Classification Summary Page for *NIH Guidelines*

The complete *NIH Guidelines* are available HERE.

Section III-A: Experiments that require Institutional Biosafety Committee (IBC) approval, Recombinant DNA Advisory Committee (RAC) review, and NIH Director approval before initiation of experiments.

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/OBA and IBC 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 that require IBC and Institutional Review Board (IRB) approvals, and NIH/OBA registration before 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 involving the introduction of recombinant DNA into Risk Group (RG) 2 or RG3 agents for use in animal experiments or for modifying cells for use in animal experiments. Examples include gene transfer experiments using viral vectors including adenoviral vectors, murine retrovirus vectors, or lentiviral vectors. Depending upon the details, experiments with such agents may be conducted at BL1, BL2, or BL3. Experiments in which DNA from RG-4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. The IBC may approve the specific lowering of containment for particular experiments to BL1.

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 UNC IBC is required .

III-D-4-c-1	Experiments involving the generation of transgenic rodents that require BL1.
III-D-4-c-2	The purchase or transfer of transgenic rodents. It is not required to register transgenic animals modified only by gene knock-outs.
III-F-1	Recombinant DNA molecules that are not in organisms or viruses.
III-F-2	Recombinant DNA molecules that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
III-F-3	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-4	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-5	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-V of the "NIH Guidelines".
III-F-6	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.