UNIVERSITY of WISCONSIN
UWMILWAUKEE

Institutional Animal Care & Use Committee

IACUC Guidance on Prompt Reporting of Adverse Events and Unexpected Outcomes at UWM

Last Review Date: 4/2022

Revision History:

What is an unexpected outcome?

Unexpected outcomes are undesirable effects that result from or occur during or following, a research procedure or teaching activity (e.g., use of a mediation, medical device, or other biological product, surgical procedure, handling, pilot study, genetically modified animals, etc.). These undesirable effects negatively impact animal welfare and were not expected or anticipated during the planning of the research. They may or may not be caused by a product or device.

Who should report unexpected outcomes?

Unexpected outcomes should be reported by anyone who encounters them to the principal investigator for the protocol that covers the affected animal(s).

What are examples of unexpected outcomes that must be reported?

- **Use of a pilot study**; when outcomes of the pilot study are different than the anticipated outcomes written in the protocol.
- **Use of genetically modified organisms**; where there is inherent potential for unanticipated phenotypes. Regardless of whether genetic manipulation is targeted or random, the phenotype that initially results is often unpredictable and may lead to expected or unexpected outcomes that affect the animal's well-being or survival at any stage of life.
- **Deaths of animals not expected or described in the protocol or when a significant number of animals die**; e.g. the majority of the animals in the protocol become sick immediately after shipping due to weather conditions when they arrive; an animal is found dead the day after surgery; significant loss of life due to a disease outbreak.
- **More death or complications than described in the protocol**; e.g., 10% of the animals die following surgery when a 5% mortality rate was expected and

justified in the animal care and use proposal; an animal appears to be in more pain or distress from a procedure than expected.

- **Study-related complications not expected as part of the research design**; e.g. an animal has an allergic reaction to a treatment; anesthetic approved for the study doesn't adequately work; animals develop an infection following surgery.

How do I avoid making many reports for things that normally happen?

A report is not required if the IACUC is aware that an adverse event may occur and the event has happened as was described in the approved protocol. If an investigator expected certain complications to occur as a result of research or teaching procedures, based upon their experience, the literature or current knowledge, those complications should be identified and explained as a possible adverse events in the protocol. For example, list potential mortalities from induced infection, expected death loss or other outcomes in the clinical signs that would warrant removal from study or euthanasia in the protocol.

What information needs to be reported?
The report should include the nature of the event, how the event and animal welfare were monitored or addressed, and what immediate and long-term steps are being taken or considered to prevent reoccurrence of the event. The Unanticipated Outcomes Form is available on the Animal Care Program website: IACUC Forms, in I-Manager, and on the aquatic SharePoint site to assist investigators in reporting adverse events and unanticipated outcomes.

Why should unexpected outcomes be reported?

The IACUC is responsible for monitoring the animal research and teaching activities described in the IACUC-approved protocol. Reporting unexpected outcomes assists the IACUC in this role. It also allows principal investigators, animal care staff, and the attending veterinarian to evaluate the cause of unexpected outcomes and consider changes in the protocol or standard operating procedures to prevent reoccurrence.

What is the IACUC process for review of unanticipated outcomes/problems, adverse events?

All adverse event or unexpected outcomes are forwarded to the IACUC for their information and are placed on the agenda for the next meeting following receipt. The IACUC Chair and Attending Veterinarian review the report to determine if immediate review is needed. If IACUC members are satisfied that the event has been appropriately addressed, the report will be filed with no further action taken; the principle investigator

will be notified of the committee's decision. If IACUC members have concerns regarding the resolution to the unexpected outcome, the IACUC will initiate communications with the investigator. The principle investigator is welcome to attend the IACUC meeting at which the report will be reviewed.

What if an adverse event occurs that negatively impacts animal welfare but is not related to research or teaching procedures?

Adverse events that occur which are not related to research, or teaching procedures that jeopardize the health and well-being of animals, should be reported to the IACUC. Generally, the individual responsible for oversight of a laboratory should inform the IACUC of the adverse events.

Examples of adverse events include:

- Facility or equipment failure has, or may have an impact on animal welfare
- Poor facility, husbandry, or care has, or may have, an impact on animal welfare

Who is responsible for ensuring that animals are shipped safely and for reporting adverse events that occur during shipping of animals to or from UWM?

The Office of Laboratory Animal Welfare (OLAW), Department of Health and Human Services, guidance indicates that "OLAW expects all partied involved to apply due diligence in assuring that animals are shipped under appropriate conditions to prevent morbidity or mortality due to temperature extremes or other adverse events. OLAW expects shipping institutions to report adverse events that occur to animals in transit. Receiving institutions should notify the shipping institution when animals are received in extremis or dead."