



Use of Controlled Substances in Research and Teaching

Policy Number: 04-002

Research/Academic Policy

Original Date of Approval: 6/7/2004

Current Revision: 1/4/2005

Responsible University Officer

- Chancellor

Responsible Offices

- Office of Research Integrity
- Environmental Health, Safety & Risk Management

Policy Statement:

Use of controlled substances in research and teaching activities at the University of Alaska Fairbanks is restricted to Authorized Persons working under the direct supervision of a University Authorized Registrant holding a valid Drug Enforcement Administration (DEA) Controlled Substances Registration Certificate. University Authorized Registrants and Authorized Persons must comply with all applicable university policies and procedures as well as all federal and state laws and regulations regarding acquisition, storage requirements, inventory maintenance, and disposal of controlled substances.

Background:

The university has the responsibility to ensure that all institutes, departments, units and employees using controlled substances in research and teaching activities comply with applicable laws and internal requirements to prevent diversion and to safely procure, store, use and dispose of all controlled substances.

Definitions:

- **Authorized Person** is an individual working within a university research or teaching program who has been granted privileges to use controlled substances in research and/or teaching activities by the head of a University Authorized Registrant (usually their director, dean, chair, or chief executive officer) holding a valid Drug Enforcement Administration (DEA) Controlled Substances Registration Certificate. Persons who handle controlled substances must be employees or agents of the registration holder and these persons must not have been convicted of a felony offense related to controlled drugs. All employees or agents of the registration holder must be at the same general physical location.

- **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 Drug Enforcement Administration. The holder of the certificate is accountable to the regulations set forth in 21CFR1300-end. 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.
- **Department of Environmental Health, Safety and Risk Management (EHS&RM)** refers to the University of Alaska Fairbanks Department of Environmental Health, Safety and Risk Management. This department oversees the University's chemical hygiene plan.
- **Disposal** refers to disposal of controlled substances that are in the original container or original form and that are outdated, surplus or no longer intended for use. Disposal also refers to waste material containing small quantities of controlled substances or waste containing controlled substances adulterated through use.
- **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.
- **Office of Research Integrity (ORI)** is office responsible for ensuring compliance of University of Alaska Fairbanks personnel with internal policies and with local, state and federal regulations governing the conduct of research.
- **UAF Quality Improvement Program** is administered by the UAF Office of Research Integrity. As part of this program, routine surveys and internal assessments are conducted in all research laboratories and animal facilities where controlled substances are maintained. The primary purpose is to ensure knowledgeable use of these substances, adequate security, and proper record keeping.
- **University Authorized Registrant** is a University Institute, Department, or Unit that has been authorized by the UAF Office of Research Integrity to obtain a *DEA Controlled Substances Registration Certificate*. The head of the University Authorized Registrant (usually a director, dean, chair, or chief executive officer) is the person responsible to ensure compliance with university policy, procedures, and federal regulations. An individual may not become a University Authorized Registrant unless prior written approval has been granted by the Chancellor or formally designated senior administrator.

Responsibilities:

In order to comply with 21CFR1300-end, the United States Drug Enforcement Administration (DEA) requires that all applications from the University of Alaska Fairbanks for *Controlled Substances Registration Certificates* be in the name of an institute, department, or unit. Registrations are non-transferable and remain with the institute, department, or unit. The director, dean, chair, chief executive officer, or other unit supervising official (permanent, acting, or interim) of the University Authorized

Registrant is the person responsible for ensuring compliance with university policy and procedures as well as 21CFR1300-end.

Only Authorized Persons (see definitions) under the direct supervision of a University Authorized Registrant may use controlled substances in the course of university research and teaching. Authorized Persons shall:

1. follow all applicable laws, regulations, policies and procedures governing the acquisition, storage, inventory maintenance, and disposal of controlled substances;
2. receive and participate in adequate in-service training and continuing education concerning the acquisition, storage, inventory maintenance, and disposal of controlled substances;
3. participate in the University's Quality Improvement Program managed by ORI;
4. fully cooperate with investigators from the Drug Enforcement Administration during periodic reviews and evaluations of acquisition, storage, inventory, and disposal of controlled substances;
5. abide by and carry out the decisions of their supervisor (University Authorized Registrant), ORI, and EHS&RM; and
6. immediately report to their supervisor or designate, the UAF Police Department, ORI, and EHS&RM any break-in, theft, or any known or suspected drug diversion.

Non-Compliance

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

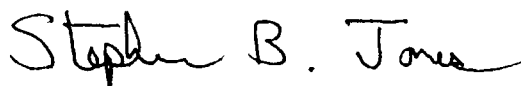
Procedures:

Administrative procedures and forms for the implementation of this policy will be formulated, maintained and distributed by the UAF Office of Research Integrity and the Department of Environmental Health, Safety and Risk Management (EH&S).

Exclusions:

This policy does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license.

Approved by:



1/4/05

Stephen Jones, UAF Chancellor

Date