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rDNA Experiments Covered by the NIH Guidelines

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					✓			

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

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• Transgenic animals other than rodents • rDNA modified arthropods								
Experiments with whole plants that involve: • Genetically engineering plants by rDNA methods • Using rDNA modified plants for experimental procedures • The propagation of rDNA modified plants • Using microorganisms or arthropods containing rDNA with the potential for detrimental impact to ecosystems • Using exotic infectious agents in the presence of arthropod vectors • 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: • rDNA modified arthropods associated with plants (BSL-2 and above); • Small animals associated with rDNA-modified plants; or						✓		

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• 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