TTUHSC RESEARCH INVOLVING CONTROLLED SUBSTANCES TRAINING MODULE

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

OFFICE OF RESEARCH

APPLICABILITY

- **This training is a requirement of TTUHSC OP 73.04: Research Involving Controlled Substances and Laboratory Apparatus.**
- **This module must be completed every three years by Principal Investigators (PIs) and their authorized users, who use controlled substances or apparatus in their research.**
- **The last page of this training module will provide the user with an acknowledgement sheet which shall be printed and signed by the trainee. The printed and signed acknowledgement sheet shall be kept with other controlled substances records and will be reviewed by auditors and inspectors.**

OVERVIEW

- **Controlled Substances are drugs or other substances or immediate precursors which are included in schedule I,II,III,IV, or V of the Controlled Substances Act.**
- **Title 21 CFR Part 1300 to end**
  - http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm
- **Controlled Precursors and Laboratory Apparatus are listed in the Texas Higher Education Coordinating Board / DPS MOU.**
  - http://www.thecb.state.tx.us/reports/PDF/1210.PDF

LICENSING AND REGISTRATION REQUIREMENTS

- **Each PI who uses or plans to use controlled substances in their research must register with the federal Drug Enforcement Administration (DEA).**

- **The license / registration must be complete *prior to* initially obtaining and using controlled substances.**

FEDERAL REGISTRATION

- **The PI must first obtain federal licensure from the DEA.**
  - Researcher New Application – DEA Form 225
- **Registration period for Researchers is <u>one year</u> (practitioner license/registration periods may differ)**
  - Renewal Application – DEA Form 225a
- **Forms may be found on the DEA website: http://www.deadiversion.usdoj.gov/drugreg/index.html#regapps**

REGISTRATION DOCUMENTS

- **Copies of all registration documents and licensing related correspondence shall be maintained by the PI.**

- **Copies of current DEA licenses shall be provided to institutional oversight committees as needed, as well as a copy forwarded to Research Integrity Office, Research Compliance Officer in Lubbock at Mail STOP 8146.**

NOTE:

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.

RESEARCH ACTIVITIES ALLOWED

Per 21CFR 1301.13 Researchers may:

- **Conduct chemical analysis with controlled substances in those schedules for which registration was issued;**

- **Manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purpose of dosage form development;**

RESEARCH ACTIVITIES ALLOWED CONT…

- **Import such substances for research purposes;**
- **Distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempt from registration pursuant to 21CFR 1301.24;**
- **Conduct instructional activities with controlled substances.**

PURCHASING

- **Before placing an order for controlled substances, PIs shall consult with the TTUHSC Purchasing Dept., Office of Research, and/or Safety Services Dept. as appropriate to review applicable rules.**
- **Only persons who are registered with DEA to handle Schedule I or II controlled substances may obtain and use DEA Form 222 (order forms).**
- **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.**

DEA FORM 222

21 CFR 1305.12:

- **A purchaser must prepare and execute a DEA Form 222 simultaneously in triplicate by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.**
- **Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided.**
- **DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only theses substances.**

DEA FORM 222 CONT…

- **The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.**
- **Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under *§1305.05.* The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.**
- **A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.**
- **The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.**

STORAGE AND SECURITY

- **All controlled substances shall be stored in a safe (affixed to a bench or wall to prevent removal) or a substantially constructed cabinet with appropriate lock(s).**
- **The room in which the cabinet is located shall have limited access during working hours, and shall be locked when unattended.**
- **The PI shall limit the number of keys allowing access to the controlled substances, and establish key control procedures for the laboratory.**
- **Controlled substances shall be kept locked in their storage location except for the actual time required to remove, work with, and replace them.**
- **Students shall not be given unsupervised access to controlled substances.**
- **The PI is responsible for any misuse of controlled substances which occur in his/her lab.**

RECORDKEEPING

- **The following records shall be kept by the PI and made available for inspection as needed. These records will be kept for at least two years from the date of the last recorded transaction. (21CFR 1304)**

  1. Receipt of Controlled Substances log: Use OP 73.04 Attachment B every time substances are received.
  2. Use of Controlled Substances log: Use OP 73.04 Attachment C every time substances are used.
  3. Inventory of Controlled Substances: Use OP 73.04 Attachment D for an initial inventory, and every two years.
  4. Disposal: Use OP 73.04 Attachment E for each occurance in which unused or expired substances are disposed.

RECORDKEEPING CONT…

- **In addition to records previously described, the PI shall maintain**
  - the original federal license and registration documents;
  - training records (last page of this module) for PI and all users;
  - a copy of the most recent annual self-inspection,
  - a current list of authorized users.
- **All documentation related to OP 73.04 shall be kept by the PI in the registered location.**
- **All documentation shall be maintained in written, typed, or printed form and shall be made available for at least 2 years. (1304.04)**
- **In the event that a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory. (1304.11(b))**

AUDITS AND INSPECTIONS

- **Annual Self Evaluation**
  - All licensed PIs using controlled substances shall complete a Controlled Substances Self- Evaluation at least annually (See OP 73.04 Attachment A). These forms shall be maintained by the PI for at least one year.

- **Principal Investigators with approved IACUC protocols for use of controlled substances with animals will be audited by the IACUC at least twice per year and by the Research Compliance Officer at least annually.**
- **Principal Investigators who do not have IACUC protocols for use of controlled substances will be audited by the Research Compliance Officer at least twice per year.**
- **These audits will include reviews of recordkeeping and security related to the applicable federal rules and the THECB/DPS MOU.**

THECB / DPS MOU

- **Individuals who do not work with DEA Scheduled Controlled Substances are required to comply with the applicable requirements of the THECB/DPS MOU.**
- **Read the MOU at: http://www.thecb.state.tx.us/reports/PDF/1210.PDF**
- **Affected researchers must implement and maintain a program within his/her laboratory for reporting information addressing the possession of certain laboratory apparatus, the sale, furnishings or transfer, or loss (other than by breakage) 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.**

MOU LIST OF CONTROLLED APPARATUS

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).

Laboratory Apparatus	
Condensers	Distilling apparatus
Vacuum dryers	Three-necked flasks
Distilling flasks	Tableting machines
Encapsulating machines	Transformers
Soxhlet extractors	Flask heaters
Heating mantles	Adapter tubes
Filter funnels, buchner funnels, and separatory funnels	Erlenmyer flasks, two-necked flasks, single neck flasks, round bottom flasks, Florence flasks, thermometer flasks, and filtering flasks

DISPOSAL

- **Controlled substances shall only be disposed by returning to a licensed reverse distributor or other approved source.**

- **PIs shall contact Safety Services for assistance with identifying authorized reverse distribution services.**

- **The sale or transfer of controlled items covered by the THECB/DPS MOU to any person or entity not holding a DPS permit (unless specifically exempted by law or rule) is prohibited. Sale of these items through TTUHSC Surplus Property is also prohibited (OP 63.11).**

LOSS OR THEFT

- **In the event that any controlled substances are lost, destroyed, or stolen, the kinds and quantities of the materials and the date of discovery of such loss must be recorded in detail.**

- **Thefts, suspected thefts, unauthorized uses, or other losses of any DEA controlled substances must be immediately reported to the TTU Police Department (or appropriate local law enforcement agency) and the Department of Safety Services.**

- **DEA Registrants must document the incident to the DEA on Form 106 within one (1) business day.**

ADDITIONAL RESOURCES

PIs are encouraged to seek out further information as needed. The following are some useful resources:

- **Several links to the rules and regulations, as well as a PPT file provided by the local DEA field office can be found on the TTUHSC Office of Research DEA / DPS website: http://www.ttuhsc.edu/research/dd_training.aspx**

- **Questions can be directed to**
  - **Research Compliance Officer: 806-743-4752**
  - **Safety Services Department: 806-743-2597**

- **Technical advice may also be provided by the Institutional Veterinarian at 806-743-2566.**

NEXT STEPS

The final page of this module is designed to serve as your record of training. Be sure to:

- **FILL out the form**
- **PRINT a hard copy**
- **SIGN your name**
- **FILE the signed form with your other controlled substances records so it will be available to inspectors**
- **SEND a copy of the signed form to**

  Laboratory Safety Manager
  Safety Services
  Mail STOP 9020
  3601 4th St.
  Lubbock TX, 79430

Controlled Substances in Research Training Acknowledgement

Texas Tech University Health Sciences Center

FIRST NAME

LAST NAME

Department

CAMPUS

I, the undersigned, acknowledge that I have read and understand the "TTUHSC Research Involving Controlled Substances" training module and further agree to abide by TTUHSC OP73.04 as required to continue my research involving controlled substances.

I understand that I must print this acknowledgement form and file it with other required records concerning controlled substances.

I understand that this training is valid for 3 years from the date below.

Signature

Date