

Adverse Events

Adverse events (AE) comprise unexpected events or outcomes impacting animal health or wellbeing, human health or well-being, or institutional integrity. Adverse events can be associated to a natural disaster (considered also in the institutional disaster plan); an animal welfare concern report; unexpected outcomes of research procedures; accusations/allegations reported in the media; and other events.

The institution should have an adverse event assessment and reporting plan that defines what is considered an AE and addresses how adverse events are assessed by the IACUC or comparable Oversight Body (OB). This plan should also address risk assessment and include development of a mitigation plan to minimize or prevent future recurrences. When appropriate, the plan should also include the procedures for reporting to appropriate internal and external oversight bodies. Council will review the effectiveness of AE oversight, including the reporting plan, as part of the triennial on-site assessment and program review.

Each accredited unit should establish its own process for reviewing potential adverse events and determining what should be reported to AAALAC in accordance with the Rules of Accreditation.

AAALAC International requires accredited units to promptly report the following significant adverse events:

1. investigations by applicable external oversight bodies;
2. public records requests, particularly those involving AAALAC documents (e.g., copies of Program Descriptions, correspondence between AAALAC International and the unit);
3. lawsuits alleging concerns regarding the animal care and use program (including the ethical conduct of studies with animal models); and
4. events anticipated to attract external attention (e.g. anticipated to elicit animal rights activities or media attention).

The unit is encouraged to contact/call the AAALAC Office if it is uncertain about the need to or the timing of reporting an adverse event.

- Download the Adverse Event Reporting i-Brief:
<https://www.aaalac.org/pub/?id=44C02288-BD4A-4D2D-898D-D36BB556102D>
- Download a full-size infographic “What’s Changed, What Hasn’t”
<https://www.aaalac.org/pub/?id=44D213CD-B8BC-C66C-0944-8EF059EDFC5D>
- Download a full-size Decision Tree
<https://www.aaalac.org/pub/?id=44E444AA-FFB4-3704-DBEC-60762ABD1ADF>
- Watch the Webinar on Adverse Event Reporting
<https://vimeo.com/1179647453/0a0f22851f?share=copy&fl=sv&fe=ci>