



# Johns Hopkins University Animal Care and Use Committee

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## Record-keeping, Storage, and Disposal of Drugs Scheduled under the Controlled Substances Act (CSA)<sup>1</sup>

**PURPOSE:** This document provides guidance based on CSA regulations for the appropriate record-keeping, storage, and disposal of controlled substances for JHU investigators conducting research with animals.<sup>2</sup>

**BACKGROUND:** Registration to obtain and use drugs that have been legally scheduled under the CSA Regulations is issued to individuals by the DEA. Registration with the Maryland Department of Health and Mental Hygiene is required prior to DEA's approval of federal registration. Although the DEA rarely audits preclinical researcher records, Public Health Service Policy includes the requirement for proper storage and record-keeping of controlled substances used for "human and veterinary drugs and treatments,"<sup>3</sup> and AAALAC International covers this issue in its triennial site visits. Thus the JHU ACUC covers this issue in its semi-annual inspections.

**Record keeping<sup>4</sup>:** Record of receipt and use of a controlled substance needs to be maintained for each lot received. Below are the basic requirements. Other information can be included as desired by the investigator.

--Name of the drug

--Source

--Date received

--Manufacturer's lot number (on the container)

--Amount received (such that total amount of drug is shown or could be derived, such as, "10 g" if powder, or "10 2-ml vials, 5 mg/ml" if liquid)

One must be able to match drug containers on hand with the record, which can be done by use of the lot number. Labelling bottles or boxes of vials with the date of receipt can be helpful. If multiple bottles or boxes of vials from the same lot are received on the same day, then putting a code (e.g., A, B, or C) on the bottle or the box of vials can be helpful to track use of that drug lot.

As the drug is used, the following information needs to be recorded (a tabular/columnar format works best):

--Date of removal

--Number of units removed (e.g., 50 mg, if powder; or Bottle A, 1 ml).

--Amount remaining (i.e., a running total of amount remaining in a separate column)

--Name or initials of the person who removed that amount of drug

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<sup>1</sup> Approved by JHU Animal Care and Use Committee: September 19, 2002. Revised April 20, 2006. Revised October 20, 2011. Revised November 19, 2015.

<sup>2</sup> The record-keeping requirements for animal research apply whether a the DEA registration is that for a researcher or as a "coincident activity" under a practitioner registration [21CFR1301.13(e)].

<sup>3</sup> *Guide for the Care and Use of Laboratory Animals*, 8th Ed., National Research Council, 2011; p. 115.

<sup>4</sup> This guidance has been derived from 21CFR1304.22. "Records for manufacturers, distributors, dispensers, researchers, importers and exporters."

**--Purpose** (this will vary across types of drugs and species. For some drugs, it may be sufficient to have a heading on the record page that states the purpose, such as, "Preparing solutions for anesthesia in mouse surgeries," "Sedation of monkeys for physical examinations").

If the drug is used to make a solution (e.g., from powder or by diluting with saline or combining two or more solutions) that will be maintained for multiple uses over some period of time, keep a separate record of use of that "working solution."

Records must be kept secure and readily retrievable for inspection, but there is no specific requirement on exactly where they must be kept. The packing slip for the shipment should be retrievable also, but it does not need to be kept in the same location as the record of use. Record of use and the packing slip for each lot are to be retained for 2 years.

**Secure Storage:** The stored controlled substances "shall be accessible only to an absolute minimum number of specifically authorized employees" (21CFR1301.72). The registrant determines who those individuals are to be. There are no paperwork requirements 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. .

Security requirements 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; the location (e.g. laboratory vs. clinic), adequacy of key control and/or combination locks, extent of unsupervised public access, and availability of security personnel. Thus research laboratories at Johns Hopkins generally already are considered relatively secure given that they are not in areas frequented by the general public and have restricted access to employees per se. For example, the "double lock" criterion can be considered satisfied when there is (1) restricted access to the room, floor, or building and (2) restricted access to the controlled substance within the room.

Expired drugs still must be securely stored. Although PHS Policy and Animal Welfare Act interpretation do not permit use of expired drugs for clinical purposes, expired controlled substances are considered subject to abuse. They remain the responsibility of the registrant.

**Disposal:** In September, 2014, the DEA issued a final rule regarding the disposal of controlled substances that has simplified requirements for animal researchers [21 CFR 1317.10(b) "non-practitioner inventory"; 1317.90]. The basic consideration in drug disposal is prevention of diversion. One methodology is use of a Reverse Distributor, which is a company authorized to receive controlled substances and to destroy them. This is a method commonly used by pharmacies and clinical settings, but the cost is typically prohibitive for basic researchers.

The new regulations do not require a particular method of destruction so long as the substances are rendered "non-retrievable." This is defined as rendering the controlled substance "unavailable and unusable for all practical purposes." Although flushing controlled substances down a drain does make the drug non-retrievable, this practice no longer is considered consistent with the Clean Water Act. An example of a reasonable method of rendering a solution non-retrievable is in animal waste or squirted onto a paper towel that goes into a biohazard bag.

Destruction of small amounts of unused solutions (e.g., left in a vial, tube, or syringe) should be recorded in the record of drug use. Destruction of larger amounts (e.g., expired unopened vials or bottles of solution) is to be recorded on DEA Form 41, available on the DEA website with instructions.