



Institutional Animal Care and Use Committee (IACUC) Directive 3.0: Expired Drugs and Materials

1.0 Directive Purpose

The purpose of this document is to provide instruction on the appropriate usage of Drugs and materials when used in animals for research, teaching, or testing at Brown University or in field research involving animals.

2.0 To Whom the Document Applies

This document applies to all individuals using Drugs, Medical Supplies and/or Devices in research using live vertebrate animals at Brown University under an IACUC-approved animal use protocol.

3.0 Directive Statement

The use of expired Drugs, Medical Supplies and/or Devices is not acceptable veterinary practice and does not constitute adequate veterinary care. The use of expired Drugs, Medical supplies and/or Devices may result in harm to an animal and may compromise the integrity of research data.

Principal Investigators (PIs) and laboratory staff are responsible for ensuring that expired Drugs, Medical Supplies and/or Devices are properly disposed of by their expiration date and not used or present in laboratory areas, procedure rooms, portable carts, or any other area in which they may be used or stored.

3.1 Expiration Date

The expiration date is the date printed on the label or package for materials with a manufacturer's expiration. Secondary containers that hold an unadulterated solution (i.e., a Drug or material from an original stock to which no drug has been added) must be clearly labeled with the name of the Drug or material and the expiration date of the original stock. For dilutions, preparations, reconstitutions, or mixtures of Drugs or fluids prepared using aseptic technique and under proper storage conditions, the expiration date is no more than 30 days from the date of preparation. Such materials must be labeled with name, drug concentration, and the new expiration date as soon as they are prepared. An item is considered expired the day after the month or date indicated on the label (i.e., an item labeled January 2020 is considered expired on February 1, 2020).

Powdered forms of Drugs or compounds (e.g., chemical grade substances ordered from Sigma) that do not list an expiration date must be labeled with an expiration date of one year from the date

received at Brown, provided they are stored aseptically in an airtight, light-proof protective container. For Drugs or solutions that are reconstituted for use, the expiration date may vary from the labeled expiration date. Reconstituted drugs and compounds that do not contain expiration or efficacy guidance in the directions must be labeled for expiration 30 days after reconstitution in a glass container.

Expired materials found in the vivarium may be discarded at any time by the Center for Animal Resources and Education (CARE) or the IACUC, unless the materials are clearly labeled “not for use in animals” and are stored separately from materials for use in animals.

3.2 Discarding Expired Chemicals

All chemicals used on or in animals must have an expiration date clearly labeled on the container. If an expiration date is not indicated by the manufacturer, or if the chemical is compounded/adulterated and the discard date is not detailed in the IACUC-approved protocol, then the below guidelines must be followed:

- Whenever possible, items should be compounded for the project the day of use and discarded immediately after use.
- When investigators wish to access sterile diluents without a manufacturer expiration date multiple times (e.g., to obtain small volumes for administration and drug mixing), the investigators can do so only if they do not add any chemical to the fluid, they access the fluid(s) aseptically, and they store the fluid(s) as recommended by the manufacturer. Under these conditions, the investigator can use the sterile fluid(s) for up to 30 days after initial opening.
- If a Drug is diluted or mixed with another compatible Drug and put into a sealed, sterile glass container, it may be used for up to 30 days or up to the earlier expiration date of the component drugs, whichever comes first, and then discarded. For example, a ketamine-xylazine rodent anesthetic cocktail (e.g., 10 mg/mL of ketamine + 2 mg/mL of xylazine in saline) when stored in a sterile sealed glass container may be kept up to 30 days without refrigeration from the date it is created. If one of the Drugs in the cocktail reaches its original date of expiration prior to the 30 days, then the solution must be discarded on or before that Drug’s date of expiration.
- Upon dilution, the container holding the chemicals must be marked with the 30-day expiration date and associated date by which the chemicals must be discarded, for example: “Discard after <insert the date 30 days in the future>.”

3.3 Recording Keeping

All records of any IACUC actions with regard to expired Drugs, Medical Supplies and/or Devices will be maintained with the Animal Research Compliance team for a period of three years from the conclusion of the matter in accordance with regulatory standards. The use of all Controlled Substances will be tracked and maintained within laboratories as specified by the Center for Animal Research and Education.

4.0 Definitions

For the purpose of this document, the terms below have the following definitions:

Controlled Substance: Any drug, substance or analog compound that falls under any of the five (I-V) Schedules identified by the United States Department of Justice/Drug Enforcement Administration and as defined by the Controlled Substances Act (CSA). Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

Drug: A substance used as a medication, including controlled substances.

Medical Supplies and/or Devices: Materials, other than drugs, for use in animals that have an expiration date. Examples include, but are not limited to, saline, sutures, ointments, gauze packs, capillary tubes, blood collection tubes, syringes, needles, and surgical gloves.

Pharmaceutical-Grade Compound: A drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by a recognized national or regional pharmacopeia (e.g., the United States Pharmacopeia (USP)-National Formulary (NF), British Pharmacopeia (BP), European Pharmacopeia (EP)).

5.0 Responsibilities

All individuals to whom this document applies are responsible for becoming familiar with and following this it. Animal research program stakeholders (IACUC, CARE, ARC) are responsible for promoting the understanding of this document and for taking appropriate steps to help ensure adherence to it.

6.0 Consequences for Violating this Notice

Violation of this document may be considered a serious event of noncompliance that is reportable to the IACUC, funding and accrediting agencies, as well as other regulatory agencies. Violations of this document are a serious matter that may adversely affect both the ability to perform animal work and acquire funding sources.

7.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, **Brown's Ethics and Compliance Reporting** System allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this document and is not an all-inclusive list of policies, procedures, laws and requirements.

7.1 Related Policies/Directives/SOPs: N/A

7.2 Related Procedures: N/A

7.3 Related Forms: N/A

7.4 Frequently Asked Questions (FAQs): N/A

7.5 Other Related Information:

- [Animal Welfare Act](#). United States Department of Agriculture Animal and Plant Health Inspection Service. November 2020. USDA-APHIS
- [The AVMA Guidelines on Euthanasia, 2020](#)
- Institute for Laboratory Animal Research, National Research Council. 2011. [The Guide for the Care and Use of Laboratory Animals, 8th edition](#). Washington, DC: National Academies Press.
- [The Public Health Service Policy on Humane Care and Use of Laboratory Animals](#), Office of Laboratory Animal Welfare

8.0 Document Owner and Contact

8.1 Owner: IACUC

8.2 Approved by: IACUC

8.3 Subject Matter Contact: Brown University Animal Research Compliance

- Telephone: 401-863-3050
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9.0 Document History

9.1 Effective Date: July 26, 2016

9.2 Last Reviewed: July 8, 2022

9.3 Update/Review Summary: This document is not new and is now being converted to an IACUC Directive; it was due for its' three-year renewal and was re-reviewed by the IACUC at its convened meeting on June 5, 2020. Old format version superseded by this version:

- IACUC Expired Drugs and Materials Policy, Date of IACUC Approval: 6/05/2020; Last updated: 9/28/2020
- IACUC Expired Drugs and Materials Policy, Date of IACUC Approval: 7/26/16; Last updated: 2/27/18