WVU IACUC POLICY:
Internal and External Reporting for Non-Compliance, 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, disease outbreaks or unexpected deaths

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. If these outcomes fall within the anticipated frequency of occurrence and the procedures are conducted as approved in the animal use protocol, then they *do not need to be reported* to the IACUC.

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.

Non-Compliance – The failure (intentional or unintentional) to comply with applicable federal, state, or local laws or regulations, IACUC Guidelines/SOPs/Policies, and/or with an approved IACUC protocol.

Serious Non-Compliance – Any noncompliant event that has negative impact on the welfare of an animal constitutes a direct violation of federal standards regulating animal activities. These standards include provisions of the Occupational Health and Safety program and the *Guide for the Care and Use of Laboratory Animals* (the *Guide*). The conduct of a significant animal procedure without IACUC approval is also a serious non-compliance. Serious non-compliance issues require reporting to the Institutional Official (IO) through the Office of Animal Welfare (OAW), Attending Veterinarian (AV), or IACUC chair. The IO will submit to federal agencies and accreditation agencies, as required.

Continuing Non-Compliance – Repeated episodes of non-compliance involving the same Principal Investigator (PI) or personnel. The committee will consider all non-compliance events over the last 3 years when evaluating compliance history for a PI.

Corrective Actions – Remediation or process changes to prevent or mitigate reoccurrence of non-compliance or adverse events.

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 AV, IACUC Chair and/or the 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.

The IACUC committee encourages self-reporting of non-compliance events to the AV, IACUC chair, and/or 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 are approved procedures and personnel on the IACUC protocol.

Anonymous Reporting of Concerns

Any concerns regarding animal welfare can also be reported anonymously. See the following link 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, or sufficient information has been gathered, the committee will review the results at a monthly meeting and determine any necessary actions. A final report of the event, including corrective actions or steps to prevent or mitigate reoccurrence, 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.

Policy (External Reporting)

WVU adheres to the reporting requirements established by OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, USDA animal welfare regulations, and AAALAC International. Reportable events are promptly conveyed to the necessary regulatory and oversight agencies by the IO. The agencies involved will depend on the type of research, nature of the event, funding, and species involved. Preliminary and final reports will be filed by the IO through the OAW.

1. OLAW Notice (NOT-OD-05-034), *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals.* This policy provides guidance on reportable events.

2. WVU OAW and IACUC committee considers the following events to be reportable events:
    a. Any serious or continuing noncompliance
    b. Any serious deviation from the provisions of the guide
    c. Any suspension of activity by the IACUC
    d. Inadequate veterinary care
    e. Unexpected animal harm or death
        i. Accidents or errors
        ii. Equipment failure
        iii. Natural disasters
    f. Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests that include AAALAC International documents)
    g. Inappropriate euthanasia techniques and/or failure to confirm euthanasia
    h. Substantiated complaints or reports regarding animal welfare concerns
    i. Internal or external reviews/inspections or other similar reports that document significant adverse events or noncompliance that resulted in animal harm or death; investigations by national oversight bodies; and other serious incidents or concerns that negatively impact animal well-being (e.g., failure to follow the approved protocol which resulted in compromised animal welfare; death during transport).
    j. Significant human health issue directly related to the animal care and use program.

3. The following items are not typically reported to external agencies:
    a. Death of animals that have reached the end of their natural life spans;
    b. Death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
    c. Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
    d. Animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
    e. Infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding.

References:

1. PHS Policy on Humane Care and Use of Laboratory Animals
2. Guide for the Care and Use of Laboratory Animals, National Research Council, 2011.
3. OLAW NOT-OD-05-034 – Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals
4. AAALAC l – Rules of Accreditation
5. Lab Animal. 2017; 46(6):244-249 - Adverse Events at Research Facilities
6. AAALAC FAQ – Managing and reporting adverse events