

UCSB Biosafety Handbook

5.0 CHAPTER 5 - RECOMBINANT DNA, GENE THERAPY & TRANSGENICS

5.1 Recombinant DNA

Experiments involving the generation of recombinant DNA (rDNA) normally require registration and approval by the IBC. [Guidelines for Research Involving Recombinant DNA Molecules](#) (April 1998) published by the National Institutes of Health (NIH), is the definitive reference for rDNA research in the United States and has been adopted by UCSB. If the experimental protocol is not covered by the guidelines, contact the UCSB Biosafety Office at 893-8894 for determination of further review. UCSB labs using recombinant DNA must submit a form for IBC approval. <http://www.rgs.ucsb.edu/rig/formsbio.htm>

If you have any specific questions about a particular host-vector system not covered by the guidelines, please call the Biosafety Office to request review by the IBC. Guidelines are published in the Federal Register.

5.2 Human Gene Therapy

All protocols involving the generation of rDNA for human gene therapy must be approved locally by the IBC prior to submission to outside agencies and the initiation of experimentation. Prior approval by the Human Subjects Program is required before commencing gene therapy in humans. For more details about IBC approval of human gene therapy protocols, call (949) 824-9888.

5.3 Transgenics

5.3.1 Transgenic Animals

Investigators who create transgenic animals must complete a BUA form and submit it to EH&S for IBC approval prior to initiation of experimentation. In addition, the Institutional Animal Care and Use Committee (IACUC) requires that these protocols be approved by EH&S prior to full approval by the IACUC.

5.3.2 Transgenic or Exotic Plants or Pests

Experiments to genetically engineer plants by recombinant DNA methods may require registration with the IBC. To prevent release of transgenic plant materials to the environment, the NIH rDNA guidelines provide specific plant biosafety containment recommendations for experiments involving the creation and/or use of genetically engineered plants. Use of transgenic or exotic plants or pests may necessitate additional training, containment, and security requirements. <http://www.aphis.usda.gov/>

