

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 (III-F-4) |
| Breeding rodents from one strain (propagation/colony maintenance) | BL2 or higher | III-D-4-b |
| Breeding rodents from two strains (generating new strain) | BL1 | III-E-3 |
| Breeding rodents from two strains (generating new strain) | BL2 or higher | III-D-4-b |
| 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 | Exempt (III-F-4) |
| Breeding of recombinant DNA modified arthropods | BL2 or higher | III-D-4-b |
| Breeding of knockouts (propagation) | BL1 | Exempt (III-F-4) |
| Breeding of knockouts (propagation) | BL2 or higher | III-D-4-b |
| Breeding of knockouts from two strains (generating new strain) | 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-6. 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 *NIH Guidelines*. 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 |
| * 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-6) |
| 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://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

For further information about the requirements of the *NIH Guidelines*, please visit the NIH Office of Biotechnology Activities web page at <http://www4.od.nih.gov/oba/> or write to us at oba@od.nih.gov