

Non-Exempt Experiments Summarized from the NIH Guidelines

Section III-A: Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation

- The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally

Section III-B: Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation

- The deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 or less than 100 nanograms per kilogram body weight)

Section III-C: Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation

- The deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic molecules, into one (1) or more human research participants

Section III-D: Experiments that Require Institutional Biosafety Committee Approval Before Initiation

- Using risk group 2, 3, 4 or Restricted agents as host-vector systems
- DNA from risk group 2, 3, 4 or restricted agents being cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems
- The use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems
- Involve whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germline (transgenic animals) and require BSL2 or higher containment
- Viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals
- Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., responses to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules
- Involve research or production of more than 10 liters of cultures of viable organisms containing recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom into germline (transgenic animals) and require no higher than BSL1 containment
- Involve influenza viruses generated by recombinant or synthetic nucleic acid molecules (e.g., generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations)

Section III-E: Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

- The formation of recombinant or synthetic nucleic acid molecules containing not more than 2/3 of the genome of any eukaryotic virus
- Experiments involving nucleic acid molecules-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecules-modified organisms associated with whole plants
- Experiments involving generations of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ line (transgenic rodents) and require no higher than BSL1 containment

If you believe your research may fall into one of the above categories, please read the applicable sections of the NIH Guidelines for more details:

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf