BROWN

Institutional Animal Care and Use Committee (IACUC)

Policy on Unanticipated Outcomes of Genetically Modified Animals

Date of IACUC Review and Approval: June 1, 2018

I. Purpose

Pursuant to the eighth edition of "*The Guide for The Care and Use of Laboratory Animals* (the *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. This policy applies to situations that include, but are not limited to, breeding of transgenic animals or crosses between strains of animals that produce phenotypes for which the corresponding IACUC protocol contains no provision for clinical care or experimental endpoints.

II. 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:

1. All novel GMAs should be monitored in the F1 generation for the development of unexpected phenotypes.

2. All unexpected phenotypes which affect the health and well-being of the animal are considered a reportable event, and should thus be reported to both the veterinary care staff and the IACUC using its Adverse Event Reporting Form. [Note that any phenotype which has been previously described in your approved IACUC protocol is not unexpected and is thus *not reportable*.]

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. It is expected that the veterinarians will be consulted to identify means of alleviating any pain or distress associated with the phenotype.

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.

III. Applicable Regulations

1. Guide for the Care and Use of Laboratory Animals: 8th edition. 2011. National Research Council. Washington: National Academies Press.