

WVU IACUC POLICY: **Reporting Adverse Events, Unexpected Outcomes and Clinical Emergencies**

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 Institutional Animal Care and Use Committee (IACUC) for assessment.

Definitions

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

- Examples of IACUC-*reportable* adverse events may include, but are not limited to:
 - Facility or equipment malfunctions
 - Natural disasters
 - Animal illness outbreaks or disease outbreaks

Unexpected outcome – An unanticipated result of IACUC-approved animal activities.

- Examples of IACUC-*reportable* unexpected outcomes may include, but 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
 - Unexpected debilitating symptoms, pain, or distress as a result of an approved protocol procedure

Expected outcome – An anticipated result of IACUC-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 IACUC if they fall within the anticipated frequency of occurrence and the procedures are conducted as approved in the animal use protocol.

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.

Clinical Emergency – A clinical emergency is any animal welfare issue that requires immediate clinical intervention to provide relief from pain/distress or prevent an imminent risk of pain/distress, morbidity, or mortality. It can be the result of an adverse event or unexpected outcome and may affect a single animal or a group of animals.

Policy (Internal Reporting of Events)

Investigators, Laboratory Staff and Animal Care Staff

All adverse events and unexpected outcomes that negatively impact or pose an imminent risk to animal welfare should be reported immediately to veterinary staff (*see Reporting Clinical Emergencies below*). Within 48 hours of discovery, a preliminary report should be submitted to the Attending Veterinarian (AV), IACUC Chair and/or Office of Animal Welfare (OAW) either directly or indirectly through a chain of command (supervisor, clinical veterinarian, etc.). This preliminary report can be conveyed by various methods (phone call, email, text, etc.). Note that if the event/outcome is initially reported to veterinary

staff (clinical veterinarians or veterinary technicians), the veterinary staff will submit the preliminary report to the AV, IACUC Chair and/or OAW. The supervisor (e.g. Principal investigator, laboratory or farm manager, etc.) is responsible for submitting the preliminary report within 48 hours *only* if veterinary staff were not previously contacted. The AV, IACUC Chair, and/or OAW will contact the relevant parties for more information, if needed, and determine if a full report should be submitted using the IACUC Event Report form that will be supplied by OAW.

Reporting Clinical Emergencies

Animals found injured, sick, morbid, or deceased by protocol personnel during routine daily checks or other activities should be promptly reported to veterinary staff, including off-hours on weekdays, weekends, holidays, and shutdown periods. Emergency veterinary contacts should be posted and kept up to date in all animal-use areas, including satellites. Individuals should first make reasonable efforts to separate animal(s) from any immediate danger (e.g. malfunctioning equipment, aggressive animals, environmental hazards, etc.) as they are able, without endangering themselves. Veterinary staff must be consulted before providing clinical care unless clinical treatments to be provided by protocol personnel are approved procedures on the IACUC protocol.

Anonymous Reporting of Concerns

Any concerns regarding animal welfare can also be reported anonymously. See the following for more information: [Contact Information- Reporting Concerns](#).

Activities of the Chair and Committee

Directed by the Chair, the IACUC will do any necessary follow-up investigation of the event. After all the information gathering has been completed, the committee will review the results at a monthly meeting and determine any necessary actions. A final report of the event will be submitted to the IO in cases where classification as an unexpected outcome or adverse event is substantiated. Reporting to external oversight agencies will be determined by the policies and guidance of those stakeholders.

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](#)