

# Guideline for Assessment and Reporting of Adverse Events, Unexpected Outcomes, and Animal Welfare Concerns

**Background:** Animals involved in research may be subject to events that have the potential to adversely impact their health or welfare. These events must be promptly reported to the Animal Care and Use Committee (ACUC) for assessment.

## **Definitions:**

Adverse event – An unexpected incident that negatively affects the health or welfare of animals.

Unexpected outcome – An unanticipated result of ACUC-approved animal activities. Examples of ACUC-reportable unexpected outcomes may include, and are not limited to:

- Animal morbidity or mortality occurring at a higher frequency than expected.
- Unanticipated debilitating defects discovered after creating or breeding genetically modified animals.

Expected outcome - An anticipated result of ACUC-approved animal activities. For example, a certain percentage of morbidity or mortality may be expected with a particular procedure, such as a surgery or disease model. These outcomes *do not need to be reported* to the ACUC if they fall within the anticipated frequency of occurrence and the procedures are conducted as approved in the ASP.

Animal welfare concern – A condition or situation that has the potential to jeopardize the health or well-being of animals, including suspected mistreatment and misuse.

Noncompliance – A deviation from policies or procedures without prior approval.

OLAW-reportable – A PHS non-compliance or reportable event. The PHS defines noncompliance as serious or continuing noncompliance with the PHS Policy, serious deviations from the provisions of the *Guide*, or any suspension of a protocol by the Institutional Animal Care and Use Committee. Reportable events include 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.<sup>4</sup>

AAALAC International-reportable – A significant adverse event relating to the animal care and use program. Examples include internal or external reviews/inspections that document these events, investigations by national oversight bodies, and other serious incidents or concerns that negatively impacted animal well-being.<sup>3</sup>

**Internal Reporting:** Adverse events, unexpected outcomes, and animal welfare concerns must be promptly reported to the appropriate ACUC, generally the IC ACUC with oversight of the animals involved. For non-research related events in shared facilities, the Lead Institute/Center (IC) ACUC is responsible; for non-research related events in central facilities, the ORS-DVR ACUC is responsible.<sup>6</sup> Some events may require immediate action by the animal program or veterinary staff to protect animal health and welfare in addition to ACUC reporting.

The process of assessment and reporting includes the following:

- Once an adverse event, unexpected outcome, or animal welfare concern has been reported to the ACUC, the ACUC notifies the Director, Office of Animal Care and Use (OACU) (or designee), who provides a preliminary report to the Institutional Official (IO), OLAW, and AAALAC International, if applicable.
- If warranted, the ACUC Chair promptly appoints an individual or subcommittee to investigate the event, unexpected outcome, or concern. The ACUC Chair may also convene an emergency meeting if immediate actions are necessary.
- At a convened meeting of the ACUC with a quorum present, the ACUC reviews the event, unexpected outcome, or concern and:
  - Decides whether to recommend external reporting through the IO (see below), and
  - Develops a corrective and preventative action plan, if applicable.
- If external reporting is recommended, the ACUC submits a final report to the IO through the Director, OACU that includes an explanation of the event and, if applicable, the corrective and preventative action plans.

The Director, OACU is available to consult with ACUCs regarding whether a specific event should be externally reported.

In the event of occurrences involving multiple ICs or for concerns originating from outside NIH, the Animal Research Advisory Committee (ARAC) Ombuds is available to coordinate or participate in the assessment process.<sup>7</sup>

**External Reporting to OLAW:** In addition to the final report to the IO, PHS Policy<sup>1</sup> requires assured institutions to **promptly report** non-compliance or reportable situations. OACU handles reporting to OLAW.

<b>OLAW Prompt Reporting Examples<sup>2</sup></b>
<ul style="list-style-type: none"><li>• 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</li><li>• Conduct of animal-related activities without appropriate ACUC review and approval</li><li>• Failure to adhere to ACUC-approved ASPs</li><li>• Implementation of any significant change to ACUC-approved ASPs without prior ACUC approval</li><li>• Conduct of animal-related activities beyond the expiration date established by the ACUC</li><li>• Participation in animal-related activities by individuals who have not been determined by the ACUC to be appropriately qualified and trained</li><li>• Failure to ensure death of animals after euthanasia</li><li>• Failure of animal care and use personnel to carry out veterinary orders</li><li>• ACUC 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 <i>Guide</i>, or the institution's Animal Welfare Assurance</li></ul>

**External Reporting to AAALAC International:** Similarly, the AAALAC International Rules of Accreditation<sup>3</sup> require **prompt reporting** of significant adverse events related to the animal care and use program. OACU handles reporting to AAALAC International for the Bethesda-based programs. For those programs covered by a separate AAALAC International accreditation (i.e., NIA, NIAID-RML, NIDA, NIEHS, and ORIP-APF), reporting to AAALAC International is handled by the individual program.

<b>AAALAC International Prompt Reporting Examples<sup>5</sup></b>
<ul style="list-style-type: none"><li>• Inadequate veterinary care</li><li>• Conditions that resulted in unexpected animal harm or deaths (e.g., accidents or errors, equipment failures, natural disasters)</li><li>• Significant animal rights activities (e.g., protests, property damage)</li><li>• Inappropriate euthanasia techniques or failure to confirm euthanasia</li><li>• Substantiated complaints or reports regarding animal welfare concerns</li></ul>

**References:**

1. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
2. OLAW NOT-OD-05-034 – [Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals](#)
3. AAALAC International – [Rules of Accreditation](#)
4. Lab Animal. 2017; 46(6):244-249 - [Adverse Events at Research Facilities](#)
5. AAALAC International FAQ – [Managing and reporting adverse events](#)
6. ARAC Guideline for [Communication Between User and Lead ACUCs, Oversight of ASP Activities and Management in Animal Facilities](#)
7. ARAC Guideline for [Responding to Animal Care and Use Complaints from Outside the NIH](#)
8. DDIR/IO Policy Memo: [Communicating Animal Care and Use Concerns within the NIH Intramural Research Program](#)

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