

Oakland University
Institutional Animal Care and Use Committee (IACUC)
Guidance on Prompt Reporting of Unanticipated Problems and Unexpected Deaths of Research
Animals

The purpose of the guidance is to identify responsibilities and reporting requirements of Biomedical Research Support Facility (BRSF) staff, investigators and others in the event of an unusual or unexpected death (s), or unanticipated problem that affects the health or well-being of an animal involved in research, teaching, and testing.

Examples of situations that the *Office of Laboratory Animal Welfare (OLAW) would consider reportable include but are not limited to conditions that jeopardize the health or well-being of animals such as natural disasters, accidents, mechanical failures, or other unanticipated adverse events or problems resulting in actual harm or death to animals.

In contrast, examples of situations that OLAW does not consider to be reportable include the following:

- Death of animals that have reached the end of their natural life spans;
- Death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- Animal death or illness when appropriate quarantine, preventative medical, surveillance, diagnostic, or therapeutic procedures were in place and followed;
- Animal death or injuries related to manipulations that fall within the parameters described in the IACUC-approved protocol; or
- Infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause is water valves jammed with bedding (frequent problems of this nature, however, must be reported along with corrective action plans and schedules)

Any unanticipated problem affecting the health or welfare of an animal or an unexpected death of an animal must be immediately reported according to the following guidelines.

Unusual or unexpected animal death

All Oakland University individuals involved in animal care and use are required to immediately report an unusual or unexpected animal death. Timely reporting with sufficient detail is critical in determining the animal's cause of death and whether additional action must be taken to mitigate or prevent further harm to animals.

The death must be initially reported to the Principal Investigator and BRSF Manager. The BRSF Manager will be responsible for contacting the University Veterinarian by phone followed by e-mail. If the University Veterinarian cannot be reached within 4 hours of discovery of the dead animal, the incident must be reported to the Director of Regulatory Support followed by the Institutional Official. Based upon the animal's condition and other facts of the case, a determination will be made whether the substitute veterinarian needs to be notified in the University Veterinarian's absence.

Upon receipt of the initial report, the University Veterinarian will determine the next steps to be followed with regard to investigating the animal's cause of death including whether a member of the BRSF staff may perform a necropsy or the animal should be preserved until the University Veterinarian is able to personally perform the necropsy. If the University Veterinarian cannot be reached, these decisions will be made by the BRSF Manager in consultation with the Directory of Regulatory Support and/or the Institutional Official. If the animal is to be preserved, the animal carcass should be placed in a double plastic bag and placed in the refrigerator in Room 110 of the BRSF. The bag should be labeled with the date, the Principal Investigator's name and the IACUC approved protocol number. In the event of an unusual or unexpected death, a necropsy must be performed.

The University Veterinarian or designee performing the necropsy will prepare a written report of the findings which will be reported to the IACUC and maintained in the IACUC approved protocol file for the study. The OU IACUC Necropsy Reporting Form is recommended.

The animal death should also be documented on the animal's cage card, individual animal records, and on any relevant Principal Investigator records. Documentation should include the date and cause of death if known. The cage card should be updated to reflect the current number of animals remaining in the cage. The Principal Investigator must report the unusual or unexpected death to the IACUC within 24 hours of becoming aware of the death using the unexpected event reporting form. The BRSF Manager must notify the Institutional Official of the unexpected death. The Institutional Official will make a preliminary determination regarding whether the death must be reported to federal or other sponsoring agencies. The IACUC may require an investigation of the unexpected death, additional monitoring, a change in the protocol, or determine that no further action is required. The outcome of the IACUC's review will be documented in the meeting minutes and reported to the Institutional Official. If applicable, the Institutional Official will submit a follow up report to federal or other sponsoring agencies.

Unexpected Problems and Adverse Events

All individuals involved in the care and use of research animals are responsible for their well-being. The Principal Investigator and the BRSF Manager will be notified immediately by phone if any animal is identified to be experiencing an adverse event or possible unanticipated problem. An initial assessment will be made to determine if the animal can be successfully treated or if its condition is such that euthanasia is recommended. If it is determined that the animal will likely respond to treatment, the University Veterinarian will be contacted immediately to determine appropriate treatment. If it is deemed that the animal should be euthanized and the cause of the animal's condition is not apparent, a necropsy will be performed.

The adverse event should also be documented on the animal's cage card, individual animal records and on the Principal Investigator records. The issue should be followed until resolution.

Once the adverse event or problem has been addressed, the Principal Investigator must determine if the adverse event or problem is unanticipated. If the observed adverse event is determined to be unanticipated, the Principal Investigator must report the event to the IACUC within 24 hours of discovery using the, "OU IACUC Unanticipated Problems/Adverse Events and Unusual or Unexpected Report Notification" form. The IACUC will determine if the corrective action plan is appropriate, additional monitoring is needed, a change in the protocol is indicated, or no further action is required. The outcome of the IACUC's review will be documented in the meeting minutes and reported to the Institutional Official. If applicable, the Institutional Official will submit a follow up report to federal or other sponsoring agencies.

Important Numbers

- University Veterinarian: 248-884-2862
- IACUC Chair: 248-370-2532
- BRSF Manager: 248-370-4440

References

*Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals (NOT-OD-05-034)

Oakland University (OU)
Institutional Animal Care and Use Committee (IACUC)
Unanticipated Problems/Adverse Events and Unusual or Unexpected Report
Notification

Reporting Information

Date: _____

Reporting Individual: _____

E-Mail address: _____

Protocol Information

Principal Investigator: _____

Protocol number: _____

Protocol title: _____

Species: _____

Strain: _____

Date of birth: _____

Sex: _____

Unanticipated problem/adverse event/unusual or unexpected death

Date of problem/event/death: _____

Approximate time of event: _____

Location of event: _____

Number of animals involved: _____

Event:

Unanticipated problem/adverse event

Unusual or unexpected death

Prior to this event, note and describe any changes or abnormalities involving:

Water Consumption: _____

Food Consumption: _____

Urination: _____

Defecation: _____

Ambulation: _____

Was the unanticipated problem/adverse event/unusual or unexpected death related to the research?

Yes

No

Provide a description of the unanticipated problem/adverse event/unusual or unexpected death:

Provide a description of how the unanticipated problem/adverse event/unusual or unexpected death was managed: _____

Provide a corrective action plan to describe how this unanticipated problem/adverse event/unusual or unexpected death will be prevented from occurring in the future: _____