

IACUC POLICY

INVESTIGATING ANIMAL WELFARE CONCERNS & NONCOMPLIANT ACTIVITIES

To ensure the humane care and treatment of animals used in research, teaching, and testing, the Drexel University Institutional Animal Care and Use Committee ([IACUC](#)) must “...review and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees” ([AWR§2.31\(c\)\(4\)](#)).

Such concerns may include incidents that involve actual or potential harm to animal and human health and well-being, including accidents, and protocol non-compliance.

From the [Guide for the Care and Use of Laboratory Animals](#):

Investigating and Reporting Animal Welfare Concerns - Safeguarding animal welfare is the responsibility of every individual associated with the Program. The institution must develop methods for reporting and investigating animal welfare concerns, and employees should be aware of the importance of and mechanisms for reporting animal welfare concerns. In the United States, responsibility for review and investigation of these concerns rests with the [Institutional Official (IO)] and the IACUC. Response to such reports should include communication of findings to the concerned employee(s), unless such concerns are reported anonymously; corrective actions if deemed necessary; and a report to the IO of the issue, findings, and actions taken. Reported concerns and any corrective actions taken should be documented. ([The Guide](#) pg 23)

The purpose of this policy is to describe the process adopted by the Drexel University IACUC to review, investigate, and report animal welfare concerns.

Initial Reporting of Animal Welfare Concern to the Institution

Direct and/or ongoing threats to animal health must be reported immediately. Incidents may be reported to the Attending Veterinarian, IACUC Chair, any member of the IACUC, or the Regulatory Compliance Department of the Office of Research.

Completely anonymous reports may be filed through the [Drexel University Compliance Hotline](#). Reports should be as detailed as possible to facilitate the resulting investigation.

Information about the Drexel University Animal Welfare Concern Reporting (Whistleblower Policy) can be found on the [IACUC – Whistleblower Policy](#) website.

Information to be Gathered

The individual initially receiving the animal welfare concern will attempt to gather all pertinent information from the reporting individual. At a minimum, the following information should be collected if known:

- Principal Investigator
- Protocol number
- Location of incident
- Species and number of animals involved
- Cage card numbers
- Personnel involved
- Date and time (if known) of incident
- Summary of incident
- Any adverse impact to animal health or well-being
- Immediate actions taken by the laboratory

- Whether the veterinary staff was contacted, and if so, which veterinarian or designee, and what veterinary care they provided

Confidentiality of Reports of Animal Welfare Concerns

Reports should be communicated as soon as possible to the Director of Regulatory Compliance (DRC) in the Office of Research. To the extent possible, all reports made directly to the IACUC or Office of Research are kept confidential.

Animal Welfare Concerns Arising out of Post Approval Monitoring

Following a routine post-approval monitoring (PAM) visit, animal welfare concerns or protocol non-compliance may be identified. The QA/QI analyst will notify the IACUC Chair, and the DRC which may result in further investigation by the IACUC. The QA/QI analyst will make every effort to identify which items may result in further investigation, propose an initial resolution plan, and notify laboratory members during the exit briefing and the PI via email.

Intervention

Program personnel are authorized to intervene to provide immediate relief and/or remove the animal from the painful/distressful situation, based upon their skills or level of training, if necessary prior to arrival of a veterinarian. Personnel should not put themselves at risk of injury or other hazards.

For incidents that result in animal death or unexpected euthanasia, a post-mortem analysis may be necessary. Necropsy requests should be submitted to the ULAR veterinarian as soon as possible to ensure that tissues are still viable and allow for appropriate and complete analysis.

If warranted, the Attending Veterinarian and IACUC chair have the authority to temporarily stop animal activity until the concern is fully investigated and reviewed by the IACUC subcommittee.

Investigation of Animal Welfare Concerns

Anyone receiving a report of a non-compliance or animal welfare concern must forward the report to the DRC no later than the close of business the day that the report is received or, if received outside of normal business hours, within three hours of the start of the next business day.

The DRC will report the animal welfare concern to the Animal Welfare Investigation Subcommittee of the IACUC. This subcommittee consists of the IACUC Chair, Attending Veterinarian, IACUC Administrator, QA/QI analyst, scientific member(s) of the IACUC, and non-animal user(s) of the IACUC. Other personnel (additional IACUC members, ULAR personnel) may be recruited onto the subcommittee.

The subcommittee will review the available facts and if necessary seek input from relevant involved individuals. Further information may also be gathered by the QA/QI analyst via a Post Approval monitoring visit and review. The subcommittee will then determine whether the available information substantiates that any of the following occurred:

- actual or potential harm to animal;
- actual or potential harm to human health and well-being;
- protocol non-compliance;
- regulatory (USDA) non-compliance;
- NIH non-compliance (with the Guide or Animal Welfare Assurance Document); or
- PHS policy non-compliance.

The Subcommittee will inform the PI involved with the Animal Welfare Concern of the ongoing investigation. At this time, the PI will be provided a factual summary of the concern and provided an opportunity to respond or gather more information if requested.

At the next convened meeting of the IACUC, the subcommittee, through the IACUC Chair's Report, will inform the IACUC of the subcommittee's activity, including an estimate of the timeframe to conclude its investigation.

Unsubstantiated Animal Welfare Concerns

If the subcommittee finds that the concern is unsubstantiated, it will be reported at the next convened meeting of the IACUC as a part of the Chair's Report to the Committee. If the IACUC agrees, the issue is closed. The PI will be notified by letter prepared by the IACUC Administrator and signed by the IACUC Chair summarizing the incident and outcome of the investigation.

If the IACUC feels that the concern needs to be investigated further, it may form a new subcommittee to continue the investigation and report its findings to the IACUC.

Substantiated Animal Welfare Concerns

Preliminary Report to OLAW

If a substantiated animal welfare concern involves PHS funded procedures or an area that could affect PHS funded activity, the subcommittee will determine if this incident should be reported to external agencies. If so, the DRC will submit a preliminary report to the Office of Laboratory Animal Welfare (OLAW)

If the subcommittee is not unanimous with its decision to report to external agencies, the DRC will contact OLAW for advice.

Corrective Actions

The subcommittee will

- Inform the Principal Investigator of the animal welfare concern requesting a response and proposal of corrective action
- Evaluate the Principal Investigator's proposed corrective action to determine if they adequately resolve the problem.
- Continue communication with the PI regarding resolution plan progress, response, and if/when the incident will be reported to regulatory authorities

Subcommittee Report to IACUC

At a convened meeting of the IACUC, the subcommittee will present the investigation results, including the proposed resolution plan, PI response, and the resolution plan progress to date.

After the presentation of the subcommittee findings, the IACUC will deliberate and vote as follows:

- Accept the subcommittee's findings and resolution plan;
- Determine that the subcommittee's findings were incorrect and that the animal welfare concern was not substantiated;
- Require additional corrective actions or changes to the resolution plan; or
- Suspend the protocol.

The IO will be informed of the outcome of the investigation and deliberation of the IACUC, either by formal written notification from the Office of Research Regulatory Compliance Department or by information described within IACUC meeting minutes.

Unless the subcommittee's findings are overturned by the IACUC, a letter summarizing the incident and investigation will be sent from the Office of Research Department of Regulatory Compliance to the PI, Department Chair, and the IO. This letter will include a resolution plan and a schedule for completing the action items described in the resolution plan. The letter will also state whether this incident will be reported to external regulatory agencies.

If the subcommittee's findings are overturned by the IACUC, the PI will be notified by letter from the IACUC Administrator summarizing the incident and outcome of the investigation.

Reporting to External Agencies (OLAW, AAALACi, USDA, and Funding Agencies)

If the substantiated animal welfare concerns were determined to be reportable the IACUC, through the Chair, will promptly notify the IO and the DRC of the IACUC's decision to report an incident to an external agency.

The report will be drafted by the Office of Research Department of Regulatory Compliance and reviewed by the IACUC Chair and Attending Veterinarian before submitting to the IO for signature.

The incident will be officially reported to OLAW through the IO.

Criteria for reporting to OLAW (NIH) or AAALACi

Incidents that involve animals under PHS-funded activity and/or that occur in accredited facilities may be reported to OLAW and/or AAALAC, respectively.

“The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a. any serious or continuing noncompliance with this Policy;*
- b. any serious deviation from the provisions of the Guide; or*
- c. any suspension of an activity by the IACUC.”*

[PHS Policy IV.F.3](#)

“Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals” will be used to identify situations that meet the above criteria.

[OLAW NOT-OD-05-034](#)

Examples of reportable situations:

- 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;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- conduct of official IACUC business during a period of time that the Committee is improperly constituted;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation 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 as required by IV.C.1.f;
- 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);
- failure to ensure death of animals after euthanasia procedures (e.g., failed CO₂ euthanasia);
- 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 the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.

Examples of situations not normally required to be reported:

- 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 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; or
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).

Criteria for reporting to USDA-APHIS

IACUC suspension of activities involving USDA-covered species must be reported to USDA- APHIS, Animal Care, division in accordance with the Animal Welfare Act and Regulations. Self- suspension of personnel or activities by the PI during an investigation will not be reported to USDA-APHIS.

“If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any federal agency funding that activity.”

[AWR§2.31\(d\)\(7\)](#)

The animal program is also required to report to the USDA-APHIS, Animal Care division, any significant deficiency (a deficiency that may be a threat to the health and safety of animals) that is not corrected according to the plan and schedule for correction. This applies to any significant deficiencies identified by the USDA during a visit as well as any identified by the IACUC during semi-annual site visits. It is imperative to contact Office of Research prior to the due date for correction if the corrective action plan and date need to be modified, to allow for revision of the plan and date of correction and preventing a scenario that must be reported to the USDA-APHIS.

“Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity.”

[AWR§2.31\(c\)\(3\)](#)

