Syracuse University

Laboratory Guidance Document

Recombinant DNA Review & Reporting

Experiments Covered by the *NIH Guidelines*

The National Institutes of Health has classified work with recombinant DNA (rDNA) in Section III of the *NIH Guidelines* into six categories (A-F) based on the potential hazards associated with the experiments.

The following table is intended to provide a general overview of the categorization and review requirements pertaining to the most common laboratory/research experiments.

Please contact EHSS at 315-443-4132 for assistance determining to which category your research applies.

Review Category	Review Process	Experiment	Example
A	Required approval prior to initiation: IBC (complete application) NIH Director	Deliberate transfer of drug resistance to microorganism that can compromise the use of the drug to control the microorganism and its disease in humans, veterinarian medicine, or agriculture.	Cloning of Erythromycin resistance into pathogenic bacteria.
B	Required approval prior to initiation: IBC (complete application) NIH OSP	Cloning toxin molecules with LD_{50} < 100ng/kg body weight.	Botulinum toxin, Staphylococcal enterotoxin B.
C	Required approval prior to initiation: IBC (complete application) IRB NIH OSP	Deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants.	Human gene transfer studies.
D	Required approval prior to initiation: IBC (complete application)	• Work involving Risk Group 2 materials. • Creation of transgenic animals containing > ⅔ of eukaryotic viral genome. • Large-scale work (>10L) regardless of biosafety level.	• Use of Risk Group 2 engineered plants. • Use of viral vectors (e.g., Lentivirus). • Creation of transgenic mice, zebrafish, or Drosophila. • Use of a 10L fermenter of rDNA culture.
E & F	Required notice simultaneous with initiation: IBC (complete rDNA registration)	• Most work involving Risk Group 1 materials.	• Use of Risk Group 1 transgenic rodents. • *Escherichia coli* K12, *Saccharomyces cerevisiae*, or *Bacillus subtilis*, and their plasmids. • Formation of rDNA molecules containing < ⅔ of eukaryotic viral genome. • PCR, oligonucleotides