

## WORKING WITH CONTROLLED SUBSTANCES IN YALE UNIVERSITY LABORATORIES: A SUMMARY FOR RESEARCHERS

### √ BACKGROUND:

The use of controlled substances (Schedule I - V drugs) in research laboratory operations (including research animals) is subject to extensive state and federal regulatory requirements. Medical doctors (MD and MD/PhD) should note that these requirements are separate from and in addition to any that apply to licensing for clinical prescriptions and patient dispensing. Under controlled substances regulations, Principal Investigators (PIs) must obtain research laboratory licensure from the State of Connecticut Drug Control Division (DCD) as well as registration from the federal Drug Enforcement Administration. The Yale Office of Environmental Health & Safety (Yale EHS), Office of the Vice President and General Counsel, and University Safety Committee have attempted to streamline paperwork and application processing; the procedures outlined below represent the most straightforward process available to us at this time.

### √ LICENSING AND REGISTRATION:

\* State Licensing: Complete the Yale EHS "PTAEO Approval for State DCD Controlled Substance License" form and the State DCD "Application for Controlled Substance Laboratory License". Retain copies for your files and submit forms (with charging instructions and business office authorizing signature) to Yale EHS for processing with the state agency. The DCD will then arrange to inspect your laboratory work area. Approved applicants will receive a one-year license to work with controlled substances, consistent with the approved uses(s) described in the application. Renewal notices will be provided by EHS several weeks before license expiration.

\* Federal Registration: Once you receive your state DCD license from EHS, you will be provided with a research laboratory registration (Form DEA-225), along with another charging instructions request for the DEA license fee. Please complete and return these forms to Yale EHS, who will process the application and payment to DEA. Note that for work with Schedule I substances, three copies of the research protocol must accompany the application form. Due to internal DEA protocols, you will receive your registration certificate (known as Form DEA-223) directly from DEA; please make a copy and forward to Yale EHS. DEA registrations remain active for a 3-year period, at which time a renewal notice will be mailed to you.

\* For modifications, transfers, or terminations of a laboratory license or registration, please forward a written request to Yale EHS for processing with the regulatory agencies. Also, renewals will be processed in the same manner as initial licenses.

### √ PURCHASING:

\* Submit a completed requisition to the Purchasing Department, and attach a copy of your current license to the Purchasing Department at the time of each purchase.

### √ STORAGE AND SECURITY:

\* Keep all controlled substances under lock and key (an approved safe must be used for Schedule I and II drugs), accessible only to authorized personnel. Store controlled substances separately from all other drugs and reagents.

\* Return controlled substances to their approved storage location(s) immediately after use, keeping them locked at all times except when removing, replacing, or actively working with them.

\* Maintain only as much stock as required for normal efficient operation.

## √ EXPORTING:

\* Federal law prohibits the export of controlled substances unless certain requirements are met. Special licenses as well as export and import permits are required to export controlled substances. Contact Yale EHS for assistance in arranging for any necessary transport of controlled substances.

## √ RECORDKEEPING:

\* All records related to your controlled substances must be retained for a period of at least three years from the date of each transaction recorded.

\* Keep a separate and current record on the receipt, storage, and use of each controlled substance.

\* Every two years, prepare a complete and accurate inventory of the controlled substances under your possession, identifying their type, strength, and quantity. The biennial inventory must be conducted within four days of May 1 of each *odd numbered year* (2005, 2007, 2009, etc.). Retain the inventory for possible inspection by state or federal agencies.

## √ DISPOSAL:

\* Dispose of controlled substances **ONLY** under witness from the DCD, DEA, or by documented return to the supplier or manufacturer. Expired material, unused product, and neat waste must be accumulated and stored under lock and key until ready for disposal. Contact the DCD, DEA, or Yale EHS to arrange for a disposal visit. Controlled substances injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures from EHS and the Yale Animal Resources Center.

## √ REPORTING OF LOSS, DESTRUCTION, THEFT OR UNAUTHORIZED USE:

\* Report thefts, suspected thefts, unauthorized uses, or other losses of controlled substances to the Yale Police Department and Yale EHS upon discovery. Document the incident for submittal to the State DCD and federal DEA within 72 hours, describing the kinds and quantities of materials and the specific circumstances involved.

## √ RESOURCES:

Department or Agency	Phone	FAX
Yale University Purchasing Department 155 Whitney Avenue	432-9955	432-9966
Yale Office of Environmental Health & Safety 135 College Street ( <a href="http://www.yale.edu/ehs">www.yale.edu/ehs</a> )	785-3550	785-7588
Yale University Police Department	911 (any Yale phone) 432-4400	432-4416
CT Drug Control Division (DCD) 165 Capitol Ave Hartford, CT 06106 ( <a href="http://www.ct.gov/dcp">www.ct.gov/dcp</a> )	860-713-6065	860-713-7242
US Dept. of Justice, Drug Enforcement Division (DEA) ( <a href="http://www.dea.gov">www.dea.gov</a> )	860-240-3700 (Hartford Area Office)	860-240-2658 (Hartford Area Office)

√ **Additional Information:** Please see the “Yale University Policy for the Use of Controlled Substances in Research Laboratories” for more detailed information (available from EHS at [www.yale.edu/ehs](http://www.yale.edu/ehs)). Copies of current drug schedules and state polices are available from the CT Drug Control Division by mail or web site ([www.ct.gov/dcp](http://www.ct.gov/dcp)).