

WVU IACUC POLICY: Unexpected Outcomes

Background

Use of animals in research may occasionally result in adverse events or unanticipated outcomes which inflict pain, distress or even death on the animal subjects. In order to meet the obligations of our assurance to the National Institutes of Health, Office of Laboratory Animal Welfare and our licensure with the United States Department of Agriculture, West Virginia University must have a mechanism for reporting these events in a timely manner. More importantly, the IACUC, in its oversight of animal care and use, must ensure there is a clear path to report these events to provide the highest quality animal care.

Definitions

An adverse event or unexpected outcome is defined as any unfavorable or unanticipated outcome that results in or causes the welfare of an animal or animals to become compromised. Examples of adverse events include, but are not limited to:

1. Life threatening birth defects discovered after creating or breeding genetically modified animals.
2. Unanticipated animal morbidity or mortality in excess of expected morbidity or mortality commensurate with approved activity/protocol.
3. Unforeseen events such as equipment failure or natural disaster that lead to the harm of animals, or that cause obvious distress not scientifically justified and approved in the protocol.
4. Unintentional or negligent misuse or accidents that negatively impact animal welfare and as such cause animal major distress, pain, morbidity or mortality.

Policy

All adverse events must be reported in writing by the principal investigator to the IACUC Chair and/or the Animal Compliance and Training Officer within 72 hours of the occurrence. This written statement must include a detailed description of the adverse event/unexpected outcome and actions taken to eliminate, modify or mitigate a repetition of the event/outcome.

Relevant Regulations and References:

1. NIH. 2002. IACUC Guidebook. NIH Office of Laboratory Animal Welfare., Washington, DC.
2. NAS. 2011. *Guide for the Care and Use of Laboratory Animals*. National Academy of Sciences Press, Washington.
3. APHIS Animal Care Policy #11
4. Public Health Service (PHS) Policy (IV,C,1,a-c)
5. Animal Welfare Act Regulations (AWAR) §2.31(d)(1) & (5)