TITLE:

**EHS-423, GUIDELINES FOR RECOMBINANT DNA EXPERIMENTS COVERED BY NIH GUIDELINES**

## 1.0 Purpose

The table below summarizes the types of experiments involving recombinant or synthetic nucleic acid molecules (rDNA) that are covered in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). The table also shows the level(s) of review/registration/approval required for each type of experiment.

- **NOTE:** rDNA experiments that are exempt from the *NIH Guidelines* are found in Section III-F and Appendix C of the *NIH Guidelines*.

| ***rDNA Experiments Covered by the NIH Guidelines*** | ***RAC[i] Review*** | ***NIH Director Approval*** | ***NIH/OBA[ii] Approval*** | ***NIH/ORDA[iii] Registration*** | ***IBC[iv] Approval before Initiation*** | ***IBC Notice upon Initiation*** | ***IAUCUC[v] Approval*** | ***IRB[vi] Approval*** |
|---|---|---|---|---|---|---|---|---|
| Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (if such acquisition could compromise ability to control disease agents in humans, veterinary medicine, or agriculture) | ✓ | ✓ | | | ✓ | | | |
| Cloning of toxin molecules with an LD50 of less than 100 ng/kg body weight | | | ✓ | | ✓ | | | |
| Human gene transfer | | | | ✓ | ✓ | | | ✓ |
| Using risk group 2, 3, 4 or restricted agents as host-vector systems | | | | | ✓ | | | |
| Exposing any animal to rDNA modified microbes | | | | | ✓ | | ✓ | |
| DNA from Risk Group 2, 3, 4 or restricted agents is cloned into a nonpathogenic prokaryotic or lower eukaryotic host vector system | | | | | ✓ | | | |
| The use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems | | | | | ✓ | | | |

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|---|---|---|---|---|---|---|---|---|
| The creation of:<br>• Transgenic rodents (housed at ABSL-2 and above)<br>• Transgenic animals other than rodents<br>• rDNA modified arthropods<br>• Knock-out rodents (housed at ABSL-2 and above) | | | | | ✓ | | ✓ | |
| The breeding of:<br>• Rodents from one strain for propagation or colony maintenance (housed at ABSL-2 and above)<br>• Rodents from two strains to generate a new strain (housed at ABSL-2 and above)<br>• Transgenic animals other than rodents<br>• rDNA modified arthropods<br>• Knock-out rodents from two strains for propagation or colony maintenance (housed at ABSL-2 and above)<br>• Knock-outs from two strains to generate a new strain (housed at ABSL-2 and above) | | | | | ✓ | | ✓ | |
| Experiments with:<br>• Transgenic rodents (housed at ABSL-2 and above)<br>• Transgenic animals other than rodents<br>• rDNA modified arthropods not associated with plants | | | | | ✓ | | ✓ | |
| The purchase or transfer of:<br>• Transgenic rodents (housed at ABSL-2 | | | | | ✓ | | ✓ | |

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|---|---|---|---|---|---|---|---|---|
| and above)<br>• Transgenic animals other than rodents<br>• rDNA modified arthropods | | | | | | | | |
| Experiments with whole plants that involve:<br>• Genetically engineering plants by rDNA methods<br>• Using rDNA modified plants for experimental procedures<br>• The propagation of rDNA modified plants<br>• Using microorganisms or arthropods containing rDNA with the potential for detrimental impact to ecosystems<br>• Using exotic infectious agents in the presence of arthropod vectors<br>• Using microbial pathogens of insects or small animals associated with plants with the potential for detrimental impact to ecosystems | | | | | ✓ | | | |
| Experiments with more than 10L of culture | | | | | ✓ | | | |
| The use of influenza viruses | | | | | ✓ | | | |
| Experiments that do not fall under Sections III-A, B, C, D, F or Appendix C of the *NIH Guidelines*. | | | | | | ✓ | | |
| Formation of rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus | | | | | | ✓ | | |
| Experiments with whole plants, except those that fall under III-A, B, D, or F, including: | | | | | | ✓ | | |

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|---|---|---|---|---|---|---|---|---|
| • rDNA modified arthropods associated with plants (BSL-2 and above);<br>• Small animals associated with rDNA-modified plants; or<br>• rDNA-modified arthropods or small animals associated with plants | | | | | | | | |
| Creation of transgenic or knock-out rodents in which the animal's genome has been altered by stable introduction of rDNA or DNA derived there from, into the germ-line. Only experiments that require ABSL-1 containment are covered by this section. | | | | | | ✓ | ✓ | |
| Breeding of rodents from 2 strains to generate a new strain or a knock-out that can be housed at ABSL-1 and don't fall under the exemption explained in Appendix C-VIII. | | | | | | ✓ | ✓ | |

[i] RAC = Recombinant DNA Advisory Committee

[ii] OBA = Office of Biotechnology Activities

[iii] ORDA = Office of Recombinant DNA Activities

[iv] IBC = Institutional Biosafety Committee

[v] IACUC = Institutional Animal Care and Use Committee

[vi] IRB = Institutional Review Board