Institutional Animal Care and Use Committee		
Title: Controlled Substances		UNTHSC
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A. BACKGROUND INFORMATION

a. All controlled substance use in approved animal research activities must follow the federal and local rules and regulations, including the procedures in this Standard Operating Procedure (SOP).

B. RESPONSIBILITIES

- a. It is the responsibility of the Principal Investigator (PI) to follow the procedures in this SOP.
- b. Anyone procuring a controlled substance must have a current Federal DEA (Drug Enforcement Agency) license.

C. PROCEDURES

- a. It is recommended that Principal Investigators obtain the proper DEA licenses in order to acquire the controlled substances listed in their protocols.
 - i. The PI should assure that all drugs needed for study are in-date and available before needed.
 - ii. Expired containers of controlled substances (with any contents remaining) must be separated from non-expired containers of controlled substances, and must be clearly labeled as being expired.
 - iii. If the PI does not have a drug at the time needed, not enough of the drug, or finds that it is expired, the PI may contact DLAM to determine if they have the drug. If DLAM has it, DLAM staff can give the needed amount of the drug to the PI and properly document this exchange in both party's controlled substance log books. The drug must be properly labelled with drug name, lot number, expiration date, and the initials of the person who gave it (if the drug is in another container other than the original).
- b. If an Investigator will not use a controlled drug frequently, the Investigator can contact DLAM (Department of Laboratory Medicine) to determine if DLAM can acquire and administer the controlled substances. In this case, no one other than DLAM staff can handle the controlled substance.

D. REFERNCES

- a. <u>UNTHSC Controlled Substances Website</u> Information on the Purchase, Storage and Disposal of Controlled Substances
- b. UNTHSC SOP for Expired Controlled Substances Waste Disposal
- c. Drug Enforcement Agency Website
- d. DEA Controlled Substances Schedules

- e. DEA Controlled Substances Registration Application
- f. Office of Diversion Control Online Registration Application
- g. DEA Record Keeping Requirement