Purpose of Policy: This policy is intended to ensure that the use of controlled substances in animals used in teaching or research at Western University of Health Sciences (WesternU) is in compliance with federal and state laws regarding their use and storage.

Policy Information: A) Licensing: Title 21, Section §822 of the United States Code (USC) Controlled Substances Act states that “Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him” and that “Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

The Research Advisory Panel of the State of California’s Department of Justice, Office of the Attorney General, states that “Any planned research project to be conducted in California requiring the use of a Schedule I or II Controlled Substance, NOT Schedule, III, IV, and V, as its main study drug including comparing drug, must be submitted to the Research Advisory Panel of California for review and approval prior to start-up in the following areas:

- Non-Human Research (animal models or in vitro) of Schedule I medications
- Multi or Single Center Clinical Drug Trial Research sponsored by a pharmaceutical company evaluating or comparing any Schedule II medications

Policy: Investigators wishing to use a controlled substance covered by USC Title 21 must be properly registered with the Justice Department by completing and submitting the application form to the Drug Enforcement Administration (DEA) Office of Diversion Control. A link to the application form can be found on the Institutional Animal Care and Use Committee’s website under Important Forms. Investigators wishing to use Schedule I controlled substances in either of the bulleted situations
described above must also have approval from the Research Advisory Panel of California. The IACUC will not review or approve protocols using Schedule I controlled substances unless the investigator has a DEA license and approval from the Research Advisory Panel of the State of California.

B) Storage: Investigators are referred to Title 21, section §1301.72, of the Controlled Substances Act for details regarding the requirements for storage of controlled substances.

Policy: In compliance with the regulations, WesternU has adopted the following minimum requirements for the storage of controlled substances.

- All controlled substances must be stored in a securely locked, substantially constructed, cabinet or safe devoid of any markings indicating the purpose for which it is used.

- Cabinets or safes used for the storage of controlled substances must be resistant against 30 man-minutes of surreptitious entry and 10 man-minutes of forced entry.

- Safes weighing less than 750 pounds that are used for the storage of controlled substances must be bolted or cemented to the floor or wall in such a way that they cannot be readily removed.

- Access to the room in which controlled substances are stored must be restricted to a limited number of authorized personnel.

- Where key locks are used, a limited number of authorized personnel may have keys to the storage unit.

- Where combination locks are used, a limited number of authorized personnel may have the combination. The combination must be changed upon termination of employment of anyone knowing the combination.

- Non-controlled substances and other materials may not be stored in the same storage unit with controlled substances.