

Animal experiments covered under the *NIH Guidelines for Research Involving Recombinant DNA Molecules*



ACTIVITY	MINIMUM BSL	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 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 recombinant DNA modified arthropods	BL1	III-D-4-a
Creation of recombinant DNA modified arthropods	BL2 or higher	III-D-4-b
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-VII)
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 of transgenic animals other than rodents	BL1	III-D-4
Breeding of transgenic animals other than rodents	BL2 or higher	III-D-4
Breeding of recombinant DNA modified arthropods	BL1	III-D-4
Breeding of recombinant DNA modified arthropods	BL2 or higher	III-D-4
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 knockouts 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-VII)

Breeding of knockouts 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 DNA modified arthropods associated with plants	BL1	III-E-2-b-(5).
Experiments with recombinant DNA modified arthropods associated with plants	BL2 or higher	III-E-2
Experiments with recombinant DNA modified arthropods not associated with plants	BL1	III-D-4-a
Experiments with recombinant DNA 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 DNA. If the protocol does involve the use of recombinant DNA 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 R-DNA IN AN ANIMAL (TRANSGENIC OR OTHERWISE)		
Experiments with r-DNA modified microbes in any animal (transgenic or otherwise)	BL1/BL1-N	Not permitted at BL1*
Experiments with RG2 r-DNA modified microbes in any animal (transgenic or otherwise)	BL2/ BL2-N	III-D-1-a
Experiments with RG3 r-DNA modified microbes in any animal (transgenic or otherwise)	BL3/ BL3-N	III-D-1-b
Experiments with RG4 r-DNA modified microbes in any animal (transgenic or otherwise)	BL4/BL4-N	III-D-1-c
Experiments with r-DNA modified restricted agent in an animal (transgenic or otherwise)	BL4/BL4-N	III-D-1-d
Experiments with r-DNA 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 R-DNA involving whole animals not covered by Sections III-D-1 or III-D-4-a	Set by IBC	III-D-4-b
GENE DRIVE MODIFIED ORGANISMS RESEARCH		
Experiments involving gene drive modified organisms generated by recombinant or synthetic nucleic acid molecules	BL2 or higher	III=D-3-8
Experiments Involving Whole Animals or Section III-D-8, Experiments Involving Gene Drive Modified Organisms.	BL2-N or higher	Section III-D-4-b
Experiments involving the generation or use of gene drive modified animals require a minimum of BL2 containment and are covered under III-D-8, Experiments Involving Gene Drive Modified Organisms.	BSL-2 N or higher	III-D-4-c-(3)
Experiments involving gene drive modified organisms in arthropods or insects: Appendix G-III-B. Arthropod Containment Guidelines, Version 3.2, 2019, and Addendum 1 Containment Practices for Arthropods Modified with Engineered Transgenes Capable of Gene Drive, 2022, American Committee of Medical Entomology, American Society of Tropical Medicine and Hygiene, Arlington, Virginia.	ACL-2 or higher	III-D-3-8 III-D-4-b
Gene Drive Modified 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-VI)
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 DNA modified arthropods	BL1	III-D-4
Purchase or transfer of recombinant DNA modified arthropods	BL2 or higher	III-D-4

PLANT EXPERIMENTS WITH ANIMALS OR ARTHROPODS		
Experiments with microorganisms or insects containing recombinant DNA 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 DNA-modified plants.	BL1	III-E-2
Experiments with rDNA-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 DNA Molecules (NIH Guidelines)* are available at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

For further information about the requirements of the *NIH Guidelines*, please visit the NIH Office of Biotechnology Activities web page at <http://oba.od.nih.gov> or write to us at oba@od.nih.gov