

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. These outcomes are reportable to the ACUC when they differ from what is described in the ACUC-approved Animal Study Proposal (ASP). Examples of ACUC-reportable unexpected outcomes may include, but are not limited to:

- Animal morbidity or mortality occurring at a higher frequency than expected.
- Unanticipated deleterious phenotypes 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 occur as described in the approved 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 – Failure to follow approved policies or procedures without prior approval.

Office of Laboratory Animal Welfare (OLAW)-reportable – A noncompliance or reportable event. The Public Health Service (PHS) defines noncompliance as serious or continuing noncompliance with the PHS Policy(1), serious deviations from the provisions of the *Guide*(2), or any suspension of an activity by the ACUC.

AAALAC International-reportable – A significant adverse event relating to the animal care and use program that carries potential external, regulatory, or legal implications.

Internal Reporting: Promptly report adverse events, unexpected outcomes, and animal welfare concerns to the appropriate ACUC(3). In most cases, this is the Institute or Center (IC) ACUC responsible for overseeing the animals involved. For shared or central facilities, report events unrelated to the conduct of research (such as facility, husbandry, or equipment issues) to the Lead IC ACUC or the ORS-DVR ACUC, as appropriate. Some events may also require immediate action by the animal program or veterinary staff to protect animal health and welfare, in addition to reporting the event to the ACUC.

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. Appropriate documentation must be maintained to demonstrate the process of assessment, management, and monitoring.
- 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(4).

External Reporting to OLAW: In addition to the final report to the IO, PHS Policy requires assured institutions to **promptly report non-compliance** or **reportable situations**(5). OACU handles reporting to OLAW.

OLAW Prompt Reporting Examples(5)
• 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 ASPs • Implementation of any significant change to ACUC-approved ASPs 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 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 the <i>Guide</i> • Participation in animal-related activities by individuals who have not been determined by the ACUC to be appropriately qualified and trained • Failure to ensure death of animals after euthanasia • Failure of animal care and use personnel to carry out veterinary orders • 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

OLAW Prompt Reporting Examples(5)
Any situation in a functional, programmatic, or physical area that could affect activities subject to the PHS Policy, regardless of funding source

External Reporting to AAALAC International: Similarly, the AAALAC International Rules of Accreditation require **prompt reporting** of events related to the animal care and use program that carry potential external, regulatory, or legal implications(6). OACU handles reporting to AAALAC International for the Bethesda-based programs. Programs with a separate AAALAC International accreditation (NIA, NIAID-RML, NIDA, and NIEHS) report independently.

AAALAC International Prompt Reporting Examples(7)
- Investigations by external oversight bodies - Public records requests involving AAALAC documents - Lawsuits alleging concerns related to the program of animal care and use - Events anticipated to attract media or activist attention

References:

- Office of Laboratory Animal Welfare. Public Health Service Policy on Humane Care and Use of Laboratory Animals 2015 [Available from: <https://olaw.nih.gov/policies-laws/phs-policy.htm>.
- Institute for Laboratory Animal Research. Guide for the Care and Use of Laboratory Animals. 8th ed. Washington (DC): National Academies Press; 2011.
- Deputy Director for Intramural Research NIH. DDIR Institutional Official Policy Memo: Communicating Animal Care and Use Concerns within the Intramural Research Program 2022 [Available from: https://oacu.oir.nih.gov/system/files/media/file/2022-09/Communicating-Concerns-2022_0.pdf.
- NIH Animal Research Advisory Committee. Guidelines for Responding to Animal Care and Use Complaints from Outside NIH: NIH OACU; 2023 [Available from: <https://oacu.oir.nih.gov/system/files/media/file/2023-07/c2-Responding-Complaints.pdf>.
- Office of Laboratory Animal Welfare. NOT-OD-25-148: Notice on Update to Guidance on Prompt Reporting to OLAW Under the PHS Policy on Humane Care and Use of Laboratory Animals. 2026.
- AAALAC International. Rules of Accreditation 2022 [Available from: <https://www.aaalac.org/accreditation/what-is-aaalac-accreditation1/rules-of-accreditation/>.
- AAALAC International. FAQ - Adverse Event Reporting 2025 [Available from: <https://www.aaalac.org/accreditation/faqs/#AdverseEvents>.

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