



Date: October 28, 2008
To: Laboratory Principal Investigators and Research Staff
From: Janet Ives *JJ*
Biosafety Officer
Subject: Institutional Approval for Transgenic Animal Development: Effective November 1st

In light of new information received from the National Institutes of Health Office of Biotechnology Activities, the UR Institutional Biosafety Committee (IBC) has expanded its registration requirements to include the breeding, cross breeding, and back crossing of transgenic animals. The NIH Guidelines for Research Involving Recombinant DNA (NIH Guidelines) requires IBC approval of experiments involving whole animals in which the animal's genome has been altered by the stable introduction of recombinant DNA or DNA derived thereof, into the germline.

Transgenic animals are those which fit the following criteria:

1. Generated either through recombinant DNA technology, or
2. Generated through breeding or crossbreeding of animals which are genetically different from each other **AND** which were originally created using recombinant DNA technology, or
3. Generated through back crossing transgenic animals, which were originally created using recombinant DNA technology with wild type animals.

Per NIH, animals are defined as belonging to the Kingdom Animalia and include more than animals approved under UCAR protocols.

Principal Investigators whose research involves transgenic animal development are obligated through the NIH Guidelines to declare these experiments to the IBC. The IBC is, in turn, obligated to review and approve of these experiments. **However, since NIH does allow for experiments requiring biosafety level 1 containment to begin simultaneously with submitting the IBC registration document, little or no delay is anticipated for the majority of transgenic animal development. A streamlined IBC registration document and review process has been developed specifically for these experiments.** A FAQs help page is available at this web link ([FAQs for Transgenic Animals](#)).

To determine whether the streamlined IBC registration form (TA-form) is applicable for registering your transgenic animal development experiments refer to the following criteria.

- Experiments involve one or more of the criteria as listed below:
 1. Breeding or cross breeding of animals which were originally created using recombinant DNA technology **AND** which are genetically different from each other,
 2. Back crossing transgenic animals, which were originally created using recombinant DNA technology with wild type animals.
- In addition, experiments also involve either:
 1. Experimental agents which are **NOT** pathogens, recombinant DNA, eukaryotic cells, tissues, fluids, or cell lines, or viral vectors, **OR**
 2. No experimental agents.

The TA-form and other IBC registration documents can be found at this web link: [IBC Forms Page](#)

If you have further questions regarding this policy change, please contact me at jives@safety.rochester.edu or X53014.

Thank you for your attention.