Name of Policy: The Use of Controlled Substances in Animal Research

Policy Number: 3364-70-27

Approving Officer: President

Responsible Agent: VP of Research

Scope: All University Research

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(A) Policy statement

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

To obtain and use controlled substances in UT Institutional Animal Care and Use Committee (IACUC)-approved animal research, an Investigator must be either:

(1) A Registrant: holds a current DEA registration and a Board of Pharmacy Terminal Distributor of Dangerous Drugs (TDDD) License

or

(2) An Authorized Agent: conducts their research as an authorized agent of a university official or investigator who holds a current DEA registration and Board of Pharmacy TDDD License.

(B) Purpose of policy

The purpose of this policy is to outline the procedures necessary to comply with federal and state laws and regulations governing controlled substances in animal research laboratories.

(C) Scope

This policy applies to all UT faculty, students and staff using controlled substances in animal research.
(D) Definitions

Controlled Substances – a drug regulated by U.S. government including illegal and prescription drugs.

Controlled Substance schedules – up to date list of schedules can be found at http://www.deadiversion.usdoj.gov/schedules/index.html.


IACUC – the University of Toledo Institutional Animal Care and Use Committee or an IACUC officially authorized in writing by the University

(E) Procedure

(1) Approved use: Controlled substances obtained pursuant to this policy may only be used for authorized scientific research purposes as approved by the Federal, state or university research protocols to the extent permitted by the law. When using controlled substances in research on animals, investigators with a DEA research or instructing registration may do so only pursuant to an IACUC-approved protocol, which defines the specific agent(s), dosage(s), and method(s) of administration of controlled substances used in the research protocol.

(2) Permitted Users

(a) Registrant: Holds a DEA registration and a TDDD.

(b) Authorized Agent: An individual working in a research laboratory who is specifically listed on a University of Toledo Authorized Agent List associated with a controlled substance registration. Authorized Agents using controlled substances are also required to comply with the terms of this policy and procedures within.

(3) Licensing and Registration Requirements

(a) Investigators who propose to use controlled substances in their IACUC protocol(s) must inform the Institutional Animal Care and Use Committee as to how they will obtain controlled substances:

(i) As a current Registrant,

(ii) Applying for a new license and registration, or
(iii) as an Authorized Agent, specifying which Registrant they will be working under.

(b) To apply for a new license and registration, the investigator must first obtain a TDDD as stated in the Ohio Administrative Code Sections 4729-12-02, 4729-13-06 and 4729-13.16. A TDDD license application can be obtained on the Ohio State Board of Pharmacy website: http://pharmacy.ohio.gov/phlic.htm.

(c) After the TDDD is acquired, they must apply for a DEA registration. The application can be obtained from the DEA website at: http://www.deadiversion.usdoj.gov/drugreg/index.html.

(i) DEA registration options:

(a) Practitioner: A licensed healthcare or veterinary medicine practitioner who has a current Ohio Board of Pharmacy TDDD License and DEA Practitioner registration is permitted to dispense or administer a controlled substance in the course of her/his professional practice at the university, or as an investigator conducting research at the university. Clinical practitioners must not issue a prescription to themselves to obtain controlled substances to be stored or dispensed for research purposes.

(b) Researcher or Instructor: An investigator with a current Ohio Board of Pharmacy TDDD License and DEA research or instructing registration may purchase and use controlled substances in research animals. Investigators with DEA research or instructing registrations may not use controlled substances in research involving the use of human subjects, or dispense or write prescriptions.

(d) It is the investigator’s responsibility to renew their TDDD every year, but DEA renewal varies based upon the type for the DEA registration (see website).

(e) TDDD license and DEA registration should be maintained in a readily available place in the principal location of the research activity.

(4) Purchasing controlled substances

The purchase of controlled substances must be in accordance with the Code of Federal Regulations §1305, the Ohio Administrative code §4729-9-13 and university policy.
(a) The Registrant is the authorized purchaser as established by the current TDDD license and the DEA registration.
(b) Documentation should be provided to the UT Purchasing Department verifying that the Registrant is authorized to purchase.
(c) Controlled substances must be purchased using The University of Toledo purchasing procedures found in purchasing policy #3364-40-15.

(5) Storage and security controls

In accordance with Ohio Administrative code §4729-13-05:
(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.
(b) Etophine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. government class V security container.

(6) Accountability

The Code of Federal Regulations §1304.04 and Ohio Administrative code §4729-13-04 require that the Registrant is responsible for recordkeeping and maintaining such records for a period of at least ten (10) years from the date of last recorded transaction:
(a) Receipt of received controlled substances must be signed by receiving authorized purchaser and should include:
   (i) Date received,
   (ii) Name and address of supplier,
   (iii) Type,
   (iv) Concentration/strength, and
   (v) Amount (volume/weight) of controlled substance.
   See University of Toledo Purchasing/Receiving Log.
(b) Recording keeping should include tracking use of the controlled substance including:
   (i) Date,
   (ii) Laboratory building and room location,
   (iii) Specific research experiment,
   (iv) Application of substance in research
   (v) Type,
   (vi) Quantity,
   (vii) Concentration/strength of each substance,
(viii) Waste,
(ix) Balance remaining, and
(x) Each record must be signed by the authorized user.

See University of Toledo Controlled Substance Usage Logs.

(c) Inventory must be conducted by the registrant as assigned and must be recorded by May 15 of each year. The type, strength and quantity of all substances must be documented and include date and signature of authorized conductor of the inventory and retained for review should a regulatory agency request. See University of Toledo Inventory Log.

(7) Disposal

(a) The Code of Federal Regulation §1307.21 and Ohio Administrative Code §4729-9-06 address disposal of controlled substances.

(b) See the UT RSP/IACUC Controlled Substance SOP for instructions.

(c) Prior to disposal of controlled substances, ensure that all records are complete and up-to-date, and the controlled substances are stored securely until the disposal.

(8) Report of Loss, Destruction, Theft or Unauthorized Use

Controlled substances that are lost, destroyed, stolen or used by unauthorized user must be reported to the Ohio State Board of Pharmacy and the DEA according to the Code of Federal Regulations §1304.74 and §1301.76 and Ohio Administrative Code §4729-9-15.

(a) Should a theft, suspected theft, unauthorized uses, drug diversion, or other losses of any controlled substances occur on any of the university campuses, call The University of Toledo Campus police immediately to report.

(b) A written document must be submitted to the Ohio State Board of Pharmacy and DEA within 72 hours and copied to the IACUC (retain a copy for your records). The document must include:

(i) The type of controlled substance,
(ii) The quantity of controlled substance,
(iii) The specific circumstances involved,
(iv) The location of the occurrence, and
(v) Evidence of police report.

(9) Inspections/Audits
(a) The IACUC, Research & Sponsored Programs’ Compliance Officer, Ohio State Board of Pharmacy and the DEA have the right to inspect and audit laboratories at any time to ensure compliance according to the CFR §1316.03 and Ohio Administrative Code §3719.13 and §3719.27.

(b) UT Environmental Healthy and Radiation Safety perform laboratory inspections routinely and may assess controlled substance handling during these inspections.

(c) All Registrants and Authorized Agents will be regularly audited by the IACUC to ensure compliance with DEA and Board of Pharmacy regulations and this policy.

Resources:
Ohio State Board of Pharmacy 614-466.4143 http://pharmacy.ohio.gov
DEA Diversion Control http://www.deadiversion.usdoj.gov

Attachments:
Form 1 University of Toledo Authorized Agent List
Form 2 University of Toledo Purchasing/Receiving Log
Form 3 University of Toledo Controlled Substance Usage Logs
Form 4 University of Toledo Inventory Log

Approved by:

/s/
Sharon L Gaber, Ph.D.
President

July 16, 2018
Date

Review/Revision Completed by:
Compliance and Privacy Officer
Vice President for General Counsel
VP Research

Policies Superseded by This Policy:

• N/A

Initial Effective Date: July 16, 2018

Review/Revision Date: N/A

Next review date: July 16, 2021