations regarding controlled substances and dangerous drugsobtained or manufactured as part of UToledo animal or in-vitro research, including details not set forth in this policy and updates that occur after the effective date of this policy.

1. Licensing and Registration Requirements
    a. Before initiating the acquisition of controlled substances, UToledo researchers proposing such use in their research must inform the Office of Research and Sponsored Programs (RSP) via email (IACUC@utoledo.edu) and disclose the mechanism under which they will obtain controlled substances:
        i. As a current Registrant with DEA;
        ii. As a new Registrant with an intent to apply for a new license andregistration, specifying the type of license and registration;
        iii. As an Authorized Agent, identifying the specific UToledo Registrantunder whose license they will be receiving controlled substances.
        iv. Current and new Registrants must obtain a separate Ohio Board of Pharmacy

TDDD license for non-clinical research (e.g., animal, analytical, or in-vitro research).

b. Before initiating the acquisition of dangerous drugs, UToledo researchers must inform the Office of Research and Sponsored Programs (RSP) via email (IACUC@utoledo.edu) to ~~disc~~lose the mechanism under which they will obtain dangerous drugs:
   i. As a current TDDD;
   ii. As new TDDD with an intent to apply for a new license andregistration, specifying the type of license and registration;
   iii. As an Authorized Agent, identifying the specific UToledo TDDD under whose license they will be receiving dangerous drugs.

c. Prior to applying for a controlled substance license, Terminal Distributer of Dangerous Drugs (TDDD) and DEA registration, the UToledo researcher must first provide written notification to the Office of Research and Sponsored Programs (RSP) via email (IACUC@utoledo.edu) that contains the following information:
   i. Type of DEA registration (i.e., Researcher vs Practitioner)
   ii. Identification of DEA controlled substance schedule(s)
   iii. Location of Controlled Substance Storage
   iv. List of anticipated controlled substances to be manufactured or used inthe research project(s)
   v. Project or usage summary

d. Upon receipt of TDDD license and DEA registration, expiration dates of license and/or registration, location where materials will be stored, and controlled drugs under license and/or registration must be forwarded to the Office of Research and Sponsored Programs (RSP) via email (IACUC@utoledo.edu).

2. Training
   a. Registrants and Authorized Agents are required to take and pass Controlled Substance Training, prior to the beginning of use and additionally at the discretion of the IACUC Office or the Vice President for Research.

3. Purchasing controlled substances and dangerous drugs
   The purchase of controlled substances must be in accordance with US. Code of Federal Regulations 21 CFR § 1305. Purchase of controlled substances and dangerous drugs must be in accordance with UToledo policy number 3364-40-15.
   a. The Registrant must be an authorized purchaser with a current TDDD license andDEA registration for controlled substance purchases.
   b. Purchases of Schedule I or II controlled substances must be made in conformancewith 21 CFR part 1305.13 (completion of DEA form 222).
   c. Dangerous drugs must be purchased by an authorized purchaser with a current TDDD license.

4. Manufacturing controlled substances
   The manufacture/synthesis of controlled substances and the use of List I or List II Chemicals must be done through a DEA researcher registration in accordance with 21CFR § 1301.13, 1309.71-1309-73 and this policy.
   a. Purchasing and use records of List I Chemicals (only those used in manufactureof controlled substances) must be kept and maintained by the Registrant for a period of at least three (3) years after the conclusion of the research project or protocol.
   b. List I Chemicals must be securely stored to prevent unauthorized access.
      i. Each Registrant must survey, record, and reconcile the relevant List I Chemical

inventory contained in their possession annually, by January31.

ii. The Registrant must provide a copy of relevant inventory records to their Department Chair and College Dean's office annually.

c. Prior to, or at any time during commencement of research and/or manufacture of controlled substances, RSP or UToledo Office of Environmental Health and Radiation Safety staff may inspect the laboratory in which such manufacture willoccur.

5. Storage and security controls for controlled substances and dangerous drugs
In accordance with Ohio Administrative Code (OAC) OAC § 4729-13-05, 4929-9-05,4729-9-11, and 21 CFR § 1301.72:
   a. All controlled substances must be kept under lock and key in a securely locked, substantially constructed cabinet with access given only to authorized users.
      i. Schedule I and II substances must be kept in a securely locked, substantially constructed cabinet that is bolted to the floor or wall with access given only to authorized users.
   b. Criminal background checks must be obtained by the Registrant through the UToledo Police Department for all personnel who will be manufacturing or handling Schedule I or II controlled substances.
      i. Personnel with criminal backgrounds may be banned from participating inresearch that involves manufacturing or handling Schedule I and II controlled substances.
   c. All dangerous drugs must be stored in an area secured by a physical barrier withlocks to deter and detect unauthorized access.

6. Controlled Substance Accountability
   According to 21 CFR §1304.04, 1304.11 and OAC §4729-13-04, 4729:5:3-07 and this policy, the Registrant is responsible for recordkeeping and maintenance of records for a period of at least three (3) years after the conclusion of the research project or protocol.
   a. The investigator must follow all other applicable laws or policies governing the retention or management of records, including but not limited to the Policy on records management and retention (UToledo Policy Number: 3364-5-05).
   b. The Registrant must keep a list of Authorized Agents through the use of aControlled Substance Authorized Agent List form.
   c. The Registrant must sign for receipt of purchase of controlled substances andkeep purchasing/receipt logs.
   d. Record keeping must include details regarding use of the controlled substance by Registrant, any Authorized Agent(s), students, and staff.
   e. Each Registrant must survey, record, and reconcile the relevant controlled substances' inventory contained in his/her possession annually, by January 31.

7. Dangerous Drug Accountability

   According to OAC §4729-13-04, 4729-9-14, 4729-9-22 and this policy, the Registrant is responsible for recordkeeping and maintenance of records for a period of at least three (3)years after the conclusion of the research project or protocol
   a. Record keeping must include details regarding use of the dangerous drugs (i.e.,Use logs with Administration information) by Registrant, any Authorized Agent(s), students, and staff.
   b. Each Registrant must survey, record, and reconcile the relevant dangerous drugs' inventory contained in their possession annually, by January 31.

8. Disposal/Destruction
   a. Disposal of controlled substances must be performed pursuant to 21 CFR

§1307.05, 1317.90 and OAC §4729:5-3-01. See the UToledo Controlled Substance in Research website (https://www.utoledo.edu/research/rsp/RC/controlled- substances-and-dangerous-drugs/) for instructions.

b. Disposal of dangerous drugs must be performed pursuant to OAC §4729:5-3-06.See the UToledo Controlled Substance in Research website (https://www.utoledo.edu/research/rsp/RC/controlled-substances-and-dangerous- drugs/) for instructions.

c. Prior to disposal or destruction of controlled substances and dangerous drugs, Registrant must ensure that all records are complete and up-to-date, and the controlled substances and dangerous drugs are stored securely until disposal ordestruction.

9. Report of Loss, Theft or Unauthorized Use
   a. The Registrant must notify the Field Division Office of the DEA Administrationin his or her area, in writing, of any significant loss or theft of any controlled substance within one business day of discovery of the theft or loss (21 CFR §1304.74 and §1301.76, and OAC §4729:5-3-02). The Registrant must also report such loss or theft to their department chair and dean, the IACUC Office (orRSP), UToledo Police Department, and the Ohio Board of Pharmacy.
   b. Upon discovery, the Registrant must report any significant loss or theft of dangerous drugs to the Ohio Board of Pharmacy (OAC §4729:5-3-02. The Registrant must also report such loss or theft to their department chair and dean,the IACUC Office (or RSP), and the UToledo Police Department (ORC 2921.22).

10. Inspections/Audits
    a. UToledo IACUC Office, UToledo Department of Internal Audit and Compliance, RSP staff, Ohio State Board of Pharmacy and the DEA may inspectand audit laboratories and records at any time to ensure compliance according to 21 CFR §1316.03 and OAC §4729.54, 4729:5-3-03 and this policy.
    b. UToledo Environmental Health and Radiation Safety staff perform laboratory inspections routinely and may assess controlled substance handling during these inspections.
    c. All Registrants and Authorized Agents are subject to audits by UToledo IACUC twice annually, or more, to ensure compliance with DEA and Board of Pharmacy regulations and this policy.

(F) Non-compliance or misuse of controlled substances or dangerous drugs

1. Failure of registrants and authorized agents to follow the requirements of this policy mayresult in personal civil and criminal liability under state and federal law. Failure may alsoresult in university disciplinary action under applicable university policies and/or rules, including loss or limitation of privileges to conduct animal or laboratory research at the university, or termination of employment.

2. When issues of non-compliance are identified, the college and/or department of the registrant, in consultation with applicable university units, will be responsible for determining the corrective action plan and/or disciplinary actions to be taken. Corrective action plans may include, but are not limited to, re-training of faculty, staff, and students;purchasing ability limitations; and laboratory shutdown.

3. Purchases made with grant or external funding that are not in compliance with this policy may be re-allocated to either the appropriate person or appropriate department account.

Resources:
Ohio State Board of Pharmacy 614-466.4143 http://pharmacy.ohio.gov
U.S. Drug Enforcement Administration – https://www.dea.gov/
U.S. DEA Diversion Control http://www.deadiversion.usdoj.gov

Approved by: /s/_____ Gregory C. Postel, M.D. President May 27, 2022 _____ Date *Review/Revision Completed by: Compliance and Privacy Officer, Vice President and General Counsel, Vice President for Research, Senior Leadership Team*	**Policies Superseded by This Policy:** • *N*/A **Initial Effective Date***:* July 16, 2018 **Review/Revision Date:** May 27, 2022 **Next review date:** May 27, 2025