❖BRL BULLETIN❖

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This issue of the *BRL Bulletin* provides an overview on steps investigators must take to obtain state and federal licenses for the use of controlled substances in animal research. Information is also provided on how investigators may purchase pharmaceutical substances necessary to complete animal research. Procedures for the purchase of pharmaceuticals for the use in human patients is outside the scope of this bulletin.

OVERVIEW

Pharmaceutical substances can be broadly divided into two categories: non-controlled substances and controlled substances. Examples of non-controlled pharmaceutical substances include antibiotics and prescription strength anti-inflammatory drugs. Non-controlled pharmaceutical substances needed for animal research can be purchased from online sources, the BRL surgery department, and through the UIC Ambulatory Care Pharmacy Services. To purchase non-controlled substances from the BRL surgery department, please send an email message to *brlsurgery@listserv.uic.edu* and include the following information: name, concentration, and amount of drug, and the investigator's name, BRL account number, and ACC protocol number. An I-Card and account number are required for purchasing substances through the UIC Ambulatory Care Pharmacy Services. Ambulatory Care Pharmacy Services locations and phone numbers can be found at *http://hospital.uillinois.edu/Patient_Care_Services/Pharmacy.html*.

A controlled substance is a drug, substance, or an immediate precursor that has the potential to be addictive or habit forming. Controlled substances are categorized as schedule I-V by the Drug Enforcement Agency (DEA) according to whether or not they have a currently acceptable medical use, the potential for abuse, and the likelihood of causing dependence when abused.

Schedule I substances have no currently accepted medical use, lack accepted safety standards for use by medical professionals, and have a high potential for abuse. Examples of Schedule I substances include heroine and LSD.

Schedule II substances are used by medical personnel, but they have a high potential for severe psychological and physical dependence. Examples of Schedule II substances include morphine, fentanyl, and some euthanasia solutions.

Schedule III substances have a potential for abuse, but less than schedule II substances. Abuse of drugs in this category may lead to moderate or low physical dependence or high psychological dependence. Examples of schedule III substances are Telazol®, ketamine, buprenorphine, and some euthanasia solutions.

Schedule IV substances have a low potential for abuse relative to schedule III substances. Examples of Schedule IV substances include benzodiazepam and butorphanol.

Schedule V substances are considered to have the lowest potential for abuse. They include cough syrups containing less than 200 milligrams of codeine per 100 milliliters.

A complete list of the DEA schedule for controlled substances can be found on the website *dhttp://www.deadiversion.usdoj.gov/schedules/*.

LICENSURE

Because of inherent risks of controlled substances, such as theft and abuse, there are numerous federal and state regulations governing purchase, access to, and use of controlled substances.

A Federal DEA License ***and*** State License from the Illinois Department of Financial and Professional Regulation (IDFPR) are required to purchase controlled substances in Illinois. At UIC, the State and Federal DEA Licenses can be held at the department or individual level. Throughout this bulletin, the department or individual holding these licenses is termed the registrant.

Investigators who require the use of controlled substances to conduct animal research should

apply as soon as possible since the process to obtain both licenses can be quite lengthy and take up to six months.

STATE LICENSURE
Registration with the State of Illinois Department of Financial and Professional Regulation (IDFPR) is a **prerequisite** for obtaining a Federal DEA License (*www.idfpr.com/*). The application for researchers to obtain a state license is located at *www.idfpr.com/ renewals/apply/forms/f0719cs.pdf.*

The following are key points to consider when registering with the State of Illinois:

- Depending on the nature of the work, more than one registration may be required.
- Different types of licenses are approved for varying periods of time.
- IDFPR will conduct an inspection of the facility prior to licensure.

The purpose of the inspection is to ensure that the applicant has put in place appropriate physical controls and procedures to guard against theft and diversion.

Specific requirements put forth on the IDFPR website for the storage of controlled substances include:

- A safe that has an Underwriters' Laboratories Burglary Rating of T-20, E or better, or the equivalent of such a safe.
- If the safe weighs less than 750 pounds, it must be bolted or cemented to the floor or wall in such a way that it cannot be readily removed.

The requirements to store controlled substances increase with the quantity and type of substance. Additional requirements that may be imposed include an alarm system which sounds directly to the UIC or Chicago police department.

FEDERAL LICENSURE
After a state license is obtained, investigators are able to apply for a Federal DEA License. Application is made by completing DEA Form 225. Instructions on how to complete this form and links to the form can be found at *www.deadiversion.usdoj.gov/ drugreg/reg_apps/225/225_instruct.htm*. In order to complete this application, you must list all controlled substances you intend to use, and you must provide your state license number.

For both Federal and State licensure, different types of activities or different schedules of drugs may require different registrations. Additionally, maintenance of a current license is the responsibility of the registrant. License renewals must be performed online.

UIC-SPECIFIC FORMS
There are two UIC specific forms that must be completed in order to purchase controlled substances at UIC. These forms are found on the website of the Office of the Vice Chancellor for Research (*http://research.uic.edu/compliance/cs*).

UIC CONTROLLED SUBSTANCE USE FORM
Each department or individual licensed by the DEA and the IDFPR must complete a UIC Controlled Substance Use Form before they can purchase controlled substances. This form includes:

- DEA registrant's name, I-card number, contact information, and signature
- The controlled substances required for research
- The names, I-card number, and phone number of any additional authorized users who may receive controlled substances on the registrant's behalf.

A copy of this form must be on file with the Ambulatory Care Pharmacy Services to order and receive controlled substances. The form must be updated on an annual basis or whenever new users are authorized to receive controlled substances for a registrant. The registrant must maintain copies of these forms in their controlled substance records. An I-Card must be presented at the pharmacy when picking up controlled substances.

UIC AUTHORIZED USER SCREENING FORM
The DEA requires that all persons with access to controlled substances complete a screening process to assess the likelihood of the person committing a drug security breach. The need to know this information is a matter of business necessity and essential to overall controlled substances security; therefore, each and every person who is authorized to use substances on behalf of a department or a principal investigator must complete the Controlled Substances Use in Animal and Laboratory Research Appendix B (UIC Authorized User Screening Form).

PURCHASING CONTROLLED SUBSTANCES
All controlled substances that are purchased for

use in animal research must be pharmaceutical grade per ACC policy. Non-pharmaceutical grade controlled substances may only be used in animals when scientifically justified and approved by the ACC.

Because of limits in the license held by the UIC Ambulatory Care Pharmacy Services, non-UIC personnel cannot purchase controlled substances through the Ambulatory Care Pharmacy Services. Conversely, UIC registrants are **required** to purchase schedule II-IV controlled substances through the UIC Ambulatory Care Pharmacy Services with the exception of Buprenorphine SR Lab (see below). Schedule V controlled substances are uncommonly used in animal research, carry a low abuse potential, and are not subject to this same requirement. To place an order, Ambulatory Care Pharmacy Services must have on file a current State and DEA license and a UIC Controlled Substance Use Form. In addition, a UIC Ambulatory Care Pharmacy Services requisition and voucher form must be completed.

The DEA recently informed Zoopharm, the company that manufactures Buprenorphine SR Lab, that they are only allowed to dispense under a prescription from a licensed veterinary practitioner. Dr. Kelly Garcia will provide a prescription to any investigator with Buprenorphine SR Lab listed on an approved protocol. However, there are complications regarding available methods to pay for the drug. Consequently, Dr. Garcia is now working with a few investigators to identify methods to set-up accounts and order this substance. Investigators will receive an update after a mechanism is developed. In the meantime, please contact Dr. Garcia if you have need of Buprenorphine SR Lab.

For schedule II drugs, a triplicate copy of DEA Form 222 signed and dated by the DEA license holder or authorized user with power of attorney is required. DEA 222 Forms are sent to registrants at the time their license is approved. Additional DEA 222 Forms are ordered through the DEA website.

UIC registrants that require schedule I controlled substances in their research must purchase these agents through a licensed schedule I pharmacy using a triplicate copy of DEA Form 222. For those substances that are not commercially available, requests must be made to the National Institute on Drug Abuse.

RECORDKEEPING REQUIREMENTS

DEA registrants must maintain complete records of purchases, disposition, and inventory of controlled substances. These records must be maintained by the registrant for a minimum of **two years** following the use or disposal of the controlled substance. It is strongly advised that each registrant have a single designated location in which all records relating to controlled substances are kept. Access to these records should be limited to the registrant and authorized users only.

Purchasing records should include:

- A signed copy of the purchasing receipt
- A record of the lot number, date of expiration, and Narcotic Record Certificate of Disposition serial number listed on the disposition form(s)

Controlled substance disposition records: A written record of the dispensation and use of all controlled substances must be maintained by the registrant on the **Narcotic Record Certificate of Disposition Form**. Disposition records should be kept with the controlled substance, completed at the time the substance is dispensed, and include the following information:

- The name of the drug
- The amount of drug dispensed (when dispensing liquids be sure to account for dead space in syringe and needle)
- The reason for dispensing the drug
- The person who dispensed it
- A signature of the registrant and the date the Narcotic Record Certificate of Disposition Form was completed (e.g. balance equals zero)
- If more than one form is required to zero out an order, the serial numbers of the forms should be cross referenced on each form and the number of forms (e.g. 1 of 3 COD forms) should be indicated on each form.

Completed Narcotic Record Certificate of Disposition Forms should be submitted to the UIC Ambulatory Care Pharmacy Services and a copy of this form must be maintained in the registrant's controlled substance records.

Controlled substance inventory records: The registrant, or an authorized user, must perform an inventory of all controlled substances used in animal research on at least a **semiannual** basis.

The inventory should reconcile purchasing records, disposition records, and disposal records with the amount of controlled substances on hand at the time of the inventory. Semiannual inventory records must include:

- A record that inventory was conducted
- The date the inventory was conducted
- Minor discrepancies in inventory must be documented, but do not require reporting to the DEA
- The name of the registrant or authorized user who conducted the inventory audit and their signature

DRUG DIVERSION, LOSS, OR THEFT

Drug Diversion: The position of the DEA is that any employee who has knowledge of drug diversion has an obligation to report such information. Such information can be reported to the University Police (312-996-2860). The UIC police will take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. Failure to report information on drug diversion will be considered in determining the feasibility of allowing an employee to continue working in a drug security area. The employer shall inform all employees of this policy.

Drug Theft or Loss: If a theft or loss of a controlled substance is detected, it must be reported to the following agencies immediately.

DEA Office Chicago Division
Kluczynski Federal Building
230 South Dearborn Street, Suite 1200
Chicago, IL 60604
Diversion Number: (312) 353-7875

UIC Police Department
(312) 355-5555

In addition to the immediate telephone reporting to the above agencies, a DEA Form 106 (Report of Theft or Loss of Controlled Substances) must be completed and submitted to the nearest DEA Office or online to the **DEA Division of Diversion**. A copy of the report must be maintained with the registrant's controlled substance records.

Breakage and/or spills of controlled substances do not need to be reported as a loss. However, this type of loss must be documented on the disposition record with the registrant's signature. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g. tablets) must be placed in the disposal/destruction waste stream.

DISPOSAL OF EXPIRED, UNWANTED, OR CONTAMINATED CONTROLLED SUBSTANCES

To minimize waste, registrants should aim to only purchase quantities they intend to use and which can be used prior to expiration. Damaged, expired, unwanted, or contaminated controlled substances must be disposed of in accordance with state and federal regulations and records of disposal must be maintained.

When a DEA registrant has controlled substances that are expired or unwanted, the registrant must contact the Ambulatory Care Pharmacy Services and make arrangements to transfer the ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. This process may involve completion of DEA Form 222 or DEA Form 41. The Ambulatory Care Pharmacy staff will assist with this process.

ANNOUNCEMENTS

Facility Security: Animal facility security plays an essential role in ensuring research integrity and personnel safety. The BRL and all other UIC animal facilities are restricted access. Only individuals who are listed on an approved ACC protocol and who have undergone a health assessment by UHS and an orientation by a member of the BRL veterinary staff are authorized to be in an animal facility. Should you see someone who you do not believe belongs in an animal facility, please notify the facility supervisor or a member of the veterinary staff; if after hours, notify UIC police. Doors to animal facilities should not be propped open. If you come across a propped open door, please close it and notify a facility supervisor. Finally, the BRL business office has a sign-in log. All individuals entering the BRL animal housing area through the business office, including research staff with approved access, are required to sign-in and state the intended purpose of their visit.