

Animal Care and Use Program Policy



Unexpected Experimental Outcomes

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Background

The Guide indicates that fundamental to scientific inquiry is the investigation of novel experimental variables which may affect animal wellbeing. There is a potential for unexpected outcomes when such variables are introduced.

Scope

This policy applies to all teaching and research activities involving animals at OHSU. Examples of unexpected outcomes which must be reported include, but are not limited to, the following:

- I. An unexpected phenotype arising from a genetic modification or mutation that negatively affects animal well-being;
- II. Physical restraint that results in lesions, illness, or behavioral changes;
- III. When discovered, a higher than expected morbidity or mortality rate (e.g. recurrent post-surgical infection in multiple animals).

Policy

- I. It is the responsibility of the Principal Investigator or designee to promptly report any unexpected outcome(s) that may negatively affect animal health or wellbeing.
- II. Any unexpected outcome(s) should be reported as described below under Procedures as soon as possible after the occurrence.
- III. All unexpected outcomes will be presented to the IACUC Leadership Team (ILT) and the responsible IACUC. The responsible IACUC will determine if proactive measures are needed to circumvent or alleviate the impact of the unexpected outcome on animal wellbeing.

Procedures

- I. Unexpected outcomes should be reported via email or telephone call to any of the following: DCM veterinary staff; IACUC office; Research Integrity Officer (RIO); or IACUC Chair.
- II. The RIO for the campus on which the unexpected outcome occurred will be responsible for assuring that the ILT and appropriate IACUC are made aware of the event.

Definitions

Unexpected outcome - Any effect of an experimental or teaching procedure which is not described in the protocol or anticipated during the planning of the research that negatively affects animal wellbeing.

Responsible IACUC - determined by the location where the animals are housed.

Morbidity - the relative incidence of disease, is a diseased state, disability, or poor health due to any cause, The term may be used to refer to the existence of any form of disease, or to the degree that the health condition affects the patient.

Mortality - death; the state of being mortal, or susceptible to death;

Authority

PHS Policy

AWA Regulations

References

Guide for the Care and Use of Laboratory Animals 2011, *Unexpected Outcomes*, p. 28-29.