

 BROWN	Institutional Animal Care and Use Committee (IACUC): SOP for the Investigation of Animal Welfare Concerns	SOP 10.10.11
		Effective Date: Pending Approval

1.0 Standard Operating Procedure (SOP) Purpose

The purpose of this SOP is to establish procedures by which the IACUC and relevant administrative personnel will abide when responding to animal welfare concerns raised by a **Whistleblower**.

5.0 SOP

To ensure that Brown University upholds the highest ethical standards, laws, regulations, and policies governing use of animals in teaching, testing, and/or research, the following procedures will be followed when addressing animal welfare concerns received by Brown.

5.1 Receipt of Whistleblower Animal Welfare Concern

When Brown University receives a Whistleblower concern through a report to the Brown Anonymous Reporting Hotline (the “reporting hotline”), or through a direct report to the IACUC, the Attending Veterinarian (AV), the Institutional Official (IO), or the Office of Research Integrity (ORI), the recipient of the concern shall inform the IACUC Chair. The IACUC Chair will work in collaboration with the Office for Research Integrity (ORI) and the Center for Animal Resources and Education (CARE), as needed and when appropriate, to determine:

- whether the concern falls within the IACUC’s jurisdiction; and
- whether/which allegations are sufficiently credible and specific to enable an investigation to proceed.

For an allegation to be sufficiently credible and specific, it must provide details regarding the circumstances and/or situation that creates or resulted in the animal welfare concern, including, for example, the species involved, the laboratory or personnel involved, the activity involved, and a general time-frame for when the activity occurred (or otherwise state that the activity is ongoing). If the allegation is determined not to be sufficiently credible and specific, ORI will document in writing this determination and will not proceed to investigation.

If the IACUC Chair or any individual from the ORI or CARE involved in this determination has a conflict of interest, that individual will self-recuse from the assessment. If the report is made against any of the individuals responsible for assessing the concern, that individual(s) will not be engaged in the assessment and an appropriate alternate, as determined by the IACUC Chair (or the ORI, if the IACUC Chair is named in the report) will be identified. Any of these parties may work with Brown’s Office of General Counsel (OGC) and/or the Institutional Official (IO) to determine what constitutes an appropriate alternate. Additionally, the OGC and/or the IO may advise that the matter be investigated by an independent party external to Brown.

5.2 Concern Within the IACUC’s Jurisdiction

If the concern is determined to fall within the IACUC's jurisdiction, the IACUC Chair, in collaboration with CARE, when and as appropriate (and, as needed, the ORI), shall determine whether the matter must be addressed immediately, as in the case of animals reported to be in imminent harm. In such cases, the Director of CARE/Attending Veterinarian (or designee) has the authority to take immediate action. A formal investigation will then follow.

The IACUC Chair (or the Chair's designee) shall appoint a subcommittee of the IACUC to investigate. The subcommittee shall have three to five members. The IACUC subcommittee will be administratively supported throughout the investigation by the ORI. Any proposed subcommittee members with a real or perceived conflict of interest shall refrain from participating in the subcommittee. The investigative subcommittee shall operate as an independent fact-finder on behalf of the IACUC and provide an objective review of concerns. It will take reasonable steps to ensure that the investigation is kept confidential.

The ORI shall notify in a timely manner the relevant laboratory and/or units about the Whistleblower concern and IACUC investigation. ORI will also notify the cognizant Dean/Chair and will consult with Human Resources about appropriate notifications if a Brown staff member is a subject of the investigation. The ORI will inform the laboratory/unit of the confidentiality of the investigation and the Rhode Island Whistleblowers' Protection Act and Brown University's Non-Retaliation Policy.

The IACUC subcommittee investigating the concerns may interview relevant witnesses (including but not limited to those reporting the incident, if known, personnel of the relevant school/unit associated with the subject of the concern, and pertinent experts in the topic of concern); review relevant records; inspect any facilities involved in the concern; and/or directly observe any procedures relevant to the concern.

At the completion of its fact-finding, the IACUC subcommittee shall prepare a written report describing the subcommittee findings and outlining any recommendations. The subcommittee shall present the report at a convened meeting of the IACUC for review, discussion, and deliberation. The IACUC may vote to accept the report as written, determine that further investigation is needed, or revise the recommendations of the subcommittee. Once the IACUC completes its review, determines appropriate action, and is satisfied with the recommendations, it will issue its approval. Final approval of the report and recommendations may be issued via email outside a convened meeting of the IACUC following an opportunity for all IACUC members to review requested revisions.

Once the IACUC has approved the report, the ORI (or University Compliance, if the concern is received anonymously via the reporting hotline) shall notify the Whistleblower, if known to the ORI, that the issue has been reviewed and resolved. The ORI will also submit any required reports to external regulatory bodies or agencies. The ORI may engage OGC at any point during the review process for legal counsel regarding interpretation and application of relevant federal and state laws or regulations and/or reporting requirements.

5.3 Concern Outside the IACUC's Jurisdiction

If the concern is determined to fall outside the IACUC's jurisdiction, the ORI shall refer the matter to the appropriate office at Brown.

5.4 Whistleblower Protection

Whistleblowers may make allegations anonymously and request that anonymity be preserved throughout the investigation. In these cases, all individuals involved in the assessment and any subsequent investigation will take reasonable steps to keep the Whistleblower's identity confidential. Any concerns about possible retaliation raised by the Whistleblower shall be reported to Brown University Human Resources and/or the ORI.

If the identity of the Whistleblower is known, the ORI will take reasonable steps to convey to the individual the protections afforded under the Rhode Island Whistleblowers' Protection Act and Brown University's Non-Retaliation Policy, when applicable.

5.5 Alleged Criminal Activity or Threat to Human Safety

The ORI will report any matter involving alleged criminal activity or a potential threat to human safety promptly to Brown University law enforcement and/or Occupational Health and Safety, as well as other parties as needed and as determined within the ORI's discretion.

6.0 Definitions

For the purpose of this SOP, the term below has the following definition:

Institutional Official: The individual who, as a representative of senior administration, bears ultimate responsibility for the animal research program and is responsible for resource planning and ensuring alignment of program goals with the institution's mission. At Brown the Institutional Official is the Vice President for Research.

Whistleblower: Any individual internal or external to Brown University who reports in good faith any animal welfare concern(s) or any activity that may involve inhumane care or treatment of an animal(s) used for teaching, testing, or research at Brown University.

7.0 Responsibilities

All individuals to whom this SOP applies are responsible for becoming familiar with and following this SOP. University supervisors are responsible for promoting the understanding of this SOP and for taking appropriate steps to help ensure compliance with it.

5.0 Related Information

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

5.1 Related University Policies:

- Brown University's Non-Retaliation Policy

5.2 Related SOPs: N/A

5.3 Related Forms: N/A

5.4 Frequently Asked Questions (FAQs): N/A

5.5 Other Related Information:

- [The Rhode Island Whistleblower's Protection Act](#)

6.0 SOP Owner and Contact(s)

6.1 SOP Owners: Vice President for Research

6.2 SOP Approved by: Vice President for Research

6.3 Subject Matter Contact: Brown University Animal Research Compliance

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

7.0 SOP History

7.1 SOP Issue Date: October 10, 2017

7.2 SOP Effective Date: Pending Approval

7.3 SOP Update/Review Summary: This SOP was reviewed by the IACUC at its convened meeting on November 5, 2021. Prior versions of this policy are listed below:

- IACUC SOP: Animal Welfare Investigations, date of IACUC review and approval: October 2, 2020.
- IACUC SOP: Animal Welfare Investigations, date of IACUC review and approval: October 10, 2017.