HSC OP: 73.04, **Research Involving Controlled Substances and Laboratory Apparatus**

PURPOSE: This Health Sciences Center Operating Policy and Procedure (HSC OP) describes the use of controlled substances and laboratory apparatus in research activities at Texas Tech University Health Sciences Center (TTUHSC).

REVIEW: This HSC OP will be reviewed on June 1 each odd-numbered year (ONY) by the Assistant Vice President for Research Integrity, and the Senior lists of DEA Controlled Substances

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The Texas Higher Education Coordinating Board (THECB) has entered into a Memorandum of Understanding (MOU) between the Texas Department of Public Safety and the Texas Higher

3. **LICENSING AND REGISTRATION.**

PIs must register with the federal Drug Enforcement Administration (DEA) and the Texas Department of Public Safety (DPS) to obtain the appropriate license or registration for the controlled substances to be used, prior to initially obtaining and using controlled substances.

i. **Federal Registration**: The PI must first obtain federal licensure from the DEA. The application can be obtained from the DEA website: DEA Controlled Substance Registration, DEA registrations remain active for a 1-year period. (State of Texas no longer issues state licenses for controlled substances.)

ii. **THECB/DPS MOU:** The PI must implement and maintain a program within his/her laboratory for reporting information concerning controlled substances, controlled substance analogues, chemical precursors, and chemical laboratory apparatus used in education or research activities. This program will address the sale, furnishings or transfer of controlled items, including glassware, covered by the MOU to any person or entity not holding a DPS permit, unless the recipient is specifically exempted by law or rule. The PI must notify TTUHSC Department of Safety Services prior to any sale, furnishings or transfer of controlled items covered by the MOU (HSC OP 63.11).

iii. **Notification:** Copies of all registration and licensing related correspondence shall be maintained by the PI. Copies of the DEA and DPS licenses shall be provided to the Institutional Animal Care and Use Committee (IACUC) and the TTUHSC Research Compliance Officer at TTUHSC-Lubbock Mail Stop 8146, or email a PDF to researchoffice@ttuhsc.edu prior to initial ordering of controlled substances, and following renewal or amendment to the license.

Compliance with all federal and state regulations is the sole responsibility of the PI as licensee. Failure to comply with applicable rules and regulations may result in loss of license, penalties, fines, or other actions.

4. **TRAINING.**

All licensed PIs and their authorized users shall complete the TTUHSC Controlled Substances Training Module every three (3) years. Authorized Users are individuals identified by the PI to conduct work with controlled substances, and who have completed all required training in the use of those materials and the applicable federal and state rules.

5. **ANNUAL SELF-EVALUATION.**

All licensed PIs using controlled substances shall complete a Controlled Substances Self-Evaluation at least annually (See Attachment A to this policy). These forms shall be maintained by the PI for at least one year.

6. **REVIEW AND INSPECTION.**

All Principal Investigators with DEA licenses for research purposes will have their use of controlled substances reviewed by the Research Compliance Officer at least once per year. The reviews will focus on recordkeeping and security related the applicable federal and state rules of the THECB/DPS MOU. Any problems noted during these reviews will be shared, in writing, with the investigator, the Senior Director of Safety Services, the TTUHSC Institutional Biosafety Committee and the SVPRI. Depending on the nature of the violation, the Texas Department of Public Safety and/or the DEA may also be notified.

Supplemental reviews may be conducted during routine semi-annual IACUC inspections for those investigators with approved IACUC protocols for use of controlled substances with animals.

PURCHASING.

Only licensed PIs shall order DEA scheduled drugs. Before placing a first order for controlled substances, PIs shall consult with the TTUHSC Purchasing Department, Office of Research, and/or Safety Services, as applicable or appropriate, to review applicable rules.

All research involving controlled substances must be approved by the appropriate institutional oversight committee prior to the start of any project. The Institutional Animal Care and Use Committee (IACUC) must approve research projects involving animals and controlled substances. The Institutional Review Board (IRB) must approve research projects involving humans and controlled substances. In addition, according to the scope of the project, approval by the Institutional Biosafety Committee (IBC) may be required.

Controlled substances shall not be purchased using TTUHSC Purchasing Cards (P-Cards) or personal credit cards (HSC OP 72.15). Such activities may result in loss of P-Card privileges or other administrative actions. Purchases of controlled substances shall be made through the TTUHSC Purchase Order process.

7. **STORAGE AND SECURITY CONTROLS.**

In order to guard against theft or diversion, all controlled substances shall be kept under lock and key, with access limited only to the PI and Authorized Users. A list of Authorized Users shall be provided to the IACUC (for those PIs with approved IACUC protocols for use of controlled substances with animals) and Safety Services. Changes to the list of Authorized Users shall be provided to the IACUC and Safety Services within 30 days of the change. The number of Authorized Users shall be kept to the minimum essential for operation, and the stocks of controlled substances shall be limited to the smallest quantity needed for the project(s). The PI shall limit the number of keys allowing access to the controlled substances, and establish key

i. Receipt of Controlled Substances: A separate and current record of the receipt of controlled substances, indicating date received, name and address of supplier, and the type, strength or concentration, and amount of the controlled substances received