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1. Overview

Purpose

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 these procedures is to describe the process adopted by the Drexel University IACUC to review, investigate, and report animal welfare concerns.

2. Definitions

Non-compliance - Situations where an IACUC protocol or institutional procedure is not followed as approved. Examples of non-compliance situations can be found in Section 6.1

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

3. 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 and Innovation (ORI).

Completely anonymous reports may be filed through the Drexel University Compliance Hotline. Reports should be as detailed as possible to facilitate the resulting investigation. Please refer to the list of information provided in Section 3.1 Information to be Gathered.

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

3.1 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 the incident
- Summary of the 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

3.2 Confidentiality of Reports of Animal Welfare Concerns

Reports should be communicated as soon as possible to the Director of Animal Welfare as a part of the Office of Research and Innovation. To the extent possible, all reports made directly to the IACUC or ORI are kept confidential.

3.3 Animal Welfare Concerns Arising out of Post Approval Meeting

Following a routine post-approval monitoring (PAM) visit, animal welfare concerns or protocol non-compliance may be identified. The Animal Welfare Education Specialist will notify the IACUC Chair, and the Director of Animal Welfare which may result in further investigation by the IACUC. The Animal Welfare Education Specialist 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.

3.4 Self-Reports of Non-Compliance

Self-Reports of non-compliance and adverse events are highly encouraged. Self-reports allow investigators to proactively identify areas which may be non-compliant, propose remedial action if non-compliance is discovered, and propose future preventative measures, subject to IACUC oversite. PIs who submit a self-report will be reminded that they are welcome to present and discuss the report at the IACUC meeting in which the self-report is discussed**.**

4. 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.

5. Investigation of Animal Welfare Concerns

Anyone receiving a report of a non-compliance or animal welfare concern must forward the report to the Director of Animal Welfare 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 Director of Animal Welfare will report the animal welfare concern to the Animal Welfare Investigation Subcommittee of the IACUC. This subcommittee consists of the IACUC Chair, Attending Veterinarian, Director of Animal Welfare, and the Animal Welfare Education Specialist. 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 individuals involved. Further information may also be gathered by the Animal Welfare Education Specialist 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 an animal;
- Actual or potential harm to human health and well-being;
- Protocol non-compliance;
- Animal Welfare Act non-compliance;
- NIH non-compliance
    - with the Guide
    - with Drexel's Animal Welfare Assurance Document; or
    - with the PHS policy

The Subcommittee will inform the PI involved with the Animal Welfare Concern of the ongoing investigation. At this time, the PI will be provided with 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 time frame to conclude its investigation.

5.1 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 a letter prepared by the Director of Animal Welfare 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.

5.2 Substantiated Animal Welfare Concerns

5.2.1 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 Director of Animal Welfare 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 Director of Animal Welfare will contact OLAW for advice.

5.2.2 Corrective Actions

The Subcommittee will

- Inform the Principal Investigator of the animal welfare concern, requesting a response and proposal of corrective actions.
- Evaluate the Principal Investigator's proposed corrective actions 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.

5.2.3 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 IACUC Office 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 IACUC Office 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 Director of Animal Welfare summarizing the incident and outcome of the investigation.

5.2.4 Reporting to External Agencies (OLAW, AAALAC, USDA)

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

The report will be drafted by the Director of Animal Welfare and reviewed by the IACUC Chair and Attending Veterinarian before submitting to the IO for signature.

The incident will be officially reported to OLAW in writing through the IO. Drexel University's AAALAC Unit Contact will also inform AAALAC International of the results of the investigation and any subsequent corrective measures that have been reported to OLAW or other external agencies.

6. Criteria for Reporting to OLAW (NIH)

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.

6.1 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 CO_2 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 IACUC Procedures, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.

6.2 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).

7. 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 the IACUC Office 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)

8. Criteria for Reporting to AAALAC

Unexpected adverse events can occur at any time in an animal care and use program. Such events may vary in seriousness, and they may exceed the threshold for a well-managed program. Reporting significant adverse events fosters protection of the integrity and creditability of the institution and demonstrates a culture of care. Institutions are encouraged to evaluate whether the single incidents over time collectively indicate a more significant concern. Activating the adverse event assessment and reporting plan ensures that appropriate steps have been taken to determine whether the event/concern indicates changes are necessary to minimize further risks, if a single incident may or may not be an indicator of a larger issue, and ensures that appropriate actions have been taken and that key program personnel and oversight bodies are fully informed.

8.1 Managing and reporting adverse events

The following examples are intended to illustrate the manner of reporting adverse events; however, the reporting threshold established by the institution will be tailored to the unique context of each institution:

In the AAALAC International Annual Report:

- Protocol violations which *had the potential* to compromise animal welfare
- Animal use not approved by the IACUC or comparable oversight body[1]
- Significant adverse events not previously reported as required by the Rules of Accreditation

Prompt reporting:

- Inadequate veterinary care
- Conditions that resulted in unexpected animal harm or deaths
  - Accidents or errors
  - Equipment failure
  - Natural disaster
- Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests that include AAALAC International documents)
- Inappropriate euthanasia techniques and/or failure to confirm euthanasia
- Substantiated complaints or reports regarding animal welfare concerns
- Internal or external reviews/inspections or other similar reports that document significant adverse events or noncompliance that resulted in animal harm or death; investigations by national oversight bodies; and other serious incidents or concerns that negatively impact animal well-being (e.g., failure to follow the approved protocol which resulted in compromised animal welfare; death during transport)
- Significant human health issue directly related to the animal care and use program

An adverse event report must be submitted promptly to AAALAC International. The adverse event assessment and reporting plan should be available for review by the site visit team and updated or modified as necessary.

The AAALAC International office staff are available to provide additional guidance on reporting expectations and procedures. For assistance, please call the AAALAC International Executive Office or the Regional Director responsible for your geographical area, or send your question to: accredit@aaalac.org

[1] Depending on the severity of this noncompliance or the applicable regulatory framework for the institution, this adverse event might warrant a prompt report to AAALAC International.

9. Criteria for Reporting to Department of Defense (DoD)

Institutions conducting DoD-supported or conducted Research, Development, Testing, and Evaluation (RDT&E) or Training with animals must inform the US Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO) in a timely manner of any of the following for DoD-supported or conducted work RDT&E or training: significant deficiencies, noncompliance, change in AAALAC, International accreditation status, socially sensitive matters, adverse events, protocol suspensions. This document provides guidance on when and how to submit notifications to ACURO.

1. **Definitions and Clarifications:**

a. **Significant Deficiency:** A deficiency that, in the judgement of the Institutional Animal Care and Use Committee (IACUC) and the institutional official, is or may be a threat to the health or safety of animals.

b. **Noncompliance:** Any activity not in accordance with federal, DoD, and/or Institutional polices regarding animal care and use.

c. **Adverse event:** An incident that leads to unintended and substantial injury or illness, unrelieved pain or distress, or death of an animal. Adverse events include unforeseen, unanticipated, inappropriately addressed, or inappropriately alleviated sources of pain, distress, and/or death of an animal that were NOT identified (specifically or generally) as potential risk factors or potential adverse complications in the approved IACUC protocol or policy. Some adverse events may be expected in accordance with the animal care and use protocol. Those that occur at a higher frequency or severity than expected are reportable as outlined below.

d. **Protocol suspension:** An approved activity that is suspended by the IACUC or Institute for any reason.

2. **Procedures:**

a. All IACUC-substantiated/confirmed significant deficiencies, noncompliance, change in AAALAC, International accreditation status, socially sensitive matters, adverse events, protocol suspensions must be reported to ACURO within 5 business days. This includes any official reports to outside agencies, such as the Office of Laboratory Animal Welfare, United States Department of Agriculture, or comparable international authorities.

b. When an institution is notified by the USDA that it is under investigation, the institution must report the investigation to ACURO within 5 business days of initial notification.

c. When an AAALAC International accredited organization has a change in accreditation status, the institution must report the status change to ACURO within 5 business days.

d. Institutions will promptly notify ACURO of FOIA requests or other socially-sensitive matters (e.g. activist activities) concerning or potentially impacting DoD-conducted or supported protocols.

e. It is impractical to provide a comprehensive list all reportable events. Therefore, the Institution may call or e-mail ACURO to discuss specific incidents.

f. Preliminary reporting/discussion may occur by telephone.

g. E-mail notifications must be sent to usarmy.detrick.medcom-usamrmc.other.acuro@health.mil. Include information in the subject line to identify the nature of the notification, e.g. "ADVERSE/REPORTABLE EVENT".

3. For questions regarding notifications, please contact the ACURO Office Manager by e-mail: usarmy.detrick.medcomusamrmc.other.acuro@health.mil or phone: (301) 619-6694.

10. Revisions

Edition 001/Review Date: 06/2021
Edition 002/Revision Date: 9/11/2024 and Effective Date: 9/17/2024 – Revised Document

- Change to new template
- Section 2 – Addition of adverse events and non-compliance definitions
- Section 8 – Addition of criteria for reporting to AAALAC
- Section 9 – Addition of criteria for reporting to DoD