When do I need to register my work with the Institutional Biosafety Committee?

The NIH Office of Science Policy compiles and maintains the NIH Guidelines for Researching Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019) on behalf of the NIH Director. Compliance is required for all institutions receiving NIH funding. This list is meant to serve as a guide for researchers but is not comprehensive or authoritative. Please contact a Biosafety Officer at biosafety@lists.upenn.edu with any questions or reach out to NIH OSP (NIHGuidelines@od.nih.gov).

III-A: Requires NIH & IBC Approval **Before** Initiation

Transfer of drug resistance to non-host microorganisms	If not known to acquire the trait naturally or could compromise the ability to control disease in humans, animals, or agriculture

III-B: Requires NIH & IBC Approval **Before** Initiation

Cloning of toxin molecules	If recombinant work will result in biosynthesis of toxin molecules lethal to vertebrates at LD_{50} < 200 ng/kg body weight * *contact NIH OSP for more info re: E. coli K12 specific approvals

III-C: IBC Approval **Before** Initiation

Human gene transfer	Recombinant DNA or RNA that do one of the following: contains >100 nucleotides, can integrate into the genome, replicate in a cell, be translated or transcribed

III-D: IBC Approval **Before** Initiation

Genetically-engineered plants or plant-associated insects or microbes	Exotic infectious agents, cloned genomes that may reconstitute via complementation, cloning vertebrate toxins *in planta,* recombinant microorganisms infecting small animals and insects associated with plants
Use of Risk Group 2, 3, & 4 or restricted agents	Viruses, host-vector systems, DNA encoding the above, helper virus systems (infectious or defective) in tissue culture
Whole animals	Genome editing (except rodents), modified microorganisms, modified cells
Influenza Viruses	Human H2N2 (1957-1968),H1N1 (1918) Avian H5N1 (highly pathogenic strains)
Large scale experiments (> 10 L culture)	Viral vector production, bacterial growth, tissue culture, eg

III-E: Requires IBC Approval **Simultaneous** with Initiation

Tissue culture	Culturing a single family of eukaryotic viruses containing less than <2/3rds of viral genome
Whole plants & plant-associated microbes	Noxious weeds, introducing complete genomes of non-exotic infectious agents, modified non-exotic microbes, modified arthropods or small animals associated with plants
Creation of transgenic rodents	Gene editing (eg CRISPR/Cas9), introduction of recombinant or synthetic nucleic acid into the germline of rodents (ABSL 1 only)

III-F: Exempt from NIH Guidelines*

*other state/local standards may apply

Breeding of transgenic rodents	If both parents are housed at ABSL1 and their genomes do not contain more than 50% of a eukaryotic virus genome or transgenes under control of a gammaretroviral LTR and If transgenic offspring are not expected to contain more than 50% of an exogenous viral genome
Non-replicable RNA/DNA	If it cannot replicate or generate nucleic acids, integrate into DNA, or code for a lethal toxin; will not be used in humans
Non-permeable RNA/DNA	If it cannot replicate or generate nucleic acids, integrate into DNA, or code for a lethal toxin; will not be used in humans
Naturally occurring elements	Exact sequence from a single source Prokaryotic plasmids/viruses propagated in same/similar species host DNA commonly exchanged between species
Transposable elements	If they do not contain recombinant DNA