

# IACUC Policy on Genetically Modified Animals and Unexpected Outcomes

## Background:

Fundamental to scientific inquiry is the investigation of novel experimental variables. Because of the potential for unexpected outcomes that may affect animal well-being when highly novel variables are introduced, more frequent monitoring of animals may be required. With their inherent potential for unanticipated phenotypes, genetically modified animals (GMAs) are an example of models for which increased monitoring for unexpected outcomes could be implemented

## Policy:

1. The first offspring of a newly generated genetically modified animal line should be carefully observed from birth into early adulthood for signs of disease, pain, or distress. Investigators may find that the phenotype precludes breeding of particular genotypes or that unexpected infertility occurs, situations that could lead to increases in the numbers of animals used and revision of the animal use protocol.
2. When the initial characterization of a genetically modified animal reveals a condition that negatively affects animal well-being, this should immediately be reported to the IACUC, and more extensive analysis may be required to better define the phenotype. Such monitoring and reporting may help to determine whether proactive measures can circumvent or alleviate the impact of the genetic modification on the animal's well-being and to establish humane endpoints specific to the genetically modified animal line.