

Registration and Approval of Experiments Involving RECOMBINANT DNA

YALE BIOLOGICAL SAFETY COMMITTEE

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This outline provides an overview of the “Guidelines for Research Involving Recombinant DNA Molecules” (NIH rDNA Guidelines). It is the responsibility of each investigator to make sure that their laboratory is in compliance with these Guidelines. If your experiments require registration, check the NIH Guidelines for the appropriate biosafety level and relevant section or contact the Biosafety Office or your Safety Advisor for assistance. For additional information, copies of the NIH Guidelines or rDNA registration forms, please call the Office of Environmental Health & Safety (OEHS) at 785-3550.

EHS contacts: Phone: (203) 785-3550 Fax: 785-7588 Website: www.yale.edu/oehs

Yale rDNA Forms and Information Regarding rDNA: <http://www.yale.edu/oehs/bioreqIII.htm>

NIH Office of Biotechnology Affairs website: <http://www4.od.nih.gov/oba/rdna.htm>

Experiments which must be registered and approved prior to initiation:

1. Deliberate transfer of a drug resistance trait to a microorganism (if it could compromise the use of the drug to control disease agents in human, animals, or agriculture);
2. Human gene transfer experiments;
3. Cloning DNA or RNA encoding molecules lethal to vertebrates at an LD50 of < 100 ug/kg body weight;
4. Experiments using human or animal pathogens as host-vector systems;
5. Cloning of DNA or RNA from all Risk Group 3, 4, or restricted pathogens (includes HIV and human tumor viruses), as well as Risk Group 2 experiments involving $\geq 50\%$ of genetic material;
6. Recombinant DNA experiments involving whole animals or plants;
7. Large-scale DNA work (i.e., ≥ 10 liters of culture combined).

Examples:

1. Transferring a drug resistance trait that is used, had previously been used, may be used (outside the U.S.), or that is related to other drugs that are used to treat or control disease agents. Examples include: Transfer of Erythromycin resistance into *Borrelia burgdorferi*; Transfer of Pyrimethamine resistance into *Toxoplasma gondii*; Transfer of Chloramphenicol resistance into *Rickettsia conorii*; Transfer of Tetracycline resistance into *Porphyromonas gingivalis*.
2. Use of a defective adenoviral vector to deliver the CFTR gene intranasally to patients with Cystic Fibrosis; Introduction of a HSV-TK transduced cell line into patients with epithelial ovarian carcinoma, followed by therapy with Gancyclovir.
3. Cloning toxins (or using plasmids that express toxins with low LD50's) such as Botulinum, Tetrodotoxin, Ricin, T-2, Saxitoxin, Abrin, Tetanus, Shigella Dysenteriae, Pertussis, Staph Aureus Beta, ShigaToxin, and Conotoxins;
4. Use of pathogens or defective pathogen vectors (with or without helper virus), such as Adenovirus, Adeno-Associated virus, Baculovirus, Herpes virus, Lentivirus, Retrovirus, Vaccinia and Vesicular Stomatitis Virus.
5. rDNA experiments involving any quantity of genetic material from a Risk Group 3 or higher pathogens (e.g., HIV, HTLV-1 & II, Prions, Mycobacterium tuberculosis, West Nile Virus, Lymphocytic Choriomeningitis Virus, and Rickettsia typhi. Note that rDNA experiments involving $\geq 50\%$ of genetic material from Risk Group 2 organisms must also be registered with the IBC.
6. Creation of transgenic animals or plants (mice, rats, zebra fish, drosophila, etc.), or knockout animals that leave genetic material in the animal as part of the silencing of the gene. Note: the purchase (or transfer to your lab) of previously created transgenic rodents is exempt from the regulations.
7. Use of a 10 L fermentor or growing up five 2 L flasks of rDNA culture (i.e. E. coli K-12) qualifies as a large scale experiment.