



SUBJECT: Controlled Substance and Prescription Drugs	Effective Date: 11/30/2018	Policy Number: 10.4.18	
	Supersedes: 12/04/2015 04/25/2007	Page	Of
	Responsible Authorities: Vice President, Research Institutional Animal Care and Use Committee Director, Research Integrity Director, Comparative Medicine		

- I. Background
Biomedical and wildlife research and teaching programs often require controlled substances for prevention of pain and/or distress. Those substances are not only used for anesthesia, analgesia, sedation or tranquilization but also for euthanasia and sometimes as a means to study the actions of specific drug regimen. Controlled substances have the potential for misuse, which is the reason for the requirement to obtain a DEA (Drug Enforcement Agency) license. University principles and procedures regarding procurement, distribution, use, security, and recordkeeping of controlled substances enforced by the DEA and other veterinary prescription drugs are guided by the regulations detailed in 21 CFR 1300 and Florida Regulations (i.e. Chapters 474, 499, and 893 Florida Statutes and Rule Chapter 61N, Florida Administrative Code).

- II. Purpose
To establish roles, responsibilities and requirements for conducting animal and non-animal research involving controlled substances and other veterinary prescription drugs at Florida Atlantic University. To abide by the guidance describing licensing, storage, distribution, use, and disposal of controlled substances set forth by the federal agency DEA and chapter 893, Florida Statutes as well as of other veterinary prescription and human-label drugs that are governed by federal and state regulations.

- III. General Statement
FAU researchers, employees, faculty, students or staff who use controlled substances in animal based research, testing and teaching including non-vertebrate species and cell cultures shall comply with all federal regulations, state rules, and institutional requirements. All schedule II to V controlled substances and prescription drugs must be procured through Comparative Medicine. When used in live animals, controlled substances and prescription drugs must be of pharmaceutical (USP) grade unless otherwise specified in the IACUC protocol and/or specific MOUs. Schedule I controlled

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substances are the responsibility of the particular PI who uses it in his/her research and will have to secure his/her own schedule I license.

IV. Policy

- A. The University's procedures regarding procurement, distribution, use, disposal and record keeping, of controlled substances and other prescription drugs are regulated by the Drug Enforcement Administration (DEA) and are guided by the regulations detailed in 21 CFR 1300-1316 viewable at <http://www.deadiversion.usdoj.gov/21cfr/cfr/> and/or Florida Regulations (i.e. Chapters 474, 499, and 893 Florida Statutes and Rule Chapter 61N, Florida Administrative Code).
- B. The University holds and recognizes institutional DEA registrations for basic and preclinical research protocols for **schedule II-V** with either the AV and Director, Comparative Medicine (CM) as the institutional licensee (i.e. for Boca Raton and Jupiter campuses) or the CM Clinical Veterinarian as the institutional licensee for the HBOI campus.
- C. Controlled substances **schedules II through V** including drugs procured through the National Institute on Drug Abuse (NIDA) Drug Supply Program must be purchased through Comparative Medicine unless:
 1. Issued by a consulting veterinarian working with the FAU marine mammal rescue group as reflected in a contract and/or MOU
 2. Issued by a veterinarian responsible for the health care of animals used in wildlife and/or field research as reflected in an MOU between the particular veterinarian and the AV/Institution.
- D. **DEA schedule I** controlled substances are the responsibility of the research investigator including acquiring the DEA license and overseeing procurement, storage, disposal and recordkeeping. The researcher is required to inform the Attending Veterinarian and the IACUC if they have a Schedule I DEA license.
- E. **Prescription drugs**, both veterinary and human-label prescription drugs, other than controlled substances have to be purchased through Comparative Medicine while no specific storage other than set forth by the manufacturer applies.
- F. Only controlled substances and prescription drugs listed in an IACUC protocol may be purchased for use on an animal with the exception for use in emergency situations or for veterinary medical treatment as prescribed by the veterinarian and agreed upon by the PI.
- G. Any faculty or staff member requesting and using any controlled substance acquired through the institutional licensures must be registered with Comparative Medicine c/o the CM employee responsible for ordering drugs using a *Certification of Research Personnel Using Controlled Substances* form, which will be mailed to the PI. Every two years as part of a program-wide biennial inventory of controlled substances, all personnel possessing or using controlled substances in research must re-certify with Comparative Medicine using the aforementioned form.
- H. Registrants must meet the criteria for Principal Investigator (PI) as per FAU policy (http://www.fau.edu/research/docs/policies/sponsored-programs/PI%20Eligibility%20Policy_Rev%2002-06-2018-signed.pdf) and are responsible for all aspects of these Principles and Procedures. Registrants must identify the controlled substance use in an approved IACUC protocol and/or research project, the individual(s) responsible for assisting in their compliance with these Principles and Procedures, the location where the controlled substance will be securely stored, and ensure that complete records will be maintained. Faculty must ensure

controlled substances are stored in an area of limited access and according to the DEA regulations.

- I. Request for drugs both controlled substances as well as prescription drugs must be submitted in writing via the VSATS online ordering system using the Drugs/Supplies Request Form. Sufficient time should be allowed for procurement, especially for those drugs that are irregularly used or have not been ordered before.
- J. Additional requests for a controlled substance can only be filled when the status of the previous dispersal has been verified by the responsible CM staff.
- K. Principal Investigators are responsible for proper storage, accurate recordkeeping, and appropriate administration while the controlled drug is in their possession.
- L. Principal Investigators are responsible for returning the completed controlled substance log(s) to CM. Controlled substance vials either empty or with unused drug due to a completed protocol or out-of-date drug must be returned to Comparative Medicine and will be disposed by the veterinarian according to DEA regulations.
- M. No expired drug may be used on any live animal either in survival or non-survival procedures. Any drug that is expired has to be labeled directly on the vial or in a separate box/area labeled "Expired, not for use in or on a live animal." This includes any drug in a lab where animals are used.
- N. Laboratories, storage cabinets, and logs of use are subject to unannounced and announced inspections and audits by the DEA, Division of Research Integrity, IACUC, and Comparative Medicine.
- O. Non-compliance can result in suspension of privileges to use controlled substances and/or associated animal care and use protocols.

V. Definitions

1. **Controlled Substance** is any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end).
2. **Prescription Drug** is a pharmaceutical drug that legally requires a medical prescription to be dispensed. Prescription means an order for medication or medicinal supplies by a duly licensed health professional licensed by the laws of the state.
3. **Veterinary Prescription Drug** means a prescription drug solely used for veterinary use.
4. **Human-Label Drugs** are drugs that have been approved through the Food and Drug Administration (FDA) for use in humans. Veterinarians, as licensed health professionals, have the right to purchase and prescribe human labeled prescription drugs and use them according to their best medical judgment.
5. **A Registrant** is a Principal Investigator (PI) at FAU certified to use controlled substances schedules II through V agreeing to abide to the laws and regulations governing the maintenance, storage, recordkeeping and administration of such.
6. **Drug Enforcement Administration (DEA):** The unit within the United States Department of Justice that establishes and enforces the federal regulations for controlled substances. The DEA employs federal agents to oversee the provision of the federal regulations.

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Describing all experimental procedures in the animal care and use protocol including the planned administration of controlled and/or prescription drugs.
- Proper storage, recordkeeping and administration of controlled and/or prescription drugs according to federal regulations and this policy.

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- Assuring that personnel are appropriately trained in all procedures involving controlled and/or prescription drugs.
- Assure that research personnel follows the animal care and use protocol, especially in regards to use of described medical compounds or the instructions whenever prescribed by the veterinarian.
- Return of empty, partially empty or full vials of controlled substance(s) to Comparative Medicine and the proper completed *Controlled Substance Record Usage Log*.

The IACUC will be responsible for:

- Reviewing and approving, requiring modifications in (to secure approval) or withholding approval of IACUC protocols and/or amendments, especially assess the appropriateness of the use of controlled substances and prescription drugs.
- Providing oversight for all animal procedures conducted including the use of controlled substances and prescription drugs.
- Performing regular inspections of storage, recordkeeping and administration of controlled substances and prescription drugs, at least semi-annually.
- Develop and direct an appropriate training program.

The Research Integrity office will be responsible for:

- Administrative support of the IACUC members to facilitate their regulatory function.
- Maintaining policy and assure regular review and update as necessary by the IACUC.
- Organizing, supporting and recording outcomes of regular inspections of research labs in regards to controlled substances and prescription drugs.

The Office of Comparative Medicine (CM) will be responsible for:

- Veterinary review of IACUC protocol(s) and advice PI on appropriate study design concerning procedures requiring controlled substances and prescription drugs.
- Acquiring institutional licensures for controlled substances for the different animal housing locations.
- Initiating Memorandum(s) of Understanding with other veterinarians who will support parts of the FAU Animal Care and Use Program such as wildlife/fields studies or Marine Mammal Rescue. Working with the legal office at the Division of Research and the veterinarian(s) to execute the appropriate MOU(s).
- Ordering, dispensing and lawfully disposing expired or otherwise superfluous controlled substances and/or prescription drugs.
- Providing support and training for all CM personnel involved in ordering, storing, administration and recordkeeping of controlled/prescription drugs as per SOP.

VII. Procedures

1) Registration and Ordering Procedures

- A. The Principal Investigator must complete Certification of Research Personnel Using Controlled Substances form every two years if the use of controlled substances is approved in his/her IACUC protocol(s) and/or research project. This will be initiated by Comparative Medicine in conjunction with the biannual inventory of controlled substances.
- B. This completion of the above mentioned form is not necessary for prescription drugs that are not regulated through the DEA.
- C. If drugs will be procured through the NIDA Drug Supply Program the PI will need to

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complete the Request Package as required and specified on the NIDA website. Ordering Guidelines for Research Chemicals and Controlled substances can be found at <https://www.drugabuse.gov/ordering-guidelines-research-chemicals-controlled-substances>. Comparative Medicine staff will complete the DEA Order Forms 222 & 223 per the order request of the PI and communicate these and the Request Package with NIDA.

- D. The request to purchase drugs must be submitted in writing via the VSATS online ordering system using the Drugs/Supplies Request Form.
 - i) Some drugs will be maintained in stock at all times. Others may have to be ordered.
 - ii) Protocols or research projects are checked for drug match as applicable.
 - iii) The drug will be issued and appropriate paper work will be completed.
 - iv) Charges for the cost of the drug will be added to the monthly invoice for animal use and so identified.
- E. Controlled substances and prescription drugs received from other sources must be registered with Comparative Medicine unless otherwise approved in the protocol or issued by a veterinarian responsible for the health care of animals used in wildlife and/or field research including marine mammals as reflected in an MOU between the particular veterinarian and the AV/Institution.

2) Maintenance, Storage and Recordkeeping Procedures

A. Controlled Substances

- i) Each vial of controlled substances procured under the University's institutional DEA licenses is marked with a unique identifying code that corresponds to that substance's schedule, Federal Drug Code number, and a consecutive vial inventory number, which corresponds with the associated paperwork.
- ii) Comparative Medicine maintains records of all controlled substance distributions to Principal Investigators. These records consist of a chronological log of all controlled substance dispersals indexed by substance and principal investigator. The PI or his/her designee signs off when receiving the controlled substance. A *Controlled Substance Usage Log* will be issued and must be kept up to date at all times by the responsible person (registered PI).
- iii) Schedule I controlled substances require the principal investigator to have his/her own DEA license and therefore is accountable for the appropriate recordkeeping.
- iv) Principal Investigators are responsible for maintaining accurate records of controlled substances used while in their possession.
 1. The *Controlled Substance Usage Log* should be kept in a secure place.
 2. Each time the controlled substance is used the date, the amount used, the amount remaining in each vial and the initial of the person using the drug is recorded on the *Controlled Substance Record Usage Log*.
 3. When the vial of controlled substance is depleted or returned to CM for any reason, the PI signs the log confirming that the log accurately reflects the usage and returns it to the responsible CM staff member.
- v) Principal Investigators are responsible for returning the Controlled Substance Record of Use Log to CM when their inventory is depleted, not needed anymore or expired. Any empty vial and unused controlled substance, either associated with a completed protocol or expired must be returned.
- vi) All controlled substances have to be maintained under the responsible person's control at all times. The person who signed for the drug is held legally responsible for the drug until it is returned to the Veterinarian for disposal.

- vii) When controlled substances are not in use, they have to be securely locked in a substantially constructed cabinet.
 - (1) Controlled substances must be secured behind two locks. Laboratory doors can be considered one lock, if doors of unattended labs are kept locked at all times.
 - (2) Keys to the controlled substances cabinet must be maintained in a secure place by the responsible person, i.e. registrant or his/her designee.
 - (3) Controlled substances can never be left unattended, even for short amounts of time, while in use.

B. Non-Controlled Substances (Prescription Drugs)

Non-controlled substances should be stored as recommended by the manufacturer and maintained /disposed in accordance with Environmental Health and Safety guidelines.

3) Disposal of Controlled Substances

- A. Once the drug container is empty or contaminated, or the drug is expired or no longer needed, the bottle, its contents, and the Controlled Substance Log should be returned to the veterinarian as soon as possible.
- B. The veterinarian will dispose of the bottle and its contents in accordance with Environmental Health and Safety, vendor, and/or other federal guidelines (e.g., DEA guidelines).

4) Inspections

- A. DEA can make unannounced inspections and audits at any time and has to be given access to cabinets, all stored controlled substances and associated records.
- B. The IACUC will make at least semi-annual inspections of all controlled substances. In preparation for inspections, Comparative Medicine will provide the IACUC with a report of all controlled substances that have been dispensed with their locations and identity.
- C. Comparative Medicine will make periodic, unannounced inspections of drugs, drug storage, and logs.

VIII. Policy Renewal Date
11/30/2021

IX. References

POLICY APPROVAL

Initiating Authority

Signature: _____

Date: _____

Name: Daniel C. Flynn, Vice President for Research