



BROWN

Institutional Animal Care and Use Committee (IACUC)

Policy on Reporting Animal Welfare Concerns, Adverse Events, Unanticipated Problem(s), and Non-compliance

Date of IACUC Review and Approval: June 16, 2016, Revised November 14, 2018

- I. **Purpose:** The Institutional Animal Care and Use Committee (IACUC) developed this policy to promote transparency and consistency in its evaluation of non-compliance, adverse events, and animal welfare concerns. In addition, it is intended to assist members of the Brown University (Brown) community with determining what, when and how concerns regarding animal welfare should be reported.
- II. **Background:** Brown is highly committed to ensuring that laboratory animals receive humane care and treatment while involved in research or training protocols in accordance with the ethical standards, laws, regulations and policies governing animal research. Safeguarding animal welfare is the responsibility of every individual involved with the care and use of laboratory animals at Brown. The IACUC's charge requires review of each animal welfare concern in a timely and systematic manner and, when necessary, taking prompt and appropriate corrective actions.

Experimental use of animals in research, testing or teaching may occasionally result in serious, unanticipated, or adverse clinical outcomes. Adverse events, unanticipated problems, and non-compliance (including protocol deviations) must be reported to the IACUC in order to determine the cause and to prevent recurrence. Prompt reporting also helps the IACUC meet its federal requirement to monitor animal activities. Reporting is intended to be an interactive process and is not a unilateral cause for punitive action against investigators, but an effort to facilitate research effectiveness and improve animal care. The Brown University IACUC shall determine which events/outcomes must be reported to oversight agencies, whether protocol modifications are required (e.g., changes in procedures, monitoring, humane endpoints, etc.), or whether specific corrective actions are required to ensure animal well-being.

III. Definitions:

Adverse Events: An instance of unfavorable or unanticipated (not in the approved protocol) signs or outcomes where there is direct harm to animals or personnel. Adverse events include suboptimal well-being (i.e., poor welfare), animal death, disease, distress, or trauma that was not the anticipated result of the approved protocol.

Unanticipated Problems: Not all unanticipated problems involve direct harm to animal subjects. Events can occur which are unexpected and result in new circumstances that increase the risk of harm to animals or research/support staff without directly harming them. In each case, while the

event may not have caused any detectable harm or adverse effect to subjects or others, they nevertheless represent unanticipated problems and should be promptly reported.

Non-Compliance: Can occur when an IACUC protocol, [policies](#), procedures, or decisions are not followed. Instances of protocol noncompliance include:

- Conduct of animal-related activities without IACUC review and approval, or beyond the expiration date established by the IACUC
- Failure to adhere to IACUC-approved protocols
- Implementation of any significant change to IACUC approved protocols without prior IACUC approval
- Failure to correct deficiencies identified during the semiannual evaluation by the date set by the IACUC
- Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained. [See IACUC Training Policy](#)
- Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures)
- Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂)

Animal Welfare Concerns: Concerns or deficiencies in the care and/or treatment of animals or any activities related to animal care that appear improper or inhumane should be reported. Examples of animal welfare concerns include: conditions that jeopardize the health or well-being of animals; failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.

IV. **Reporting Adverse Events, Unanticipated Problems, Non-Compliance, and Animal Welfare Concerns:**

All members of the Brown University community may report adverse events, unanticipated problems, animal welfare concerns, and instances of suspected non-compliance with laws, rules, regulations and policies. Reports may be made to the Institutional Official (Office of the Vice President for Research), the IACUC Chair, the Attending Veterinarian, any member of the IACUC, or to the Office of Research Integrity. Brown University prohibits [unlawful retaliation](#) against employees as a consequence of good faith actions in the reporting of allegations of wrong-doing. Concerns can be reported verbally, in writing, or electronically through the Brown University's anonymous and confidential [Ethics and Compliance Reporting System \(EARS\)](#). Brown University's mechanisms for reporting concerns are posted in prominent locations in the animal facilities and on applicable Brown University websites with instructions on how to report concerns and to whom.

Individuals are encouraged to submit a [Non-Compliance/Adverse Event Report](#) (Appendix A) and submit it within to the [IACUC Chair](#), [Office of Research Integrity](#), or [Attending Veterinarian](#) or make an anonymous report via [Brown's Ethics And Compliance Reporting System \(EARS\)](#).

V. **IACUC Actions Following a Report:**

Conditions that could jeopardize the health or well-being of animals will be evaluated immediately. The Attending Veterinarian (AV) is authorized to halt procedures that in his/her clinical judgment, do not comply with humane care and use of animals or conflict with institutional policy, until the IACUC can meet. Under Veterinary Authority, the AV (or his/her designee) may also euthanize animals deemed to be suffering with no apparent or impending relief. Upon receipt of a reported

concern, the IACUC Chair will contact the ORI to add the matter to the agenda of the next scheduled IACUC meeting, or convene a special meeting of the IACUC, depending on the nature and severity of the matter. After initial review of the complaint, the IACUC shall determine whether it requires: (a) immediate action (perhaps in addition to further investigation), (b) further investigation, (c) corrective action (e.g. retraining of the laboratory members), or (d) no action needs to be taken. Once this decision has been made, the IACUC shall determine whether notification or reporting to institutional or federal officials is required at that time.

If immediate action is warranted because animal or human welfare may be compromised, the Chair (or his/her designee) will notify the Institutional Official (IO) and proceed accordingly. Veterinary medical intervention, suspension of a research activity or research personnel, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare. If an activity is suspended, the IO shall promptly report that action to the appropriate federal oversight and accrediting bodies.

The IACUC, through the IO, is required to promptly provide all oversight bodies including the Office of Laboratory Animal Welfare (OLAW), the National Science Foundation (NSF), the Department of Defense (DOD), U.S. Department of Agriculture (USDA) and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#)
2. Any serious deviations from the provisions of the [Guide](#)
3. Any suspension of an activity by the IACUC

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 noncompliance¹. When evaluating reported noncompliance, the IACUC's first step, if possible, will be to find a way to bring the protocol into compliance. If allegations of animal misuse or protocol non-compliance are verified, the IACUC can apply sanctions. The IACUC procedures for suspending an ongoing activity and/or personnel are as follows:

1. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the [Animal Welfare Act](#), the [Guide](#), or Brown University's Assurance with OLAW.
2. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
3. If the IACUC suspends an activity involving animals, or any other intervention results in the temporary or permanent suspension of an activity due to noncompliance, the IO, in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation in writing to the previously mentioned oversight bodies.

VI. Other Considerations: There may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the PHS Policy or the *Guide*. The following examples of 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

¹ <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>

- Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed
- Animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol