



# SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

## Institutional Animal Care & Use Committee

<b>IACUC Policy #:</b>	<b>550</b>
<b>Policy Title:</b>	<b><i>Policy on Unexpected Outcomes of Genetically Modified Animals</i></b>
<b>Date Approved:</b>	<b>July 15, 2019</b>
<b>Date Reviewed:</b>	<b>May 15, 2024</b>
<b>Who must know:</b>	<b>Principal investigators, personnel, and/or researchers who work with genetically modified animals</b>

### **Purpose:**

As per the “*Guide for the Care and Use of Laboratory Animals*”, 8<sup>th</sup> Edition (The Guide), policies and procedures must be in place to monitor the phenotype of genetically modified animals (GMAs). This policy applies to situations that include, but are not limited to, breeding of GMAs or crosses between strains of animals that produce phenotypes for which the corresponding IACUC protocol contains no provision for clinical care or experimental endpoints.

### **Definitions:**

Adverse Event: the occurrence of an unforeseen event that negatively impacts the welfare of the research animal(s), involving pain and/or death of the animal. AEs are not identified as potential risks or outcomes in the approved IACUC protocol and are due to the animal’s genotype.

Researchers: in addition to principal investigators and other personnel, the term researcher also includes volunteers and/or students approved to complete research in the designated protocol.

### **Policy:**

1. All novel GMAs should be monitored for the development of unexpected phenotypes.
2. Adverse events should be reported within one week of being discovered; this report must contain a detailed description of the event and should be emailed to the IACUC office (IACUC@siu.edu).
3. If unexpected phenotypes are identified as described below under “Phenotypic Monitoring” then additional monitoring and analysis may be warranted. This should lead to a better understanding of the condition and could result in steps that can be taken to better define humane endpoints for the line in question. It is expected that the Attending Veterinarian (AV) is consulted.
4. Phenotypes that are highly recurrent within a given line should be described in an amendment to the IACUC protocol to avoid the necessity of continued reporting. Once the amendment is approved, the phenotypic condition will not be subject to further reporting as it is no longer unexpected.



# SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

## Institutional Animal Care & Use Committee

### Phenotypic Monitoring

The *Guide* outlines the responsibilities of the Principal Investigator (PI) and the IACUC regarding the generation of novel GMAs, either by creation of a new line, or by intercrossing established lines to generate a new compound genotype.

The following points should be noted:

Examples of events that are required to be reported as AEs:

- a. Animal mortality or morbidity in excess of that described in the approved IACUC protocol.
- b. Unforeseen events that lead to pain or death of the animal(s) not justified and approved in the protocol.

Examples of events that are not required to be reported as AEs:

- a. Injury/illness unrelated to approved procedures and being treated by the Attending Veterinarian (AV).
- b. Death due to reasons unrelated to the animal's genotype.
- c. Death or morbidity of animals described in the approved IACUC protocol.

### **References**

National Research Council. (2011). *Guide for the care and use of Laboratory Animals (8 eds.)*.

The National Academies Press.

<https://nap.nationalacademies.org/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth>

Ormandy, E. H., Dale, J., & Griffin, G. (2011). Genetic engineering of animals: Ethical issues, including welfare concerns. *The Canadian veterinary journal* 52(5), 544–550.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078015/>