ANIMAL EYE CONSULTANTS OF IOWA

Animal Eye Consultants of Iowa

Institutional Animal Care and Use Committee

Policy #37 — Reporting Adverse Events, Abnormal Behavior/Conditions and Incidents

Approval Date: 3/27/2024 (Replacing Version 1/27/2021)

A. Purpose

To describe the process and expectation for the timely reporting of adverse events, abnormal behavior/conditions, and incidents to the clinical veterinary staff, the Office of the AEC Veterinary Staff (if not already acting as the veterinarian of service) and the Institutional Animal Care and Use Committee (IACUC).

B. Background

Manipulation of animals in research or teaching may occasionally result in serious, unanticipated, or adverse clinical consequences. Unexpected events unrelated to the protocol may also adversely impact animals. Prompt and effective communication between researchers, veterinarians, and animal care staff is crucial for clear and timely management of animal disease, injury, adverse outcomes, or other adverse events.

The IACUC is also required to monitor ongoing research and teaching activities related to animal use. To assist the IACUC in fulfilling this requirement, unanticipated study-related adverse events or non-study related adverse events that result in serious animal welfare issues must be reported to the IACUC. This allows the IACUC, PI, facility managers and Attending Veterinarian to work together to evaluate the cause and, when possible, identify changes that can be implemented to help prevent re-occurrences.

Reporting is not intended as a punitive action against investigators, but an effort to facilitate research effectiveness, communication and improve animal care. Certain adverse events and incidents require reporting to regulatory, funding and/or accrediting organizations, so timely notifications are essential.

Definitions

Unanticipated Adverse Event: Any event that harms an animal owned by AEC and/or covered by a AEC IACUC approved Animal Subjects Approval Form (ASAF) meeting one of the conditions:

1. The event is research-related but is not identified in the protocol or is occurring at a rate or severity higher than is indicated in the approved protocol.
2. The event is not research-related but results from a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.

Incident: Any event that does not immediately impact animal welfare but has the potential to (e.g., prolonged power outages) or is likely to generate negative media attention (e.g., animal rights activity, facility break-in, etc.).

Abnormal Behavior/Conditions: Animals showing signs of unusual behavior, injury, or illness unrelated to study procedures (e.g., animal is treated for bloat, pasture injuries, fight wounds, barbering, etc.) or are found dead.

C. Policy

The IACUC expects that everyone involved in the care and use of animals is aware of the need to promptly report issues and is trained on the procedures to report unanticipated adverse events, abnormal conditions and/or incidents. Reporting to the proper clinical veterinarian must be in a timely manner to ensure adequate veterinary care, minimize the effect on animal welfare and identify ongoing trends.

Responding to and reporting an adverse event, abnormal behavior/condition, or incident:

1) **Ensure animal care:** When appropriate in an urgent situation, provide immediate 'first-aid' (to the level that personnel are qualified/have clearance) to alleviate animal pain/distress and then notify veterinary staff.
2) **Notify the veterinary staff:** If immediate veterinary assistance is required, call the AEC Veterinary Staff at (509)335-6246 or if after-hours at (509) 330-1871 or call the project or facility's assigned clinical veterinarian (if other than AEC).
3) Contact the Principal Investigator and/or research personnel who are using the animals. The veterinary and research staff will work together on a plan.
4) All abnormal animals must be entered into the AEC Animal Health Database located at https://animal-eye-iowa.com/forms/. If you do not have access or have not been trained on this reporting procedure, please email the AEC Veterinary Staff at animaleyeiowa@gmail.com.

   It is essential for any clinical veterinarian that is not within AEC to have a clear mechanism for communicating health issues within their facilities to the Attending Veterinarian. The AV is ultimately responsible for the health and welfare of all AEC owned animals so needs to be informed as issues arise. Please refer to the AEC IACUC Policy #3 and AEC BPPM 45.42 for additional information.
5) Unanticipated adverse events and incidents as defined above also require a report to the IACUC. This is typically submitted following discussion with AEC or the AWP and once the issue has been addressed and a corrective action plan determined. The reporting form can be found online at the IACUC website and submitted to AWP Office at IACUC@animal-eye-iowa.com. Adverse events will be discussed during a convened IACUC meeting.
6) Reporting to external agencies may be necessary depending on the type of event. This will be coordinated by the AWP Office. The AWP follows the online guidance provided by AAALAC and OLAW on what requires reporting and how to report.

Examples of unanticipated adverse events and incidents requiring notification to AEC /clinical veterinarian and the IACUC include:

- Unexpected clinical signs potentially related to a protocol procedure not currently described in the protocol or occurring at increased severity or rate.

- A significant increase in morbidity or mortality related to protocol procedures.
- Phenotypes associated with transgenic animals (e.g., tumor development, early death) that negatively impact the welfare of an animal.
- Protocol deviations, departures or mistakes made by the research team inconsistent with the approved protocol resulting in harm to the animals.
- An incident that has potential for negative public media attention.
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire, pump failure in an aquatic system) that negatively impact the welfare of an animal.
- A high rate of surgical complications such as anesthetic deaths, infections, or wound dehiscence.

Abnormal Behavior/conditions that require veterinary notification but do not typically require a report to the IACUC:

- Anticipated clinical signs/possible adverse events described in a protocol or amendment, as they are potentially expected from the research activities.
- Injury or illness unrelated to study procedures (e.g., animal is treated for bloat, pasture injuries, fight wounds, barbering, age-related mortality, etc.)
- Facility or weather-associated events (e.g., HVAC or power failure, flooding, fire, etc.) that have not negatively impacted the welfare.
- Surgical complications such as anesthetic deaths, infection, or wound dehiscence that occur rarely. High complication rates will likely require a report to the IACUC.

If there is a question regarding the need for reporting, AEC veterinarians or Animal Welfare Program (AWP) staff will be able to provide guidance.

D. References

1. Animal and Plant Health Inspection Service, USDA. US Animal Welfare Act (AWA 1990) and Regulations (PL-89-544, as amended, 7USC Ch. 54) 2008. CFR Title 9, Subchapter A - Animal Welfare. U.S. Government Printing Office, Washington, D.C.
2. National Research Council. 2011. Guide for the Care and Use of Laboratory Animals. 8th Edition. The National Academies Press, Washington, DC.
3. Public Health Service Policy on Humane Care and Use of Laboratory Animals http://grants.nih.gov/grants/olaw/references/phspol.htm.
4. AAALAC International – Managing and Reporting Adverse Events
5. OLAW – Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals