



Institutional Animal Care and Use Committee (IACUC) Directive 16.0: Prompt Reporting

1.0 Directive Purpose

The purpose of this directive is to assist the Brown University (Brown) community with determining when a prompt [Animal Research Event Report](#) is required to be submitted to the IACUC for review and to provide transparency with respect to the IACUC's expectations and process.

2.0 To Whom the directive Applies

This directive applies to all individuals using live vertebrate animals under an IACUC-approved animal use protocol at Brown University.

3.0 Directive Statement

Safeguarding animal welfare is the responsibility of every individual involved with animals in research, testing, or teaching ("animal research activities") at Brown University. Experimental use of animals may occasionally result in unanticipated or adverse outcomes. Brown is highly committed to ensuring that animal research activities are conducted with humane care and treatment in accordance with federal laws, regulations, policies, and ethical standards governing animal research. These animal research events must therefore be reported to the IACUC promptly to identify and correct causative factors and ultimately prevent recurrence.

Reporting is intended to be an interactive process and is not a unilateral cause for punitive action against investigators; rather, it is an effort to facilitate research effectiveness and improve animal care. Upon receipt of an event report, the IACUC shall determine which events/outcomes must be further reported to oversight agencies, whether protocol modifications are required (e.g., changes in procedures, monitoring, humane endpoints, etc.), or whether additional specific corrective actions are required to ensure animal well-being.

3.1 Prompt Reporting of Animal Research Events and Concerns

Animal Research Events and Concerns must be reported to the IACUC as soon after the event as possible through the [Animal Research Event Reporting Form](#). Note that the IACUC ultimately makes the final determination regarding whether or not an event meets the requirements for reporting under this Directive. Thus, it is in the best interest of the research team to contact Brown University Animal Research Compliance (ARC) whenever there is a question about the need to report to the IACUC.

3.2 Reporting Guidelines

The following situations must be reported to the IACUC promptly:

- Incidents of animal injury, disease, distress, or death not described within an approved IACUC animal use protocol.

- Circumstances during animal research activities that result in potential or direct harm to animals or personnel.
- Concerns or deficiencies in the use, care, and/or treatment of animals.
- Failure to follow an approved IACUC protocol or institutional policy/directive.

There may be levels of morbidity and mortality in virtually any animal-related activity, including animal research activities, that are not the result of reportable activities. The following situations may not meet the threshold for reporting:

- Death of animals that have reached the end of their natural life spans
- Death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate
- Animal illness or death from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed
- Animal injury or death related to manipulations that fall within parameters described in the IACUC-approved protocol, unless deemed by the veterinarian to exceed humane limits.

Further guidance regarding what events are reportable can be found on the Brown IACUC website.

3.3 Where to Report Animal Research Related Events

Any member of the Brown community may report animal research events and instances of suspected non-compliance with laws, rules, regulations and policies. To report an event that occurs during animal research activities, an individual must submit an event report form by email to IACUC@Brown.edu as soon as possible after the incident. A copy of the report must also be sent to CARE.

If an individual would like to make an anonymous report of animal welfare concern, they should utilize [Brown's Anonymous Reporting Hotline](#). Brown University prohibits unlawful retaliation against employees as a consequence of good faith actions in the reporting of allegations of wrong-doing. Brown University's mechanisms for reporting concerns are posted in prominent locations in the animal facilities and on applicable Brown websites with instructions on how to report concerns and to whom. For more information on reporting animal welfare concerns and the IACUC's process for investigation, please refer to the IACUC's approved [Standard Operating Procedure \(SOP\) on the Investigation of Animal Welfare Concerns](#).

3.4 The IACUC's Evaluation of Animal Research Events and Concerns

Any condition that could jeopardize the health or well-being of animals will be evaluated immediately. The AV is authorized to halt procedures, utilizing their clinical judgment, that do not comply with humane care and use of animals or conflict with institutional policy/directive until the IACUC can meet. Under veterinary authority, the AV (or their designee) may euthanize animals deemed to be suffering with no apparent or impending relief.

Veterinary medical intervention, suspension of research activity or research personnel, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken to protect animal or human welfare. If an activity is suspended, the IO will be

notified and will promptly report that action to the appropriate federal oversight and accrediting bodies.

Each Animal Research Event Report will be discussed at a convened IACUC meeting. If more information is needed from the research team prior to the IACUC meeting, a member of the ORI and/or CARE will follow-up with the research team requesting the additional information. Depending on the nature of the report, the Principal Investigator may be invited to the meeting to discuss the concern with the IACUC. The IACUC determines whether the concern requires further investigation, corrective action (e.g. retraining of the laboratory members), reporting to external regulatory and or accrediting agencies, or no further action. Closure of the event concern results in formal communication from the IACUC to the PI via a letter or email communication.

3.5 Regulatory Reporting Requirements

The IACUC, through the IO, is required to promptly report animal research events and or incidents of noncompliance to respective governing and accrediting authorities. Further, the IACUC is obligated, through its Assurance with the Public Health Services' (PHS) Office for Laboratory Animal Welfare (OLAW), to self-report serious and/or continuing incidences of noncompliance. If allegations of animal misuse or protocol non-compliance are verified, the IACUC can apply sanctions.

4.0 Definitions: N/A

5.0 Responsibilities

All individuals to whom this directive 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 Document

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 Anonymous Reporting Hotline](#) 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:

- Directive on Training and Education for Personnel working with Laboratory Animals
- SOP on the Investigation of Animal Welfare Concerns

7.2 Related Procedures: N/A

7.3 Related Forms:

- Animal Research Event Report Form

7.4 Frequently Asked Questions (FAQs): N/A

7.5 Other Related Information: References:

- AAALAC International Adverse Events Reporting Criteria FAQ
- Department of Defense (DoD) 3216.0, Use of Animals in DoD Conducted and Supported Research and Training
- The Guide for the Care and Use of Laboratory Animals- 8th edition, NRC. 2011
- The Public Health Service Policy on the Humane Care and Use of Laboratory Animals, 2015
- The United States Department of Agriculture (USDA) Animal Welfare Act Regulations, 2019

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 (ARC)

- Telephone: 401-863-3050
- Email: IACUC@Brown.edu

9.0 Document History

9.1 Effective Date: June 16, 2016

9.2 Last Reviewed: August 4, 2023

9.3 Update/Review Summary: This document was moved to the directive format and reviewed and approved by the IACUC on August 4, 2023.

- This document is not new. It was reviewed by the IACUC and revised significantly May 1, 2022 to include a new name and a streamlined approach for what needs to be promptly reported to the IACUC.