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Levels of Review Required for Recombinant DNA Research

This table summarizes the types of approvals and reviews required from various boards and committees for the use of recombinant DNA research.

NIH Guidelines Section	Experiments covered under *NIH Guidelines*	NIH/ Recombinant DNA Advisory Committee (RAC) Review	NIH Approval	Institutional Approval/Review		
				IBC Approval	IBC Review	IRB/ IACUC Approvals
Section III-A	Transfer of drug resistance trait to a microorganism not known to acquire the trait naturally	YES	YES (NIH Director)	YES		
Section III-B	Cloning of toxin molecules with LD50 less than 100ng/kg body weight	YES		YES		
Section III-C	Gene transfer into humans by recDNA	YES		YES		IRB Contingent on IBC Approval
	recDNA in vaccines			YES		IRB Contingent on IBC Approval
Section III-D	Recombinant risk group 2, 3, or restricted agents a. As host-vector systems b. DNA is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems			YES		
	Infectious virus or replication defective virus in presence of helper virus in tissue culture systems (e.g., viral vectors)			YES		
	Whole transgenic animals and recDNA-modified microorganisms tested on whole animals			YES		YES
	recDNA modified whole plants			YES		
	More than 10 L of recDNA culture			YES		
	Influenza viruses (specific strains) generated by recombinant methods			YES		
Section III-E	Those not above			YES		

	Less than 2/3 eukaryotic virus genome			YES		
	recDNA modified whole non-pathogenic plants and plants associated microorganisms			YES		
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Section III-F	Not in organisms, cells, or viruses				YES	
	No chromosomal or viral DNA of single source				YES	
	Prokaryotic DNA with indigenous plasmids or viruses when propagated in same system or when transferred				YES	
	Eukaryotic DNA, propagated in same system				YES	
	Physiological exchangers				YES	
	Not a significant risk to health or environment				YES	

Note: Work with human embryonic stem cells (hESC) and induced pluripotent stem cells (iPS) require IBC review.