Administrative Policy

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Subject: Use of Controlled Substances in Research

1.0. PURPOSE:

The purpose of this policy is to set forth procedures governing the acquisition, storage, use and disposition of controlled substances in research by persons or groups working under the auspices of the University.

2.0. ORGANIZATIONS AFFECTED:

All units of the University, including auxiliary organizations.

3.0. REFERENCES:

3.1. Code of Federal Regulations: Title 21, Chapter II (Parts 1300 to end).

3.2. Health and Safety Code Division 10: California Uniform Controlled Substances Act.

3.3. University Administrative Procedure 009 - Risk Management and Safety Committee

4.0. POLICY:

It is the policy of the University to provide a safe and healthful, working and educational environment, and to meet all appropriate federal, state and local health and safety regulations.

5.0. DEFINITIONS:

5.1. Authorized Principal Investigator - A tenured/tenure-track faculty member who has responsibility for the research project under the auspices of her/his University appointment.

5.2 Authorized Personnel - Members of a research group headed by an Authorized Principal Investigator who are authorized to handle controlled substances.

5.3. Controlled Substances - Drugs and certain other chemicals, which are listed by the Drug Enforcement Administration in the five Schedules of Controlled Substances.

5.4. Criminal Background Check - The process of comparing an individual's fingerprints to databases of the Federal Bureau of Investigation and Department of Justice.

Approved: _____ Date: _____

5.5. DEA - The Drug Enforcement Administration of the U.S. Department of Justice.

5.6. DEA Registration Certificate - A document issued by the DEA to individuals who apply for and obtain approval to acquire, handle, and store controlled substances.

5.6.1. Individual Research Certification - DEA Registration obtained by each Authorized Principal Investigator who wishes to acquire, handle and/or store controlled substances.

5.6.2. Institutional Research Certification - DEA Registration obtained by the University for oversight of the use of controlled substances in research.

5.7. Form 222 - A form issued by the DEA that must be filled out in order to purchase or transfer controlled substances. The dispenser or vendor sends a copy of the form to the Federal Drug Enforcement Administration.

5.8. Form 106 - The Report of Theft or Loss of Controlled Substances form issued by the DEA.

5.9. IACUC - Institutional Animal Care and Use Committee (IACUC), which is charged with oversight of the use of vertebrate animals in research and instruction.

5.10. IRB - Human Subjects Committee - The Institutional Review Board (IRB), which is charged with oversight of the use of human subjects in research.

5.11. Research - For the purposes of this policy, research is defined as systematic, organized investigation or experimentation designed to result in new knowledge, learning or application of information or theory.

5.12. Schedule of Controlled Substances - Any of five (5) categories of controlled substances, which are categorized by the DEA based upon their relative potential for abuse, status of accepted medical use, and the degree of physical or psychological dependence that may be caused by abuse of the material.

6.0. RESPONSIBILITIES:

6.1. The Office of Research and Development will:

6.1.1. Have oversight of the use of controlled substances in animal research, through interaction with the IACUC.

6.1.2. Have oversight of the use of controlled substances in human subject research, through interaction with the IRB – Human Subjects Committee.

6.2. The Dean of Graduate Studies and Research will:

6.2.1. Serve as the Institutional Official with oversight over the use of controlled substances in research.

6.2.2. Obtain and keep current the Institutional DEA Registration for the use of controlled substances in research.

6.2.3. Have the authority to obtain, store and use controlled substances for use in research under circumstances where an Individual DEA Registration is not in force.

6.3. Procurement and Contracts and University Auxiliary Services, Inc. will review purchase requisitions for controlled substances, ensuring that copies of valid DEA Registrations are included prior to placing the order. In addition, they will ensure that orders for Schedule I and II substances are accompanied by DEA Form 222. A copy of the final/processed Purchase Order shall be provided to the ordering department.

6.4. The Student Health Center Pharmacy will:

6.4.1. Receive, reconcile, log and securely store orders of federally controlled substances to be used in research at the University.

6.4.2. Communicate with the Authorized Principal Investigator to arrange transfer of shipment and custody.

6.4.3. Provide a monthly tracking log of research controlled substance transactions to the Dean of Graduate Studies and Research and the Director of Research and Development.

6.5. Environmental Health and Safety will:

6.5.1. Have oversight of institutional risk and safety issues associated with the use of controlled substances in research, assure compliance with DEA regulations, and authorize storage facilities.

6.5.2. Schedule inspections of controlled substance storage facilities and required documents (i.e., drug log and inventory records).

6.5.3. Arrange for disposal of unwanted, unused or expired controlled substances and controlled substance waste in accordance with state and federal laws.

6.5.4. Provide training of Authorized Principal Investigators and other personnel in the proper handling, storage, and inventory of controlled substances.

6.6. The Authorized Principal Investigators will:

6.6.1. Comply with University, federal and state regulations pertaining to the acquisition, storage, use and disposal of controlled substances.

6.6.2. Maintain strict control over inventory and security of controlled substances.

6.6.3. Ensure that all individuals in their research group (authorized personnel) who have access to controlled substances pass a criminal background check administered by the University Department of Public Safety. Any individual who has ever been convicted of a crime in connection with controlled substances under state or federal law, or who has any such action pending, shall not be allowed to participate in research which involves access to controlled substances.

6.7. The University Police will:

6.7.1. Investigate all suspected thefts or misuse of controlled substances obtained for use in research.

7.0. PROCEDURES:

7.1. DEA Registration – The use of controlled substances in research requires the provision of appropriate approval by the DEA.

7.1.1. Authorized Principal Investigators wishing to use controlled substances as a component of their research must apply for and receive an individual DEA Registration Certificate prior to their acquisition.

7.1.2. Information and application forms for DEA Registration will be obtained by Authorized Principal Investigators from the Office of Research and Development.

7.1.3. The DEA Registration will indicate the specific controlled substances to be used in research. A separate DEA Registration is required for each principal place of business or professional practice where controlled substances are stored, administered or dispensed.

7.1.4. Copies of DEA Registration Certificates shall be provided to Environmental Health and Safety, the Student Health Center Pharmacy, and the Office of Research and Development.

7.1.5. All individuals who wish to be designated as Authorized Personnel in order to have access to controlled substances as members of research groups must pass a criminal background check administered by the

University's Department of Public Safety. All fees associated with this check are the responsibility of the applicant.

7.1.6. The Dean of Graduate Studies and Research will also act on the institution's behalf to obtain an Institutional DEA Registration.

7.1.7. Some animal care/research units may require controlled substances for the health maintenance and treatment of animals. These substances shall be kept in an approved storage site, separate from controlled substances used in teaching and research. Documents must be available upon request to demonstrate the substances were purchased or prescribed for treatment of animals.

7.2. Ordering and Receipt of Controlled Substances

7.2.1. Orders for controlled substances must include a copy of the Authorized Principal Investigator's DEA Registration Certificate, and DEA Form 222 for Schedule I or II substances.

7.2.2. The shipping address for controlled substances must be the following:
Student Health Center Pharmacy
Attn: Pharmacy Director
California State University, Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8411.

Shipments must not be addressed to Shipping and Receiving.

7.2.3. Upon receipt, the Student Health Center Pharmacy will:

7.2.3.1. Reconcile, log and securely store orders of controlled substances to be used in research, following their established procedures.

7.2.3.2. Notify the Authorized Principal Investigator and document transfer of custody on the tracking log that will be provided monthly to the Dean of Graduate Studies and Research and the Director of Research and Development.

7.2.3.3. Complete the Notification of Receipt of Merchandise or Cancellation of Purchase Order memorandum (Appendix 8.1.) and forward to Shipping and Receiving to ensure proper processing of all payments.

7.2.4. All orders for controlled substances must be placed by Procurement and Contracts, regardless of whether the controlled substances are purchased or obtained free of charge from the supplier.

7.3. Secure Storage of Controlled Substances

7.3.1. Controlled substances and Usage Logs must be securely stored in a locked non-movable container which meets the requirements of the DEA. Information on acceptable storage conditions and locations is available from the Office of Research and Development. Proper storage of both drugs and Usage Logs is the responsibility of the Authorized Principal Investigator, and is subject to inspection by Environmental Health and Safety.

7.3.2. Access to secured substances and Usage Logs must be limited to the Authorized Principal Investigator.

7.3.3. Any individual with knowledge of theft, loss or fraudulent activity related to controlled substances must immediately report such information to Environmental Health and Safety, who will thoroughly investigate the discrepancy and subsequently notify other units of the University (such as University Police) and federal authorities, as appropriate.

7.3.4. Principal Investigators and other personnel may not transfer controlled substances to or from other researchers or institutions without prior approval by the Office of Research and Development. There shall be no transfer of controlled substances between researchers without following proper procedures, including documenting the transfer of custody of material, and obtaining DEA Registration for the recipient of the controlled substance.

7.3.5. Under no circumstances are controlled substances to be abandoned. In rare occasions when this situation may arise due to sudden termination of employment, closure of research, departure of the Principal Investigator, or other events, the chair/director of the department/division/school must contact Environmental Health and Safety, who will coordinate disposal in accordance with DEA regulations.

7.4. Recordkeeping and Inventory Requirements

7.4.1. Authorized Principal Investigators are required by federal and state law to document the use of controlled substances. Records must include the date of order and record of pick up from the Student Health Center Pharmacy, Usage Logs documenting each instance of use, and records documenting final disposition of the controlled substance.

7.4.2. Records must be kept secure in a locked area, preferably in the same secure storage with the associated controlled substances.

7.4.3. Usage Logs must include the name of the drug, strength, amount received, name of Authorized Principal Investigator and date of pick up from the Student Health Center Pharmacy. Usage Logs must indicate the amount of each use, date of use, name and signature of the Authorized Principal Investigator using the drug, and an exact, perpetual remaining balance each day.

7.4.4. Authorized Principal Investigators must perform and document a formal inventory of all controlled substances annually, at the beginning of each calendar year.

7.4.5. All records must be kept for at least three (3) years, and be available for inspection by Environmental Health and Safety and the DEA. Contracts or regulations may require longer retention periods.

7.4.6. Any person who fails to keep appropriate records or abandons controlled substances may be subject to reprimand and/or disciplinary action, following procedures specified in collective bargaining agreements between the Board of Trustees of the California State University and the employee's relevant bargaining unit, University policies and procedures applicable to non-represented staff, policies and procedures of University Auxiliary Services, Inc., or the CSU Student Conduct Procedures, as applicable.

7.5. Disposal of Controlled Substances

7.5.1. Disposal of unused controlled substances must be arranged by contacting Environmental Health and Safety, who will coordinate disposal in accordance with DEA regulations. All relevant records of receipt, custody, storage and use of controlled substances must be made available.

7.5.2. Empty containers of controlled substances must be disposed of in consultation with Environmental Health and Safety.

7.6. Loss or Theft of Research-Related Controlled Substances

7.6.1. Any loss, theft, or disappearance of controlled substances must be reported to the University Police and to Environmental Health and Safety immediately upon discovery.

7.6.2. The Authorized Principal Investigator will also complete a Report of Theft or Loss of Controlled Substances form (DEA Form 106) and forward it to the DEA.

7.6.3. The University Police will investigate and file a police report, and submit a copy to the appropriate University Vice President(s).

8.0. APPENDICES:

8.1. Notification of Receipt of Merchandise or Cancellation of Purchase Order memorandum.