ENVIRONMENTAL HEALTH & SAFETY
UNIVERSITY of WASHINGTON

EXPERIMENTS COVERED BY THE NIH GUIDELINES

The NIH Office of Science Policy dictates that the Principal Investigator (PI) must self-identify the sections of *The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* that apply to their research. The NIH requires the PI to make an initial assessment before starting research with recombinant or synthetic DNA or RNA (rDNA). Projects that fall under Sections III-A to III-D may not begin until the Institutional Biosafety Committee (IBC) reviews and grants approval. The table below summarizes the experiments covered in each section of the NIH Guidelines.

SECTION	EXPERIMENTS COVERED	EXAMPLES
Section III-A	Experiments that require RAC review, NIH Director approval, and IBC approval before initiation	▪ Deliberate transfer of drug resistance to a microorganism that is not known to acquire it naturally, if such acquisition could compromise the ability to control disease in humans, animals, or agriculture
Section III-B	Experiments that require NIH Office of Science Policy and IBC approval before initiation	▪ Cloning of toxin molecules with LD_{50} less than 100 ng/kg
Section III-C	Experiments that require IBC approval and Institutional Review Board (IRB) approval before enrolling participants	▪ Human gene transfer
Section III-D	Experiments that require IBC approval before initiation	▪ rDNA modified Risk Group 2 microorganisms ▪ Viral vectors for gene transfer ▪ Transgenic animals other than rodents ▪ Gene drive modified organisms (GDMOs) ▪ Any rDNA administered to an animal
Section III-E	Experiments that require IBC notice simultaneous with initiation	▪ rDNA in Risk Group 1 microorganisms ▪ Experiments involving whole plants at BL1-P
Section III-F	Exempt experiments	▪ Recombinant or synthetic DNA/RNA that is not in organisms or viruses ▪ *E. coli* K-12, *B. subtilis* and *S. cerevisiae* used for cloning

Questions?

Contact EH&S for assistance at ehsbio@uw.edu or 206.221.7770.