



Animal Facility SOP 12.2 Access to Controlled Substances

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Prepared by	Michelle Dennis and Ingrid Tulloch
Reviewed by	Matt Terzi, Julie Watson, Ingrid Tulloch

Purpose

This document is intended as a guide for all personnel who will use controlled substances in animal care and research. **As of 1/28/2021 Ketamine is the only controlled substance in use.**

II. Scope Maryland State and Federal laws limit the possession, use, and distribution of controlled substances. This SOP provides legal definitions and MSU policies and procedures for researchers and staff to secure access to, use and maintain records of pharmaceutical drugs classified as controlled substances.

III. Legal Definitions and types of controlled substances

- Schedule I Controlled Substances:** Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.
 - Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").
- Schedule II/IIN Controlled Substances (2/2N).** Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.
 - Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®).
 - Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone. Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).
 - Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.
- Schedule III/IIIN Controlled Substances (3/3N)** Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.
 - Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).
 - Examples of Schedule IIIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.
- Schedule IV Controlled Substances** Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

- a. Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).
5. **Schedule V Controlled Substances.** Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.
 - a. Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

IV. Controlled substances most commonly used in vertebrate animal research are:

- Ketamine – an anesthetic agent (schedule 3)-
- Sodium pentobarbital – anesthetic/euthanasia agent also known as Nembutal®, Euthasol®, etc. (schedule 2)
- Buprenorphine – a narcotic analgesic (schedule 3)
- Butorphanol – an analgesic (schedule 4)

For a complete list of Controlled Substances, visit the [DEA website](#)

V. Authorization: Principal Investigators must have an approved Controlled Substance Use Authorization from Maryland Department of Health and the Drug Enforcement Agency to access and use Controlled substances. (See facility director about acquiring these). The facility manager keeps a list of all approved controlled substance users.

VI Purchase: All controlled substances must be purchased through the Purchasing Department under MSU institutional DEA research registration. NOTE: A purchase requisition is required, even if the drugs are being provided by the vendor without charge.

VII Storage: Controlled substances and the records of use must be kept securely locked using a two lock system in accordance with DEA regulations, Access will be limited to only those individuals specifically authorized to use them. A completed Controlled Substances Log must accompany all vials or containers.

- **Records & Documentation:** A detailed log must be kept to record and account for all use of controlled substances to include all required DEA forms.
- **Disposal:**
 - Controlled substances which have expired or are no longer needed by the laboratory, as well as all empty vials, require the animal facility director or animal facility manager to coordinate disposal through MSU's reverse distributor Chesapeake Waste Management.. Empty vials or expired drugs must be kept secure per storage policies above until removed by reverse distributor.
 - Controlled drugs must not be discarded or disposed of in the trash or down the drain.

Procedures

1. **Note:** Student researchers cannot request or administer controlled substances. Researchers not cleared for controlled substance use cannot pick up or administer controlled substances to animals. Only the veterinarian, animal facility director and manager or cleared PIs can administer controlled substances. Administration of controlled substances to animals must be done in the vivarium.
2. If you have your own controlled substance license and plan to store the controlled substances in your own lab, you must provide proof-locked safe kept in a locked cabinet behind a locked door (i.e. the controlled substances are double-locked), that is accessible only by authorized personnel and you must keep your own records of use. When you are ready to discard empty vials or expired drugs, contact the Animal Facility Director to arrange pick up with Chesapeake Waste management.
3. When a controlled substance is required, investigators must complete and submit a **controlled substance administration request form** no later than one week before the date of use.
4. On receipt, each bottle is numbered and the date of arrival, drug name and quantity is recorded in the log, and the number written in indelible ink on the bottle label.
5. On administration, the date, protocol #, animal # (where appropriate) volume administered and volume remaining is recorded in the log relating to the bottle number, and the user signs the entry.
6. IF drugs are to be disposed of, 2 people (one of whom is the facility manager) need to record the volume to be disposed of under the appropriate bottle number and both people sign the log. The animal facility manager contacts Chesapeake Waste Management to arrange disposal. Waste management personnel sign the log on pick-up.

Ref. <https://www.deadiversion.usdoj.gov/schedules/#define>

CONTROLLED DRUG LOGS

Controlled Drug Log

https://docs.google.com/document/d/1JHOa_vKW5RM1vrM4ABBU-aGkmKUAqG6V69GVrvaKhVE/edit?usp=sharing