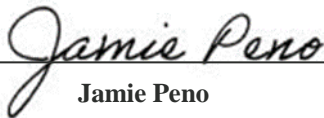
 <div style="display: inline-block; vertical-align: middle;"> <b>DIVISION OF RESEARCH &amp; INNOVATION</b>        Research Integrity &amp; Compliance     </div>		<b>Institutional Animal Care and Use Committee</b>  <b>Standard Operating Procedures</b>	
<b>Title: Use of Controlled Substances</b>			
<b>Effective Date:</b>	December 22, 2020	<b>Document Number:</b>	IACUC-SOP-02-18.00
<b>Approval/Date:</b>  <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">   <hr style="width: 100%;"/> <b>Jamie Peno</b>          Director, Research Integrity and Compliance       </div> <div style="text-align: center;"> <hr style="width: 100%;"/>         12/22/2020  <b>Date</b> </div> </div>			
<b>REVISION HISTORY</b>			
<b>Date</b>	<b>Section</b>	<b>Author</b>	

## PURPOSE

The use of controlled substances in research animals is federally regulated. All use of controlled substances at UNT must follow applicable federal, state, and local guidelines. Controlled substances used in research animals at UNT must be approved by the UNT IACUC.

## SCOPE

It is the responsibility of the Principal Investigator or a Co-Investigator named on the approved protocol to hold and maintain the required licenses to use and obtain controlled substances at UNT.

It is the responsibility of the Principal Investigator to retain the appropriate records required by DEA and be able to provide them at any time to the UNT IACUC upon request.

It is the responsibility of the Principal Investigator to ensure all staff responsible are appropriately trained, with documentation of training, to use and administer controlled substances under their license and in congruence with approved animal use protocols.

## DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton

IACUC- Institutional Animal Care and Use Committee

SOP/SOP's- Standard Operating Procedure(s)

AUP- Animal Use Protocol

PI- Principal Investigator

AV- Attending Veterinarian

LAF- Lab Animal Facility

DEA- Drug Enforcement Agency

Controlled Substance- a substance, including a drug listed in Schedules I through V or

Penalty Group 1 through 4 of the Health and Safety Code, Chapter 481, the Texas

Controlled Substance Act.

## **PROCEDURES**

- I. Controlled Substance Licensing**
  - A.** The DEA requires controlled substances be purchased and used under a DEA license.
    - 1. To obtain a license one must register and submit to an inspection and certification process by the DEA.
    - 2. Licenses must be renewed annually.
    - 3. Records of procurement, storage, use, and disposal must be strictly maintained.
  - B.** Licenses may be restricted to certain class schedules and regulations must be adhered to by the PI and staff per the type of license issued.
  - C.** PI's obtaining and maintaining a DEA license on campus should register it with UNT Biosafety in Risk Management Services.
  - D.** For guidance in obtaining and maintaining a DEA license on campus contact the Biosafety Officer in Risk Management Services (RMS).
  - E.** Controlled Substance licenses and records are subject to IACUC and RMS inspection upon request.
- II. Records and Storage of Controlled Substances**
  - A.** Each lab should maintain documented training and a log of signatures for those approved to use controlled substances under each DEA license as an Authorized User.
    - 1. An Authorized User is an individual who has been approved by the registrant for access to the controlled substance(s).
    - 2. All Authorized Users must be approved personnel on an approved IACUC Protocol to be used in research animals.
    - 3. Authorized Users may be added via the routine protocol amendment process.
    - 4. Registrants are responsible for all activities of the Authorized Users. Registrants should choose Authorized Users who are reliable, trustworthy, and without adverse histories regarding controlled substances.
  - B.** A Master Inventory should be maintained to include records of procurement:
    - 1. Substance Name
    - 2. Substance Categorical Schedule
    - 3. Substance unique identification number
    - 4. Lot#
    - 5. Expiration Date
    - 6. Specific Quantity
    - 7. Specific Volumes and amounts of drug per individual container.
    - 8. Date of receipt
    - 9. Personnel receiving and documenting receipt
    - 10. Source/ Shipping documentation/ 222 forms
  - C.** Records of storage should be maintained to show specific Lot#, expirations, and quantities stored in each DEA approved lockbox/ location.
    - 1. Records should indicate if controlled substances are relocated to another approved lockbox under the same license.
    - 2. Controlled substances cannot be transferred between licenses without DEA approved distributor/ vendor status and licensing, as well as the appropriate documentation.
  - D.** Records of use should document:

1. Animal ID
2. Quantity in appropriate measure (as labeled on substance original packaging (ie. mL, mcg, patch, etc.))
3. Personnel removing the substance from inventory
4. Date of use

**E.** Records of disposal should document:

1. Lot# and Expiration
2. Quantity of unused substance disposed of
3. Date of disposal
4. Signature of personnel disposing of the substance
5. Signature of witness to disposal
6. For large quantities of substances that require disposal through a 3<sup>rd</sup> party vendor, retain all documentation of transfers, shipping, and disposal confirmations.

**F.** Records and inventory should be routinely reviewed by the license holder during the annual controlled substance audit and maintained for five years

**G.** Storage must be in a DEA approved restricted access location assigned to the license, appropriate for the Schedule and environmental requirements of the substance.

**H.** Options for storage of Schedule II-V Controlled Substances are:

1. In a locked container inside a locked cabinet. Preferably, the locked container should be secured to an immovable surface such as a wall or shelf secured to a wall.
2. In a locked cabinet in a locked room. NOTE: The 'locked room' must always be locked when it is not occupied by either the registrant or an authorized user. Leaving lab associates not on the Authorized Users list in the lab when no Authorized user is present in the lab is a violation.
3. Locks may be cipher locks (combination locks) or key locks; key locks are preferred.
4. Combinations or Keys must not be readily accessible to individuals not on the 'Authorized Users' List.
5. If key locks are used:
  - a) The two locks must be keyed differently
  - b) The two keys must not be stored together (not on the same ring).
  - c) Both keys must be safeguarded and not accessible to unauthorized users
6. It is best practice to store Schedule II drugs separate from Schedule III-V drugs (i.e., a separate shelf within the same locked cabinet or safe).
7. Schedule I agents have more stringent security requirements and must be maintained in a securely locked and substantially constructed cabinet. A strong metal cabinet or heavy safe fastened to a permanent structure in a limited access room is typically adequate.

**III.** Use of Controlled Substances in Animals

**A.** The use of all controlled substances must be described in an approved animal use protocol.

1. The PI or a Co-PI may hold the DEA license for the study as long as they are UNT Faculty.
2. The license owner should be listed in the protocol and may be verified through UNT Biosafety prior to approval.

**B.** Each lab should have written procedures for the use, documentation, and disposal of controlled substances.

**C.** Personnel listed in the approved protocol as administering controlled substances should have appropriately documented training maintained under the DEA license holder.

**D.** Inventory of stock should be well maintained and managed to keep a minimal amount of controlled substances based on need. Expired controlled substances should be discarded appropriately and should remain part of inventory records until discarded.

#### **IV. Disposal of Controlled Substances**

- A.** Controlled substances must be disposed of according to DEA regulations and may only be disposed of by the license holder or approved designees.
- B.** If controlled substances are found unattended or abandoned and the licensed owner cannot be identified, University Police should be contacted for removal and disposal.
- C.** For discard of small amounts of an unused substance that has been removed from the original container and assigned to a 'patient', a witness is required to observe the disposal and document the method and observation.
- D.** Accidental disposal or losses such as a broken bottle should be documented promptly to describe the incident in detail, including estimated quantity and a witness observation of clean-up procedures. All losses should be reported within 24hrs to DEA by the registrant.
- E.** For disposal of large quantities of expired or unused controlled substances, a 3<sup>rd</sup> party service with 'reverse distributor' licensing may be used.

#### **REFERENCES**

- 1. Drug Enforcement Administration regulations detailed in 21 CFR 1300-1308
- 2. Health and Safety Code, Chapter 481, the Texas Controlled Substance Act
- 3. DEA Diversion Control Division <https://www.dea.gov/diversion-control-division>

#### **APPENDICES**

IACUC Standard Operating Procedures