POLICY

TITLE:	**Controlled Substances**
Policy Number:	**2014-050**
Responsible Department:	**Institutional Animal Care and Use Committee**
Policy Contact: **Designation:** **E-Mail:**	**Donald E. Walters, Ph.D.** **Chair, Institutional Animal Care and Use Committee** **dewalters@westernu.edu**
Approval Date:	**10/8/14**
Reviewed:	**2/14/18; 7/8/2020 (No changes)**
Revised:	**2/14/18 (Added requirements for Sections B, D and E); 4/17/18 (Added Oregon & on-line training requirements); 9/13/18 (Added background checks; new ordering and tracking policy and unannounced inspections); 2/7/19 (Revised Section E); 7/8/2020 (Added staff handling CS must also complete training)**
Legislation:	**Title 21 United States Code, Subchapter 1, Part C, §822; Subchapter 2, §1301.72**

Purpose of Policy: To ensure that the use of controlled substances in animals for teaching or research at any facility owned or operated by Western University of Health Sciences (WesternU) is in compliance with federal and state laws regarding their acquisition, use, storage and disposal.

Policy Information:

NOTE: All individuals who may work with or in proximity of controlled substances, including but not limited to faculty and student investigators, research assistants and laboratory managers, may be subject to a background/criminal screening process facilitated through human resources

(A) Registration: 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."

Pursuant to **Oregon** Administrative Rules, the Board of Pharmacy requires that "persons conducting research with controlled substances in Sections I through V within this state…may, upon furnishing the Board a copy of a current federal registration certificate issued for such a purpose, receive written verification of such submission from the Board's Executive Director".

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.

A **California investigator** who wishes 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 is currently registered with the DEA for the use of Schedule I controlled substances **and** has been approved by the Research Advisory Panel of the State of California for the use of Schedule I controlled substances. Investigators must be able to provide proof of approval from the Research Advisory Panel upon demand by the IACUC or by an authorized state official.

After obtaining a DEA Registration, an **Oregon investigator** who wishes to use a controlled substance in research must request an exemption for Controlled Substance Registration for Research Purposes from the Oregon Board of Pharmacy. In a paragraph or two, the investigator must make the request, on WesternU letterhead, and briefly describe the research, including the names and uses of the desired Controlled Substances. The letter should be addressed to:

Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Ste 150
Portland, OR 97232.

On the letter, include the above and RE: Controlled Substance Registration – License Exemption. A copy of the DEA Registration must accompany the letter. When a DEA Registration is renewed, a new letter must be sent to the Oregon Board requesting another exemption along with a copy of the renewed DEA Registration. Investigators must be able to produce their letter of verification from the Board of Pharmacy upon demand by the IACUC or by an authorized state official.

All WesternU investigators engaged in animal research at any location owned or operated by WesternU must provide a copy of their DEA registration certificate(s) to the IACUC Chair. Newly submitted IACUC protocols that involve the use of controlled substances will not be reviewed, and active protocols could be suspended, in the absence of proof of DEA registration by the investigator. Investigators and their staff who may handle controlled substances must also complete the **on-line Controlled Substances Training Program** prior to using controlled substances in animal research. The Program may be accessed on eLearning. A user name and password is required to enter the site.

B) Acquisition: WesternU's IACUC requires that investigators who use controlled substances in animals as part of their teaching or research activities must be registered with the DEA. Investigators not registered with the DEA may not use controlled substances in animals except when such use is

under the direct supervision of a registered investigator as part of an approved IACUC protocol; i.e., the non-registered person must have a legitimate role in the project, as determined by the IACUC, and be named in the protocol. A registered investigator may not be a source of controlled substances for a non-registered investigator who does not meet this requirement.

Investigators registered with the DEA who wish to acquire a controlled substance must first complete the **Controlled Substance Acquisition Request Form** available on the IACUC's website or from the Controlled Substances Program Manager (nsgonzalez@westernu.edu). This form must be submitted at the time the order is placed in Elixir. In addition, DEA Registrants who wish to order Schedule I or Schedule II Controlled Substances must complete and submit DEA Form 222 to the Program Manager. Schedules III, IV and V controlled substances do not require DEA Form 222 for ordering. DEA Registrants may authorize one other person to order Schedule I or Schedule II controlled substances in their absence by completing the **Controlled Substances Schedules I & II Power of Attorney** form, also available on the IACUC's website or from the Controlled Substances Program Manager (nsgonzalez@westernu.edu), and submitting it to the Program Manager for review and approval. California and Oregon regulations require that all **completed forms must be kept on file for a minimum of three years** and be available for inspection by the IACUC, Controlled Substances Program Manager, DEA agents or other authorized individuals together with other order records.

Upon notification of the arrival of a controlled substance, the DEA Registrant, or their Authorized Representative, must arrange to pick up the item(s) from the Patient Care Center Pharmacy at which time they must sign the **Controlled Substances Chain of Custody** form documenting that they have taken possession of the item(s). This form must accompany the item(s) each time the item(s) change hands. This form must be kept in a secure location, preferable with the controlled substance, and produced on demand for inspection by the IACUC, Program Manager, DEA agents or other authorized individuals.

C) Storage: Upon receipt of a controlled substance, the item(s) must be immediately placed in the approved secure location. 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.

D) Recordkeeping: Investigators who are registered with the DEA to use controlled substances as part of their teaching or research activities at any facility owned or operated by WesternU must maintain accurate records pertaining to the acquisition and use of such substances. California and Oregon regulations require that all **completed forms must be kept on file for a minimum of three years.** Federal regulations require that, for Schedules I & II controlled substances, an exact count must be made at least biennially for each item on hand and, for Schedules III, IV & V controlled substances, an approximate count must be made at least biennially for each item on hand. However, a quarterly count of each controlled substance is recommended. These records must be made available on demand for inspection by the IACUC and by authorized clients and government officials. The following forms must be used to record this information:

- IACUC Controlled Substances Physical Inventory – Schedule I Only
- IACUC Controlled Substances Physical Inventory – Schedule II Only
- IACUC Controlled Substances Physical Inventory – Schedules III, IV and V Only
- IACUC Controlled Substances Usage Log.

These forms may be obtained from the IACUC Office or from the IACUC's Controlled Substance website.

E) Disposal of Expired Controlled Substances: Controlled substances that are beyond the expiration date printed on the container label by the manufacturer **may not, under any circumstances, be used in animals used in teaching or research activities** at WesternU. Controlled substances that are expired or that are no longer wanted must be disposed of by means of a Reverse Distributor.

Reverse Distributors: A *reverse distributor* is defined as a person or entity registered with the DEA as a reverse distributor to acquire controlled substances from another registrant for the purpose of return or destruction of controlled substances.

The IACUC requires that each DEA registrant contact a Reverse Distributor properly registered with the DEA to dispose of expired or unwanted controlled substances. A list of current DEA-approved Reverse Distributors can be found **here**. The Patient Care Center Pharmacist-In-Charge may be of assistance in processing the controlled substance through a reverse distributor.

An alternative method of disposal of controlled substances acceptable to the DEA is to render the substance "non-retrievable" through destruction of the substance. The DEA defines non-retrievable destruction of controlled substances as "The process utilized to render a substance "non-retrievable" shall permanently alter the substance's physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes. A substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue."

The DEA permits on-site incineration of controlled substances and animal and animal tissues contaminated with controlled substances as a means of rendering a controlled substance non-retrievable. However, WesternU does not have an on-site incinerator and the DEA has not provided guidance on methods other than on-site incineration for rendering a controlled substance irretrievable. **The IACUC therefore requires that a Reverse Distributor be used as the sole method of disposal of controlled substances**.

F) INSPECTIONS: Random, unannounced, inspections of all records pertaining to the acquisition, storage, recordkeeping and disposition of controlled substances may be made by the IACUC, Program Manager, DEA Agents or other authorized individuals.