Classification Summary Page for *NIH Guidelines*

The complete *NIH Guidelines* are available HERE

Section III-A: Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation

Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine or agriculture.

Section III-B: Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation

Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kg body weight (e.g., microbial toxins such as tetanus toxin).

Section III-C: Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation

Experiments involving the deliberate transfer of (1) recombinant DNA or (2) DNA or RNA derived from recombinant DNA into one or more human subjects.

Section III-D: Experiments that require IBC approval before initiation of experiments.

Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems; Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems; 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; Experiments Involving More than 10 Liters of Culture; Experiments Involving Influenza Viruses; Experiments involving the generation of transgenic rodents that require BL1. It is not required to register transgenic animals modified onlyby gene knock-outs.

Section III-E: Experiments that require IBC notice simultaneously with initiation.

Experiments involving the formation of rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (All viruses from a single Family being considered identical.) may be propagated and maintained in cells in tissue culture using BL1 containment. Human cells used as host cells or used for production of viral vectors require BL2 containment. It must be shown that the cells lack helper virus for the specific Families of defective viruses used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Section III-F: Experiments that are exempt from *NIH Guidelines.* However, registration with the IBC is required.

III-F-1	Synthetic nucleic acids that (1) can neither replicate nor generate nucleic acids that can replicate in any living cell and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. Any synthetic nucleic acid deliberately transferred into human research participants is not exempt.
III-F-2	Recombinant DNA molecules that are not in organisms or viruses and that have not been modified to be capable of penetrating cellular membranes.
III-F-3	Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature
III-F-4	Recombinant DNA molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
III-F-5	Recombinant DNA molecules that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or closely related strain of the same species).
III-F-6	Recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. See Appendix A-I through A-VI of the “NIH Guidelines”.
III-F-7	Genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA
III-F-8	Recombinant DNA experiments that do not present a significant risk to health or the environment as determined by the NIH Director, RAC and following appropriate notice and opportunity for public comment. See Appendix C of the NIH Guidelines.