STANDARD OPERATING PROCEDURES

DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

SOP#: 014.6 Date Issued: 11/00 Date Revised: 01/22 Page 1 of 5

TITLE:	**Controlled Substances**
SCOPE:	Research and Animal Program Personnel
RESPONSIBILITY:	Research Coordinator, Veterinary Care Manager, Facility Managers, and All Animal Program Personnel
PURPOSE:	To Outline the Program of Controlled Substances

I. PURPOSE

1. To establish appropriate procedures for procurement, distribution, use, record keeping, and disposal of controlled substances used in research and teaching protocols.

II. RESPONSIBILITY

1. It is the responsibility of the Assistant Director to administer the Controlled Substance Program for Comparative Medicine. The Assistant Director receives the controlled substance(s), maintains the ***Master Log***, disperses to Facility Managers, conducts biennial inventories, and administers the final closeout/disposal of all controlled substances.

2. The Assistant Director is responsible for maintaining records of certification of all principal investigators (PI) and their designated research staff using DEA Schedules II-V controlled substances in IACUC approved preclinical research at the University of South Florida.

3. Any DEA Schedule I-V controlled substances for non-preclinical use should contact Research Integrity & Compliance.

4. Facility Managers are responsible for dispensing controlled substances and maintaining records of all controlled substance use associated with the facility they manage.

III. POLICY

1. University policies regarding procurement, distribution, use, security, and record- keeping of controlled substances regulated by the Drug Enforcement Administration (DEA) are guided by the regulations detailed in ***21 CFR 1300-1308***.

2. **Any faculty member requesting, possessing, or using any Schedules II-V controlled substance in IACUC approved preclinical research or teaching must be registered with the Division of Comparative Medicine**, c/o the Assistant Director at MDC 20, phone 974-9876, or fax 974-9432.

3. **Registrants must be faculty members** and are responsible for all aspects of this policy. Registrants must identify the controlled substance(s) used in an approved IACUC protocol, the individual(s) responsible for assisting in their compliance with these policies, and the location where the controlled substance will be securely stored, and they must ensure that complete records will be maintained. Faculty must ensure controlled substances are

stored in an area of limited access securely locked in a substantially constructed cabinet. Controlled substances must be secured behind two locks. Laboratory doors can be considered one lock, if doors of unattended labs are kept locked.

4. **Registered faculty must procure all controlled substances from the Division of Comparative Medicine**. Controlled substance distribution to faculty located at the Byrd Alzheimer's Institute, College of Medicine, J.A. Haley V.A. Hospital, Psychology CSD, College of Public Health, Interdisciplinary Research Building, College of Arts & Sciences, Stabile Research Building, Heart Institute, Center for Advanced Medical Learning & Simulation, and satellite facilities are made through the Facility Managers at those locations.

5. The University holds and recognizes one institutional DEA registrations for IACUC approved preclinical research protocols (i.e., a Schedule II-V registration), with the Director of Comparative Medicine as the institutional licensee. All other registrations for DEA Schedules II-V substances required for IACUC approved preclinical research are in violation of University policy and must be surrendered to the Division of Research Integrity & Compliance, 974-5638.

6. Each vial of controlled substance procured under the University's Comparative Medicine DEA Schedule II-V license is **assigned a unique identifying code** that corresponds to that substance's Schedule, Federal Drug Code number, and a consecutive vial inventory number.

7. The Division of Comparative Medicine maintains records of all such controlled substance distributions to Principal Investigators. These records consist of a chronological log of all **controlled substance dispersals indexed by substance and principal investigator**.

8. Request for controlled substances must be submitted in writing to the appropriate Facility Manager using the **Supplies, Equipment, and Services** order form (CMDC #107) at least 24 hours prior to being dispensed.

9. Additional requests for a controlled substance can only be filled when the status of the previous dispersal has been verified with the appropriate Facility Manager.

10. **Principal Investigators are responsible for maintaining accurate records of controlled substances used while in their possession** by recording, on the ***Controlled Substance Record of Use Log***, the amount used and the amount remaining in each vial.

11. **Principal Investigators are responsible for returning the signed *Controlled Substance Record of Use Log*** to the Division of Comparative Medicine when their inventory is depleted. Any unused controlled substance, a controlled substance associated with a completed protocol, or an out-of-date controlled substance must be returned to the Division of Comparative Medicine.

12. Laboratories, storage cabinets, logs of use, and inventory records are subject to unannounced inspections and audits by the DEA, Division of Research Integrity & Compliance, and Division of Comparative Medicine.

13. Non-compliance can result in suspension of privileges to use controlled substances.

IV. PROCEDURES

1. Procedures for receiving and dispersing controlled substances:
    a. The Assistant Director is responsible for receiving all controlled substances from outside vendors.
    b. Requests for controlled substances by research staff are made through the appropriate Facility Manager in writing using the ***Supplies, Equipment and Services*** order form (CMDC #107).
    c. When controlled substances arrive, they are checked and approved by the Assistant Director and then assigned a unique identifying code that corresponds to that substance's schedule number, Federal Drug Code number, and a consecutive vial inventory number.
    d. The controlled substance is then entered on the ***Controlled Substance Master Inventory***, listing:
        1. the unique substance identification number
        2. substance name
        3. source
        4. 222 number (Schedule I & II substances only))
        5. amount received
        6. date received
        7. received by
    e. Controlled substances are dispersed to Facility Managers and are tracked by entering the following information on the ***Controlled Substance Master Inventory***,
        1. dispersal date
        2 dispersed by
        3. dispersed to
        4. expiration date of substance

2. Procedures for managers receiving dispersed controlled substances:
    a. Controlled substances are dispersed from the Assistant Director to a Facility Manager and are tracked by entering the following information on the ***Controlled Substance Facility Inventory-Substance*** log (indexed by substance name):
        1. Unique substance identification number
        2. Date received
        3. Amount received
        4. Date of expiration

3. Procedures for research staff requesting controlled substances:
    a. Faculty, having completed the process of registration and certification, can order controlled substances only when described in their approved IACUC protocol(s) by placing an order with the appropriate Facility Manager.
    b. Requests for controlled substances must be submitted in writing using the ***Supplies, Equipment and Services*** order form (CMDC #107). Although many commonly requested drugs are stocked in the pharmacy, requests should be made in advance of an anticipated need to insure availability. Additional time should be allotted for any unique substances that need to be ordered or for the request of Schedule II controlled substances not currently described on the University's registration to allow for amending the registration prior to being ordered.
    c. Completed order forms may be submitted via campus mail, fax, e-mail, or hand delivered to the appropriate manager.
    d. Prior to filling an order, the Manager 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 secured. The Manager then reviews the IACUC protocol referenced on the order form to determine if the controlled substance is described within. Finally, the Controlled Substance/Facility Inventory is reviewed to determine if all prior dispersals have been accounted for.

e. 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 to be picked up at the facility's pharmacy.

4. Procedures for dispensing controlled substances:
    a. A controlled substance is dispensed by locating its unique identification number in the ***Controlled Substance Facility Inventory-Substance*** log and adding the following information:
        1. Date dispensed
        2. PI issued to
    b. The controlled substance being dispensed is similarly tracked by entering the following information on the ***Controlled Substance Facility Inventory-PI*** log (indexed by principal investigator):
        1. Unique substance identification number
        2. Substance name
        3. Date dispensed
        4. Amount dispensed
        5. Date expires
        6. IACUC number
        8. Individual dispensed to and initials
        9. Phone #
        10. Storage location where substance is secured
    c. A controlled substance ***Record of Use Log*** is filled out and issued with every controlled substance being dispensed and includes the following information:
        1. Name of substance
        2. Unique identification number
        3. Date issued
        4. Principal investigator
        5. IACUC or CS number
        6. Name & signature of recipient
        7. Telephone number of laboratory where used
        8. Location where drug will be securely stored
        9. Volume received
        10. Date of expiration
        11. Issuing facility
    d. When both ***Controlled Substance Facility Inventory*** records are completed (one indexed by substance and one by PI), the ***Record of Use Log*** issued, and the person receiving the drugs has signed for them, the drugs may be dispensed.
    e**. Additional controlled substance cannot be dispensed until the status of the previously dispensed substance has been determined**.

5. Procedures for maintaining the ***Controlled Substance Record of Use Log***:
    a. The ***Record of Use Log*** should be kept in a secure place, preferably stored with the controlled substance.

b. Each time the controlled substance is used, the date, the volume removed from the vial, the initials of the person removing it, and the balance remaining in the vial is recorded on the ***Record of Use Log***.
c. When the vial of controlled substance is depleted, the PI signs the log confirming that the log accurately reflects the usage and returns it to the appropriate Comparative Medicine Facility Manager.

6. Procedure for conducting the closeout of a controlled substance:
    a. The PI completes the ***Record of Use Log***, signs it, and returns it to the appropriate Manager to close out their use.
    b. The Manager enters the date the ***Record of Use Log*** is received on the top of the form and on the ***Controlled Substance Facility Inventory-PI*** log form to close out their dispensation. Once checked in, the ***Record of Use Log*** is submitted to the Assistant Director.
    c. The Assistant Director enters the date the ***Record of Use Log*** is returned on the ***Controlled Substance Master Inventory*** to close out the dispersal inventory records. ***Record of Use Logs*** are filed numerically.

7. **Any controlled substance that becomes outdated, is no longer in use, or is associated with a completed protocol will be returned**, with the ***Record of Use Log***, to the appropriate Manager for proper storage or disposal and closeout.

8. Audits and inspections of Controlled Substance procurement, dispersal, use, storage, and recordkeeping may be conducted, unannounced, by the DEA, Division of Research Integrity & Compliance, and Division of Comparative Medicine.

9. Audits and inspections of individual investigator's laboratories and Record of Use Logs are conducted jointly by Division of Research Integrity & Compliance and the Division of Comparative Medicine.

10. At least every two years, the registrant (i.e., Comparative Medicine) shall take a new inventory of all stocks of controlled substances on hand as required by **21 CFR Section 1304.11**. This **biennial inventory** may be taken on any date which is within two years of the previous biennial inventory date.

11. Access to controlled substances within the animal facility is limited to:
    a. Veterinarians have keys to the College of Medicine facility dispensing cabinet.
    b. All Facility Managers have keys to the dispensing cabinets located within their facility.
    c. The Associate Director and the Assistant Director for Regulatory Affairs have keys to the Master Inventory Cabinet located at the College of Medicine.

Approved: **Date:**