

## Exempt Experiments Requiring Case IBC Review before Letter of Exemption

### Examples of Exempt Experiments:

- 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.
- 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.
- Expression of genes in yeasts unless the source of DNA is from a classified pathogen.
- Cloning of all other DNA in *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host-vector systems (with the exception of DNA from Class 2, 3, or 4 pathogens).
- Introduction into cultured cells of any recombinant DNA (not-virus vector) containing less than half of a eukaryotic viral genome (with the exception of Class 2, 3, or 4 pathogens).
- Purchase or transfer of transgenic rodents except those requiring BL-2 or higher containment.

### As found in the NIH Guidelines for Research Involving Recombinant DNA Molecules

\*Refer to the [Guidelines, Section III-F](#) for a detailed explanation of exempt experiments below:

- III-F-1: Experiments that are not in organisms or viruses.
- III-F-2: Experiments that consist entirely of DNA segments from a single nonchromosomal or viral DNA source.
- III-F-3: Experiments that consist entirely of DNA from prokaryotic host when propagated only in that host or transferred to another host by a well established physiological means.
- III-F-4: Experiments that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host.
- III-F-5: Experiments that involve DNA segments from different species that exchange DNA by known physiological processes.
- III-F-6: Experiments that do not pose a risk to health or the environment, as determined by the NIH Director, with the advice of RAC and following appropriate notice and opportunity for public comment.

\*Refer to the [Guidelines, Appendix C](#) for a detailed explanation of exempt experiments below:

- Appendix C-1: Recombinant DNA (not virus-vector) conducted in tissue culture; containing less than half of a eukaryotic viral genome (with the exception of Class 2, 3, or 4 pathogens); under BL-1 conditions.
- Appendix C-II: *Escherichia coli* K-12 host-vector system conducted at BL-1.
- Appendix C-III: *Saccharomyces* host-vector system conducted at BL-1.
- Appendix C-III: *Bacillus subtilis* or *Bacillus licheniformis* host-vector systems conducted at BL-1.
- Appendix C-IV: Purchase or transfer of transgenic rodents, except those requiring BL-2 or higher containment.
- Appendix C-V: DNA experiments involving recombinant DNA molecules derived entirely from extrachromosomal elements of a gram positive organism distributed and maintained in organisms (from this list) which are conducted at BL-1.