

**University of Rochester Institutional Biosafety Committee**  
***Registration of Transgenic Animals Breeding and Crossbreeding***

The NIH Guidelines for Research Involving Recombinant DNA requires registration of experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA or DNA derived there from, into the germ-line. These animals are called transgenic animals. 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. (Section III-D-4, Section III-E-3)

Generating transgenic animals using recombinant DNA technology:

Defined as the stable addition of foreign DNA or subtraction of a portion of the animal genome using recombinant DNA technology.

Examples of recombinant DNA technology used to generate transgenic animals include

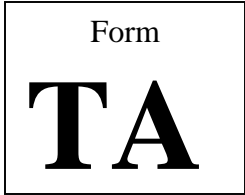
- (1) Direct microinjection of a chosen gene construct from another member of the same species or from a different species into a pronucleus of a fertilized ovum;
- (2) Insertion of the desired DNA sequence by homologous recombination into a culture of embryonic stem cells;
- (3) Use of a plasmid or virus to transfer genetic material into germ cells.

**Animals are defined as belonging to the Kingdom Animalia and include more than animals approved under UCAR protocols.**

1. Use this document to register breeding or cross breeding of animals which were originally created using recombinant DNA technology **AND** which are genetically different from each other.
2. Use this document to register backcrossing transgenic animals that were originally created using recombinant DNA technology with wild type animals.
3. Do not use this form if you are proposing to create de novo transgenic animals using recombinant DNA technology. Instead you must complete the IBC Grant / Project Registration Form (G form).
4. Do not use this form if you intend to administer recombinant DNA or other biologicals to animals. Instead you must complete the IBC Grant / Project Registration Form (G form).
5. Breeding to maintain lines or colonies of transgenic animals does not have to be declared to the IBC beyond registering the initial creation of the animals **UNLESS** the animals require BSL-2 or higher containment solely as a result of their genetic make-up. Then you may use this form to register, but only if your experiments do not also include the use of recombinant DNA or other biologicals in these animals. In this case, you must declare the breeding and the use of the biologicals by using the IBC Grant / Project Registration Form (G form).
6. Animals developed using "Selective Breeding" are not covered by the NIH Guidelines and therefore do not have to be registered with the IBC **UNLESS** the experiments involve the use of recombinant DNA or other biologicals in these animals. In this case, you must use the IBC Grant / Project Registration Form (G form).
7. Purchasing or transferring transgenic rodents requiring BSL1 containment **AND** in absence of breeding or administering recombinant DNA or other biologicals is exempt from IBC registration. (Appendix C-VI)
8. Submission of an IBC **LAB** Registration is **NOT** required to register experiments involving breeding only. **Note: If recombinant DNA or other biologicals are administered to the animals, a G form must be used to register the experiments; and a LAB Registration must accompany the G form.**
9. More Questions: Refer to the [FAQs for Transgenic Animals and the Use of Recombinant DNA in Animals](#).

New: 10/22/08

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Principal Investigator: Dept: Phone:  
 Co-Principal Investigator: Dept: Phone:  
 Technician or Alternate Contact: Dept: Phone:  
 Project or Grant Title:  
 Box #: UCAR # or NA: Transgenic Animal Protocol Registration #: TA-

**Part 1:** *Describe the existing genetics of each parental transgenic animal by completing the appropriate tables. Cut and paste the table below to describe more than one cross.*

	<i>Parent 1</i>	<i>Parent 2</i>
<b>Specify species &amp; strain(s)</b> e.g. Balbc mouse; Drosophila melanogaster; C. elegans		
<b>What does your insert encode</b> (e.g. name of gene product or nature of regulatory region)? <b>Write NA if not applicable.</b>		
<b>What was deleted</b> (e.g. name of gene product or nature of regulatory region)? <b>Write NA if not applicable.</b>		
<b>Specify source of inserted sequence</b> (e.g. mouse, human, etc.)		
<b>Specify any potentially hazardous agent that may be encoded in INSERTED sequence</b> (e.g. toxin, pathogens, oncogene) Write NA if not applicable.		

**Part 2:** *Complete the following questions with regards to the progeny.*

**Question 1.** *Will the progeny likely be selectively vulnerable to specific pathogens? (e.g. pathogens that may be present in their immediate environment that may be transmissible to humans or to other animals)*

	<i>No</i>	
	<i>Yes</i>	<i>Explain briefly in this box.</i>

**Question 2.** Will the progeny likely have a survival advantage that could be genetically transmitted to feral populations? (e.g. If the animal escapes, how likely will it die fairly quickly or how likely is it to reproduce with feral animals to produce viable offspring?)

	No	
	Yes	Explain briefly in this box.

**Question 3.** Will the progeny likely shed a pathogen that is transmissible to humans or a toxin that may affect humans?

	No	
	Yes	Explain briefly in this box. Be sure to list the pathogen or toxin and how the agent may be shed from the animal.

**Question 4.** Will the resultant progeny result in the expression of transgenes or the dysregulation of endogenous gene-products?

	No	
	Yes	Explain briefly in this box.

**Principal Investigator Affirmation:**

By signing below, I certify that the above information is accurate and complete. I will ensure that my employees comply with University standards, policies, and procedures. Furthermore, if during my research new information or data should reveal or strongly suggest that the phenotypes of the animals are not as anticipated, and pose a risk to human health or the health of the University's animal colonies, I will immediately communicate this to the IBC.

Principal Investigator: \_\_\_\_\_

Date: \_\_\_\_\_

**If applicable:**

Secondary PI: \_\_\_\_\_

Date: \_\_\_\_\_