

Chapter 5 Recombinant DNA

Experiments involving the generation of recombinant DNA (rDNA) require review and approval by the IBC. "Guidelines for Research Involving Recombinant DNA Molecules," published by the National Institutes of Health (NIH), is the definitive reference for rDNA research in the United States and has been adopted by the UofA. If you have any specific questions about a particular host-vector system not covered by the Guidelines, please call the IBC Office for assistance. Guidelines are published in the Federal Register and are also available from the IBC Office and on-line.

It is the policy of the University of Arizona IBC that research defined as exempt by the NIH Guidelines must be documented by a Memorandum of Understanding and Agreement (MUA) and be reviewed and approved by the IBC. In accordance with the NIH Guidelines, the IBC considers research involving polymerase chain reaction (PCR) and the use of oligonucleotide primers and DNA and RNA probes as rDNA research that requires the completion of an MUA.

The IBC has the following responsibilities:

1. Review all recombinant DNA research protocols for compliance with the NIH Guidelines.
2. Review all rDNA research protocols to ensure that the work being done is appropriately contained.
3. Review and approve all emergency plans covering accidental spills of rDNA materials.
4. Report all violations of the NIH Guidelines to the Vice President for Research.

Human Gene Therapy

All protocols involving the generation of rDNA for human gene therapy must be approved by the IBC prior to submission to outside agencies such as the Recombinant DNA Advisory Committee (RAC) 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 the IBC Office.

Transgenics

Transgenic Animals

Investigators who create transgenic animals must submit an MUA prior to initiation of the experiment. In addition, the appropriate Institutional Animal Care and Use Committee (IACUC) documents must be completed and approved prior to initiating the research.

Transgenic Plants

Experiments to genetically engineer plants by recombinant DNA methods require IBC review and approval. To prevent release of transgenic plant materials into the environment, the NIH rDNA guidelines provide specific plant biosafety containment recommendations for experiments involving the creation and/or use of genetically engineered plants.

Quiz

1. The Institutional Biosafety Committee (IBC) is responsible for:
 - Reviewing all recombinant DNA (rDNA) research protocols for compliance with the NIH Guidelines.
 - Review all rDNA research protocols to ensure that the work being done is appropriately contained.
 - Review and approve all emergency plans covering accidental spills of rDNA materials.
 - All of the above.
2. Currently, the IBC considers research involving polymerase chain reaction (PCR) exempt from review.
 - True
 - False
3. Currently, the IBC considers research involving oligonucleotide primers and DNA and RNA probes exempt from review.
 - True.
 - False.
4. The major reference document used by The University of Arizona in the oversight of recombinant DNA research is:
 - The Occupational Health and Safety Act of 1970 (OSHAct) as administered by the Arizona Department of Occupational Health and Safety (ADOSH).
 - The Environmental Protection Act of 1970 (EPA).
 - National Institutes of Health, "Guidelines for Research Involving Recombinant DNA Molecules", current addition.
 - None of the above.
5. Research involving the generation of rDNA for human gene therapy must be reviewed by:
 - National Institutes for Health Recombinant DNA Advisory Committee (RAC).
 - Institutional Biosafety Committee.
 - Human Subjects Protection Committee
 - All of the above.
6. Principal Investigators who propose conducting human gene therapy research must provide the following to the IBC:
 - Copy of the National Institutes for Health Recombinant DNA Advisory Committee (RAC) review letter.
 - Copy of the Investigator's Brochure from the sponsor of the research.
 - Memorandum of Understanding and Agreement form (MUA).

- All of the above.
7. Principal Investigators may not administer human gene therapy to patients until both the Human Subjects Protection Committee and the Institutional Biosafety Committee approve the protocols.
- True.
 - False.
8. Principal Investigators who propose conducting human gene therapy research must provide information about how staff will be protected from unnecessary exposure during preparation and administration of the gene therapy material.
- True
 - False
9. A transgenically modified organism (GMO) refers to any animal (vertebrate or invertebrate) or plant in which there has been a deliberate modification of the genome.
- True.
 - False.
10. Investigators who are considering using transgenically modified mice are exempted from the requirements of the Institutional Animal Care and Use Committee (IACUC).
- True.
 - False.