

University of Massachusetts Medical School Institutional Biosafety Committee

Summary of NIH Recombinant DNA Guidelines V. 4/2002

Category	NIH Section	APPROVAL					EXAMPLES	
		IBC	RAC	NIH Director	NIH OBA	IRB		
1	III-A	Prior	Prior	Prior			Deliberate transfer of a drug resistance trait to microorganisms not known to acquire the trait naturally.	
2	III-B	Prior			Prior		Cloning of toxins lethal to vertebrates with an LD50 < 100 ng per kg body weight. Examples: cloning of botulism, tetanus, diphtheria, or shigella toxins.	
3	III-C	Prior	Prior			Prior	Deliberate transfer of recombinant DNA (or derived RNA) into one or more human subjects.	
4	III-D	Prior					<p>Recombinant DNA prepared from risk group-2 to -4 organisms, or use of such organisms as vectors. Large-animal transgenics. Rodent transgenics involving risk group-2 to -4 genes. Testing of viable recombinant microorganisms on whole animals.</p> <p>BL3: Recombinant live lentiviruses and pathogenic bacteria like <i>Yersinia</i>. Use of infectious or defective risk group-3 viruses in the presence of helper. Recombinant, replication-deficient BL3 viruses may typically be safely handled at BL 2 or BL2+.</p> <p>BL2: Recombinant live vaccinia or adenoviral vectors for most genes, except oncogenes. Enteropathic <i>E. coli</i> O157:H7 as vector. Transfer of risk group-2 or group-3 DNA into non-pathogenic prokaryotes or lower eukaryotes.</p>	
5	III-E	Simultaneous						<p>BL1: Highly defective viral vectors. Risk group-1 organisms like recombinant murine retroviruses, or non-pathogenic <i>E. coli</i>. Experiments involving the formation of recombinant DNAs containing no more than 2/3 the genome of any eukaryotic virus. Rodent transgenics using risk group-1 genes. Routine arthropod transgenics.</p>
6	III-F	Exempt						Routine manipulation of recombinant DNA, including the routine use of YACs and BACs as cloning vectors. Non-recombinant experiments consisting entirely of DNA segments from a single non-chromosomal source, or single non-infectious viral source. Experiments consisting entirely of DNA from a prokaryotic host (including its indigenous plasmids or viruses) when propagated only in that host, or transferred by physiological means. Experiments consisting entirely of DNA from a eukaryotic host (including chloroplasts, mito, or plasmids, but excluding viruses) when propagated only in that host. Experiments that consist entirely of DNAs from different species that exchange DNA by known physiological processes.