Responsibilities of Researchers Using Recombinant DNA/ Human Gene Transfer Experiments

If you are doing research involving recombinant DNA, you are responsible for complying with the "NIH Guidelines for Research Involving Recombinant DNA Molecules," no matter what the source of your funding is. It is impossible to summarize the whole of those guidelines, but there are three groups of experiments that probably encompass the majority of work being done on campus. If your work does not fall clearly into one of these groups, consult the NIH Guidelines, by clicking on "Recombinant DNA" at the website http://www.ehs.unc.edu.

Exempt Experiments

Some recombinant DNA work is exempt from the Guidelines (Section III-E) and do not require approval by the Institutional Biosafety Committee (IBC). These experiments should be reported on Appendix A of the Internal Processing Form from Office of Research Services when applying for a grant. All such research must be conducted using Biosafety Level 1 Practices (BL-1) (see reverse side). This group includes (but is not limited to) experiments that:

1) use as host-vector systems *E. coli* K-12, *Saccharomyces cerevisiae*, *Saccharomyces uvarum*, or *Bacillus subtilis*, and their plasmids;
2) rDNA molecules containing less than one-half of any eukaryotic genome that are propogated and maintained in cells in tissue culture.

Experiments Requiring Prior Approval

The following experiments require prior approval from either the NIH, Recombinant DNA Advisory Committee (RAC), Food and Drug Administration, and/or the IBC. These experiments are to be described on the form "Registration of Recombinant DNA Experiments", (Schedule G of the Laboratory Safety Plan) and sent it to Environment, Health and Safety (EHS).

1) Gene transfer experiments in humans;
2) Genes for toxins lethal for vertebrates;
3) Release of genetically engineered organisms to the environment;
4) Those using human or animal pathogens (biosafety level 2 and higher) as host-vector systems, including adenovirus vectors and murine retroviruses that infect human cells;
5) Cloning DNA from human or animal pathogens (biosafety level 2 and higher) into a non-pathogen host-vector system;
6) Cultures of more than 10 liters; and,
7) Experiments involving whole plants or animals, including transgenic organisms.

Experiments Requiring IBC Notice Simultaneous with Initiation

Some recombinant DNA work requires IBC review and approval, but prior approval is not required, and may be conducted at BL1 containment. These experiments are to be described on the form "Registration of Recombinant DNA Experiments", and sent to EHS. Examples include:

1) Recombinant DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (with some restrictions) propogated and maintained in cells in tissue culture. It must be demonstrated that the cells lack helper virus for the specific families of defective viruses being used.
2) Many, but not all, experiments involving whole plants.

To obtain electronic copies of the forms access the EHS website: http://www.ehs.unc.edu and click on " Biological Safety", then on "Recombinant DNA".

- Some plant experiments do not require prior approval. Work with recombinant DNA in plants or any work with plant pathogens must also comply with USDA and EPA regulations.

Submission of Experiments to the IBC

To submit a proposal to the IBC, please complete the Schedule G of the Laboratory Safety Plan form "Registration of Recombinant DNA Experiments and send it Environment, Health and Safety. The information provided must be in sufficient detail to allow for an informed review by the committee. The registration documents must be typed. To obtain electronic

copies of the forms access the EHS website: http://www.ehs.unc.edu and click on "Biological Safety" , then on "Recombinant DNA". You can access the NIH Guidelines at the same website.

The IBC meets monthly. If you anticipate submitting a proposal for IBC approval you should do so before the 15th of each month. The committee will then review the proposal within three weeks.

Reporting Significant Problems and Serious Adverse Events

The IBC also reminds you that the NIH Guidelines requires principal investigators to report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/ORDA within thirty days. Reports are to be sent to the Institutional Biosafety Committee, Environment Health and Safety, CB# 1650 and to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.

Principal Investigators who have received authorization from FDA to initiate a human gene transfer protocol must report immediately in writing any serious adverse event to the local Institutional Biosafety Committee, Institutional Review Board, Office for Protection from Research Risks (if applicable), NIH/ORDA, and FDA. Reports of serious adverse events may be submitted by e-mail to: ci4e@nih.gov, fax to: 301-496-9839, or by mail to: the Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, MD 20892-7010. For more information on reporting requirements see the UNC Recombinant DNA and Human Gene Transfer Experiments policy on our website http://www.ehs.unc.edu or Appendix M-VII-C of the NIH Guidelines.

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