Safety Considerations

Section II of the *NIH Guidelines* focuses on safety considerations for research with recombinant and synthetic nucleic acids.

Section II – Risk Groups

- **Appendix B of the *NIH Guidelines* lists biological agents known to infect humans as well as selected animal agents that have the potential to infect humans.**
- **Biological agents are assigned to one of four risk group based on the potential effect of the agent on a healthy human adult.**

Section II – Risk Groups

RG 1	RG 2	RG 3	RG 4
Agents that are not associated with disease in healthy adult humans	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)

Containment

In proposing research, the PI must make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*.

The PI must also propose appropriate microbiological practices and laboratory techniques to be used for the research

Physical Containment

- **Four biosafety levels are described in Appendix G of the *NIH Guidelines*. These biosafety levels consist of a combination of lab practices and techniques, safety equipment, and lab facilities appropriate for the operations being performed.**
- **Biosafety level 4 provides the most stringent containment conditions, biosafety level 1 the least stringent.**

For more information see:
http://oba.od.nih.gov/oba/rac/guidelines_02/Appendix_G.htm

Physical Containment (continued)

APPENDIX P - PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RECOMBINANT DNA RESEARCH INVOLVING PLANTS

Appendix P of the *NIH Guidelines* specifies physical and biological containment conditions and practices suitable to the greenhouse conduct of experiments involving recombinant DNA-containing plants, plant-associated microorganisms, and small animals.

http://oba.od.nih.gov/oba/rac/guidelines_02/Appendix_P.htm

Physical Containment (continued)

APPENDIX Q - PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RECOMBINANT DNA RESEARCH INVOLVING ANIMALS

Appendix Q specifies containment and confinement practices for research involving whole animals, both transgenic animals and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.

Appendix Q supersedes Appendix G when research animals are of a size or have growth requirements that preclude the use of containment for laboratory animals. The animals covered in Appendix Q include but are not limited to cattle, swine, sheep, goats, horses, and poultry.

http://oba.od.nih.gov/oba/rac/guidelines_02/Appendix_Q.htm

Biological Containment

- **Biological containment is the application of highly specific biological barriers. Such barriers limit either the infectivity of a vector for specific hosts, or its dissemination and survival in the environment.**
- **Vectors can be genetically designed to decrease, by many orders of magnitude, the probability of dissemination of recombinant DNA outside the lab.**

For more information see:
http://oba.od.nih.gov/oba/rac/guidelines_02/Appendix_I.htm