



Dartmouth College

Animal Care and Use Program

Institutional Animal Care and Use Committee

IACUC Policies and Procedures

Title: Controlled Substance Management for Research Laboratories

Purpose: The Drug Enforcement Agency (DEA) requires physicians and research personnel who regularly engage in administering controlled substances to maintain records of drugs purchased, distributed and dispensed.

For the purpose of this document, a controlled substance includes all drugs listed by the DEA in Schedules I-V. Examples of the most frequently used drugs are sodium pentobarbital, thiopental sodium, fentanyl, buprenorphine and Ketamine.

The IACUC, Environmental Health and Safety, or ultimately, the DEA shall have access to all records pertaining to Controlled Substances for inspection and/or copy.

This adoption of this policy will affect all research laboratories as of September 1, 2004.

Policy:

Subsection 1: For Labs that purchase their own Controlled Substances

Acquisition

- If the annual usage of a Controlled Substance will be 5 or more of the standard size bottle or ampule, the lab should acquire their own DEA license and purchase these drugs as necessary.

Records

- Maintenance of a controlled substance logbook is mandatory for all laboratories using schedule I-V drugs.
- Create a separate section or page in a logbook for each controlled substance.
- Upon receipt in laboratory of a new shipment of drugs, create a separate log sheet for each bottle/vial. A sample log sheet (with a sample entry) is attached to this policy*. Record the information on the log sheet as the substance is dispensed. The logbook should be set-up to show current inventory. The IACUC will examine these records on a regular basis.
- An inventory is to be taken once a month. The physical inventory is compared to the inventory balance in the logbook. Any discrepancies are to be noted in the log. Expiration dates are also checked at this time to assure proper disposal of outdated drugs. If a controlled substance has expired without depletion of vial, contact Environmental Health & Safety for pick-up and incineration. The bottle (noting expiration date) and log sheet should be marked so that expired drugs are not used on any additional animals. Never allow outdated drugs to remain in your laboratory, as this is a serious violation of the Animal Welfare Act (AWA) and Dartmouth Policy.
- When the bottle/vial has been depleted place the completed log sheet(s) in either a file or three ring binder for future reference. This log sheet must remain on file (at Dartmouth) for at least 3 years.
- The laboratory may discard an empty vial, provided that the bottle is triple rinsed and the label is destroyed.

- If a controlled substance has expired without depletion of vial, contact Environmental Health & Safety for pick-up and incineration. The bottle (noting expiration date) and log sheet should be marked so that expired drugs are not used on any additional animals.

Storage

- All Primary Investigators who purchase controlled drugs, must purchase and install a double locking cabinet of the type pictured below. The drug cabinet must be bolted to a wall. Controlled substances must be stored in the double-locked cabinet at all times, unless the drug is currently being used in a procedure (it may be unlocked for the duration of the procedure).. The keys to the drug cabinet must be kept on the person of the PI and/or on the person of additional authorized user/s. The keys to the drug storage cabinet should not be stored in the lab. Key access should be given to a minimum number of employees. In the event that the combination locks are used, the combination should be limited to a minimum number of employees and should be changed upon termination of employment of an employee.
- The type of box that is required, example pictured below, can be found at <http://www.healthcarelogistics.com> The box is item # 3704 and is called a "Narcotic Cabinet, Double Lock, Double Door". If you want to purchase an equivalent type box from another company please contact Brian Ermeling first to make sure it fits the requirements.



Many laboratories have already installed these storage cabinets; a researcher who purchases only a small amount of controlled drugs and who does not have such a safe may be able to store the materials in another laboratory. It should be noted that the laboratory that owns the drug is still ultimately responsible for the drug.

Subsection 2: For Labs that purchase their Controlled Substances from the ARC

Acquisition

- If annual usage of a Controlled Substance will be less than 5 of the standard size bottle or ampule; the lab can either get their own DEA license or purchase the drugs from the ARC. Investigators wishing to purchase a Controlled Substance from the ARC must complete a Controlled Substance Request and Authorization Form. This form will include the drug needed and anticipated usage amount (either on a per month or per year basis). It will also include who is authorized to purchase, track and return drugs on behalf of the investigator. This form also contains assurances that the PI will be responsible for maintaining appropriate records of use of the drug as well as appropriate locked storage. Upon purchase of drugs from the ARC, the ARC staff or EH&S may visit the lab unannounced to check documentation records. These records may also be checked as part of the IACUC semiannual laboratory visits or DEA visits.

Records

- When a Controlled Substance is needed, the PI (or designee) places an order with the ARC Laboratory Technologist. The Technologist checks the Authorization Form, prepares the product, and records the amount on the Form and in the logbook. Maintenance of a controlled substance logbook is mandatory for all laboratories using schedule I-V drugs. The Technologist also needs to fill out the top part of the ARC Controlled Drug Tracking Form and give that to the authorized person along with the drug. If the amount exceeds the anticipated amount, the PI is notified to update the Authorization Form prior to dispensing this amount. This form should be updated prior to the sale and needs to be renewed annually. Before the Technologist dispenses a replacement of a drug, the previous tracking form must be returned with the empty or expired bottle or container. A member of the veterinary staff may authorize exceptions on a short-term basis.
- An authorized lab personnel is responsible for picking up the drug. This person must be listed on the Authorization Form and must sign the Miscellaneous Service/sale slip and Authorization Form to indicate receipt of the drug. Requests for delivery should be arranged with of the Technologist.
- Quantities dispensed should normally not exceed that which will be used within one month. Exceptions may be granted and documented by the veterinary staff.

Storage

- All Primary Investigators who purchase controlled drugs through the ARC, or would like this option in an emergency, must purchase and install a double locking cabinet of the type pictured. The drug cabinet must be bolted to a wall. Controlled substances must be stored in the double-locked cabinet at all times, unless the drug is currently being used in a procedure (it may be unlocked for the duration of the procedure).. The keys to the drug cabinet must be kept on the person of the PI and/or on the person of additional authorized user/s. The keys to the drug storage cabinet should not be stored in the lab. Key access should be given to a minimum number of employees. In the event that the combination locks are used, the combination should be limited to a minimum number of employees and should be changed upon termination of employment of an employee.
- The type of box that is required, example pictured above, can be found at <http://www.healthcarelogistics.com> The box is item # 3704 and is called a "Narcotic Cabinet, Double Lock, Double Door". If you want to purchase an equivalent type box from another company please contact Brian Ermeling first to make sure it fits the requirements.

Many laboratories have already installed these storage cabinets; a researcher who purchases only a small amount of controlled drugs and who does not have such a safe may be able to store the materials in another laboratory. It should be noted that the laboratory that owns the drug is still ultimately responsible for the drug.

All Laboratories – Theft

- In the event of theft, please notify Environmental Health and Safety. *If the drug was bought from the ARC, please notify Dr. Brian Ermeling as well.*

(for laboratories purchasing own drugs)

<i>Laboratory Name</i>	<i>Contact person</i>	<i>Phone</i>	<i>Lab or Room</i>
Burton	Jane Doe	234-2345	Rubin 123

<i>Brand or Generic Name</i>	<i>Drug Size</i>	<i>Drug Concentration</i>
Ketamine	10ml	100mg/ml

<i>Date Received</i>	<i>Expiration Date</i>	<i>Serial Number or Vial ID</i>
1/2004	2/2006	Jhks38923

<i>Date Administered</i>	<i>*Species</i>	<i>*Individual ID</i>	<i>Amount</i>	<i>Balance</i>	<i>Drug Expiration Check</i>	<i>Signature Or Initial</i>
2/15/04	Dog	123456	1ml	9ml	X	jd

Example

* List individual ID number, i.e. cage card number or lab assigned ID for species other than rodent or bird.

ARC CONTROLLED SUBSTANCE REQUEST AND AUTHORIZATION FORM,
REV. 11/07

Name of PI _____ Department _____

Type of storage device _____ Room# _____

Telephone number _____ Protocol number _____

Personnel other than PI who hold key to storage box (generally limited to 1 besides PI)

Controlled substance needed:

Anticipated usage amount /mo or year:

Please complete one form for each substance needed

I assure that the above drugs will be stored according to DEA and IACUC policy (locked in a double locking cabinet or safe) and that records will be kept of usage, using ARC Controlled Drug Tracking Form. These records include date, lot/serial#, species and number, amount used, initials of person involved, and balance remaining. An ARC Controlled Drug Tracking Form will be completed per bottle/container dispensed and returned with the empty or expired bottle before additional will be dispensed. Such records will be available to personnel from the ARC, IACUC, EH&S and DEA. In addition, I assure that the key or combination to the controlled drug storage is consistent with the DEA and IACUC policy and that the I take full responsibility for drugs stored within my laboratory.

Signature of Principal Investigator

Date

DATE OF PURCHASE	QUANTITY DISPENSED	INITIALS OF ARC PERSONNEL	BALANCE REMAINING	SIGNATURE OF AUTHORIZED LAB PERSONNEL

****This form must be updated annually. Not valid after _____**
ARC Controlled Drug Tracking Form
(for drugs dispensed from the ARC)
(Complete one form for each bottle/container dispensed)

Name of PI _____

Date Dispersed _____ Expiration Date _____

Drug Dispersed _____ Serial/Lot/Tracking# _____

