Guidelines for Principal Investigators Working with Transgenic Animals

The creation, generation, breeding and propagation of transgenic animals are covered under Section III-D-4 of the NIH Guidelines. These activities are not exempt from the NIH Guidelines and must be reviewed by the Institutional Biosafety Committee (IBC). This includes models that involve the introduction of DNA into the germ line. Knock-out (gene silencing, gene ablation, etc.) models may be exempt from IBC review if the method used to generate the model does not leave any "new" genetic material or any markers in the animal. If the recombinant or synthetic nucleic acid molecules that are used to create the knock-out are permanently inserted into the genome the experiment must be reviewed by the IBC. Models that have mutations or genetic modifications that are the result of natural variation, chemical mutagenesis or radiation exposure, and that have not had any molecular manipulation, are not typically reviewed by the IBC.

Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3 of the Guidelines, *Experiments Involving Transgenic Rodents,* and, as such, require IBC Committee notice simultaneous with initiation. Transgenic and knockout animals made in the mouse core facility will be registered on an annual basis by the core facility. Thus, if your transgenic animals are made by the mouse core facility, you do not need to register separately.

Experiments involving the breeding of certain BL1 transgenic rodents are exempt if the requirements described in Appendix C-VIII of the NIH Guidelines are met:
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 BL1 containment are exempt if:

(1) Both parental rodents can be housed under BL1 containment; and

(2) Neither parental transgenic rodent contains the following genetic modifications: (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gamma-retroviral long terminal repeat (LTR); and

(3) 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.

Non-exempt work with transgenic animals must be registered with the IBC using the online registration sysyem, BioRAFT.

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