

## Risk Groups and Biosafety Levels for Research Involving Recombinant and Synthetic Nucleic Acid Molecules

Risk Group	Definitions for Risk	Typical Routes of Exposure	Biosafety Level (BSL)	Example Research Materials
1	Low, minimal Low individual & Low community Human disease unlikely No disease in man, no threat to environment	None Possible (Ingestion)	1  BSLs are a combination of work practices, protective equipment and the lab facility	Non-Pathogenic materials including: Escherichia coli K-12 cells, Bacillus subtilis, Saccharomyces cerevisiae, murine cells, dog cells, rabbit cells, other non-human or non-human primate cells. Recombinant experiments with these cells Recombinant vectors that contain less than 50% of the genome of a Risk Group 2 Pathogen (pBR, pSC, pcDNA vectors) Adeno-Associated Virus, SV40 Virus, Sendai virus
2	Ordinary Moderate risk for individual, limited community Possible threat to lab workers, unlikely to spread to environment	Ingestion Through Skin Through Eyes, Nose or Mouth	2  The BSL selected is a combination of the Risk Group of the research materials plus consideration of the procedures performed.  BSL1 and BSL2 labs share similar design features.  Aerosols are confined within biosafety cabinets or equivalent devices at BSL2	Human cells and other human materials, Non-human primate cells and other materials from non-human primates Toxins of biological origin Human oncogenic materials Recombinant experiments with greater than 50% of the genome of a Risk Group 2 Pathogen (examples below, links to full lists at end of table). Recombinant experiments with defective Pathogen vectors, including (Retroviruses, Lentiviruses, Adenoviruses, Herpesviruses, Vaccinia virus, Lab strains of Vesicular Stomatitis Virus, Sindbis virus)  Bacillus anthracis, Botulinum neurotoxin, Rabies virus, Hepatitis B and C viruses, Salmonella typhimurium, Pseudomonas aeruginosa, Plasmodium falciparum, Trypanosoma brucei, Candida albicans, Streptococcus pneumoniae, Staphylococcus aureus

3	Special, to individual High individual risk, limited community Severe threat to lab workers, small risk to population	Inhalation and all listed above	3  BSL3 requires specialized laboratory facilities to protect research personnel, those within the building and the public.	Recombinant DNA Experiments involving Risk Group 3 agents: (Risk Group 3 agents include) Mycobacterium tuberculosis, West Nile Virus, Chikungunya virus, Rickettsia prowazekii, Rickettsia conorii, St. Louis Encephalitis Virus, Powassan virus, Human Immunodeficiency virus, Yersinia pestis, Francisella tularensis, Brucella melitensis, Lymphocytic Choriomeningitis Virus
4	High individual, high community Serious hazard to lab worker and community	All Routes of Exposure	4  BSL4 labs are containment buildings within exterior buildings. Researchers wear a positive pressure suit or work within a sealed biosafety cabinet	No BSL4 research at Yale University  Ebola virus, Marburg virus, Equine Morbillivirus, Nipah and Hendra viruses, Tick-Borne Encephalitis viruses

Appendix B of NIH Guidelines – Classification of Etiologic Agents on the Basis of Hazard

[https://osp.od.nih.gov/wp-content/uploads/2019\\_NIH\\_Guidelines.htm#\\_Toc3457093](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093)

American Biological Safety Association (ABSA) Risk Group Tables

<https://my.absa.org/tiki-index.php?page=Riskgroups>