

**Animal experiments covered under the
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**

ACTIVITY	MINIMUM BL	SECTION
CREATION OF TRANSGENIC ANIMALS		
Creation of transgenic rodents	BL1	III-E-3
Creation of transgenic rodents	BL2 or higher	III-D-4-b
Creation of gene drive modified rodents	BL2 or higher	III-D-8
Creation of transgenic animals other than rodents	BL1/BL1-N	III-D-4-a
Creation of transgenic animals other than rodents	BL2/BL2-N or higher	III-D-4-b
Creation of gene drive modified animals other than rodents	BL2/BL2-N or higher	III-D-8
Creation of recombinant or synthetic nucleic acid molecule modified arthropods	BL1	III-D-4-a
Creation of recombinant or synthetic nucleic acid molecule modified arthropods	BL2 or higher	III-D-4-b
Creation of gene drive modified arthropods	BL2 or higher	III-D-8
Creation of knock-out rodents	BL1	III-E-3
Creation of knock-out rodents	BL2 or higher	III-D-4-b
BREEDING OF TRANSGENIC ANIMALS		
Breeding rodents from one strain (propagation/colony maintenance)	BL1	Exempt
Breeding rodents from one strain (propagation/colony maintenance)	BL2 or higher	III-D-4-b
Breeding rodents from two strains (generating a new strain) providing neither parental 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 gammaretroviral long terminal repeat (LTR); <u>and</u> (3) the rodent that results from the breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.	BL1	Exempt (Appendix C-VIII)
Breeding rodents from two strains (generating new strain) if the parental 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 gammaretroviral long terminal repeat (LTR); <u>or</u> (3) the rodent that results from the breeding contains more than one-half of an exogenous viral genome from a single family of viruses.	BL1	III-E-3
Breeding rodents from two strains (generating new strain)	BL2 or higher	III-D-4
Breeding gene drive modified rodents	BL2 or higher	III-D-8
Breeding of transgenic animals other than rodents	BL1	III-D-4
Breeding of transgenic animals other than rodents	BL2 or higher	III-D-4
Breeding gene drive modified animals other than rodents	BL2 or higher	III-D-8
Breeding of recombinant or synthetic nucleic acid molecule modified arthropods	BL1	III-D-4
Breeding of recombinant or synthetic nucleic acid molecule modified arthropods	BL2 or higher	III-D-4
Breeding gene drive modified arthropods	BL2 or higher	III-D-8
Breeding of knockout rodents from one strain (propagation/ colony maintenance)	BL1	Exempt

Breeding of knockout rodents from two strains (propagation/colony maintenance)	BL2 or higher	III-D-4
Breeding of knockout rodents from two strains (generating new strain) providing neither parental 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 gammaretroviral long terminal repeat (LTR); <u>and</u> (3) the rodent that results from the breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.	BL1	Exempt (Appendix C-VIII)
Breeding of knockout rodents from two strains (generating new strain) if the parental 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 gammaretroviral long terminal repeat (LTR); <u>or</u> (3) the rodent that results from the breeding contains more than one-half of an exogenous viral genome from a single family of viruses	BL1	III-E-3
Breeding of knockouts from two strains (generating new strain)	BL2 or higher	III-D-4-b
EXPERIMENTS WITH TRANSGENIC ANIMALS		
Experiments with transgenic rodents	BL1	III-D-4-a* (see note)
Experiments with transgenic rodents	≥ BL2 set by IBC	III-D-4-b
Experiments with transgenic animals other than rodents	BL1	III-D-4-a
Experiments with transgenic animals other than rodents	≥ BL2 set by IBC	III-D-4-b
Experiments with recombinant or synthetic nucleic acid molecule modified arthropods associated with plants	BL1	III-E-2-b-(5)
Experiments with recombinant or synthetic nucleic acid molecule modified arthropods associated with plants	BL2 or higher	III-E-2
Experiments with recombinant or synthetic nucleic acid molecule modified arthropods not associated with plants	BL1	III-D-4-a
Experiments with recombinant or synthetic nucleic acid molecule modified arthropods not associated with plants	BL2 or higher	III-D-4-b
*The purchase or transfer of transgenic rodents requiring BL1 containment is exempt under Appendix C-VI. Subsequent use of these animals is also exempt providing the experimental protocol does not involve the use of recombinant or synthetic nucleic acid molecules. If the protocol does involve the use of recombinant or synthetic nucleic acid molecules then the research is covered under III-D-4-a. All experiments involving the use of other transgenic animals at any Biosafety Level and the use of transgenic rodents requiring BL2 or higher containment are subject to the <i>NIH Guidelines</i> . See above for applicable sections.		
EXPERIMENTS WITH RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES IN AN ANIMAL (TRANSGENIC OR OTHERWISE)		
Experiments with recombinant or synthetic nucleic acid molecule modified microbes in any animal (transgenic or otherwise)	BL1/BL1-N	Not permitted at BL1*
Experiments with RG2 recombinant or synthetic nucleic acid molecule modified microbes in any animal (transgenic or otherwise)	BL2/ BL2-N	III-D-1-a
Experiments with RG3 recombinant or synthetic nucleic acid molecule modified microbes in any animal (transgenic or otherwise)	BL3/ BL3-N	III-D-1-b
Experiments with RG4 recombinant or synthetic nucleic acid molecule modified microbes in any animal (transgenic or otherwise)	BL4/BL4-N	III-D-1-c
Experiments with recombinant or synthetic nucleic acid molecule modified restricted agent in an animal (transgenic or otherwise)	BL4/BL4-N	III-D-1-d

Experiments with recombinant or synthetic nucleic acid molecule modified animal pathogens in an animal (transgenic or otherwise)	BL4/BL4-N	III-D-1-d
Introduction of less than 2/3 of eukaryotic viral genome into a non-human vertebrate or invertebrate	BL1/BL1-N	III-D-4-a
Propagation of animals containing viral vector sequences not leading to transmissible infection	BL1/BL1-N	III-D-4-a
Experiments with recombinant or synthetic nucleic acid molecules involving whole animals not covered by Sections III-D-1 or III-D-4-a	Set by IBC	III-D-4-b
* Other than viruses which are only transmitted vertically, the experiments may not be conducted at BL1. A minimum of BL2 or BL2-N is required.		
CLONING ANIMALS		
Cloning animals	BL1 or higher	Not covered
PURCHASE OR TRANSFER OF TRANSGENIC ANIMALS		
Purchase or transfer of transgenic rodents	BL1	Exempt (Appendix C-VII)
Purchase or transfer of transgenic rodents	BL2 or higher	III-D-4
Purchase or transfer of transgenic animals other than rodents	BL1	III-D-4
Purchase or transfer of transgenic animals other than rodents	BL2 or higher	III-D-4
Purchase or transfer of recombinant or synthetic nucleic acid molecule modified arthropods	BL1	III-D-4
Purchase or transfer of recombinant or synthetic nucleic acid molecule modified arthropods	BL2 or higher	III-D-4
PLANT EXPERIMENTS WITH ANIMALS OR ARTHROPODS		
Experiments with microorganisms or insects containing recombinant or synthetic nucleic acid molecules with the potential for detrimental impact to ecosystems.	BL3-P or BL2-P plus biological containment	III-D-5-a or III-D-5-b
Experiments with exotic infectious agents in the presence of arthropod vectors	BL4-P	III-D-5-c
Experiments with microbial pathogens of insects or small animals associated with plants with the potential for detrimental impact to ecosystems.	BL3-P or BL2-P plus biological containment	III-D-5-e
Small animals associated with recombinant or synthetic nucleic acid molecule modified plants.	BL1	III-E-2
Experiments with recombinant or synthetic nucleic acid molecule modified arthropods or small animals associated with plants.	BL1	III-E-2-b-(5)
OTHER		
Transfer of a drug resistance to microorganisms compromising the use in veterinary medicine	Set by NIH (case by case)	III-A-1-a

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* are available at:

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

For further information about the requirements of the *NIH Guidelines*, please e-mail: NIHGuidelines@od.nih.gov