Biosafety Protocol Registration Form B - Recombinant/Synthetic Nucleic Acids

Protocol Title:

Principal Investigator (PI)/ Teaching Lab Instructor:

Section 1 - Description of Biological Agent(s)

1. Recombinant/synthetic nucleic acid(s) (includes mobile genetic elements):

Gene/Genetic Information	Relevant Protein	Host (if virus is source)	Antibiotic/Drug Resistance

2. Plasmid(s):

Plasmid Name	Antibiotic/Drug Resistance	Empty Vector (Y/N)	Host Gene/Genetic Information Cloned/Relevant Protein (include risk group[a])	Source

[a] *Risk groups are defined on page 2 after question 3.*

3. Organism(s) (bacteria/fungi/parasite/virus):

Organism Name (Species)	Strain Number	Genotype/Relevant Characteristics	Antibiotic/Drug Resistance	Source	Risk Group[b]

[b]Risk groups are defined as:

- Risk group 1 – agent that is not associated with *disease in healthy adult humans [requires laboratory-specific biosafety manual for biosafety level 1]*
- Risk group 2 – agent that is associated with human disease which is rarely serious and for which preventive or therapeutic interventions are available *[requires laboratory-specific biosafety manual for biosafety level 2]*
- Risk group 3 – agent that is associated with serious or lethal human disease for which preventative or therapeutic interventions may be available (high individual risk but low community risk)
- Risk group 4 – agent that is 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)

Section 2 - Protocol Details

4. If virus is source of nucleic acid molecules, is it more than 2/3 of genome? ☐ Yes ☐ No

5. Will any of the following be used?

☐ Helper Virus ☐ Packaging System ☐ Complementary Cell

6. Is the solution volume ≥ 10 Liters? ☐ Yes ☐ No

7. Select any of the following that will be exposed to nucleic acid molecules:

☐ Mammalian cells or cell lines ☐ Human subjects ☐ Insects
☐ Animals ☐ Plants ☐ Field release

8. Will this project involve the use of CRISPR/Cas9 or a similar system? ☐ Yes ☐ No

* *If yes, must also submit "Form F- Gene Drive Modified Organisms."*

Section 3 - Dual Use Research

(Questions listed for concerns dealing with increasing virulence/pathogenicity of organisms)

9. Can any part of your project be classified as Dual Use Research? ☐ Yes ☐ No

**Dual Use Research describes investigations that yield new technologies or information with the potential for both benevolent and malevolent applications. Dual Use Research of Concern is research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel. For more information on Dual Use Research, go to Biosafety and Biosecurity Policy - Office of Science Policy (nih.gov)*

10. If yes, indicate the nature of your research below. Check all that apply.

- ☐ Enhances the harmful consequences of a biological agent or toxin
- ☐ Disrupts immunity or the effectiveness of an immunization against of a biological agent
- ☐ Confers to a biological agent or toxin resistance to drug treatment
- ☐ Makes a useful vaccine ineffective Increases pathogen virulence or transmissibility
- ☐ Interferes with or facilitates evasion of diagnostic or detection methods
- ☐ Facilitates weaponization of a biological agent or toxin

Section 4 - Risk Assessment Acknowledgement by PI/Instructor - *Please initial next to each requirement*

- ☐ PI/instructor will maintain a laboratory-specific biosafety manual
- ☐ PI/instructor will maintain a laboratory-specific acute toxin Standard Operating Procedures
- ☐ PI/instructor is responsible for conducting risk assessment training for all personnel working under this protocol and maintain record that all personnel trained understand risks associated
- ☐ PI/Instructor assures that the use of the toxin will be conducted in accordance with the BMBL (Biosafety in Microbiological and Biomedical Laboratories) published by the CDC and NIH