

PURPOSE

This policy describes the procedures for the review and approval of all scientific research at the University of Missouri that includes the use of transgenic animals, including production and breeding, by the Institutional Biosafety Committee in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

DEFINITIONS

IBC: Institutional Biosafety Committee. This committee meets the requirements for membership specified in Section IV-B-2 of the NIH Guidelines and reviews, approves, and oversees projects in accordance with the responsibilities defined therein.

NIH: National Institutes of Health

ACUC: Animal Care and Use Committee. This committee is responsible for reviewing and approving all protocols involving live vertebrate animals, ensuring compliance with federal regulations, inspecting animal facilities and laboratories and overseeing research, training, and educational programs.

Transgenic animal: An animal that carries a foreign gene deliberately inserted into its genome

Recombinant and synthetic nucleic acids: In the context of the NIH Guidelines, these are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules, and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or (iii) molecules that result from the replication of those described in (i) or (ii) above.

SCOPE

All University of Missouri Principal Investigators and research staff must comply with this policy, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and all other applicable University of Missouri research policies. Research activities that involve transgenic animals in any way, including breeding and producing transgenic animals by use of DNA technologies described in the NIH Guidelines, must be reviewed and approved by the IBC.

This policy does not apply to the following exempt activities:

- the purchase or transfer of transgenic rodents that require ABSL1 containment
- the breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at ABSL1 containment if:
 - o both parental rodents can be housed under ABSL1 containment, and
 - o the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses, and
 - o neither parental transgenic rodent contains the following genetic modifications:

- o incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, or
- o incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat

POLICY

Research activities that involve the use of transgenic animals on the University of Missouri campus require registration with and approval by the Institutional Biosafety Committee. This includes the creation of new strains through the breeding of existing transgenic strains or transgenic and wild type animals. Before initiating any research project that involves the purchase, transfer, or generation of whole transgenic animals (except those described above as exempt), the Principal Investigator must:

1. Apply and obtain approval from the IBC and ACUC . Both applications are available electronically at <https://ecompliance.missouri.edu/>.
2. If transgenic animals or their fluids or tissues will be shipped between the University of Missouri and scientists at other institutions or companies, investigators must have the appropriate agreements, permits, and Department of Transportation training to ship and/or receive the animals or materials. International shipments may require special review due to import/export requirements.
3. Describe in research application materials the disposal method for all classes of investigational animals and animal products. These materials must be disposed of in a way that prevents any product from the transgenic animal from entering the food or feed supply. The recommended method of disposal is through incineration, but other methods may be available, e.g., composting and burial.

This requirement applies to transgenic animals, potentially transgenic animals, “no-takes” in the production of transgenic animals, and progeny of transgenic animals. Appropriate records are to be kept of animal identification and disposition.

4. Report any inadvertent release of transgenic animals, improper disposal of transgenic animals or other incidents in the laboratory or vivaria to the Biosafety Officer, who shall report them to the IBC, MU Attending Veterinarian and, if necessary, the NIH.

REFERENCES

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#)

Experiments that Require Institutional Biosafety Committee Approval Before Initiation – Section III-D of NIH Guidelines

Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation – Section III-E of NIH Guidelines

Exempt Experiments – Section III F of NIH Guidelines

NIH FAQ on Genetically Modified Animals :<https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/faqs-for-research-on-genetically-modified-transgenic-animals-may-2019/>

If there are any questions regarding this policy, please contact the Biosafety Professional at 882-7018.