

Reporting Animal Concerns and Incidents

NIH OACU Guide 03/05/2021

In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)¹, the IC ACUC is responsible for reviewing concerns involving the care and use of animals.

The PHS Policy requires the prompt reporting of the following:

- Any serious or continuing noncompliance with the PHS Policy;
- Any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals (Guide)*²; and
- Any suspension of an activity by the IC ACUC.

Investigation Process:

- The IC ACUC Chair receives a report of a concern or incident involving the care and use of animals.
- The IC ACUC Chair notifies the Office of Animal Care and Use (OACU).
- The IC ACUC Chair appoints a subcommittee to conduct an investigation of the concern or incident.
- The subcommittee conducts an investigation and formulates recommendations.
- At a convened meeting of the IC ACUC with a quorum present, the IC ACUC deliberates the investigative report and associated recommendations, formulates additional conditions and/or corrective actions, and either:
 - Awaits further information from the subcommittee, or
 - Closes out the investigation and renders a final report.
- The IC ACUC Chair submits the final report to the OACU who forwards the report to the Office of Laboratory Animal Welfare (OLAW) through the NIH Institutional Official (IO) if it meets the prompt reporting requirements.
- The OACU forwards the OLAW acknowledgement to the IC ACUC Chair.
- The IC ACUC includes a list of reportable incidents in Section G of the semiannual report.

If the concern or incident occurred in a shared or central facility, refer to the ARAC Guideline for [ACUC Oversight of Animal Study Proposal Activities in Shared and Central Facilities](#).

If the concern or incident was initiated by the NIH ARAC Ombudsman, refer to the ARAC Guideline for [Responding to Animal Care and Use Complaints from Outside the NIH](#).

Incident Report Format and Contents:

- Address memo to the NIH IO: Michael M. Gottesman, M.D., Deputy Director for Intramural Research
- Reference the NIH Animal Welfare Assurance number: D16-00602
- Include a concise description of the incident, corrective actions, and implementation schedule
- Omit proper names, personal identifiers, room/building numbers, photographs, etc.

Please refer to the attached report template and example report for additional guidance.

Examples of reportable situations³:

- 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 ACUC review and approval;
- Failure to adhere to ACUC-approved protocols;
- Implementation of any significant change to ACUC-approved protocols without prior ACUC approval;
- Conduct of animal-related activities beyond the expiration date established by the ACUC;
- Conduct of official ACUC business requiring a quorum (e.g., full Committee review of an activity or suspension of an activity) in the absence of a quorum;
- Conduct of official ACUC 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 ACUC has approved an ASP-specific deviation from the *Guide* based on written scientific justification;
- Participation in animal-related activities by individuals who have not been determined by the ACUC 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);
- 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
- ACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

References:

1. PHS Policy on Humane Care and Use of Laboratory Animals, 2015: <https://olaw.nih.gov/policies-laws/phs-policy.htm>
2. Guide for the Care and Use of Laboratory Animals, NRC, 2011: <https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>
3. NIH OLAW Notice Number: [NOT-OD-05-034 – Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals](#)

Attachments:

- Incident Report Template
- Example Incident Report

Revised 06/01/2005, 06/14/2006, 05/10/2011, 01/02/2013, 03/03/2021

Please note: This is intended for the NIH Intramural Research Program and is not to be considered guidance from the Office of Laboratory Animal Welfare (OLAW) or any other oversight entity.



March 5, 2021

To: Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH
From: **Name of IC ACUC Chair**, Chair, **IC** Animal Care and Use Committee
Subject: Animal Incident Report

In accordance with Assurance D16-00602 and PHS Policy IV.F.3., the **IC** ACUC provides this report of an incident that occurred involving the care and use of animals in biomedical research.

Summary of Incident:

In narrative form, provide a description of the incident, including the following details:

- *Date of the incident;*
- *Description of the incident, including what happened, when and where, the species and number of animal(s) involved, and the category of individuals involved (e.g., principal investigator, technician, animal caretaker, student, veterinarian, etc.);;*
- *When the incident was discovered, who discovered it, and who reported it to the ACUC;*
- *When the incident was reported to OACU, and by whom;*
- *When the investigative team reviewed the incident;*
- *What the investigative team discovered and concluded;*
- *When the ACUC reviewed the investigative team's findings; and*
- *What the ACUC concluded. If a noncompliance was identified, describe it using the terms from OLAW's [Guidance on Prompt Reporting](#).*

Corrective Actions:

If applicable, provide a list of the corrective actions and implementation schedule.

The **IC** ACUC feels these actions will prevent the occurrence of a similar incident in the future.

Sincerely,

/signature/

Name of IC ACUC Chair
Chair, **IC** Animal Care and Use Committee



March 5, 2021

To: Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH
From: Jane Smith, Ph.D., Chair, IC Animal Care and Use Committee
Subject: Animal Incident Report

In accordance with Assurance D16-00602 and PHS Policy IV.F.3., the IC ACUC provides this report of an incident that occurred involving the care and use of animals in biomedical research.

Summary of Incident:

On January 01, 2021, the Animal Program Director (APD) notified me of an incident that occurred on December 31, 2020. During routine health observations, a veterinary technician noted a cage containing one guinea pig with an abdominal surgery incision. This animal was assigned to a non-surgical Animal Study Proposal (ASP).

On January 02, 2021, the incident was reported to the NIH Office of Animal Care and Use, and an ACUC subcommittee, composed of the APD, ACUC Coordinator, and Facility Manager, was formed to investigate the incident. The investigation revealed that the Principal Investigator (PI) performed the surgery prior to ACUC review and approval of the procedure. The PI assumed full responsibility for the incident.

After discussion at a convened meeting on January 28, 2021, the ACUC concluded that this was a reportable incident involving the conduct of animal-related activities without appropriate ACUC review and approval.

Corrective Actions:

To address the situation, the following corrective actions were taken:

- The PI must complete refresher training offered by the NIH Office of Animal Care and Use, and
- The PI must submit an amendment for the addition of the surgical procedure and wait for ACUC review and approval before performing any additional surgical procedures.

The NIH ACUC feels these actions will prevent the occurrence of a similar incident in the future.

Sincerely,

/signature/

Jane Smith, Ph.D.
Chair, IC Animal Care and Use Committee