

SUMMARY OF NIH GUIDELINES for RESEARCH INVOLVING RECOMBINANT DNA MOLECULES.

Experiments involving recombinant DNA covered by the NIH guidelines are discussed in Section III of the NIH Guidelines, as follows:

SECTION III.	EXPERIMENTS COVERED BY THE NIH GUIDELINES
Section III-A.	Experiments that Require Institutional Biosafety Committee Approval (IBC), RAC Review, and NIH Director Approval Before Initiation
Section III-A-1.	Major Actions under the <i>NIH Guidelines</i>
Section III-B.	Experiments That Require NIH/OBA and IBC Approval Before Initiation
Section III-B-1.	Experiments Involving the Cloning of Toxin Molecules with LD ₅₀ of Less than 100 Nanograms per Kilogram Body Weight
Section III-C.	Experiments that Require IBC and Institutional Review Board Approvals (IRB) and RAC Review Before Research Participant Enrollment
Section III-C-1.	Experiments Involving the Deliberate Transfer of Recombinant DNA, or DNA or RNA Derived from Recombinant DNA, into One or More Human Research Participants
Section III-D.	Experiments that Require IBC Approval Before Initiation
Section III-D-1.	Experiments Using Risk Group (RG) 2, RG 3, RG 4, or Restricted Agents as Host-Vector Systems
Section III-D-2.	Experiments in Which DNA From RG 2, RG 3, RG 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
Section III-D-3.	Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
Section III-D-4.	Experiments Involving Whole Animals
Section III-D-5.	Experiments Involving Whole Plants
Section III-D-6.	Experiments Involving More than 10 Liters of Culture
Section III-E.	Experiments that Require IBC Notice Simultaneous with Initiation
Section III-E-1.	Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus
Section III-E-2.	Experiments Involving Whole Plants
Section III-E-3.	Experiments Involving Transgenic Rodents
Section III-F.	Exempt Experiments

CONTAINMENT: The Recombinant DNA Guidelines include a Classification of Microorganisms on the Basis of Hazard (Appendix B), which should be used to determine the level of containment required for a given organism.

NOTE: The Upstate Institutional Bio-Safety Committee requires that an application be submitted for review for all experiments involving recombinant DNA.