

<b>IACUC SOP:</b>	<b>Statement on Controlled Substance</b>	
<b>SOP#115.00</b>	<b>IACUC Approval: 12/2/2022</b>	<b>IO Approval: 12/20/2022</b>

## Purpose

To provide guidance regarding controlled substance used in research or teaching.

## Policy

- A. This policy addresses the acquisition, use, record keeping, and disposal of controlled substances (narcotic and non-narcotic) regulated by the Drug Enforcement Administration (DEA). This SOP is endorsed by the Texas A&M University-San Antonio Institutional Animal Care and Use Committee (IACUC). The practice and enforcement of these policies will keep all animal care researchers and personnel in compliance with federal, state, and local laws.
- B. All TAMUSA employees, contractors and visitors conducting research with animals are required to comply with these policies. All controlled substances on TAMUSA or dispensed at any time for any purpose are subject to regulation the IACUC, or any other designated agent of TAMUSA.
- C. Contact the BSO at [iacuc@tamusa.edu](mailto:iacuc@tamusa.edu) for specifics related to DEA registration for the use of controlled substances in research animals at A&M-SA.

## Procedures

### Responsibilities

1. The IACUC responsibilities include:
  - Review animal use protocols (AUP) to ensure that researchers using controlled substances in animals are appropriately registered with DEA
  - Review AUPs to ensure appropriate clinical applications and handling procedures for controlled substance use in animals
2. Principal investigators are responsible for the following items.
  - Approved DEA registration for the use of controlled substances
  - Order, receive, store, responsibly dispense, and legally destroy all controlled substances
  - Have an approved AUP to conduct animal research using controlled substances
  - Provide appropriate security for controlled substance
  - Maintain records of controlled substance used in animal research at A&M-SA using the log provided by the BSO (attached below).
  - Provide access to controlled substance log during semi-annual program review and other inspections

### Methods

1. Controlled substances can only be used under an approved and current AUP that contains provisions for the use of controlled substances. Use of controlled substances not included in the relevant IACUC-approved AUP is not allowed.
2. Principal Investigators or their designees holding DEA licenses must file a photocopy of their DEA registration with the IACUC Coordinator to verify registration and active status.
3. All controlled substance records are subject to inspection by IACUC, or other authorized review/compliance individuals without prior notice.

**History:**

Version 01 - Initial Approval: 12/2/2022

IO Approved:



TEXAS A&M UNIVERSITY  
SAN ANTONIO

# Vial Use Log

Vial Number: \_\_\_\_\_

<b><u>Principal Investigators (PI)</u></b> <b><u>Name:</u></b>	<b><u>PI DEA License #:</u></b>	<b><u>IACUC Protocol Number(s):</u></b>
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<b><u>Substance name:</u></b>	<b><u>National Drug Code (NDC):</u></b>	<b><u>Manufacturer expiration date:</u></b>
<b><u>Net contents:</u></b>	<b><u>Lot:</u></b>	<b><u>Dilution:</u></b>
<b><u>Date Received:</u></b>	<b><u>Date opened:</u></b>	<b><u>Date used:</u></b>

	<b><u>Date Used</u></b>	<b><u>Amount Used (mL)</u></b>	<b><u>Remaining (mL)</u></b>	<b><u>Animal ID</u></b>	<b><u>User</u></b>	<b><u>Amount Waste/Witness</u></b>	<b><u>P.I.</u></b>
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Container Disposal Date: \_\_\_\_\_ Volume Remaining: \_\_\_\_\_

Method of Disposal: \_\_\_\_\_

Disposed By: \_\_\_\_\_

Print

Signature

Witness By: \_\_\_\_\_