Registration of Transgenic Organisms

This statement outlines the requirements as identified by the A&M- SA Institutional Biosafety Committee (IBC) for registration of transgenic animals defined by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*.

Introduction

According to the *NIH Guidelines*, recombinant or synthetic nucleic acid work either requires full Institutional Biosafety Committee (IBC) review (Section III-A through III-E) or is exempt from IBC review (Section III-F). Section III-E-3 (Experiments Involving Transgenic Rodents) "covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids 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*." All Section III-E projects must be filed with the IBC before or concurrent with experiment initiation.

- The *NIH Guidelines* address two pathways for generation of a transgenic rodent: altering the animal's genome using recombinant or synthetic nucleic acid technology, or breeding one or more transgenic rodents to create a new transgenic rodent. On January 19, 2011, the *NIH Guidelines* were revised to allow exemption of the following genetically modified rodents from IBC review: The purchase or transfer of existing transgenic rodent strains for experiments that require ABSL1 containment is exempt from IBC review under Section III-F (Appendix C-VII).
- The breeding of two different transgenic rodents or the breeding of a transgenic and non-transgenic rodent resulting in a new transgenic strain that can be housed at ABSL1 containment is exempt under Section III-E-3 (Appendix C-VIII) if:
    1. Both parental strains can be housed at ABSL1 containment,
    2. Neither parental strain contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses or a transgene that is under the control of a gammaretroviral long terminal repeat (LTR), and
    3. The resulting transgenic rodent is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

Statement

The A&M- SA IBC has adopted the following statement:

The IBC will review and approve the generation of transgenic lines, including, but not limited to, stable introduction of recombinant DNA into the germ line via DNA microinjection, embryonic stem cell-mediated gene transfer, retrovirus-mediated gene transfer, and/or rederivation, as performed at A&M- SA or at another institution via contract from A&M-SA. This position pertains to all genetically modified organisms.

The IBC will not require registration for the purchase and/or transfer of existing transgenic rodent lines or for congenic rodents as defined by the *NIH Guidelines*.

Compliance with the above policy requires the following actions:

Principal Investigator

The Principal Investigator is responsible for full compliance with the *NIH Guidelines* regarding recombinant or synthetic nucleic acid research. As part of this responsibility, the Principal Investigator shall:

- Register all strains that are generated via stable introduction of recombinant or synthetic nucleic acids into the germ line.
- Identify strains that are exempt from review by the IBC as defined by the *NIH Guidelines* (Section III-F).
- Identify breeding of parental strains that results in progeny that contains more than one-half of an exogenous viral genome from a single family of viruses and register with the IBC (*NIH Guidelines* Appendix C-VIII).
- Identify and register all transgenic strains that require ABSL2 or higher containment (Section III-D-4).
- Attest that the information contained in the biological use authorization (BUA) application for registration of transgenic animals is accurate and complete to the best of their knowledge.

Institutional Biosafety Committee

On behalf of A&M- SA, the IBC shall:

- Review BUA applications for registration of transgenic animals for compliance with the *NIH Guidelines* with the same precision as any recombinant or synthetic nucleic acid molecule project.
- Inform the Principal Investigator of the results of the IBC review.
- Screen proposed use of genetically modified rodent strains for exemption from IBC registration requirements in compliance with the *NIH Guidelines*.

History: Adopted 6/14/2023

References: The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules