Genetically Modified Animals
Transgenic Animals

***Purpose***

*The purpose of this guidance document is to assist investigators, the IACUC, and the IBC in evaluating the biological risks when creating and/or breeding genetically modified animals (GMAs).*

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# Definitions

**Genetically Modified Animals (GMA) or Transgenic Animals** are any whole vertebrate animal in which the animal's genome has been altered by stable introduction of recombinant DNA into the germ-line of the animal.

# Regulatory Requirements

All activities that are conducted with the goal of producing transgenic animals by use of recombinant or synthetic DNA technologies, as described in the NIH guidelines must be reviewed and approved by the Institutional Biosafety Committee (IBC), and in addition the Institutional Animal Care and Use Committee (IACUC) if using vertebrate animals. This includes all methods for producing transgenic animals, including but not limited to DNA microinjection, retrovirus-mediated gene transfer, embryonic stem cell mediated gene transfer.

# The role of the IACUC and IBC

Physical and Biological Containment Levels: The containment levels required for research involving rDNA associated with or in animals, is based on the experiments as described/outlined in Section III of the NIH Guidelines. For physical containment of smaller animals there are four containment levels established in Appendix G of the NIH Guidelines (BL1, BL2, BL3 and BL4). For larger animals such as cattle, swine, sheep, goats, horses and poultry there are also four containment levels outlined in Appendix Q (BL1–Animals (N), BL2-N, BL3-N and BL4-N).

The physical and biological containment levels for experiments involving Whole Transgenic Vertebrate Animals must conform to NIH Guidelines.

**NOTE:** the purchase or transfer of commercial whole transgenic rodents is exempt from IBC review under the NIH Guidelines [Section III-D-4-c (2) and Appendix C-VII].

## Section III-E-3 - Experiments Involving BL1 Containment Transgenic Rodents

This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section

## Section III-D-4 - Experiments Involving BL2, BL3, or BL4 containment Whole Transgenic Animals

This section covers experiments involving **whole vertebrate animals** in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA inserted into or derived from the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.

**Note:** Designations such as “whole transgenic animals” and “whole animals” include transgenic rodents for this section unless covered in Section III-E-3 “Experiments Involving Transgenic Rodents (BL1) as described above.

# Instructions for Compliance

Before initiating any research project that is expected to generate whole transgenic vertebrate animals the Principal Investigator must conduct the following steps:

1. The PI must receive approval via application from the IACUC and IBC.
2. Based on the application, the IBC will determine the extent of institutional evaluation, and if the project requires review by the NIH Office of Biotechnology Activities (OBA).
3. Before transgenic animals or their tissues can be shipped or sold outside of the university the IBC and IACUC (if vertebrate animals) must grant approval for shipment. International shipments may require special review due to export requirements.
4. Any breeding of transgenic, non-rodent vertebrate animal species (including but not limited to sheep, cows, pigs and other large vertebrate animals) requires registration and approval by the IBC and IACUC.
5. Any cross-breeding of two or more different transgenic vertebrate animal models requires registration and approval of the IBC and IACUC.

# References

*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, April 2016. <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html>