

 LEHIGH UNIVERSITY	Animal Care and Use Committee (IACUC) Guidance: Reporting Animal Welfare Concerns and Policy Violations to the IACUC		
	DATE	AUTHOR	PAGE
	26-Mar-2020	N. Coll	1 of 3

The intent of this Institutional Animal Care and Use Committee (IACUC) guidance is to outline the process for reporting animal welfare concerns and policy violations to the IACUC.

Introduction and Background

Federal animal welfare regulations (under the Animal Welfare Act) state that all employees, students, or concerned parties must have the means to report deficiencies in animal care and treatment. The federal Animal Welfare Regulations state that “no facility employee, committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulations or standards under the Regulations.”

The IACUC is required to investigate concerns involving the care and use of animals used in teaching and research at Lehigh University. This includes reports made by the public, reports made anonymously, and reports made by employees or students. Reports may concern any aspect of the animal care and use program and can include alleged instances of animal mistreatment, abuse or neglect, violations of approved protocols, violations of standard operating procedures, the use of animals not covered by approved protocols, violations of any animal-related regulation, institutional or facility policy, or standard (such as the Animal Welfare Act, Public Health Service Policy, the Guide, the IACUC policy, or Central Animal Facility [CAF] Rules and Procedures, links to which are set forth in the References section below), or reports regarding the care received by animals housed in Lehigh University laboratory animal facilities.

The IACUC will determine, through evaluation of the report and consultation with the Institutional Official (IO), whether reported animal welfare concerns or policy violations are reportable to OLAW and other agencies as applicable, and determine whether reported concerns are isolated incidents or systemic issues.

Examples of Reportable Incidents

OLAW has provided a list of examples that demonstrate the threshold at which OLAW expects to receive a report. The IACUC is the responsible party at Lehigh University for assessing incidents and making reports to OLAW. All reportable incidents should be submitted to the IACUC for investigation.

While recognizing that a comprehensive list of definitive examples of reportable situations is impossible, the following examples are reportable to the IACUC, and in turn, may be reportable to OLAW:

- Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- Conduct of animal-related activities without appropriate IACUC review and approval;
- Failure to adhere to IACUC-approved protocols, including but not limited to failure to provide food and/or water to animals for more than 24 hours if not otherwise approved in the protocol;
 - Modifications to the requirement to provide food and/or water to animals every 24 hours may be permissible when approved by the IACUC and/or implemented during emergency campus closures
- Implementation of any significant change to IACUC-approved protocols without prior IACUC approval;
- Conduct of animal-related activities beyond the expiration date established by the IACUC;
- Incidences of sick or injured animals that are not immediately euthanized;
- Chronic failure to provide space for animals in accordance with recommendations from the Guide based on written scientific justification;
- Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained;
- 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 maintain appropriate animal-related records (e.g. identification, medical, husbandry);

 LEHIGH UNIVERSITY	Animal Care and Use Committee (IACUC) Guidance: Reporting Animal Welfare Concerns and Policy Violations to the IACUC		
	DATE	AUTHOR	PAGE
	26-Mar-2020	N. Coll	2 of 3

- Failure to ensure death of animals after euthanasia procedures (e.g. failed euthanasia with CO₂);
- Failure of animal care and use personnel to carry out veterinary orders (e.g. treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with PHS Policy, the Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.
- Conditions in a genetically modified animal that reveal a negative effect on animal well being.

Procedures for Reporting a Complaint or Violation

1. Any person who believes that a laboratory animal or animals is/are subject to mistreatment, abuse or neglect or that there is a potential violation of a protocol, standard operating procedure, policy or standard (even if immediate harm is not presented), is strongly encouraged to report perceived or actual mistreatment of laboratory animals or policy violations immediately. Reporting procedures are posted conspicuously throughout the animal facilities. The information includes the Lehigh University Ethics and Compliance Hotline [website portal](#) or hotline (888-924-4450) for easy public access for reporting anonymously.

Alternatively, reports may also be submitted directly to:

- Director of Research Policy and Compliance – nac314@lehigh.edu or 610-758-2985
 - IACUC Chair – iniacuc@lehigh.edu (written reports only)
 - CAF Director and CAF Manager – inluaf@lehigh.edu (written reports only)
 - Institutional Official – vpresearch@lehigh.edu or 610-758-2585
2. Reports may be submitted orally (when possible) or in writing. Reports should include, to the extent available, a description of the violation, the time and date of the violation, the location, the type of animal involved, the individual(s) involved, and any other information relevant to the report.
 3. If the report is provided orally, the recipient of the report will reduce the complaint to writing as soon as possible. Investigations are implemented per the process outlined in [Lehigh University's Assurance of Compliance](#).

Conditions that reportedly jeopardize the health or well-being of animals are evaluated immediately. The Director of the CAF is authorized to temporarily suspend activities which he/she believes to be inconsistent with institutional policies or federal regulations until the IACUC can be convened to consider the matter more formally.

Investigation of and all communications about the complaint must be documented in writing and maintained in the Office of Research Integrity and/or the Institutional Official.

Institutional policy and federal regulations prohibit retaliation against, and intimidation of, anyone who reports or is believed to have reported concerns involving the care and use of animals used in teaching and research at Lehigh University. Encouraging others to retaliate is also prohibited. Complaints of retaliation should be reported to the Institutional Official. Any such retaliation may result in disciplinary action including, but not limited to, loss of privileges and/or access to animal research facilities.

The confidential nature of the complaint and violation procedures must be respected by all parties involved. Reports will be dealt with confidentially to the extent possible. If necessary, the source of the report may be identified to the IACUC as an aid to discerning the degree to which the concern comes from a knowledgeable source. The identity of the person reporting the concern will be kept confidential within the IACUC upon request and to the extent possible.

 LEHIGH UNIVERSITY	Animal Care and Use Committee (IACUC) Guidance: Reporting Animal Welfare Concerns and Policy Violations to the IACUC		
	DATE	AUTHOR	PAGE
	26-Mar-2020	N. Coll	3 of 3

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http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals. U.S. Department of Health and Human Services, National Institutes of Health, Office of Laboratory Animal Welfare. 2015.
3. *Guide for the Care and Use of Laboratory Animals*, 8th Ed., National Research Council; National Academy Press: Washington, DC, 2011. <http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth>
4. Lehigh University Assurance of Compliance.
<https://research.cc.lehigh.edu/sites/gradresearch.cc.lehigh.edu/files/documents/Lehigh%20University%20policy.pdf>
5. CAF Rules and Procedures. Available hard-copy in the Central Animal Facility and on the Lehigh University Central Animal Facility course website. 2005.