Division of Research
Comparative Medicine

Original Date Released: 12/4/15 Version: 02 Date Last Revised/Reviewed: 1/15/19

SOP # 004	**Title: Controlled Substances**

SCOPE: This SOP is applicable to all Comparative Medicine personnel

SOP OWNER: Attending Veterinarian

PURPOSE: To outline appropriate procedures for procurement, storage, distribution, Administration, recordkeeping and disposal of controlled substances.

LOCATION: All vivaria and research labs

Approved by: Sylvia Gografe, D.V.M., Ph.D. Director Comparative Medicine

1. **Responsibilities**
    a. Lab Animal Technician
        i. Adhere to procedures as outlined in this SOP.
        ii. Adhere to recordkeeping requirements as outlined in this SOP.
    b. Facility Manager
        i. Adhere to procedures as outlined in this SOP.
        ii. Ensure procedures are followed as outlined in this SOP.
        iii. Ensure appropriate training is provided to particular personnel depending on function/job description and assurance that Training Checklist is signed
    c. Training Coordinator/Administrative Assistant
        i. Adhere to and ensure procedures are followed as outlined in this SOP.
        ii. Ensure appropriate training is provided to particular personnel depending on function/job description and assurance that Training Checklist is signed
        iii. Order and receive controlled substances, maintains the *Controlled Substance Master Log*, disperses to research personnel, and collects the completed *Controlled Substance Usage Log*.
    d. Director/Veterinarian

i. Acquires institutional licenses for the Boca Raton and the Jupiter campuses.
ii. Initiates 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).
iii. Conducts biennial inventories and administers the final closeout/disposal of all controlled substances under the institutional licenses.
iv. Ensure appropriate training is provided to particular personnel and necessary resources are available.

2. General

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 and/or relevant Florida Regulations.
b. The University holds and recognizes institutional DEA registrations for basic and preclinical research protocols for **schedule II-V** with either the AV and/or Director, Comparative Medicine as the institutional licensee (i.e. for Boca Raton and Jupiter campuses), the CM Clinical Veterinarian as the institutional licensee for the HBOI campus. Applications for DEA licenses have to be submitted every three (3) years.
c. Consultants to the sea turtle program or the Marine Mammal Rescue program are responsible for their own DEA licenses when prescribing controlled substances (see MOU's) and not covered by this SOP.
d. The veterinarian holding the DEA license(s) supervises responsible CM staff members in the handling and use of controlled substances, regularly reviews paperwork and conducts biennial inventories.
e. 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 as set forth in the IACUC Policy 10.4.17. except for animals that are covered by MOUs with outside veterinarians.
f. **DEA schedule I** controlled substances are the responsibility of the research investigator including acquiring the DEA license and overseeing procurement, storage, disposal and recordkeeping.
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. Every two years as part of a program-wide biennial inventory of controlled substances, all personnel possessing or using controlled substance in research must re-certify.
h. Comparative Medicine maintains appropriate records of procurement, distribution, usage and disposal.

3. Procedures

a. Procedures for Receiving and Dispersing Controlled Substances

i. A copy of the relevant DEA license is provided to the distributor as requested.

ii. Controlled substances are ordered to be shipped to the location where those compounds will be used.

iii. Request for controlled substances by research staff are made through the VSATS ordering system.

iv. If drugs will be procured through the NIDA Drug Supply Program the PI will need to 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.

v. When controlled substances arrive, they are checked and approved by the responsible person of the particular area. This includes comparing received number of containers/drug with the attached invoice and integrity of all containers. If controlled substance containers are broken, spilled or damaged the controlled substance must be disposed of (if recoverable) and accounted for according to DEA requirements. At a minimum, take a picture of the affected container and inform the responsible veterinarian immediately who will follow DEA requirements including paperwork.

vi. The received controlled substances are assigned a unique identifying code that corresponds to that substance's schedule number, the drug lot number, and a consecutive vial inventory number. This unique identifying code has to be found/written directly on the drug vial with a sharpie while in addition the consecutive vial number only should be written on the outer container/carton if applicable.

vii. The controlled substance is then entered on the *Controlled Substance Master Log,* listing:

1. The unique substance identification number
2. Substance name
3. Source/vendor
4. Date of receipt
5. Amount received
6. Received by.

viii. Each substance has its own *Controlled Substance Master Log,* which all are kept in a large binder at the specific location.

b. Procedures for Research Staff Requesting Controlled Substances

i. Faculty have to complete the *Certification of Research Personnel Using Controlled Substances* form every two years coinciding with the controlled substances inventory performed at each of the DEA registration cites. A separate spread sheet (*Certification Verification* form) will be kept to assure that each research lab requesting the use of controlled substances is current.

ii. Request for controlled substances has to be submitted in writing through the VSATS ordering system allowing enough time to order the compounds, especially if it is a drug not regularly ordered.

iii. Prior to filling the order, the responsible CM staff member:
    1. Ensures the PI's *Certification of Research Personnel Using Controlled Substances* is current and that the certification form adequately describes the personnel requesting and using the controlled substance, and the location where the substances will be stored.
    2. Reviews the IACUC protocol referenced on the order form to determine that the ordered drug is listed and approved.
    3. Reviews the inventory to assure all prior dispersals have been accounted for.

iv. A controlled substance may be dispensed only when all the above requirements have been met. The PI will be notified when their order is available for pick up.

c. Procedures for Dispensing Controlled Substances

i. A controlled substance is dispensed by locating its unique identification number in the *Controlled Substance Master Log.* The following information will be added:
    1. Date of dispersal
    2. Dispensed to (PI name)
    3. Individual dispensed to and initials
    4. Expiration date of the dispensed drug (Mo/Yr)

ii. A *Controlled Substance Usage Log* is completed and issued with every controlled substance. It includes the following information:
    1. Drug name
    2. Unique identification number (i.e. Bottle #)
    3. Expiration date of the drug
    4. Date Issued
    5. PI receiving the drug (name and phone number)
    6. Authorized custodian (name)
    7. Building/room of secure storage
    8. Signature of PI and date of log returned
    9. Amount received in ml

iii. When both the *Controlled Substance Master Log* and *Controlled Substance Usage Log* have been filled out and the latter issued, the person receiving the drugs has initialed in the *Controlled Substance Master Log*, the drug(s) may be dispensed. Additional support documents such as *Guidelines for Use of Buprenex in Rodents* might be provided at this time.

iv. Additional controlled substances cannot be dispensed until the status of the previously dispensed substance has been clarified.

d. Procedures for Conducting the Closeout of Controlled Substances
   i. The PI completes the *Controlled Substance Usage Log,* signs it, and returns it together with the vial (empty, partially empty or unused) to the responsible CM staff member to close out its use.
   ii. The responsible CM staff member enters the date the *Controlled Substance Usage Log* is received on the top of the form as well as in the *Controlled Substance Master Log* sheet to close out its dispensation.
   iii. The *Controlled Substance Master Logs* are filed numerically and by drug name.
   iv. Empty vials are discarded after checking correct unique identification number and emptiness per EH&S recommendations.
   v. Vials that still contain a controlled substance are stored at the lowest shelf of the drug cabinet, which is labeled for expired or returned drugs only until lawfully disposed by the veterinarian.
   vi. The veterinarian communicates with the applicable Florida DEA office regarding the appropriate method for destruction of controlled substances, follows this guidance and completes associated DEA forms.

4. Procedures for Recordkeeping

a. Licensures are kept within a binder together with master logs at each relevant location, i.e. Boca Raton, Jupiter and HBOI as applicable.
b. Invoices, the *Controlled Substance Master Logs* for each controlled substance, the Certification Verification form, the *Certification of Research Personnel Using Controlled Substances,* the *DEA Biennial Controlled Substance Inventory* form and completed DEA form 41 are kept in one binder.
c. Completed *Controlled Substance Usage Logs* organized numerically by drug are kept in another binder.
d. Documents are archived every 2 years coinciding with the biennial inventory of the controlled substances as applicable.

Review Date	Revision Date	Revision Number	Description of Revision
01/15/19	01/15/19	2	Included NIDA order option, updated information on controlled substance usage log