UTDPP1042 - Management of Controlled Substances

Policy Statement

Purpose

This policy establishes minimum standards for controlled substance procurement, storage and use within The University of Texas at Dallas and should be followed concurrently with the policies and procedures found in Policy Memorandum 01-III.27-84 Controlled Items, Precursor Chemicals, and Chemical Laboratory Apparatus. The purposes of these policies are to maintain compliance with federal (Code of Federal Regulations [CFR] 21 Part 1300 to end) and applicable state statutes of the Health and Safety Code and to minimize diversion of controlled substances.

Scope

This policy applies to controlled substances in basic and applied research and instructional settings.

Responsibilities

1. Faculty members who purchase, receive, use, or intend to use controlled substances in research or teaching are responsible for obtaining and maintaining their license(s) from the U.S. Department of Justice, Drug Enforcement Administration and the Texas Department of Public Safety. Forms for applying for these licenses must be obtained from the University Safety Officer. The completed forms must be returned to the University Safety Officer to be reviewed and processed. All renewals must also be processed through the University Safety Officer.
2. Faculty members who purchase or receive controlled substances are responsible for all aspects of security, record keeping, use, and disposal as described in this policy.
3. The University Safety Officer is responsible for monitoring compliance with provisions of this policy, maintaining a copy of all licenses, maintaining a roster of all licensees, and providing advice and counsel for achieving and maintaining compliance.
Approval

1. Animal Research Protocols utilizing controlled substances are reviewed for approval by the University’s Institutional Animal Care and Use Committee (IACUC), and the University Safety Officer.
2. A request to purchase, receive and use a controlled substance in research and/or teaching activities must be approved by the School Dean and the University Safety Officer.
3. The University Veterinarian may bring controlled substances to campus to be used in procedures on animals that he/she personally conducts in the animal facility. He/she may not house any controlled substances in the campus animal facility.

Procurement and Transfers

1. All controlled substances shall be purchased through the University Purchasing Office utilizing a University Purchase Order. The University Safety Officer will expedite the purchase through the system to safeguard the DEA registration number. All controlled substances shall be received in the Central Receiving Office and sent to the University Safety Officer, who shall check authorization documentation and disseminate the purchase to the appropriate faculty member. Small Order System (SOS) purchases and credit cards may not be used to purchase controlled substances.
2. Transfer of controlled substances between licensed Investigators is allowed provided a UTD Controlled Substance Form is filled out and forwarded to the University Safety Officer, who logs it in the master log and verifies that the licensing is valid and correct at the time of the transfer.
3. Transfers to and from points outside of The University of Texas at Dallas:
   1. Only full containers with their seal intact may be transferred.
   2. Items may be shipped to the University Safety Officer and held for an arriving new investigator until they are properly licensed.
   3. Items to be transferred to another location for the convenience of the investigator will be sent to the institution’s Safety Officer for safekeeping. Upon receipt of proper documentation, the University Safety Officer will package and send the item(s) to the appropriate individual at the receiving institution as required by the institution’s policy and procedures.
Security

1. All employees who possess or use controlled substances are responsible for establishing and maintaining effective controls and procedures against unauthorized access to controlled substances.
2. All controlled substances (Drug Enforcement Agency [DEA] Schedules I-V) must be stored and securely locked behind at least three sets of locks, in a substantially constructed cabinet or security cabinet in accordance with CFR 21 Section 1301.72. At a minimum, such cabinet is interpreted as a structure of wood or metal so constructed as to resist easy entry by simple tools of attack, with internally-mounted hinges, and secured by a deadbolt lock. The cabinet should be permanently constructed or attached to the building structure to prevent physical removal. Access to the cabinet must be limited to only those individuals specifically authorized to use the controlled substances.
3. No employee who has been convicted of a felony or any state or federal law regarding controlled substances may be allowed access to controlled substances. All employees with access to controlled substances must consent to a background check regarding conviction of a felony or any state or federal law pertaining to controlled substances. The background checks will be requested from the University Police by the University Safety Officer.

Records

1. Complete and accurate records of purchase or receipt and use of all controlled substances (DEA Schedules I-V) will be kept in a bound ledger in accordance with the Texas Department of Public Safety Health and Safety Code and federal regulations CFR 21 Section 1304.04.
2. Records of purchase, acquisition, or disposal of controlled substances shall include the following without limitation.
   1. Name, quantity and strength of the drug;
   2. Invoice number, or purchase order number;
   3. Date of purchase or acquisition;
   4. Date and amount dispensed, administered or disposed of;
   5. True name and current address of person receiving the controlled substance (not applicable for animal or wet-bench use);
   6. Reason for dispensing (IACUC protocol number, if applicable).
7. The ledger will have a section divided into incoming and outgoing categories for each drug and will be further divided by drug strength.
   1. On the incoming side the date, invoice or purchase order number and quantity of drugs received will be listed. A column for total on-hand amount will include those quantities already possessed.
2. On the outgoing side will be listed information in VII.B.4.-6. above.

**Disposal**

All expired controlled substances, or controlled substances to be discarded must be transmitted to the University Safety Officer.

**Loss or Theft**

Any loss or theft of controlled substances shall be reported immediately to the University Police and the University Safety Officer.

**Inspections**

1. All facilities where controlled substances are used or stored will be inspected by the University Safety Officer or his/her designee at intervals of not less than six months. Inspections will be unannounced.
2. The University Safety Officer shall notify in writing the faculty member and Dean of the applicable School of any deviations from this policy.

**Terminations**

1. Upon termination of one of the following:
   1. termination of the Licensee from the University;
   2. discontinuance of the requirement of controlled substances in the work of the Investigator; or
   3. cancellation or revocation of the licenses by issuing agencies;
4. the University Safety Officer will:
   1. secure all controlled substances for proper disposal and/or transfer;
   2. safeguard the University’s drug log;
   3. retrieve the current licenses for cancellation; and
   4. provide the investigator with a copy of the drug log and or licenses on request.

**Policy History**

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