POLICY REGARDING GENETICALLY MODIFIED ANIMALS

PURPOSE:

This policy serves to establish specific considerations that must be made in animal use protocols involving genetically modified animals (GMAs). This applies to all instances involving genetically modified animals, including transgenic or targeted mutations created to study gene expression. The Guide states: "With their inherent potential for unanticipated phenotypes, GMAs are an example of models for which increased monitoring for unexpected outcomes could be implemented."

POLICY:

Protocols that utilize genetically modified animals must consider the following criteria when designing protocols:

- The effect that the genetic modification will have on the health of the animal must be described in detail. If this is a new modification and the health effects are unknown, describe the likely health outcomes of the genetic change according to current understanding of the gene in question and the disease state under study.
- Endpoints to address potential or known adverse health effects:
    - The PI must provide general humane endpoints in case a severe debilitating phenotype develops and should provide the IACUC with this information in writing when the new mutant has been developed or at the next annual review of the protocol.
    - Endpoints are relevant both in the context of experimental procedures and with regard to the potential pain or distress that is caused by the genetic modification itself.
    - The protocol should include endpoints for the initial phase of the study when the phenotype of new genetic modification is being characterized, as well as for later phases of the study for both experimental and non-experimental (i.e. breeding) animals.
- Animal number estimates for each phenotype
- Institutional Biosafety Committee considerations, including:
    - Function of the gene being inserted, or the biological effect of the knock-out gene
    - Risks associated with the GMA that may create a greater hazard for personnel
    - If GMAs are being bred, what is the expected biological outcome of the novel strain

Any newly developed genetically modified animals that have not previously been characterized must be closely scrutinized for general health and behavioral abnormalities that may impact the animal's well-being.

Many GMA's have already been developed and characterized. For animals with a known phenotype, a maximum holding period should be set to avoid the development of known or predictable problems in strains that have debilitating phenotypes.