



BROWN

## Institutional Animal Care and Use Committee (IACUC)

### Expired Drugs and Materials Policy

Date of IACUC Approval: July 26, 2016

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- I. **Purpose:** The Brown University IACUC has adopted the following policy to provide instruction on the appropriate usage of drugs and materials in animal research studies performed in Brown University animal facilities or in field studies.
  
  - II. **Background:** *The Guide to the Care and Use of Laboratory Animals, 8<sup>th</sup> Edition* states that pharmaceutical grade chemicals should be used, when available, for all animal-related procedures. The use of lower grade substances/compounds with undefined or higher levels of impurities or poorly formulated non-commercial preparations can introduce unwanted experimental variables or toxic effects. A pharmaceutical grade compound should be used when available. The use of pharmaceutical grade chemicals helps ensure that the substances administered meet established documentable standards of purity and composition, which may also prevent adverse effects on animals or research outcomes. Administration of non-pharmaceutical grade compounds to animals must be scientifically justified and approved by the IACUC.

According to the USDA Animal Welfare Regulations Animal Care Policy #3 on Veterinary Care, “the use of expired medical materials (e.g. drugs, fluids, sutures, anesthetics, sedatives, or analgesics) during any survival surgical procedure on a regulated species is not considered acceptable veterinary practice and therefore not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.” The finding of expired drugs and/or materials during a USDA inspection may result in a citation for inadequate veterinary care.

- III. **Scope:** This policy applies to all drugs, medical supplies and/or devices used for animal studies at Brown University.

#### IV. Definitions:

- **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), etc.).
- **Controlled Substance:** Any material containing any quantity of a substance with a stimulant, depressant or hallucinogenic effect on the higher functions of the central nervous system, and having the tendency to promote abuse, physiological or psychological dependence.
- **Drug:** A substance used as a medication, including controlled substances.
- **Medical Supplies or Devices:** Materials, other than drugs, for use in animals that have an expiration date (saline, sutures, ointments, gauze packs, capillary tubes, blood collection tubes, syringes, needles, surgical gloves, etc.).

- V. **Policy:** 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 the animal and may compromise research data.

Each researcher is responsible and accountable for ensuring that expired materials are not used or present in his/her lab areas, procedure rooms, portable carts, etc. 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.

**Expiration Date:** Expired materials found in the vivarium may be discarded by Animal Care or the IACUC at any time, unless the materials are clearly labeled “Not for use in animals” and are stored separately from materials for use in animals.

The expiration date is the date printed on the label/package for materials with a manufacturer’s expiration. 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 thirty (30) days from the date of preparation. Such materials should be labeled by name, drug concentration, and include the new expiration date as soon as they are prepared. Secondary containers which hold an unadulterated solution (i.e. a drug or material from an original stock to which no drug has been added) should be clearly labeled with the name of the drug or material and the expiration date of the original stock. An item is considered expired the day after

the month or date indicated on the label (i.e. an item labeled January 2016 would be considered expired on February 1, 2016).

Powdered forms of drugs or compounds (e.g., chemical grade substances ordered from Sigma) that do not bear an expiration date should be labeled with an expiration date of one (1) year from the date of receipt provided that they are stored aseptically in an air tight, light 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 labeled directions are to be labeled for expiration thirty (30) days after reconstitution.

**Discard Date:** All chemicals used on or in animals must have a discard 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 approved IACUC protocol, follow these guidelines:

- Whenever possible, items should be compounded for the project the day of use and discarded immediately after use.
- Sterile diluents without a manufacturer expiration date: When investigators wish to access sterile diluents multiple times (i.e. 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 thirty (30) days after initial opening.
- If a drug is diluted or mixed with another compatible drug and put into a sealed, sterile container, it may be used for up to thirty (30) days (or at the earlier expiration date of the component drugs, whichever comes first).

For example, a ketamine-xylazine rodent anesthetic cocktail (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 thirty (30) days without refrigeration. If one or the other of the drugs reaches its original date of expiration prior to the thirty (30) days, then the solution must be discarded on or before the date of expiration.

- Upon dilution, the container must be marked with the thirty (30) day expiration date, for example: “*Discard after <insert the date thirty (30) days in the future>*”

**VI. Exceptions:** There are currently no exceptions to this policy. Any exception must be approved and documented by the IACUC.

**VII. Record Keeping:** All records of any IACUC actions with regard to expired drugs, medical supplies and/or devices will be maintained in the IACUC files for a period of three (3) years from the conclusion of the matter in accordance with USDA standards or longer if required by applicable Brown University approved policies and procedures for records retention. The use of all controlled substances will be tracked and maintained within laboratories as specified by the Animal Care Facility.

**VIII. References:**

The Animal Welfare Act is posted on the USDA website at:

[http://www.aphis.usda.gov/animal\\_welfare/downloads/awa/awa.pdf](http://www.aphis.usda.gov/animal_welfare/downloads/awa/awa.pdf)

The Animal Welfare Regulations are posted on the USDA website at:

[https://www.aphis.usda.gov/animal\\_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf](https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf)

The AVMA Guidelines on Euthanasia, 2013, are posted on the AVMA website at:

[https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx?utm\\_source=prettyurl&utm\\_medium=web&utm\\_campaign=redirect&utm\\_term=issues-animal\\_welfare-euthanasia-pdf](https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx?utm_source=prettyurl&utm_medium=web&utm_campaign=redirect&utm_term=issues-animal_welfare-euthanasia-pdf)

*The Guide for the Care and Use of Laboratory Animals*, Institute of Laboratory Animal Resources is available from National Academy Press and posted on the web at: [http://www.nap.edu/catalog.php?record\\_id=12910](http://www.nap.edu/catalog.php?record_id=12910)

The Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare is posted on the DHHS website at:

<http://grants.nih.gov/grants/olaw/references/phspol.htm>