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Cheat Sheet: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2013 Revision)

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The 2013 revisions to the NIH guidelines have classified recombinant and synthetic nucleic acid experimentation into six categories. The following table has been developed to ease the primary investigators' duty to identify and classify their research plans and protocols. Compliance with the NIH guidelines is mandatory for all institutions receiving NIH funding for research involving recombinant or synthetic nucleic acids.

Abbreviations: IBC: Institutional Biosafety Committee; IRB: Institutional Review Board; OBA: Office of Biotechnology Activities; RAC: Recombinant DNA Advisory Committee

Experiments that require IBC approval, RAC review and NIH Director approval BEFORE initiation (Section III-A) 1) The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture • Considered MAJOR ACTIONS • See Appendix D for those experiments already approved under this category	**Experiments that require NIH/OBA and IBC approval BEFORE initiation (Section III-B)** 1. Experiments involving the cloning of toxin molecules with an LD50 of less than 100ng/kg body weight 2. Experiments that have been approved as a MAJOR ACTION under Section III-A of the guidelines.
Experiments that require IBC and IRB approvals and RAC review BEFORE initiation (Section III-C) Human gene transfer is the deliberate transfer into human research participants of either: 1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules 2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria: • Contain more than 100 nucleotides • Possess biological properties that enable integration into the genome • Have the potential to replicate in a cell • Can be translated or transcribed.	**Experiments that Require IBC approval BEFORE initiation (Section III-D)** 1. Experiments using Risk group (RG) 2, 3, 4 or restricted agents as host-vector systems 2. Expts where DNA from RG 2, 3, 4 or restricted agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems 3. Expts 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 4. Experiments involving whole animals 5. Experiments involving whole plants at BL-2-P+ or higher 6. Experiments involving more than 10L of culture 7. Experiments involving Influenza viruses (1918 H1N1, HPAI H5N1 and human H2N2)
Experiments that require IBC notice SIMULTANEOUS with initiation (Section III-E) Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section 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 2. Experiments involving whole plants at BL-1P or 1P+ 3. Experiments involving transgenic rodents at BL-1 only	**Exempt Experiments (Section III-F)** 1. synthetic nucleic acids that: a) can neither replicate nor generate nucleic acids that can replicate in any living cell b.)are not designed to integrate into DNA 2. Nucleic acids that are not in organisms, cells, or viruses 3. Those where propagation occurs in its natural host 4. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes 5. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), See Appendix C, Exemptions under Section III-F-8 for other classes of experiments which are exempt from the NIH Guidelines

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