

Purpose

Incidents involving animals used in research and teaching can include Unanticipated Outcomes, Protocol Deviations, Adverse Events, and Animal Welfare Concerns. These incidents need to be reported to assist the IACUC, Principal Investigators (PIs), animal care staff, and the Attending Veterinarian in finding the cause and preventing recurrence. Reporting also helps the IACUC meet its federal and accreditation requirements to monitor animal activities.

Incident reporting is intended to be an interactive process with the PI and the IACUC. It is not intended as punitive action against investigators, but an effort to facilitate research effectiveness and to improve animal care.

Policy

Immediately upon becoming aware of an incident, as defined below, an individual must report the incident to the Attending Veterinarian and the Office of Research Integrity via phone, email, Microsoft Teams, or the [anonymous reporting portal](#). After this initial report, the individual must submit an Event Reporting Form via the IRBNet system within 72 hours of becoming aware of the incident. This form can be found in IRBNet and on the [Office of Research Integrity website](#).

Definitions

Unanticipated Outcome: Unexpected adverse result of IACUC-approved animal activities, including allergic reactions, surgery complications, birth defects from genetic modification, and higher morbidity or mortality than anticipated.

Protocol Deviation: Conduct of animal-related activities without appropriate IACUC review and approval.

Adverse Event: Incident that negatively affects the health or welfare of animals that is not related to IACUC-approved animal activities, including death or illness due to equipment failure, natural disaster, and spontaneous disease.

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

Contact Information

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References

National Institutes of Health. (2021, March 5). *Guidelines for Assessment and Reporting of Adverse Events, Unexpected Outcomes, and Animal Welfare Concerns*. https://oacu.oir.nih.gov/system/files/media/file/2023-07/C10-Assessment-Reporting-Adverse-Events_0.pdf

National Research Council. (2011). *Guide for the Care and Use of Laboratory Animals: Eighth Edition*.
<https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>

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