Dr. Nettie La Belle-Hamer
Vice Chancellor for Research
907-474-6000
907-474-5993 fax
nettie.labellehamer@alaska.edu
research.uaf.edu

Office of the Vice Chancellor for Research
P.O. Box 757270, Fairbanks, Alaska 99775-7270

Controlled Substances in Research & Teaching Procedures

In order to safely and responsibly utilize controlled substances for research and teaching purposes, it is imperative to follow a well-defined procedure that adheres to legal regulations and ethical guidelines. The Centers for Disease and Control and Prevention (CDC) plays a vital role in regulating and overseeing the use of controlled substances in research and teaching, ensuring compliance with federal regulations, and promoting safety and responsible practices in such endeavors. The Drug Enforcement Administration (DEA) also plays a distinct role in regulating the use of controlled substances in research and teaching. The collaboration of the CDC and DEA ensures that controlled substances are handled safely and responsibly in these settings.

The DEA requires researchers who intend to work with controlled substances in research and teaching within the United States to apply for and obtain a DEA researcher registration. This registration is specific to the individual researcher and authorizes them to handle controlled substances for research purposes. The researcher is responsible for complying with all DEA regulations and maintaining the required security measures, record-keeping, and reporting associated with controlled substances.

DEA's Role:

- Licensing and Registration: The DEA is primarily responsible for regulating the manufacturing, distribution, dispensing, and research use of controlled substances in the United States. Researchers and institutions that want to work with controlled substances must obtain the necessary DEA registration and licensing.
- Controlled Substance Scheduling: The DEA classifies drugs into various schedules based on their potential for abuse and medical utility. This classification affects the level of control, documentation, and security measures required for handling these substances.
- Compliance Oversight: The DEA conducts audits and inspections to ensure that entities holding DEA registrations are adhering to federal regulations regarding controlled substances. This includes verifying proper storage, record-keeping, and security measures.

Drug Enforcement Administration Diversion Control Program

- This website provides excellent information, including listings of all controlled substances, links to 21 CFR, Chapter II, 1300-end, online informational documents, brochures, and forms.
- DEA Registration forms are available on this site. Before applying, you must gain approval from the Vice Chancellor of Research (VCR). Please contact the ORI Research Compliance Officer, Office of Research Integrity (ORI) by emailing uaf-ori@alaska.edu for assistance before applying for a Research Registration.

Not all compounds given to animals are controlled substances. Over-the-counter or prescription drugs and other compounds may also be given to animals as part of research, teaching, or testing activities. Regardless of their legal classification, all compounds given to animals, their dosage, route of delivery, etc. must be identified in an approved IACUC protocol or prescribed by a veterinarian for therapeutic reasons.

Legal Definitions

Controlled Substances are compounds subject to the jurisdictional control of the Drug Enforcement Agency (DEA) under Title 21, Chapter II, Parts 1300-end of the Code of Federal Regulations (CFR) (the CFR can be accessed here.) Compounds are placed in one of the following schedules (I -V) depending on their potential for abuse.

- **Schedule I** - Compounds with the highest potential for abuse. Licensing for obtaining schedule I substances requires a special application. These must be obtained by individual researchers for specific projects. Contact the Office of Research Integrity for assistance before submitting a Schedule I application. Examples: LSD, heroin, marijuana, and methamphetamine.
- **Schedule II** - Includes the main opioids used in wildlife capture work and some of the barbiturates. Note that although carfentanil and etorphine are schedule II, the DEA maintains a list of approved individuals who may obtain these potent narcotics. Therefore, having a DEA license for Schedule II drugs is not enough to purchase these two drugs. The use of schedule II drugs necessitates the recording of every dose taken from a bottle. At UAF we provide a record sheet with each issued bottle containing a Schedule II substance. Examples: pentobarbital, carfentanil, amphetamine, morphine, and phencyclidine.
- **Schedule III** - Contains several barbiturates, narcotics, as well as ketamine and Telazol. Anabolic steroids also are within this schedule. Examples: ketamine, Telazol®, and some euthanasia solutions containing pentobarbital, buprenorphine, and anabolic steroids.
- **Schedule IV** - Includes benzodiazepine tranquilizers and some other opioids, primarily the agonist-antagonists. Examples: diazepam, midazolam, butorphanol, chloral hydrate, and pentazocine.

- **Schedule V** - Some examples are cough preparations with less than 200 milligrams of codeine or per 100 millimeters (Robitussin AC), Lomotil, Motofen, Lyrica, and Parepectolin.

Registration for schedule I

This requires special approval and justification by the DEA. Contact the Office of Research Integrity (ORI) Research Compliance Officer and the Director of Environmental Health, Safety, and Risk Management (EHSRM) for guidance.

For registration with DEA, separate applications must be submitted for Schedule I substances and Schedule II–V substances.

Registration for schedules II through V

Registration forms and detailed instructions are available on the DEA website https://www.deadiversion.usdoj.gov/drugreg/index.html

- For research or laboratory chemical analysis, use DEA form 225 for a new application and form 225A for annual renewal.
- For Veterinary medical use, DEA forms 224 for a new application and 224A for renewal.
- Coincident Activities allowed. 21 CFR 1301.13(e)(1)(iv) *Practitioner: May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute.* (Although acceptable in Alaska, other states may not allow research or instructional activities under a practitioner registration)

Check the "*Exemption from Application Fee*" to indicate eligibility to waive the DEA registration cost. **This must be certified by the Office of the Vice Chancellor for Research (VCR)**.

Activities under your DEA registration are limited to the business address on your registration.

Screening Employees

Designated agents (i.e., designated employees) of the registrant (usually the Principal Investigator or Program Director) may engage in approved activities under the direction of the registrant. Approved activities may include:

- Access to the controlled substance storage unit. This generally means using, controlling, or possessing a key to the storage unit or the means to unlock the storage unit.

- Administration of controlled substances.
- Record keeping of controlled substances.
- Destruction of controlled substances.

The registrant **must** screen potential authorized users (21 CFR 1301.90) before assigning work with controlled substances using the UAF Authorized Agent Questionnaire. Providing access to persons who answer 'yes' to any of the mandated questions is a violation of federal law.

The registrant must keep completed questionnaires on file at the registered location as per the DEA registration form (See Forms section below).

DEA recommends that registrants inquire about employees' criminal records (21 CFR 1301.93).

The DEA registrant is wholly responsible for the behavior of their agents.

Ordering scheduled substances

Registrants are not to purchase controlled substances with procurement cards (a.k.a pro-cards). The only exception is for the UAF Attending Veterinarian (AV).

To order schedule II substances, in addition to the standard procedures, the registrant must use DEA Form 222. DEA Form 222 may be ordered by the registrant on the DEA Diversion Control Division website: https://www.deadiversion.usdoj.gov/

Ordering scheduled substances:

1. Complete the Procurement Ordering form and attach all necessary documentation.
2. Upon completion of the Procurement Ordering form, ORI and EHSRM will review that the form is completed in all accordance.
3. ORI will process the Procurement Ordering form to the UAF Procurement office.
4. UAF Procurement Office will review and process the order.

Controlled substances will be delivered to the address on the DEA registration (the address must be an authorized address where FedEx and UPS can deliver). If you have any questions, please contact the ORI Research Compliance Officer.

Contact UAF Procurement and Contract Services (ua-pcs-main@alaska.edu) for procedures to order controlled substances.

Recordkeeping requirements

The following records are to be maintained at the registrant's location (as identified on the registration). All records must be readily available to a DEA inspector, EHSRM, ORI, and, if applicable, to the UAF AV or IACUC.

- Employee screening and authorization records
- Completed order forms and invoices
- Inventory records (initial record and, as a minimum, a biennial inventory)
- Controlled substance tracking records (including drug administration records)
- Keep schedule I and II substances in a log separate from the log for schedule III, IV, or V.
- Records must include all combination and compounded drugs
- Transfer logs
- Records of disposal/destruction
- Medical records including immobilization, anesthesia, and pain management records must be readily available

If the registrant wishes to maintain controlled substance records at a central location other than the registered location, they must send a notification to the DEA. Requirements regarding the information submitted in the notification are available in 21 CFR 1304.04.

Record retention requirements

- Initial inventory from the time of registration issuance must be maintained and made available for the life of the registration.
- DEA requires that all required records be maintained for a minimum of 2 years from the date of such records.
- UAF, based on NIH and NSF guidelines, recommends that all required records be maintained for 3-5 years past the end of the funded research project.

- Once work involving substances is completed and registration is closed out, copies of all records **must** be transferred to ORI.

Controlled substance tracking and inventory

Contact UAF Veterinary Services, Animal Resources Center if you need guidance on processes and forms.

Controlled substances may be transferred between two DEA registrants. All transfers must be logged. A transfer of a Schedule II substance must be accompanied by a DEA Form 222 completed by the registrant receiving the substances. A transfer of a schedule III-V substance must be recorded and a sales receipt generated.

See the Non-Compliance section of the Policy regarding the consequences of improperly transferring controlled substances.

Storage and Security

Every registrant must provide effective controls and procedures to guard against theft and diversion of controlled substances. Controlled substances, whether used in the laboratory or field research, must be kept in secure lockable containers that meet or exceed requirements stipulated in 21 CFR 1301.71 through 1301.77

Storage locations must be consistent with the locations identified on the registrant licenses. Registrants are generally permitted to keep controlled substances in substantially constructed, double-locked cabinets or safes as described below. Commercially available narcotics cabinets are strongly recommended to ensure the registrant's storage complies with regulations.

Schedule I controlled substances must be stored in a securely locked safe or steel cabinet of substantial construction (e.g., vault or General Services Administration (GSA) class 5 rated safe, cabinet, or a secure containment apparatus approved by the DEA). Safes or cabinets weighing less than 750 lbs. must be bolted, cemented to the floor, or secured to something of substantial construction. The safe/cabinet should have an inner and outer door with the locks for each door keyed differently.

Schedule II substances must be kept in a substantially constructed double-locked cabinet or safe that cannot be easily forced open, with the cabinet secured to a wall or otherwise not removable.

Some Schedule II controlled substances used in wildlife capture require additional security measures for acquisition and storage (thiafentanil, carfentanil, etorphine, and diprenorphine). The registrant must have a practitioner's registration and additional authorization from DEA to acquire the specific drug(s). They must be stored in a safe or steel cabinet equivalent to a GSA class 5 security container (21 CFR 1301.75).

Schedule III, IV, and V substances must be kept in a stationary, substantially constructed double-locked cabinet or safe.

Physical security requirements are found in 21 CFR 1301.71 to 76. Acquisition of controlled substances will not be permitted until adequate security and storage can be demonstrated.

NOTE: The registrant must not leave the keys to the cabinet in the laboratory. Keys allowing access to controlled substances must be under the control of the registrant.

Theft or Loss

If there is a theft or loss of controlled substances, the registrant must notify the UAF Police, direct supervisor, Office of the VCR, Director of EHSRM, and the ORI Research Compliance Officer as soon as the theft or loss is discovered.

The registrant must notify the area DEA Field Office in writing within 24 hours of discovering the theft or loss. The registrant must also complete and submit DEA form 106 (Report of Theft or Loss of Controlled Substances) to the area DEA Field Office (21 CFR 1301.76).

See: https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

Disposal

Spent or emptied controlled substance containers must be treated like medical waste. Keep them secure until they can be properly turned over to EHSRM for proper destruction.

Expired, unwanted, or contaminated drugs (full or partially full containers) must be transported to a reverse distributor for proper destruction. Contact UAF Veterinary Services for guidance and a list of registered reverse distributors. Proper record keeping and security are required while storing unwanted substances before shipping to a reverse distributor. To ensure that they are not accidentally used on research animals, expired and unwanted controlled substances must be identified and marked while stored in your secure cabinet.

DEA Form 41 is used to record the disposal of controlled substances.

NOTE: Use of expired drugs on research animals, controlled or otherwise, is a violation of federal regulation and policy.

Abandoned Controlled Substances

Under no circumstances is a DEA Registrant to abandon controlled substances.

If abandoned controlled substances are found, contact the Director of EHSRM immediately for assistance.

Inspections and Audits

Access to storage and all records must always be readily available.

Inspections and audits of registrant locations may be conducted by EHSRM, ORI, UAF Police, the IACUC, and/or Veterinary Services.

Unannounced visitation by a DEA Diversion Agent and ORI can occur at any time. All required records must be readily retrievable in a reasonable amount of time.

Forms

- Authorized Agent Application of Use Questionnaire
- Authorized Personnel Log
- Record of Controlled Substances - IACUC
- Controlled Substances Biennial Physical Inventory
- Dispensed Drug Log
- Controlled Substances in Research and Teaching Recordkeeping QUICKTIP