A. Purpose: This policy describes policies and procedures for procurement, distribution, storage, use, record keeping, and disposal of controlled substances and DEA regulated chemicals for nonhuman use (i.e., administered to animals for teaching or research) at the University of Maryland, College Park (UMCP) campus.

B. Policy. Controlled substances and DEA regulated chemicals will be used solely for research and teaching. Adequate controls will be established to prevent unauthorized use. Controlled substances and DEA regulated chemicals can only be purchased from vendors by users with DEA and Maryland licensure. The address on the DEA license is the only location for receipt of controlled substances and DEA regulated chemicals from vendors.

C. Scope: All UMCP personnel who use controlled substances or DEA regulated chemicals in nonhuman research or teaching programs are subject to the provisions of this policy even when they have their own licensure.

D. Definitions:

1. Controlled Substances are drugs and other materials that by common, unusual, chemical, or brand name are specifically designated under the Comprehensive Drug Abuse and Control Act of 1970 as amended and detailed in 21 CFR 1300-1308.

2. DEA Regulated Chemicals are chemical precursors, reagents and solvents required for the manufacture of controlled substances, which appear on List I and II in 21 C.F.R. Part 1310.02.

3. Regulatory Agencies. The United States Drug Enforcement Administration (DEA) and the Maryland Department of Health and Mental Hygiene govern the use of controlled substances for research and teaching purposes.

4. Licensure. Procurement, possession, and use of controlled substances and DEA regulated chemicals require registration with DEA and the State of Maryland. Controlled substances but not DEA regulated chemicals may be may be procured from the Department of Laboratory Animal Resources (DLAR) located at the Central Animal Research Facility (CARF), Building 087, under its Director’s practitioner’s license. Licensure of the user is not required when controlled substances are procured from DLAR.

5. Controlled Substance User is most commonly a state employee responsible for the oversight and use of controlled substances or DEA regulated chemicals in his/her area of responsibility (e.g., investigator, physician, or veterinarian).

E. Responsibilities.
1. The Director, Department of Laboratory Animal Resources (DLAR) is responsible for:
   a. Ensuring compliance with all DEA requirements (21 C.F.R. Part 1300 -1308) outlined in this policy.

   b. Maintaining a database of all controlled substances issued by DLAR to CS users. The database will contain a record for each substance dispensed. The record will include the name of the substance, quantity dispensed, lock box number and responsible CS user. The database will also contain the inventory of controlled substances in the DLAR pharmacy.

   c. Conducting the training course “Acquiring and Safeguarding Controlled Substances, Nonhuman Use” for CS users.

2. Controlled substance users are responsible for:
   a. Ensuring compliance with all DEA requirements (21 C.F.R. Part 1300 -1308) outlined in this policy.

   b. Registering with DLAR located at CARF, Building 087.

   c. Identifying individual(s) responsible for assisting in compliance with these policies and the location where the controlled substance will be stored.

   d. Attending the training course entitled "Acquiring and Safeguarding Controlled Substances, Nonhuman Use” and ensuring similar training of all individuals who will handle controlled substances in their areas in the appropriate handling, record keeping and security procedures prior to being granted access to these substances.

   c. Submitting a “Controlled Substance Authorization” form to the Director, DLAR. By signing the form, the CS user validates that procedures in accordance with this policy will be followed.

   d. Establishing a lock box for securing controlled substances and ensuring that all controlled substances used within his/her area of responsibility are kept secured.

   e. Maintaining current records for all controlled substances used within his/her area of responsibility.

G. Procedures for procuring controlled substances and regulated chemicals.

1. Controlled substances and DEA regulated chemicals may be procured directly from a vendor if the user obtains licensure from the DEA and the State of Maryland Department of Health and Mental Hygiene, Division of Drug Control. Licensure from each agency must be renewed annually.

2. Licensure.

   a. Registration for DEA licensure may be initiated and renewed online at www.deadivision.usdoj.gov DEA-225 should be used. As a state employee, fees are exempt.
b. Registration with the state of Maryland at http://www.dhmh.state.md.us/drugcont/ As a state employee, fees are exempt.

3. Alternately, users may procure on a limited basis, controlled substances but not Schedule I controlled substances or DEA regulated chemicals from the DLAR under its Director’s practitioner’s license.

4. The user will complete the required training course entitled "Acquiring and Safeguarding Controlled Substances, Nonhuman Use” and ensure similar training of all individuals who will handle controlled substances in their areas in the appropriate handling, record keeping and security procedures prior to being granted access to these substances.

6. Establish a lock box, security cabinet or safe in the area the controlled substances will be used.

7. Submit a completed “Controlled Substance Authorization” form to the Director, DLAR

8. If obtaining controlled substances from DLAR:
   a) The Director, DLAR will issue a “Controlled Substance Record for Nonhuman Use” form and control numbers with each controlled substance. The forms are used to track the disposition of issued controlled substances.

   b) Arrange for pick-up of the substances from DLAR. The user will sign the DLAR CS Tracking form and the charge-back log.

I. Physical Security.

1. The CS user is responsible for the proper use and security of controlled substances in his/her area of responsibility. The user shall ensure that all controlled substances are maintained in the appropriately numbered and registered lock box. The user is responsible for control of the combination and/or key(s) for their lock boxes.

2. Random, unannounced visits by the Director, DLAR or designee will be conducted to monitor compliance with these security requirements. These inspections are in addition to self-inspections by the user.

3. Controlled substances and DEA regulated substances must be secured in a lockable container under two locks. The door to the container may have two locks or may have two lockable doors. Laboratory doors can be considered as one lock if unattended labs are kept locked. Lockable file cabinets or desks of reasonable construction in locked rooms are also acceptable. Safes of over 750 pounds must be used to secure Schedule I drugs.

4. A controlled substance lock box designation is assigned by the Director, DLAR to a specific user for a specific lock box location.

J. Record-Keeping Requirements.

1. The “Controlled Substance Record for Nonhuman Use” form(s) issued with each controlled substance must be locked in the same room where the controlled substances are stored. The forms must
be accessible for review and recording at all times. The entries must be written, typed or printed; electronic records are not acceptable. Inventory records of Schedule II drugs must be kept separate from Schedule II and V.

2. When recording the use of a controlled substance, a line entry is made using one line per procedure or animal treated. Entries on the “Controlled Substance Record for Nonhuman Use” form shall be made by the individual withdrawing the drug from the lock box at the time the item is withdrawn. Each line entry will include the date, the signature of the individual removing the drug from the lock box, the quantity withdrawn, the balance remaining, and the purpose for administration. Units of measure must remain constant on an individual CS record and accurately reflect the amount of controlled substance in stock (ex. mg, ml, tablet count, or gm).

3. Formats for documenting the “purpose”
   a. Animals with an individual chart and ID number - record the animal ID number, species and the reason why the controlled substance was administered such as euthanasia or anesthesia.
   b. Animals without an individual chart or ID number - record the species, the protocol number and the reason why the controlled substance was administered. When a group of animals of the same species without individual charts or identification numbers are treated at the same time, with the same dose, for the same purpose, a one-line entry can be made with a vertical line drawn to indicate same-as-above.
   c. When no animals are involved, describe the in-vitro or training use of the substance.

4. Each container (vial, bottle or ampule) of controlled substance procured from DLAR will be assigned a unique identifying control number that corresponds to that substance’s schedule and a consecutive container inventory number.

5. DLAR will maintain records of all controlled substances it distributes to users. These records consist of a chronological log of all controlled substances dispersals indexed by substance and user.

K. Expiration, Accidental Destruction or Contamination

1. When contents of the bottle are contaminated or expired in amounts of more than one ml, contact DLAR. The bottles will be collected and disposed of through a company specializing in disposal of controlled substances. A line entry will be made on the “Controlled Substances Record for Nonhuman Use” or log book. The amount is entered under the “waste” column. Each line entry shall include the date, description of circumstances (e.g. expired), signature of the person delivering the drug to DLAR, signature of the person receiving the substance at DLAR and balance. A copy of the “Controlled Substances Record for Nonhuman Use” or log book page will be maintained by DLAR.

2. When a controlled substance has been accidentally destroyed, damaged, or contaminated outside of the bottle OR expired/contaminated with less than one ml remaining, a line entry is made on the “Controlled Substances Record for Nonhuman Use” or log book. The amount is entered under the “waste” column. Each line entry shall include the date, description of circumstances (e.g. contaminated), signature of the person destroying the substance, signature of at least one individual witnessing the destruction of the substance, and balance. If the amount to be
destroyed is more than one ml, a UMCP police office should be witness to the destruction of the substance. Under most circumstances, liquid substances of Schedule II through V can be dried on paper in a fume hood and the disposed in the waste system. For exceptions, contact the Division of Environmental Safety.

3. Once empty, the labels from the bottles shall be disposed of in the sanitary waste or in a broken glass container.

4. When a dose is withdrawn from a lock box and recorded on the “Controlled Substance Record for Nonhuman Use” and only partially administered to an animal, the remaining excess should be destroyed as stated above and logged as such on the “Controlled Substance Record for Nonhuman Use” form.

5. If procured from DLAR, controlled substances must be transferred to DLAR when the user no longer requires them. Contact DLAR to arrange the transfer of the controlled substance and the corresponding “Controlled Substances Record for Nonhuman Use.”

L. Bulk Powdered Controlled Substances.

1. In general, bulk powdered controlled substances are provided in jars with removable and replaceable lids.

2. Conducting an inventory.

   a. Remove the tamper proof seal.

   b. Determine the total weight of the jar, lid and contents.

   c. On the first line of the “Controlled Substances Record for Nonhuman Use,” make an entry that includes: the date; the total weight of jar, lid and contents in mg; the signature of person making the entry; and in the balance column record the weight of the controlled substance contained in the full jar as stated on the manufacturer’s label.

3. Dispensing powdered controlled substances.

   a. Prior to opening the jar, weigh the jar, lid and contents and verify the weight with that previously recorded on the “Controlled Substances Record for Nonhuman Use” form.

   b. Remove the lid from the jar and place the jar containing the powder on an electronic balance and tare the balance.

   c. Remove the powder until the electronic balance indicates that the required amount has been removed.

   d. Make a line entry on the “Controlled Substance Record for Nonhuman Use” with the date; the total weight of jar, lid and contents in mg; the signature of person making the entry; and in the balance column record the weight of the controlled substance contained in the full jar as stated on the manufacturer’s label.
e. Replace the lid and verify the weight of the jar, lid, and contents, which should be minus the amount removed.

4. Reconstitution. Record the following information on the “Controlled Substances Record for Nonhuman Use”: the date reconstituted, final concentration of solution that was made, name of individual who made the solution, and the final volume of solution in mls.

M. Mixes. – If a controlled substance is mixed with another product, the drug must be tracked as if it is from a single stock. The drug is recorded as used on the “Controlled Substance Record for Nonhuman Use” or log book when dispensed, not when mixed. Mixed drugs must continue to be maintained under the same security. A separate “Controlled Substance Record for Nonhuman Use” form is used to track the mixture. The vial containing the mixture must labeled with the date mixed, products and concentrations, and expiration date. Mixes can only be held for 14 days.

N. Form Completion and Records Retention.

1. Upon completion of each “Controlled Substances Record for Nonhuman Use,” the balance of the controlled substance remaining should be zero. Occasionally, manufacturers will overfill vials so there may be a negative balance. Prior to returning the completed form to DLAR (if obtained from DLAR) the user shall retain a photocopy for his/her records. Copies shall be filed by drug and are required to be kept for a period of two years by the user.

2. If at any time all entry lines are filled in on a given “Controlled Substance Record for Nonhuman Use” and there is still a quantity of the drug remaining, the user shall continue using a copy of a blank back page of a “Controlled Substances Record for Nonhuman Use”.