

Ordering, Maintaining, & Disposing of Controlled Drugs for Animal-related Research and Teaching (revised July 8, 2016)

Controlled drugs are those drugs regulated by the Drug Enforcement Agency (DEA). The majority of prescription drugs, while acquisition is regulated, are not controlled substances. Commonly used drugs that are controlled substances include buprenorphine, butorphenol, euthanasia solutions, ketamine, midazolam, morphine, oxymorphone, pentobarbital, and tramadol. The DEA has very strict rules for obtaining, maintaining, and disposing of controlled substance.

Obtaining controlled drugs:

There are three ways to obtain controlled substances.

1. If controlled substance use is infrequent and small, then the investigator can ask the Department of Animal Care and Technologies (DACT) clinical veterinarian for pre-drawn syringes containing the needed drugs. The investigator will be charged for the drugs and the syringes used. The PI does not need a DEA license, but does need to have the drug and dose in an approved IACUC protocol. Controlled drugs acquired in this manner must be used promptly after acquisition and definitely by the end of the day. Controlled substances cannot be stored without a DEA license. If the investigator is unable to use the drug on the day it was issued, then the syringe containing the drug must be returned to the DACT clinical veterinarian or designee.
2. Investigators may procure from DACT an unopened bottle of any drug that is listed in their IACUC-approved animal use protocol. For controlled drugs, a copy of the investigator's researcher DEA license that the drugs are being transferred to must be on file with DACT before delivery of the drugs will be made.

To Order Drugs From DACT - Send Larisa Gilley (Larisa.Gilley@asu.edu) an email listing the name of the principal investigator (PI), IACUC protocol number, drug name, concentration, amount, and the Advantage account number to be charged. For Schedule II drugs (e.g., pentobarbital, oxymorphone, morphine, Sleep Away®), the PI must also provide Larisa with a DEA 222 form. Larisa (or her designee) will respond with the time and place the order may be picked up. For commonly used drugs (e.g., ketamine, buprenorphine, euthanasia solution) DACT may have a bottle for distribution in stock, and delivery can be within days. However, this is not the case for less used drugs and may not be the case for commonly used drugs in some circumstances. Therefore, allow sufficient time for DACT to order the drug from a vendor, receive the drug, and transmit it to you, which can take 2-4 weeks. You can call Larisa for availability or if you have other questions. When controlled drugs are transferred, the recipient must be an individual listed on the PI's DEA license and that individual must sign a Transfer of Controlled Substances form which documents the transfer of the drug from the DACT Distributor license to the investigators DEA license.

3. While we strongly encourage you to obtain controlled substances through DACT, anyone with a DEA license can obtain controlled substances directly from commercial suppliers, provided they find a provider that will sell to them without requiring they have a license to practice medicine (this is a requirement of many drug providers). If you purchase controlled drugs directly, you should still report all purchases to Dr. Dale DeNardo (denardo@asu.edu) so that the bottles can be entered into the ASU controlled drug tracking tool. By doing so, not only does the University have a better idea of all controlled substances on its campuses but also the investigator will receive expiration reminders from the tool to help ensure that replacement bottles are acquired prior to the expiration of the existing bottle.

Maintaining controlled drugs:

1. *Security and Storage:*

Controlled drugs must be stored in a secure, double-locked location. The storage location must be identified in the DEA license application. Changes to the storage locations must be submitted to the DEA.

2. *Recordkeeping:*

A. Controlled Substance Usage Log

All controlled drug use must be documented in a Controlled Substance Usage Log. If you obtain your bottle of controlled drugs from DACT, DACT will provide you with a copy of this log with the bottle details already filled in. If you purchase your own bottles of controlled drugs, you can obtain a Controlled Substance Usage Log from the DACT web site in the “Investigator Resources” section. It is absolutely critical that this log be kept current and that all columns on the log be filled out.

B. Drug Inventory

Each registrant must produce a drug inventory of all controlled substances on hand and the date that the inventory was conducted. This record must be maintained as a hard copy at the registered location. After the initial inventory is taken, the registrant should make a new inventory of all controlled substances on hand annually, but must do so at least biannually. A “DEA Biennial Inventory form” is available in the “Controlled Substances” folder within the “Investigator Resources” section of the DACT web site.

Each inventory must contain the following information:

- 1) Date the inventory was taken
- 2) A list of all unopened bottles by drug name, including the drug name, the number of bottles, the drug concentration or unit size (e.g., 100mg/ml or 50 mg tablets), and the amount of drug in the bottle (e.g., mls or tablets). For example: ketamine, 2 bottles, 100 mg/ml, 10 ml per bottle.
- 3) A list of all opened bottles and, for each bottle, the drug name, the drug concentration or unit size (e.g., 100 mg/ml or 50 mg tablets), and the amount of drug in the bottle before opening, (e.g., mls/bottle or tablets/bottle) and the remaining units. For example: ketamine, 100 mg/ml, originally 10 ml per bottle, 4.5 ml remaining.

C. Record Retention

The following records must be retained for a period of 2 years at the storage site identified in the DEA application:

- 1) Controlled Substance Usage Log
- 2) Drug inventory
- 3) Copies of purchase invoices (obtained from vendor or from DACT)
- 4) Copies of DEA Form 222 (blue copy) – required only for Schedule II drugs
- 5) Copies of DEA Form 41 (produced during destruction of cocktails only and can be obtained from DACT when the bottle is given to them)
- 6) Controlled Substance Transfer forms

D. Inventories and records of Schedule I and II drugs must be kept separately from records maintained for Schedules III–V drugs.

3. *Reporting Theft and Loss of Controlled Substance:*

Federal regulations require that registrants notify the DEA Field Division Office in their area in writing of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft. The loss or left should be reported on form 106 using the online tool at <https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>. Investigators must also notify Dr. DeNardo via e-mail (denardo@asu.edu) within one business day of discovery of loss or theft.

Disposal of Controlled Substances and empty vials/bottles:

1. *For drugs in the original vial/bottle and that have expired or are no longer going to be used:*
These drugs must be destroyed through a formal process called reverse distributing. If the drug is purchased through DACT, DACT will provide this service free of charge (DEA regulations do not allow us to collect drugs that did not originate from us). Deliver the drug, a copy of the Controlled Substance Usage Log, and a completed Drug Transfer form (available on the DACT website or from DACT) to the DACT office (ISTB1 122). For Schedule II drugs, fill out DEA form 222 as well. DACT cannot redistribute or dispose of Schedule I drugs.
2. *For cocktails that are in the vial/bottle in which they were made:*
Contact Dale DeNardo (denardo@asu.edu) for instruction on how to properly destroy cocktails containing DEA controlled drugs. There are strict guidelines for this including completion of DEA form 41.
3. *For empty vials/bottles:*
Deliver the vial/bottle and a copy of the Controlled Substance Usage Log to the DACT office (ISTB1 122) for disposal.
4. *For drugs that have been drawn into a syringe but not used:*
The investigator can waste the drug by writing in the drug log that it has been wasted and the reason for wastage. A witness who observed the wasting of the drug should sign the log. We suggest wasting the drug by emptying the syringe into a sharp's container.