WVU IACUC POLICY:
Reporting Adverse Events/Unexpected Outcomes Policy

Background

The use of animals in research may occasionally result in an adverse event or unexpected outcome which may inflict pain, distress or even death upon the animal subject. In order to meet the obligations of our assurance to the Office of Laboratory Animal Welfare (OLAW) and our registration with the United States Department of Agriculture (USDA), West Virginia University must have a mechanism for reporting these events in a timely manner. The IACUC, in its oversight of animal care and use, must ensure there is a clear path to report these events in order to provide the highest quality animal care.

Definitions

An adverse event or unexpected outcome is defined as any event or outcome that results in or causes the welfare of an animal(s) 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 corresponding with an activity or procedure.
3. Unforeseen events, such as equipment failure or biological events, that lead to the harm of animals or that causes obvious pain/distress not scientifically justified and approved in the protocol.
4. Unintentional human error or accidents that negatively impact animal welfare and as such may cause animal distress, pain, morbidity or mortality.

Policy

All adverse events should be reported to the IACUC Chair and/or the Office of Research Integrity and Compliance (ORIC) and/or the Attending Veterinarian (AV) within a reasonable time frame post-discovery of the event or outcome. An “Adverse Events and Unexpected Outcomes Reporting Form” is available on the ORIC website under Reporting Concerns. If you have any questions or concerns regarding this policy or the reporting form, please contact the ORIC office at acuc@mail.wvu.edu or call 304-293-7073.

Relevant Regulations and References:

2. Public Health Service (PHS) Policy (IV,C,1,a-c)
3. Animal Welfare Act Regulations (AWAR) §2.31(d)(1) & (5)