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

B. Policy. Controlled substances will be used solely for research and teaching. Adequate controls will be established to prevent unauthorized use. Controlled substances 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.

C. Scope: All UMCP personnel who use controlled substances in nonhuman vertebrate 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. Select controlled substances but not DEA regulated chemicals 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 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 records of all controlled substances issued by DLAR to CS users. The records will document each substance dispensed and include the name of the substance, quantity dispensed, lock box number and responsible CS user. The records 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. The CS Authorization and Training form will be used to document training.

2. Controlled substance users who obtain their own licensure are responsible for:

   a. Ensuring compliance with all DEA requirements (21 C.F.R. Part 1300 -1308) outlined in this policy.

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

   c. Maintaining accurate records for all controlled substances used within his/her area of responsibility.

3. In addition to requirements listed in Section E.2., controlled substance users who obtain drugs from DLAR are also responsible for:

   a. Registering with DLAR located at CARF, Building 087 (5-4921).

   b. Attending the training course entitled “Acquiring and Safeguarding Controlled Substances, Nonhuman Use”.

F. Procedures for procuring controlled substances.

1. Controlled substances 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 kept current.

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/](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.

   a. Authorized DLAR staff will log each transaction as follows:

      1) Record the date dispensed, amount dispensed, balance, control number, and user name on the CS Inventory Record form for each drug. Sign as issuer. Separate CS Inventory Record forms will be maintained for each controlled substance.

      2) Record the date dispensed, amount dispensed and control number on the bottom of the CS Authorization and Training form for the user and the drug. Separate CS Authorization and Training forms will be maintained for each user and each drug.

      3) Record the date dispensed, the controlled substance, and the number of containers in the procurement log to allow for the billing on the user’s FRS number.

   b. The user will sign the CS Inventory Record form and the procurement log.

   c. Authorized DLAR staff will issue a CS Record for Nonhuman Use form with each controlled substance. The substance and the control number will be noted on the form.

   d. Users must return the original CS Record for Nonhuman Use form before additional controlled substances can be issued. The only exception is when the user is close to finishing a container. The date the form is returned is noted on the CS Authorization and Training form by DLAR staff as the date the transaction is reconciled.

G. Receipt of Controlled substances by DLAR.

1. The Admin Assistant will order Controlled Substances at the Direction of the Director, DLAR.

2. Upon receipt, authorized DLAR staff will assign control numbers to each substance based on the next sequence. The control numbers will be written on the box and bottle of each substance. The amount received, balance, and control numbers will be noted on the CS Inventory Record Form.

H. 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.

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 or office doors can be considered as one lock if the rooms are kept locked when not occupied. Lockable file cabinets or desks of reasonable construction in locked rooms are also acceptable.

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 CS Record for Nonhuman Use form(s) issued with each controlled substance must be locked in the same room where the controlled substances are stored. If controlled substances were obtained under a researcher’s license, information required on the CS Record for Nonhuman Use form must be entered in a log book. The forms and log book must be accessible for review and recording. The entries must be written, typed or printed. 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. Entries on the CS Record for Nonhuman Use form or log book shall be made by individuals who have received training on acquiring and safeguarding controlled substances for CS users. Each line entry will include the date, the animal ID number or the protocol number, the species, the purpose for administration, the signature of the individual removing the drug from the lock box, the quantity removed, and the remaining balance. 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). The CS is normally tracked as if it is from a single stock and the amount that is actually injected into the animal is recorded on the CS Record for Nonhuman Use form. Non-controlled substances such as saline, xylazine and acepromazine are not recorded. Published dosages of ketamine and xylazine mixtures for rodents (see attached) list the tracking volumes for ketamine.

3. Alternatively, when injected volumes of mixtures are so small that tracking becomes difficult, a second CS Record for Nonhuman Use form may be used to track all components of the mixture. See ATTACHED sample CS Record for Nonhuman Use forms. The volume of the controlled substance removed is noted under QUANTITY REMOVED and the designation of the mixture (e.g. A or 1) is noted under PURPOSE on the first CS Record for Nonhuman Use form. On the second CS Record for Nonhuman Use form, the mixture designation is noted on the left margin next to the DATE. The starting balance is noted on the right margin next to the CURRENT BALANCE. Subsequent volumes injected into animals are noted under QUANTITY REMOVED. Mixtures may not be stored for more than 14 days. Any unused mixtures must remain secured in the lockbox. The amount destroyed after 14 days is noted under WASTE as a separate line entry.
4. 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.
   c. When no animals are involved, describe the in-vitro or training use of the substance.

5. 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.

6. 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, return the bottle and original CS Record for Nonhuman Use form to DLAR. A separate line entry will be made on the form. The date, description of the circumstances (e.g. expired), amount, signature and balance will be entered. The calculated amount is entered under waste. The bottles will be held in a lockbox until disposal through DES.

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 form. The date, description of the circumstances (e.g. expired), amount, signature and balance will be entered. The amount is entered under WASTE. There will also be a signature of at least one individual witnessing the destruction of the substance. Under most circumstances, liquid substances can be placed on an absorbent towel in a fume hood until evaporated. The towel is then disposed in the sanitary waste.

3. When using attachable needles, up to 0.05 mls may be lost in the hub at every draw. After 20 draws, 1 ml of CS can be lost. This amount should be accounted for by making a line entry on the Controlled Substances Record for Nonhuman Use form. The date, description of the circumstances (e.g. wasted in syringe), amount (0.05 X number of draws), signature and balance will be entered. The amount is entered under WASTE.

4. Once empty, the bottle can be placed in the trash, a sharps container or a broken glass container.
5. When a dose is withdrawn from a lock box and recorded on the CS Record for Nonhuman Use form and only partially administered to an animal, the remaining excess should be destroyed as stated above and logged as such on the CS Record for Nonhuman Use form.

6. If procured from DLAR, controlled substances and the corresponding CS Record for Nonhuman Use form must be transferred to DLAR when the user no longer requires them. CS may not be transferred between users.

N. Form Completion and Records Retention.

1. Upon completion of each Controlled Substances Record for Nonhuman Use form, the balance of the controlled substance remaining should be zero. Occasionally, manufacturers will overfill vials so there may be a negative balance identified with parenthesis or minus sign.

2. If at any time all entry lines are filled in on a given Controlled Substance Record for Nonhuman Use form and there is still a quantity of the drug remaining, the user shall forward the balance to a second form and continue tracking usage.

3. 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.