

Helpful Links & Frequently Asked Questions

Office of Biotechnology Activities:

<http://www4.od.nih.gov/oba/>

Investigator Responsibilities Under the NIH Guidelines for Research Involving Recombinant DNA Molecules.

<http://oba.od.nih.gov/oba/ibc/InvestigatorEducationalBrochureRecombinant%20DNA.pdf>

National Center for Biotechnology Information:

<http://www.ncbi.nlm.nih.gov/>

The Health Canada website (contains MSDS sheets for many organisms):

<http://www.phac-aspc.gc.ca/msds-ftss/index.html>

Review Process for Human Gene Transfer Trials posted on the OBA website:

http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm

Frequently Asked Questions:

1. How do you know if you need RDC approval?

If you are growing up bacteria that have plasmids into which gene sequences of interest have been cloned, using a cDNA or genomic library, mammalian cells which contain vectors or similar reagents, you are doing recombinant DNA research, and you will need approval.

If the only DNA work you are doing uses oligonucleotides, siRNA, primers or PCR products that are not cloned, you are not doing recombinant DNA research, and you do not need RDC approval.

2. When is recombinant DNA research considered “exempt”?

Research is categorized as “exempt” for several reasons specified in the NIH Guidelines, Section III-F and Appendix C,

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

Examples of Common Exempt Experiments:

- Experiments which use *E. coli* K-12 host-vector systems (i.e. strains that cannot survive outside of the laboratory) provided that no elements which will alter its host range are present and no harmful genes are cloned (eg. human toxins).
- Experiments which use *S. cerevisiae* and *S. uvrum* host-vector systems (i.e. laboratory strains).
- Eukaryotic cells cultures containing recombinant DNA (not otherwise considered as RG 2-4) in less than 10 liters. Note: if you plan to use viral vectors to introduce recombinant DNA into cultured cells, this work is not exempt (see item 3 below).

3. What is considered “Class 2” Recombinant DNA Work?

Examples: Work with retroviruses lentiviruses and adenoviruses most often are class 2. A complete list of Class II reagents may be found in Appendix B-2 of the NIH Guideline,

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

Biosafety Level 2 precautions must be followed and an Inventory List needs to be provided with the RDC forms. Work is subject to annual review by the RDC committee. Research involving Class III and IV agents is not allowed at any Lifespan facility