Institutional Animal Care and Use Committee
Clemson University

POLICY #27: INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
POLICY FOR REPORTING ADVERSE EVENTS OR UNEXPECTED OUTCOMES

Use of animals in research may occasionally result in adverse events or unanticipated outcomes which inflict pain, distress or even death on our animal subjects. In order to meet the obligations of our assurance to the National Institutes of Health, Office of Laboratory Animal Welfare, our licensure with the United States Department of Agriculture and our accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care, International, Clemson 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 in order to provide the highest quality animal care.

1.1 An adverse event or unexpected outcome is defined as any unfavorable or unexpected outcome that results in or causes the welfare of an animal or animals to become compromised. Adverse events are reported by the principal investigator. Examples of an adverse event include, but are not limited to:
   A. Life threatening birth defects discovered after creating or breeding genetically modified animals
   B. Unanticipated animal morbidity or mortality in excess of expected morbidity or mortality commensurate with approved activity/protocol.
   C. Unforeseen events such as equipment failure or natural disaster that lead to the harm of animal(s) or that cause obvious distress not justified and approved in the protocol
   D. Unintentional or negligent misuse or accident that results in animal morbidity or mortality or negatively impacts animal welfare.

1.2 A separate policy exists for reporting animal concerns (IACUC Policy #15 for Reporting and Investigating Animal Concerns). Animal concerns are usually reported by persons who are concerned about compliance with animal welfare regulations. Mistreatment of animals is a form of non-compliance but the broader definition includes any animal use activity not approved by the IACUC.

1.3 All adverse events/unexpected outcomes should be reported in writing by the PI to the Attending Veterinarian and the IACUC Administrator within 72 hours of occurrence. This written statement should describe the adverse event/unexpected outcome in detail and any actions taken to eliminate, modify or mitigate a repetition of the event/outcome.