Policy 308

Genotypic and Phenotypic Monitoring of Genetically Modified Animals (GMAs)

Responsible Official:	Research Administration
Administering Division/Department:	IACUC / Research Compliance and Regulatory Affairs
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308.1 Policy

The Emory Institutional Animal Care and Use Committee (IACUC) is under a federal mandate to monitor all research activities related to animal use. Pursuant to the eighth edition of "The Guide for The Care and Use Of Laboratory Animals (Guide)," policies and procedures must be in place to monitor the phenotype and genotype of genetically modified animals (GMAs) and a reporting process must be in place to notify the IACUC of unexpected phenotypic outcomes that adversely affect the health and well-being of the animals.

308.2 Phenotypic Monitoring:

Pages 28-29 of the eighth edition of the Guide outline the responsibilities of the Principal Investigator (PI) and IACUC in regard to 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:

308.2.1 All novel GMAs should be monitored in the F1 generation for the development of unexpected phenotypes. Animals should be monitored in the F1 generation for the development of unexpected phenotypes from birth to early adulthood.

308.2.2 All unexpected phenotypes which affect the health and wellbeing of the animal would be considered a reportable event and should thus be reported to the IACUC on the attached form in a timely fashion. [Note that any phenotype which has been previously described in your approved IACUC protocol is not unexpected and is thus not reportable].

308.2.3 If unexpected phenotypes are identified as above, 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 alleviate the impact of the alteration, or to better define humane endpoints for the line in question.

308.2.4 All instances of events as defined above must be reported. Therefore, phenotypes which are highly recurrent within a given line should be described in an IACUC modification to avoid the necessity of continued reporting. Once the modification is approved, the phenotypic condition will not be subject to further reporting as it is no longer unexpected.

308.3 Genotypic Monitoring:

Pages 76-77 of the eighth edition of the Guide provide guidance as to "best practice" in regard to genotypic monitoring and screening of GMAs. Specifically, the following are indicated for inbred strains:

308.3.1 It is important to periodically monitor genetic authenticity of the line.

308.3.2 Appropriate management systems should be designed to minimize genetic contamination resulting from mutation and mismatching.

308.3.3 Each GMA line represents a unique resource and thus care should be taken to preserve the line through standard colony management programs. Cryopreservation of lines should be considered as a safeguard against the loss of lines, and as a protection against genetic drift over time.

308.3.4 Carefully designed breeding strategies and accurate genotype assessment should be ensured to minimize the generation of animals with unwanted phenotypes.

308.4 Principal Investigator Responsibilities:

The expectation of the IACUC is that all PIs follow the guidelines in reporting unexpected phenotypic events in a prompt manner, and to amend their IACUC protocols appropriately for ongoing strain characteristics. It is the opinion of the IACUC that proper genetic monitoring of GMAs represents true best practice but is left to the jurisdiction of the PI of exactly how that is accomplished for each colony of breeding animals. Thus, all three-year renewal protocols will ask the PI to provide assurance that best practices are followed.

308.5 Refer to the Adverse Events Policy for submission of any Adverse Event related to Genotype/Phenotype (Adverse Events Report Form (PDF))

Contact Information

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