

# NIH Guidelines for Research Involving DNA Molecules

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## *NIH Guidelines Sections*

- ❖ III-A Experiments that require Institutional Biosafety Committee Approval (IBC), RAC Review, and NIH Director Approval before Initiation
  - III-A-1 Major actions under the *NIH Guidelines* – experiments that require Institutional Biosafety Committee Approval, RAC Review, and NIH Director approval before initiation
- ❖ III-B Experiments that require NIH/OBA and Institutional Biosafety Committee approval before initiation
  - III-B-1 Experiments involving the cloning of toxin molecules with LD<sub>50</sub> of less than 100ng per kg body weight
  - III-B-2 Experiments that have been approved (under Section III-A-1-a) as major actions under the *NIH Guidelines*
- ❖ III-C Experiments that require IBC and Institutional Review Board approvals (IRB) and RAC Review before research participant enrollment
  - III-C-1 Experiments involving the deliberate transfer of recombinant or synthetic nucleic acids, or DNA or RNA derived from recombinant or synthetic nucleic acids into one or more human research participants
- ❖ III-D Experiments that require IBC approval before initiation (see Appendix B of the *NIH Guidelines* to identify your risk group).
  - III-D-1 experiments using Risk Group (RG) 2, RG 3, RG 4, or Restricted Agents as Host-Vector Systems
  - 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
  - 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
  - III-D-4 Experiments involving whole animals
  - III-D-5 Experiments involving whole plants
  - III-D-6 Experiments involving more than 10 liters of culture
  - III-D-7 Experiments involving influenza viruses

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- ❖ III-E Experiments that require IBC notice simultaneous with initiation
  - III-E-1 Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus
  - III-E-2 Experiments involving whole plants
  - III-E-3 Experiments involving transgenic rodents
- ❖ III-F Exempt Experiments, please use Biosafety Level 1 Registration Form