



# 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 includes 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

--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

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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, Revised 7/31/23.

<sup>2</sup> The record-keeping requirements for animal research apply whether a 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."

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:** Federal law (CFR-2022-Title21-vol9-sec 1317.95 Destruction procedures) specifies two methods that may be used to dispose of unusable or unneeded controlled substances. One method is transfer of the controlled substance to employees of a Reverse Distributor. That is, transfer to a company authorized to accept controlled substances for the purpose of destruction. Faculty who now hold DEA registrations most likely have specified a company they could use for this purpose when they applied for their Maryland Controlled Substances registrations prior to application for the federal registration. It is now possible for faculty also to use one of the University's chemical waste contractors, either Triumvirate Environmental or Clean Harbors, both of which are DEA-licensed Reverse Distributors. This transfer can be arranged at no charge to the registrant through the Department of Health, Safety, and Environment (HSE). They can be contacted via email at [HSEinfo@jhmi.edu](mailto:HSEinfo@jhmi.edu).

The alternative legal method of controlled substance disposal that can be used is "On site destruction." The Federal law cited above requires that two employees of the registrant "handle or observe the handling of the controlled substance until it is rendered non-retrievable" and "...shall personally witness the destruction of the controlled substance until it is rendered non-retrievable." On-site destruction of a controlled substance must be signed off on by the two witnesses in the registrant's drug record and also on DEA Form 41. DEA Form 41, with instructions on its completion, is available as an attachment to this document as well as on the DEA website.

The Hopkins Office of Chemical Safety can assist with on-site destruction by use of a product called RX Destroyer. Email HSE at [HSEinfo@jhmi.edu](mailto:HSEinfo@jhmi.edu) to schedule this service.

**Expired Drugs:** It is important that expired drugs awaiting disposal are still securely stored and are clearly distinguishable (i.e., marked as expired) from any non-expired drugs stored in the same location to avoid clinical use of a drug that is past its expiration date.