

IBRDSC Policy

Transgenic Animals

Adopted May 29, 2012

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

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.

All activities that are conducted with the goal of producing transgenic animals by use of recombinant DNA technologies described in the NIH guidelines, must be reviewed and approved by the IBRDSC and IACUC. Methods for producing transgenic animals: DNA microinjection, retrovirus-mediated gene transfer and embryonic stem cell mediated gene transfer.

Physical and Biological Containment Levels: The containment levels required for research involving rDNA associated with or in animals, is based on the experiments in **Section III of the NIH Guidelines**. For physical containment of smaller animals there are 4 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 4 containment levels outlined in **Appendix Q** (BL1–Animals (N), BL2-N, BL3-N and BL4-N).

Experiments Involving Transgenic Rodents and Animals:

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

Section III-E-3: Experiments Involving Transgenic Rodents (BL1)

“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; experiments that require BL2, BL3, or BL4 containment are covered under Section III-D-4, Experiments Involving Whole Animals.”

Section III-D-4: Experiments Involving Whole Transgenic Animals

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

- III-D-4-a: Whole Animal Experiments that do not use Risk Group 2-3 organisms. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study.
- III-D-4-b: Whole Animal Experiments that do use Risk Group 2-3 organisms. For experiments involving recombinant DNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III-D-1, Experiments Using Human or Animal Pathogens (Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems the appropriate containment shall be determined by the Institutional Biosafety Committee.

Please 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 shown above. "Caution – Special care should be used in the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions."

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 complete an Institutional Animal Care and Use Committee (IACUC) application form which will allow the IACUC to review the animal usage. They must also register the project with the IBRDSC.
2. In accordance with IBRDSC Policy, the IBRDSC registration form must include the following information:
 - the purpose of the project
 - animal species
 - transgene name

- transgene function
 - transgene source
 - vector(s) used
 - method of animal transformation
 - physical location of the laboratories and research animals at LSU
 - indication if the gene encodes a toxin or other hazardous agent
 - method of disposal
3. Based on the information on the registration form, the IBRDSC will determine the extent of institutional review. In some instances, the project may need to be referred to the NIH Office of Biotechnology Activities (OBA) for review.
 4. Before transgenic animals or their tissues can be shipped to or from the University or scientists at other institutions, the IBRDSC registration form must clearly describe the animals and/or animal tissues, and include but not be limited to, gene constructs, plasmids and genetic changes in the animals. International shipments may require special review due to export requirements.
 5. When any transgenic animal is euthanized or dies, the carcass must be disposed of by incineration (recommended) or digestion. This disposal requirement applies to transgenic animals, potentially transgenic animals, "no-takes" in the production of transgenic animals, and progeny of transgenic animals. There are no exceptions to this policy without review and written approval from the IBRDSC.
 6. The PI is responsible for reporting the inadvertent release of transgenic animals, improper disposal of transgenic animals or other incidents in the laboratory or vivarium to the Biosafety Professional, who shall report them to the IBRDSC, attending Veterinarian and to the NIH, if necessary.
 7. The PI is responsible for training graduate students, teaching assistants and staff about the policies and procedures for transgenic animal handling and appropriate carcass disposal.
 8. 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 IBRDSC and IACUC. The IBRDSC shall refer to Appendix G and Q of the NIH Guidelines to determine appropriate containment.

9. Any breeding of two different transgenic vertebrate animal models requires registration and approval of the IBRDSC and IACUC. The IBRDSC may refer to Appendix G and Q of the NIH Guidelines as necessary to determine appropriate containment.
10. For BL3-N research records regarding experimental animal use and disposal must be maintained in a permanent record book.