

3364-70-27 The use of controlled substances and dangerous drugs in animal and in-vitro research.

(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 regulations that 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 a registrant 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 security of controlled substances and dangerous drugs.

(C) Scope

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

(D) Definitions

- (1) “Registrant” UToledo employee who holds both a current DEA registration and a state of 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 of or 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 and prescription drugs. List of controlled substances found [here](#).
- (4) “Controlled substance schedules” Classification of controlled substances used by the DEA. An updated list of schedules may be found [online](#).
- (5) “Dangerous drugs” As defined by rule 4729.01 of the Administrative Code; any drug with a label prohibiting dispensing or use without a prescription or by order of a licensed veterinarian, 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 natural orifice of the human body. These are also known as “pharmaceutical grade” drugs. This does not include substances known as “chemical grade” or “reagent grade”.
- (6) “DEA” U.S. drug enforcement administration, the U.S. department of justice law enforcement agency.
<https://www.deadiversion.usdoj.gov/>
- (7) “IACUC” The UToledo IACUC or an IACUC authorized in writing by the UToledo office 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.

(E) Management of use and disposal

Controlled substances and/or dangerous drugs obtained or manufactured pursuant to this policy may only be used for UT-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/or dangerous drugs used in the research protocol.

Registrants, TDDD and authorized agents are responsible for compliance with all applicable laws, rules and regulations regarding controlled substances and dangerous drugs obtained 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 to the IACUC project administrator (Elaine.Joseph@utoledo.edu) and disclose the mechanism under which they will obtain controlled substances:
- (i) As a current registrant;
 - (ii) As a new registrant with an intent to apply for a new license and registration, specifying the type of license and registration;
 - (iii) As an authorized agent, identifying the specific UToledo registrant under whose license they will be receiving controlled substances.
- (b) Before initiating the acquisition of dangerous drugs, UToledo researchers must disclose the mechanism under which they will obtain dangerous drugs:
- (i) As a current registrant;
 - (ii) As new registrant with an intent to apply for a new license and registration, specifying the type of license and registration;
 - (iii) As an authorized agent, identifying the specific UToledo registrant under whose license they will be receiving dangerous drugs.
- (c) Prior to applying for a controlled substance license, terminal distributor of dangerous drugs (“TDDD”), and

DEA registration, the UT researcher must first provide written notification in the form of the [university of Toledo controlled substance registrant registration form](#) to their department chair and dean, and vice president for research (“VPR”). This form 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 in research project
 - (v) Project or usage summary
 - (vi) Signatures of the UToledo researcher, chair, dean or provost, and VPR
- (d) The UToledo researcher should forward the signed controlled substance registrant registration form to the IACUC administrator, who will inform the UToledo researcher of the appropriate type of license and registration for which he/she should apply.

(2) Purchasing controlled substances and dangerous drugs

The purchase of controlled substances must be in accordance with 21 C.F.R. 1305 and rule 3364-40-15 of the Administrative Code (procurement policy). Purchase of dangerous drugs must be in accordance with rule 3364-40-15 of the Administrative Code (procurement policy).

- (a) The registrant must be an authorized purchaser with a current TDDD license and DEA registration.
- (b) Controlled substances must be purchased pursuant to rule 3364-40-15 of the Administrative Code (procurement policy).

(c) Purchases of “Schedule I” or “II” controlled substances must be made in conformance with 21 C.F.R. 1305.13 (completion of DEA form 222).

(3) 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 21 C.F.R. 1301.13, 1309.71-1309-73 and this rule.

(a) Purchasing and use records of List I chemicals (only those used in manufacture of [controlled substances](#)) must be kept and maintained by the registrant for a period of at least three 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 his/her possession annually, by the thirty-first day of January.

(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 will occur.

(4) Storage and security controls for controlled substances and dangerous drugs. In accordance with Administrative Code 4729-13-05, 4929-9-05, 4729-9-11, and 21 C.F.R. 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.

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 UT police department for all personnel who will be manufacturing or handling Schedule I or II controlled substances.

Personnel with criminal backgrounds may be banned from participating in research that involves manufacturing or handling Scheduling I and II controlled substances.

- (c) All dangerous drugs must be stored in an area secured by a physical barrier with locks to deter and detect unauthorized access.

- (5) Controlled Substance Accountability
According to 21 C.F.R. 1304.04, 1304.11 and Administrative Code 4729-13-04, 4729:5:3-07 and this rule, the registrant is responsible for recordkeeping and maintenance of records for a period of at least three years after the conclusion of the research project or protocol.

- (a) The registrant must keep a list of authorized agents through the use of the [controlled substance authorized agent list form](#).
- (b) The registrant must sign for receipt of purchase of controlled substances and keep purchasing/receipt logs.
- (c) Record keeping must include details regarding use of the controlled substance by registrant, any authorized agent(s), students, and staff.

- (d) Each registrant must survey, record and reconcile the relevant controlled substances' inventory contained in his/her possession annually, by the thirty-first day of January.

The registrant must provide a copy of relevant inventory records to their department chair and college dean's office annually

(6) Dangerous drug accountability

According to Administrative Code 4729-13-04, 4729-9-14, 4729-9-22 and this rule, the registrant is responsible for recordkeeping and maintenance of records for a period of at least three 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 his/her possession annually, by the thirty-first day of January.

(7) Disposal/destruction

- (a) Disposal of controlled substances must be performed pursuant to 21 C.F.R. 1307.05, 1317.90 and Administrative Code 4729:5-3-01. See the UT 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 Administrative Code 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 or destruction.

(8) Report of loss, theft or unauthorized use

(a) The registrant must notify the field division office of the DEA administration in 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 C.F.R. 1304.74, 1301.76, and Administrative Code 4729:5-3-02). The registrant must also report such loss or theft to their department chair and dean, the IACUC office (or RSP), UT 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 (Administrative Code 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 UT police department (section 2921.22 of the Revised Code).

(9) Inspections/audits

(a) UToledo IACUC administrator, UToledo department of internal audit and compliance, RSP staff, Ohio state board of pharmacy and the DEA may inspect and audit laboratories and records at any time to ensure compliance according to 21 C.F.R.1316.03 and Administrative Code 4729.54, 4729:5-3-03 and this rule.

(b) UToledo environmental health and radiation safety perform laboratory inspections routinely and may assess controlled substance handling during these inspections.

(c) All registrants and authorized agents may be audited by UToledo IACUC administrator or RSP designee 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 may result in personal civil and criminal liability under state and federal law. Failure may also result 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 outside funding that are not in compliance with this policy will 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 –
<http://www.usdoj.gov/dea/index.htm>

U.S. DEA diversion control <http://www.deadiversion.usdoj.gov>

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Certification

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