Storage and Record-keeping for Drugs Scheduled under the Controlled Substances Act

PURPOSE: This document provides guidance to JHU investigators for the appropriate storage and record-keeping of scheduled drugs used in animal research.

BACKGROUND: Registration to obtain and use centrally acting drugs that have been legally scheduled under the Controlled Substances Act (CSA) Regulations is issued to individual investigators by the Drug Enforcement Administration (DEA). Registration in the State of Maryland is required prior to DEA's approval of federal registration. Registrants are subject to unannounced audits by the DEA, though these more commonly occur for preclinical researchers who hold Schedule I licenses. The private accrediting body, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International also includes review of storage and record-keeping in its triennial site visits.

The JHU Animal Care and Use Committee includes review of secure storage and record-keeping for controlled substances in the semi-annual inspections to assist JHU faculty in assuring that these basic functions are being carried out in their laboratories. This guidance document addresses only those two issues. Compliance with CSA regulations (21CFR, Part 1300) per se is the responsibility of the registrant (see: http://www.usdoj.gov/dea/agency/csa.htm).

PROCEDURE:

Secure Storage

The stored controlled substances “shall be accessible only to an absolute minimum number of specifically authorized employees” (Part 1301.72 of the CSA regulations). The registrant determines who those individuals are to be. There are no paperwork requirements, however, on continuing specification of those individuals once registration is approved. The approved registration application will have specified the means by which the license holder will assure secure storage of controlled substances. Laboratory members who will make use of the controlled substances need to know the storage and access requirements for the laboratory.

Security requirements are permitted to vary under the CSA depending on the particular schedule of a compound (requirements are highest for Schedule I and II compounds); quantity of controlled substance handled; the type of location (e.g. laboratory vs. clinic), the adequacy of key control and/or combination locks; the extent of unsupervised public access; and the availability of security personnel. Thus, research laboratories at Johns Hopkins generally already are relatively secure. The primary concern should be on preventing loss or theft within the laboratory setting itself.

Record keeping

The records for preclinical researchers need to contain the following information for each drug received: name, date received, the amount, by weight (e.g., total grams of powder, number of milligrams per vial), number of containers received at once (e.g., two 10-gram bottles of powder, ten 3-ml vials), and the source of the compound.

Helpful Hint: Since shipments need to be accounted for separately, it is useful to have a system for matching the record to the containers for a particular shipment (e.g., put the lot number on the record sheet; put the date of receipt on the bottle or package of vials).

The record of use of each drug needs to contain: number of units (e.g., mg or ml) removed, purpose, date of removal, the amount left, and the “written or typewritten name or initials” of the person who “dispensed” the drug. If the drug is used to make up a stock solution, keep a record of amounts dispensed from that stock and include the same pieces of information in that record.

Records must be kept readily retrievable for inspection, but there is no specific requirement on exactly where they must be kept.