Institutional Animal Care and Use Committee
Clemson University

POLICY #31: INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
POLICY FOR THE USE OF GENETICALLY MODIFIED ANIMALS (GMAs)

Background:

Based on the eighth edition of “The Guide for The Care and Use Of Laboratory Animals”, the IACUC must have policies and procedures in place to require: 1) monitoring of the phenotype and genotype of genetically modified animals and, 2) a reporting process to notify the IACUC of unexpected phenotypic outcomes that adversely affect the health and well-being of the animals.

IACUC Considerations:

When animals are genetically modified in a targeted or random fashion the phenotype is often unpredictable and may produce pain, distress or affect ability to grow and thrive. Therefore, when new genotypes are created, and there is a possibility of anatomical, behavioral or metabolic defects that could cause pain or distress, these animals must be monitored closely. The parameters monitored should include morbidity, mortality, development, anatomic/histologic abnormalities, teratogenicity, and lifespan in addition to those listed in the chart below. Additional analysis may be necessary to define the phenotype and determine if proactive measures can alleviate the impact of the genetic modification on the animal’s well-being and to establish humane endpoints. The following parameters are guidelines to consider when monitoring animals with unknown phenotypes, and should be modified according to the specific body systems affected.

1. Appropriate containment of these animals must be assured to avoid unintended sexual contact with other animals or possible transfer of either altered genetic material or viral vectors to human personnel or other animals.

2. When studies using these animals are completed, the animals should not be transferred or donated to zoos or other shelters as food for other animals or for other purposes. Normally the only transfer of genetically altered animals will be to other investigators who can guarantee the same level of care and containment required of investigators at Clemson University. The recipient of the animals must be notified that the animals are genetically altered.

3. When a genetically altered strain is to be produced here at Clemson University, the procedures must be reviewed and approved by the IBC, including those that will be used in the analysis of the resulting phenotypes.

4. The investigator should consider any adverse clinical effects that might result from the genetic manipulation, understanding that adverse effects cannot always be anticipated.

5. Close surveillance of genetically altered animals is critical. When the strain is developed at Clemson University, this surveillance should include necropsy of some representative animals. The results of this surveillance should be shared among the investigators, animal care personnel, and the IACUC. It is the
investigator's responsibility to monitor these animals and communicate with the veterinary staff and the IACUC.

6. All novel GMAs should be monitored a minimum of once daily in the F1 generation for the development of unexpected phenotypes.

7. All unexpected phenotypes which affect the health and well being of the animal would be considered a reportable event, and should thus be reported to the IACUC following Policy #27: Policy for Reporting Adverse Events or Unexpected Outcomes

Resources:

Adapted from Texas A&M IACUC Policy on Genetically Altered Animals