

 <b>BROWN</b>	<b>Institutional Animal Care and Use Committee (IACUC): Policy on Unanticipated Outcomes of Genetically Modified Animals</b>	POL 10.10.33
		Effective Date: May 30, 2022

### 1.0 Policy Purpose

The purpose of this policy is to provide guidance to research personnel regarding breeding of transgenic animals or crosses between strains of animals that produce phenotypes for which the corresponding IACUC animal use protocol contains no provision for clinical care or experimental endpoints.

### 2.0 To Whom the Policy Applies

This policy applies to all individuals using live vertebrate animals under an IACUC-approved animal use protocol at Brown University.

### 3.0 Policy Statement

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.

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.

All novel GMAs must be monitored in the F1 generation for the development of unexpected phenotypes. All unexpected phenotypes that affect the health and well-being of the animal are considered a reportable event, and must be reported to both the Center for Animal Resources and Education (CARE) and the IACUC using the Adverse Event Reporting Form. Any phenotype that has been previously described in the approved IACUC protocol is not unexpected and is thus not reportable.

If unexpected phenotypes are identified, then additional monitoring and analysis may be warranted as determined by a Brown veterinarian or requested by the IACUC. Additional monitoring and analysis could lead to a better understanding of the condition and result in actions that may alleviate the impact of the alteration or better define humane endpoints for the line in question. Brown veterinarians must be consulted by the research team to identify means of alleviating any pain or distress associated with the phenotype.

Phenotypes that are highly recurrent within a given line must be described in a modification to the corresponding approved IACUC animal use protocol 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.

### 4.0 Definitions: N/A

### 5.0 Responsibilities

All individuals to whom this policy applies are responsible for becoming familiar with and following this policy. University supervisors are responsible for promoting the understanding of this policy and for taking appropriate steps to help ensure compliance with it.

## 6.0 Consequences for Violating this Policy

Violation of this policy may be considered a serious event of noncompliance that is reportable to the IACUC, funding and accrediting agencies, as well as other regulatory agencies. Violations of this policy are a serious matter that may adversely affect both the ability to perform animal work and acquire funding sources.

Failure to comply with this and related policies is subject to disciplinary action, up to and including suspension without pay, or termination of employment or association with the University, in accordance with applicable (e.g., staff, faculty, student) disciplinary procedures.

## 7.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, [Brown's Anonymous Reporting Hotline](#) allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this policy and is not an all-inclusive list of policies, procedures, laws and requirements.

**7.1 Related Policies:** N/A

**7.2 Related Procedures:** N/A

**7.3 Related Forms:** N/A

**7.4 Frequently Asked Questions (FAQs):** N/A

**7.5 Other Related Information:** References

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

## 8.0 Policy Owner and Contact(s)

**8.1 Policy Owners:** Vice President for Research

**8.2 Policy Approved by:** Vice President for Research

**8.3 Subject Matter Contact:** Brown University Animal Research Compliance (ARC) Program

- Email: [IACUC@Brown.edu](mailto:IACUC@Brown.edu)
- 401-863-3050

## 9.0 Policy History

**9.1 Policy Issue Date:** June 1, 2018

**9.2 Policy Effective Date:** May 30, 2022

**9.3 Policy Update/Review Summary:** This policy is not new; it was converted to the University's new policy template and re-reviewed by the IACUC at its convened meeting on June 4, 2021. Previous version superseded by this version:

- IACUC Policy on Unanticipated Outcomes of Genetically Modified Animals, date of IACUC review and approval: June 1, 2018.