

STANDARD OPERATING PROCEDURES
DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

SOP#: 014.7

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TITLE:
SCOPE:

Controlled Substances

RESEARCH PURPOSE

1. To establish Comparative Medicine. The Assistant Director receives the controlled substance(s), maintains the **Master Log**, disperses to Facility Managers, conducts inventories, and administers the final closeout/disposal of all controlled substances.
2. The Assistant Director is responsible for maintaining records of certification of all 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 974-9876, or fax 974-9432.**
3. **Registrants must be faculty members** and are responsible for all aspects of their research. 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, the location where the controlled substance will be securely stored, and they must ensure complete records will be maintained. Faculty must ensure controlled substances

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, Research South 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

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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

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
 - 5.

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- 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 F