Research Involving Recombinant DNA

Background:

The University of Wisconsin - Milwaukee adheres to the NIH Guidelines for Research Involving Recombinant DNA Molecules with regard to all uses of recombinant DNA at the University. Experiments involving recombinant DNA are divided into categories denoted as classes. Presently there are 6 classes (III-A, III-B, III-C, III-D, III-E and III-F). It is the responsibility of the PI to read the NIH Guidelines in order to determine which class is applicable to the work conducted. UWM requires that all recombinant DNA work done at the University be registered with the Institutional Biosafety Committee (IBC) EVEN IF IT IS EXEMPT from the NIH Guidelines.

It is the policy of the University that the Principal Investigator is responsible for complying with the NIH Guidelines for Research involving Recombinant DNA Molecules, regardless of the source of funds supporting that research. It is not possible 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.

Exempt Experiments:

To register exempt rDNA research complete "Registration Cover Sheet", noting the reason the research is exempt and a "Recombinant DNA Registration Form for Exempt Research" and send to the UWM Biosafety Officer. The IBC via subcommittee review will certify the project as exempt. All such research must be conducted using Biosafety Level 1 (BL-1) Practices. This group includes, but is not limited to, experiments that involve:

1. Work that is not in an organism, e.g., sequencing of DNA and polymerase chain reaction.
2. DNA propagated solely in the same species (this exemption can not be used if elements of the construct such as promoters, enhancers and marker traits are derived from another organism.
3. Gene transfer between species known to exchange DNA by known physiological means.
4. rDNA molecules containing less than ½ of any eukaryotic virus genome that are propagated and maintained in cells in tissue culture.
5. Host vector systems using E. Coli K-12, Saccharomyces cerevisiae, Saccharomyces uvarum, Bacilllus subtilis, Neuospora crassa, or Psuedomonas putida and their plasmids
6. Work that does not present a risk, as determined by the NIH Director. It is not sufficient for an investigator to declare that the research does not present a risk to humans, animals, or the environment. This decision is made through special correspondence with the NIH Director.

Experiments Requiring IBC Notice Simultaneous with Initiation:

Some recombinant DNA work requires IBC review and approval simultaneous with initiation (prior approval is not required). To register non-exempt rDNA research complete "Registration Cover Sheet", and a "Recombinant DNA Registration Form for Non-Exempt Research" and send to the BSO. Examples include:

1. Recombinant DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (with some restrictions) propagated 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.

Experiments Requiring Prior Approval:

The following experiments require approval from either the NIH, Recombinant DNA Advisory Committee (RAC), Food and Drug Administration (FDA) and/or the IBC. To register these projects complete “Registration Cover Sheet”, and a “Recombinant DNA Registration Form for Non-Exempt Research” and send to the BSO with the applicable supporting documentation.

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 or 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 or higher) into non-pathogen host vector system
6. Cultures involving more than 10 liters
7. Experiments involving whole plants or animals, including transgenic organisms

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