



UNIVERSITY OF MINNESOTA

Environmental Health & Safety
IMPROVING THE QUALITY OF OUR WORK AND STUDY ENVIRONMENT

Bio Basics Fact Sheet: U of M Requirements for Working With rDNA

Purpose:

To provide an overview of the requirements for working with rDNA at the University of Minnesota .
Recombinant DNA is defined as:

1. Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.
2. Molecules that result from the replication of those molecules described above.

The intent of the following requirements is to provide a safe work environment and to meet compliance regulations.

Risk Determination and SOP Development:

- Be familiar with the risks associated with specific recombinant systems, i.e.
 - It is not possible to completely ensure that a replication-deficient virus will not gain back genes to become replication-competent.
 - Viral vectors do not need to be replication-competent in order to cause health problems such as eye damage.
 - It is possible for a "gene of interest" to be acquired by viruses or cells not expected to be associated with the gene.

Due to these safety concerns, initial biosafety containment recommendations are made according to the properties of the "wild type" virus along with hazard characteristics of the "gene of interest".

- Make an initial determination of the required level of physical and biological containment (BSL 1, 2, or 3) in accordance with *NIH Guidelines for Research Involving Recombinant DNA Molecules*, http://oba.od.nih.gov/rdna/nih_guidelines_oba.html.
- Keeping in mind the above BioSafety Level determination, select the appropriate microbiological practices and laboratory techniques to be used for your specific research. Incorporate this information in written **lab-specific** Standard Operating Procedures (SOPs), <http://www.dehs.umn.edu/PDFs/writingSOP.pdf>. For example,
 - Include the use of personal protective equipment such as eye protection when working outside the biological safety cabinet.
 - Secondary containment should be used when centrifuging rDNA material to prevent contamination.

Institutional Biosafety Committee Oversight:

- **All rDNA work, including work exempt from NIH rDNA guidelines**, must be approved by the Institutional Biosafety Committee (IBC) before work is started. Approved protocols are effective for three years with annual review.
- Submit rDNA forms by downloading from <http://cflegacy.research.umn.edu/ibc/download/index.cfm>. For prompt processing, fill out the form completely and provide any additional pertinent information the committee will need to assess the risks associated with the proposal and the proposed biosafety levels, i.e.
 - If animals are to be used in the rDNA work, include information regarding shedding of the material in order to assess the biosafety level for animal housing.
 - Describe the safety features built into constructs such as removing all regions of homology with the packaging virus to prevent recombination resulting in replication-competent viruses.
- The IBC approval process includes review of Standard Operating Procedures and proposed laboratory and animal biosafety levels in regards to the associated inherent risks and the proposed measures to be taken to reduce safety risks. Research may not commence until IBC approval is granted.

General Practices:

- Follow *NIH Guidelines for Research Involving Recombinant DNA Molecules*, http://oba.od.nih.gov/rdna/nih_guidelines_oba.html. Pay particular attention to Section II, Safety Considerations.
- No rDNA material may be released outside the laboratory, including Biosafety Level 1 material:
 - All waste must be decontaminated prior to disposal or disposed of as biohazard waste, http://www.dehs.umn.edu/bio_wastedisptble.htm.
 - All material must be contained during handling procedures.
- Complete *NIH Required IBC Training Presentations* through IBC, <http://cflegacy.research.umn.edu/ibc/training/index.cfm>
- Provide annual lab-specific safety training including review of SOPs that describe the potential biohazards, the precautions to be taken, and emergency/accident response. Document training.
- If viral vectors or other materials being used require Biosafety Level 2 practices, complete an annual biosafety evaluation and biological materials inventory update with Environmental Health and Safety, http://www.dehs.umn.edu/bio_LabSafetyVisits.htm.
- Follow all procedures for working at [BSL 2 in Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th Edition](#), and the Biosafety Manual section of the DEHS web page, http://www.dehs.umn.edu/bio_pracprin.htm.
- Transgenic or gene knock-out animals and animals injected with rDNA material can not be sent to the Raptor Center.