

Use of Controlled Substances in Research and Teaching Policy

1.0 POLICY STATEMENT

Use of controlled substances in research and teaching activities at the University of Alaska Fairbanks (UAF) is restricted to UAF-authorized registrants holding a valid Drug Enforcement Administration (DEA) Controlled Substances Registration Certificate and authorized agents working under the direct supervision of the registrant.

This policy addresses the acquisition, storage, recordkeeping, use, and disposal of controlled substances at UAF. Information and procedures are established to enable individuals and departments to comply with state and federal law and to meet appropriate safety standards. Although the registrant can delegate some activities to an authorized agent, the DEA registrant is wholly responsible and accountable for compliance with the Code of Federal Regulations (CFR) Title 21, Chapter II. A copy of every DEA Controlled Substances Registration Certificate used for research and teaching at UAF must be filed with the Office of Research Integrity (ORI).

This policy does not supersede state or federal law. In the case of inconsistency, state and federal law govern.

2.0 BACKGROUND & JUSTIFICATION

UAF recognizes that some research and teaching activity necessitates working with controlled substances. To facilitate this requirement, UAF has established processes to allow employees (usually a Principal Investigator or Program Director) to acquire a DEA research registration and identify designated agents to work under their oversight. The registrant is wholly responsible for understanding and meeting all relevant regulatory requirements for the handling of controlled substances.

UAF expects the responsible person to ensure that all employees working with controlled substances in research and teaching activities comply with applicable laws and internal requirements to prevent diversion and to properly procure, store, maintain records, and use and dispose of all controlled substances.

Applicable federal law and regulation are found in Title 21 United States Code (U.S.C.) Controlled Substances Act and Code of Federal Regulations (CFR), Chapter II, Parts 1300-end.

3.0 DEFINITIONS

- **Attending Veterinarian (AV)** is one of three federally mandated positions within the UAF animal care program. The AV reports directly to the VCR and is the Director of the UAF Animal Resources Center. The AV is licensed to practice veterinary medicine in the State of Alaska and holds a practitioner's DEA registration. If needed for research activities, the AV might also hold a research registration. The AV and the Veterinary Services Core within the Animal Resources Center can provide guidance on applying for registration, acquisition, storage, inventory, recordkeeping, and disposal of controlled substances.
- **Designated Agent** is an individual within a university research or teaching program who has been granted privileges to work with controlled substances by a registrant. Designated agents who handle controlled substances must be employees of the registrant, and these persons must not have been convicted of a felony offense related to controlled drugs. All agents of the registration holder must be at the same general physical location. See "Screening Employees" under Procedures.
- **Controlled substance** has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.). *The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.*
- **DEA Controlled Substances Registration Certificate** allows the holder to utilize controlled substances as specified by the certificate issued by the DEA. The certificate holder is wholly responsible and accountable to the regulations set forth in the Code of Federal Regulations (CFR) Title 21, Chapter II.
- **Department of Environmental Health, Safety, and Risk Management (EHSRM)** oversees the UAF's chemical hygiene plan and laboratory safety. EHSRM has the authority to inspect storage, security, and records for all chemicals, including controlled substances.
- **Drug Enforcement Administration (DEA)** is the section of the United States Department of Justice that establishes regulations for the handling and use of controlled substances. The mission of the DEA Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.
- **Institutional Animal Care and Use Committee (IACUC)** is an independent animal welfare committee reporting to and appointed by the VCR (*Institutional Official*). The UAF IACUC has the authority to inspect storage, security, and records for all pharmaceuticals, including controlled substances, intended for use in animal research or teaching.
- **University Authorized Registrant** is an individual (usually a Principal Investigator or Program Director) to obtain a *DEA Controlled Substances Registration Certificate*. The Registrant ensures compliance with university policy, procedures, and federal regulations.

4.0 REFERENCES RELIED UPON

Title 21 United States Code (U.S.C.) Controlled Substances Act and Code of Federal Regulations (CFR), Chapter II, Parts 1300-end Drug Enforcement Administration, Department of Justice.

5.0 RESPONSIBILITIES

- **University Authorized Registrant** is responsible and accountable for compliance with 21 CFR Chapter II, Parts 1300-end. The registrant can delegate certain activities to a designated agent, but the registrant remains wholly responsible for any non-compliance. Every person who engages in research or teaching activities with controlled substances must be registered with the DEA or be an authorized agent working under an existing registrant. Only a University authorized registrant and designated agent (see definitions) under their direct supervision may use controlled substances in the course of university research and teaching.

Registrants are responsible for the following:

1. Complying with all applicable laws, regulations, policies, and procedures governing the acquisition, storage, inventory, recordkeeping, use, and disposal of controlled substances.
2. Ensuring that each employee who works with controlled substances is qualified under federal regulation (21 CFR 1301.90). Completion of an employee questionnaire is required.
3. Ordering and receiving controlled substances purchased under the registrant's license.
4. Ensure controlled substances are securely stored to protect chemicals from theft or misuse.
5. Maintain proper recordkeeping for controlled substances, including inventory, tracking, and, if required, medical records, use, and dose logs.
6. Timely reporting of any theft or loss of controlled substances.
7. Proper disposal of controlled substances.
8. Receive and participate in adequate in-service training and continuing education concerning the acquisition, storage, inventory maintenance, and disposal of controlled substances.
9. Participate in the University's laboratory safety program managed by EHSRM.
10. Fully cooperate with investigators from the DEA during periodic reviews and evaluations of the acquisition, storage, inventory, and disposal of controlled substances.
11. Abide by and carry out the decisions of EHSRM, IACUC, and any other relevant UAF office or program.

12. Immediately report to their supervisor or designee, the UAF Police Department, the Office of the VCR, and EHSRM any break-in, theft, or known or suspected drug diversion.

- **Office of the Vice Chancellor for Research** approves and certifies DEA applications.
- **Office of Research Integrity** coordinates recordkeeping and schedules IACUC inspections of registrant lab locations where controlled substances are stored for use in animal research.
- **Procurement and Contract Services** assists in the acquisition of controlled substances
- **Veterinary Services, Animal Resource Center** provides guidance, limited storage, and inspection.
- **Environmental Health, Safety & Risk Management** inspects laboratories to assess security, storage, records, and proper disposal.
- **Human Resources** conducts criminal background checks.

Contact may be made to the offices of ORI, EHSRM, and Animal Resource Center (ARC) for further information regarding the responsibilities and procedures. ORI will maintain a list of DEA registrants, locations, and substances used.

6.0 NON-COMPLIANCE

Improper acquisition, security, storage, recordkeeping, use, dispensing, or disposal of controlled substances may result in civil and criminal liability, including incarceration, fines, and/or license suspension or revocation.

NOTE: It is a felony for a registrant to provide a controlled substance to a person not registered with the DEA or is not one of the registrant's authorized personnel (designated agent).

Failure to comply with this policy and associated procedures or to fully cooperate with university compliance monitoring is grounds for disciplinary action by the University and, if applicable, suspension or termination of the research, referral for misconduct proceedings, and/or reporting to state and federal authorities. Any disciplinary action the University takes will follow the employment rules governing the individual's employment category.

7.0 EXCEPTIONS

This policy does not apply to controlled substances dispensed or prescribed by a practitioner to a patient during professional medical practice as authorized by his/her license.

8.0 PROCEDURES

The ORI, in consultation with relevant UAF officials, develops and maintains procedures necessary to implement this policy. Procedures are maintained on the ORI website.

The ORI Office will maintain a list of DEA registrants.

POLICY APPROVED BY:



Daniel M. White, Chancellor
University of Alaska Fairbanks

Signed: 8/15/2023