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1. Overview

Purpose

The purpose of this procedure is to establish a consistent process for the identification, reporting, review, and management of unanticipated outcomes and adverse events involving animals used in research, teaching, or testing activities conducted under the oversight of the Drexel University Institutional Animal Care and Use Committee (IACUC).

The goal of involving the IACUC is *not* meant to be punitive. Rather, the IACUC serves as a collaborative partner that can:

- Provide guidance and resources
- Help identify practical solutions
- Support regulatory compliance
- Strengthen animal welfare practices
- Promote refinement and study success

Early communication with the IACUC often helps resolve concerns more efficiently and may prevent recurrence of similar outcomes. Open reporting fosters a culture of transparency, continuous improvement, and shared responsibility for animal care and research quality.

These procedures apply to all Drexel University faculty, staff, students, visiting researchers, research personnel, veterinary staff, and University Laboratory Animal Resources (ULAR) animal care personnel involved in the care and use of live vertebrate animals conducted under Drexel University IACUC oversight, including activities performed in Drexel-owned, affiliated, or satellite facilities.

2. Definitions

Adverse Events - An unfavorable occurrence where there is direct harm to animals or personnel. Adverse events generally must result in negative impacts on well-being (i.e., poor welfare), behavior changes, animal death, disease, or distress, that was not expected, in order to meet the definition. Examples may include but are not limited to:

- Facility or equipment malfunctions
- Natural disasters
- Improper handling
- Escaped animals
- Human error
- Transportation issues

Anticipated Outcomes - An anticipated result described in an IACUC-approved protocol. For example, if morbidity or mortality falls within the anticipated frequency of occurrence that is described in the approved IACUC protocol and procedures are conducted as approved, the morbidity/mortality do not need to be reported to the IACUC.

Unanticipated Outcomes - An unanticipated or unplanned result of IACUC-approved animal activities. Examples of IACUC-reportable unanticipated outcomes may include, but are not limited to:

- Animal morbidity or mortality occurs at a higher frequency than described in the IACUC-approved protocol
- Unanticipated health or welfare concerns discovered after creating or breeding genetically modified animals
- Unexpected clinical signs, pain, or distress as a result of an approved protocol procedure or drug administration.

Reportable Event - An event requiring formal notification to the IACUC, veterinary staff, sponsors, or regulatory agencies in accordance with institutional policy and applicable regulations.

3. Timeline for Reporting

i) If the unexpected outcome or adverse event requires veterinary consultation or assistance with clinical care, the Principal Investigator (PI) (or designee) or ULAR should immediately notify the veterinarian staff.

ii) All unanticipated outcomes/adverse events should be sent to the IACUC within 72 hours of the initial event or incident.

(a) In the event of a major disaster or emergency that prevents timely communication, reporting timelines may be extended.

(b) When reporting is delayed due to extenuating circumstances, notification must occur as soon as conditions permit

4. Report Information

i) The following information should be included with the report:

(a) Summary of the event or outcome including date(s) and location.

(b) Species and number of animals involved

(c) Impacts to animal health or well-being, injuries or health risks (human or animals)

(d) Veterinary care provided (as applicable)

(e) Immediate actions taken

(f) Corrective measures taken to prevent reoccurrence

5. Reporting Method

i) An Unanticipated/Adverse Event Form should be completed and emailed to the IACUC via at iacuc@drexel.edu. Once Novelution is implemented the report should be submitted via the IACUC protocol record within Novelution. The report will be routed to the IACUC Office.

6. Report Review and Collaborative Action Planning

i) A preliminary review of the information provided will be conducted by the IACUC Chair, Attending Veterinarian, and the Director of Animal Welfare to:

(a) Verify that all relevant information is complete and clearly understood.
(b) Discuss whether any animals may still be at risk and identify opportunities to support their ongoing care.
(c) Consider whether additional perspectives from the full committee would be helpful in strengthening the review and recommendations
    i. If the preliminary review suggests that additional input would be beneficial, the report will be scheduled for discussion at the next convened IACUC meeting to allow the committee to collaboratively review and provide guidance.
(d) Work collaboratively with the PI (or designee) or ULAR to identify and implement any additional or interim actions, as needed, to support animal welfare and study success.

ii) Reporting to external agencies (e.g. Office of Laboratory Animal Welfare) may be necessary depending on the type of event and funding for the study.

7. Responsibilities

7.1 Office for Research & Innovation IACUC Office Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, training, granting exceptions, and monitoring. For inquiries regarding these procedures, please contact the Director of Animal Welfare in the Office for Research & Innovation (ORI).

The IACUC Office supports the administrative management of the reporting and review process. Responsibilities include:

(a) Receiving, tracking, and maintaining records of all submitted unanticipated outcomes and adverse event reports.
(b) Reviewing reports for completeness and clarity and routing them for appropriate review.
(c) Serving as the primary point of contact and communicating directly with the PI or designee regarding report status, required revisions, or follow-up actions.
(d) Coordinating the preliminary review process with the IACUC Chair, Attending Veterinarian, and Director of Animal Welfare.
(e) Facilitating scheduling of reports for full committee review when additional input is warranted.
(f) Documenting review outcomes, determinations, and required actions.
(g) Assisting with preparation of reports to external regulatory agencies, when required.

7.2 Principal Investigator Responsibilities

The Principal Investigator is ultimately responsible for the conduct of all animal activities under their protocol and for ensuring appropriate reporting and follow-up of unanticipated outcomes and adverse events. Responsibilities include:

(a) Ensuring timely (within 72 hours), accurate, and complete reporting of all unanticipated outcomes and adverse events in accordance with this SOP and applicable regulations.
(b) Immediately notifying veterinary staff of any adverse event or unexpected outcome to ensure appropriate clinical care for affected animals.

(c) Reviewing all reports for accuracy, completeness, and compliance prior to submission.
(d) Providing all required report elements, including event summary, animal impact, and corrective actions.
(e) Responding promptly to requests from the IACUC Office or Committee for additional information or clarification.
(f) Collaborating with the IACUC and the Attending Veterinarian to develop and implement corrective and preventive actions.
(g) Ensuring that all study personnel comply with reporting requirements and institutional policies.
(h) Maintaining all documentation and records related to reported events in accordance with institutional and regulatory requirements.

7.3 University Laboratory Animal Resources Responsibilities

(i) Ensuring timely (within 72 hours), accurate, and complete reporting of all unanticipated outcomes and adverse events in accordance with this SOP and applicable regulations.
(j) Immediately notifying veterinary staff of any adverse event or unexpected outcome to ensure appropriate clinical care for affected animals.
(k) Reviewing all reports for accuracy, completeness, and compliance prior to submission.
(l) Providing all required report elements, including event summary, animal impact, and corrective actions.
(m) Responding promptly to requests from the IACUC Office or Committee for additional information or clarification.
(n) Collaborating with the IACUC and the Attending Veterinarian to develop and implement corrective and preventive actions.
(o) Ensuring that all personnel comply with reporting requirements and institutional policies.
(p) Maintaining all documentation and records related to reported events in accordance with institutional and regulatory requirements.

7.4 Institutional Animal Care and Use Committee (IACUC) Responsibilities

The IACUC provides oversight, review, and guidance to ensure animal welfare and regulatory compliance. Responsibilities include:

(a) Reviewing reports of unanticipated outcomes and adverse events to assess animal welfare impact and protocol compliance.
(b) Participating in preliminary or full committee review, as appropriate, to evaluate events and determine necessary actions.
(c) Collaborating with the PI and institutional stakeholders to identify practical solutions and corrective actions that support animal welfare and study success.
(d) Determining whether additional oversight, protocol modifications, or monitoring is required.
(e) Recommending or requiring corrective and preventive measures to reduce the likelihood of recurrence.
(f) Ensuring that all findings, discussions, and determinations are appropriately documented.
(g) Supporting decisions regarding whether reporting to external agencies (e.g., OLAW or sponsors) is necessary.

7.5 Attending Veterinarian Responsibilities

The Attending Veterinarian (AV) is responsible for ensuring the health and welfare of animals involved in reported unanticipated outcomes and adverse events and for providing clinical and professional guidance throughout the review process. Responsibilities include:

(a) Providing immediate consultation and clinical care for animals involved in adverse events or unanticipated outcomes, as reported by the PI or research personnel.
(b) Assessing the nature, severity, and impact of reported events on animal health and welfare.
(c) Participating in the preliminary review of reports with the IACUC Chair and Director of Animal Welfare to evaluate completeness, risk to animals, and need for further action.
(d) Recommending appropriate medical interventions, supportive care, or humane endpoints, as needed.
(e) Providing expert guidance on preventive measures and refinements to minimize pain, distress, or recurrence of adverse events.
(f) Collaborating with the PI and IACUC to develop and implement corrective and preventive action plans.
(g) Identifying any ongoing or potential risks to animal populations and advising immediate mitigation measures.
(h) Contributing to determinations regarding whether events meet criteria for reporting to regulatory agencies or sponsors, as applicable.
(i) Ensuring that veterinary assessments, recommendations, and interventions are appropriately documented.

8. Resources

PHS Policy | Grants & Funding
Animal Welfare Act | National Agricultural Library
The National Academies Press | Guide for the Care and Use of Laboratory Animals: Eighth Edition

9. Revision

9.1 Revision

Version 001/Effective Date - Original Document- Unanticipated Outcomes and Adverse Event Reporting – Standard Operating Procedures