**CASE**

CASE WESTERN RESEVE UNIVERSITY

# Institutional Biosafety Committee

As a condition of [National Institutes of Health](http://www.nih.gov/) (NIH) funding, institutions conducting or sponsoring recombinant DNA research that is covered by the [NIH Guidelines for Research Involving Recombinant DNA Molecules](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) are responsible for ensuring that the research is conducted in compliance with the provisions of the NIH Guidelines. For this purpose, the Institutional Biosafety Committee (IBC) was formed. Consisting of Case Western Reserve University (CWRU) faculty and community representatives, the committee is charged with the responsibility for the oversight and approval of research activities involving recombinant DNA conducted at or sponsored by CWRU, or research conducted by CWRU faculty (this includes investigators whose laboratories are located at the VA Northeast Ohio Healthcare System - VANEOHS), staff or students.


Research Projects Requiring IBC Registration

Recombinant DNA research conducted at the VANEOHS must be conducted with appropriate safeguards against environmental release and for protection of research personnel. Accordingly, VA funded and non-VA funded projects and proposals performed on-site or in leased space and which involve recombinant DNA molecules must be registered with the Case Institutional Biosafety Committee (IBC), prior to the initiation of research. The committee shall review for approval all work requiring containment at Biosafety Level-2, Biosafety Level-3, and Biosafety Level-4. See [Appendix G, NIH Guidelines](http://www4.od.nih.gov/oba/RAC/guidelines_02/appendix_g.htm) and the CDC's [Biosafety in Microbiological and Biomedical Laboratories, 4th Edition](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm).


***Please indicate if you are performing any of the procedures listed below.***

Experiments that Must be Registered & Approved PRIOR to Initiation:

YES [ ]  NO [ ]  Cloning of DNA encoding molecules toxic to vertebrates within LD50<100ng/kg body weight.

YES [ ]  NO [ ]  Cloning of total DNA from all Class 2, 3, or 4 human or animal pathogens (including HIV and related viruses, and human tumor viruses).

YES [ ]  NO [ ]  Experiments using as vectors more than two-thirds of the genome of infectious animal or plant viruses or defective recombinant viruses grown in the presence of a helper virus.

YES [ ]  NO [ ]  Cloning using human or animal pathogens as host-vector systems.

YES [ ]  NO [ ]  All experiments that may generate transgenic animals, including rodents constructed or purchased, or plants which may extend the host-range of human, or animal pathogen or that require BL-2 or greater containment.

YES [ ]  NO [ ]  All human gene transfer experiments.
Experiments that Require Registration Simultaneous with Initiation:

YES [ ]  NO [ ]  Experiments using as vectors less than two-thirds of the genome of defective animal or plant viruses, free of helper virus.

YES [ ]  NO [ ]  Cloning of DNA for more than one-half of the genome of Class 1 or Class 2 human or animal pathogens, or cloning of known oncogenes.

YES [ ]  NO [ ]  Generation of transgenic animals requiring ABL-1 containment.

YES [ ]  NO [ ]  Experiments involving whole plants.

Exempt Experiments that *Do Not* Require Registration:

Refer to the [Guidelines, Section III-F](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) for a detailed explanation of exempt experiments not requiring registration with the IBC.

Typical exempt experiments are:

YES [ ]  NO [ ]  Expression of proteins in prokaryotic hosts as long as culture volume is less than 10 liters, the protein is nontoxic and the source DNA is not from a classified pathogen.

YES [ ]  NO [ ]  Expression of genes from either prokaryotic or eukaryotic sources when introduced in vertebrate cells in culture as long as the vector contains less than 2/3 of a viral genome, cannot be packaged into a viral particle, and cannot replicate autonomously.

YES [ ]  NO [ ]  Expression of genes in yeasts unless the source of DNA is from a classified pathogen.

YES [ ]  NO [ ]  Generation of transgenic flies or fish unless the source of DNA is from a classified pathogen.

YES [ ]  NO [ ]  Cloning of all other DNA in *E. coli* K12, *S. cervisiae*, and *B. subtilis* host-vector systems (with the exception of DNA from Class 2, 3, or 4 pathogens).

YES [ ]  NO [ ]  Introduction into cultured cells of any recombinant DNA containing less than half of a eukaryotic viral genome (with the exception of Class 2, 3, or 4 pathogens).

YES [ ]  NO [ ]  Purchase or transfer of transgenic rodents except those requiring BL-2 or higher containment.

## Acknowledgement of Responsibility and Knowledge of Work Involving recombinant DNA

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State and local policies, regulations and CDC‑NIH Guidelines governing the use of recombinant DNA. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of rDNA.
 **Principal Investigator's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_**