

University of Alaska Anchorage	Section EHS/RMS
ADMINISTRATIVE SERVICES MANUAL	Part Policy
Policies and Procedures	Statement 31
Title <i>Controlled Substances Use In Research</i>	Effective Date 05/16/03

Drug Enforcement Administration The Drug Enforcement Administration (DEA) is the principal federal organization responsible for enforcing the appropriate use of controlled substances. In this case, controlled substances are pharmaceuticals that are listed by DEA as having a high abuse potential. The applicable regulations can be found at the following two sites:

1. www.deadiversion.usdoj.gov/21cfr/cfr/index.html
2. www.deadiversion.usdoj.gov/21cfr/21usc/index.html

The DEA is not the same as the Food And Drug Administration (FDA), which is more concerned with the development and use of pharmaceuticals for medicinal purposes. There are various other federal, state, and local agencies that may also play a role in regulating pharmaceuticals.

Medical and Dental Use This policy does not apply to medical or dental use of controlled substances. Those clinical applications are governed under different standards. This policy only applies to the use of controlled substances in research activities, which usually involve the administration of controlled substances to animals.

Registrations All principal investigators (PIs) must obtain from the DEA, through an application process, a registration to use, store and purchase controlled substances. The application material is available at:

<http://www.deadiversion.usdoj.gov/drugreg/index.html> .

Approvals These registrations are issued to individuals through the sponsorship of the university. Endorsements must be obtained from the [Institutional Animal Care and Use Committee \(IACUC\)](#) if controlled substances are to be used on animals. To expedite the DEA registration process (can take up to six months), researchers can provide to the IACUC a summary of what substances they will be using, the animals that the substances will be used on, and a brief description of the project. This can occur prior to the actual proposal submission to IACUC. The Associate Vice Provost for Research must approve all request for DEA registrations. Final

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submission of registration material to DEA must be coordinated through EHS/RMS (786-1351, ayssg@uaa.alaska.edu). EHS/RMS can assist in determining your DEA compliance questions and needs.

Registrations are renewed annually after passing a DEA investigation. Renewals are mailed to registrants and DEA periodically conducts audits to determine if the PI has abided by the conditions of the registration.

Registrations are awarded to individual PIs and follow the PIs to any institution. However, the institutions control the PIs' rights to purchase, use or store controlled substances in the course and scope of the PIs' employment. PIs who have their own registrations, which were obtained at other institutions, are also bound by this policy.

Responsibilities PIs are bound by law to abide by DEA laws and regulations as they pertain to the use of controlled substances in their research endeavors. Failure to abide could result in civil and criminal actions against the individual PIs with little or no legal support from the University.

Controlled Substances Controlled pharmaceuticals or substances are those pharmaceuticals or chemicals listed by DEA in scheduled forms located at:

<http://www.usdoj.gov/dea/pubs/scheduling.html> .

Only the specifically identified schedules or individual pharmaceuticals articulated in the PI's registration as issued by DEA and associated with a PI's unique DEA registration can be purchased, used or stored by the PI. Violations of this section carry severe criminal and civil penalties.

Hazardous Material Purchases The University classifies controlled substances as hazardous materials. Therefore, they cannot be purchased using the University Procard (MasterCard) or petty cash. Only the purchase order system can be used to procure controlled substances. Purchases of controlled substances, like other hazardous materials, are reviewed and approved by EHS/RMS and

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Procurement Services. This process usually takes place in the background and does not usually delay the procurement process.

Security and Storage

All DEA controlled substances must be stored in a secure manner. The currently required storage method at UAA is a dual digital combination and key access fire safe, which is securely mounted to the floor or massive cabinet base. The safe combinations should be selectable so as to allow PIs to change the combinations upon assignment and periodically as necessary. It is recommended that combinations be changed at least once per year or at any time that PIs believe that the combinations may have been compromised. It is also strongly advised that the safes be mounted within a cabinet and that the cabinet door be fitted with a privacy lock “out-of-site ... out-of-mind.”

Each DEA registered PI must have their own safe. PIs are not authorized to share their safes, their unique DEA licenses or their safe codes and keys with anyone including colleagues and assistants except for the backup keys and combinations as described in the *Safe Access* section in this policy. Nothing but the controlled pharmaceuticals and associated documentation may be secured in the safes.

Some controlled substances, like carfetanyl, require a Class V container. A Class V container has the following specifications (21 CFR 1301.72 (1)(I) and is estimated to cost in excess of \$5,000:

1. 750 pound - bolted to the floor
2. audible alarm wired to a continuous monitoring service
3. forced entry protection rated at thirty man-minutes
4. lock manipulation protection rated at twenty man-hours
5. radiological techniques protection rated at twenty man-hours
6. 1R locking mechanism

Safe Access

Access to a safe is only granted to the responsible and DEA registered PI with duplicate keys and combinations kept in a sealed envelope and

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deposited with the University Police Department (UPD). The seal of the envelope should be signed and dated by the PI.

If for any reason, UPD needs to access the safe, the envelope will be unsealed by UPD and signed and dated by the UPD officer. UPD is advised to have a witness available to verify the safe's inventory. The witness should be a responsible university administrator (department chair, dean, or higher) if possible.

*Disposal of
Controlled
Substances*

As with any hazardous material, PIs should only order sufficient quantities and maintain sufficient stocks that are necessary to complete their research. After completion of the research project, surplus stocks must be destroyed in accordance with current DEA regulations. Generally this occurs via a reverse distribution system, which is described at:

http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm .

[DEA Form 41](#) must be completed and submitted to DEA for approval prior to destroying controlled pharmaceuticals. A list of approved reverse distributors is attached to the form. **Do not ship drugs for transfer or disposal prior to DEA approval via a [DEA FORM 41](#) process.**

Surplus stocks need not be destroyed if the PI anticipates that the same pharmaceuticals will be needed in a reasonable period of time for another research project that they will be performing. Out-of-use or expired dates must be destroyed in accordance with DEA procedures.

Other agencies may also regulate the destruction and disposal of controlled substances such as the US Environmental Protection Agency, the Alaska Department of Environmental Conservation, local solid waste and wastewater utilities, and others. Consult with UAA Environmental Health and Safety for current disposal methods (ayssg@uaa.alaska.edu or 786-1351).

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No matter what method is used to destroy unused or expired controlled substances, credible witnesses should sign an affidavit swearing to the destruction and disposal. These affidavits are often verified by DEA through their audit process. Do not sign for anything that you cannot physically verify or witness. Signing for chain-of-custody transfers is not the same as signing for verification of destruction.

*Transferring
Controlled
Pharmaceuticals*

PIs are not authorized to transfer controlled pharmaceuticals to other non-licensed PIs' research activities. However, there are limited mechanisms to transfer controlled pharmaceuticals to other licensed PIs. Those mechanisms are described at:

http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm .

Communications with DEA on transfers or destructions can be accomplished using [DEA Form 41](#). **Never send pharmaceuticals to DEA.**

Record keeping

All records of acquisition, use, spillage, waste, transfers, destruction, or other disposition of controlled substances must be maintained and retained for five years by the registration holder (PI). It is suggested that log sheets be used for this purpose and that associated documents be retained to verify log entries.

The PIs are personally responsible and accountable for proper record keeping and any civil or criminal sanctions attributable to deficiencies due to PIs' negligence. Deficiencies in record keeping as discovered during DEA audits can result in civil and criminal sanctions.

Penalties

Unless the University is directly responsible for a DEA violation, all civil and criminal penalties are the responsibility of the DEA registration holder (PI). These penalties can range from costly fines, revocation of licenses, loss of federal grant funding, and incarceration.

Coordination

PIs should coordinate DEA communications and requests with

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With DEA

EHS/RMS. Contact EHS/RMS at 786-1351 or ayssg@uaa.alaska.edu for assistance.