?? QUESTIONS ??

 Contact the IBC at

 102 Life Sciences

 (419) 372-8753

 jbarans@bgsu.edu

 FOR OFFICE USE ONLY

IBC ID #

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## INSTITUTIONAL BIOSAFETY COMMITTEE

**MEMORANDUM OF UNDERSTANDING AND AGREEMENT** – As of April, 2020

**Please answer all applicable questions and provide the material identified…………………** ***Please COMPLETE ELECTRONICALLY****.*

* *Applications judged to be illegible, incomplete, or vague will be returned to the Principal Investigator (PI) for revision.*
* *All boxes are expandable so be sure to include complete information, attaching continuation sheets as necessary.*
* *Submit the original, signed, hard copy application and an electronic version to the Institutional Biosafety Committee (IBC), 102 Life Sciences (jbarans@bgsu.edu).*

**I. General Information:**

Name of applicant (Principal Investigator):

The investigator is (check one): [ ]  Faculty [ ]  Staff

Department or Division:       Campus Phone:

E-mail:      Fax:

*The IBC will send all correspondence to your* ***departmental*** *address unless otherwise indicated on the line below*:

Title of the Proposed Research Project:

Have you requested external support for this project? [ ]  Yes [ ]  No

 If yes, external Funding Agency or Source:

**II. Project Specific Information**

 **A.** Are any of the following genes, viruses, factors or conditions involved? (*Check all that apply)*

Yes No

[ ]  [ ]  a. Deliberate transfer of drug resistance into organisms that do not acquire them naturally? (Except for approved host-vector systems that contain antibiotic resistance markers)

[ ]  [ ]  b. Deliberate transfer of recombinant DNA into humans?

[ ]  [ ]  c. Use or production of transgenic animals or plants.

[ ]  [ ]  d. Deliberate formation of recombinant DNA-containing genes that produce vertebrate toxins with LD50 less than 100 ng/kg of body weight? (Specific approval has been given by NIH for the cloning in *E. coli* K-12 of DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 ng to 100 g per kg of body weight)

[ ]  [ ]  e. Using human or animal pathogens (Risk Groups 2-4 and restricted agents) as host-vector systems?

[ ]  [ ]  f. Using human or animal pathogen DNA cloned into non-pathogenic prokaryote or lower eukaryote host-vector systems?

[ ]  [ ]  g. Using infectious animal or plant DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems?

[ ]  [ ]  h. Altering an animal genome by recombinant DNA or testing viable recombinant DNA-modified microorganisms in whole animals? (Work with animal pathogens requires a USDA permit)

[ ]  [ ]  i. Genetic engineering of plants by recombinant DNA methods or use of plants with microorganisms or insects containing recombinant DNA? (Work with plant pathogens requires a USDA permit)

[ ]  [ ]  j. Experiments involving more than 10 liters of culture?

[ ]  [ ]  k. Deliberate release of recombinant DNA-modified plants or animals into the environment – this requires review by the USDA and the EPA

[ ]  [ ]  l. Use of human or animal prions?

[ ]  [ ]  m. Will this require immunization of research team prior to the usage of infectious agents?

 **B.** In your judgment, does the proposed project involve any of the following? (*Check all that apply)*

Yes No

[ ]  [ ]  a. Demonstrate how to render a vaccine ineffective? *(This would apply to both human and animal vaccines. Production of a vaccine-resistant smallpox virus would be an example of these types of experiments.)*

[ ]  [ ]  b. Confer resistance to therapeutically useful antibiotics or antiviral agents? *(This would apply to therapeutic agents that are used to control disease agents in humans, animals, or crops. An example would be introduction of ciprofloxacin resistance in Bacillus anthracis.)*

[ ]  [ ]  c. Enhance the virulence of a pathogen or render a nonpathogen virulent? *(This would apply to plant, animal, and human pathogens. An example would be introduction of cereolysin toxin into Bacillus anthracis.)*

[ ]  [ ]  d. Increase the transmissibility of a pathogen? *(This would include enhancing transmission within or between species. Altering vector competence to enhance disease transmission would also fall into this class.)*

[ ]  [ ]  e. Alter the host range of a pathogen? *(This would include making nonzoonotics into zoonotic agents. Altering the tropism of viruses would fit into this class.)*

[ ]  [ ]  f. Enable the evasion of diagnostic/detection modalities? *(This could include microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.)*

[ ]  [ ]  g. Enable the weaponization of a biological agent or toxin? *(This would include the environmental stabilization of pathogens. Synthesis of smallpox virus would be an example of this class of experiment.)*

 **C.** Project Description (please provide a brief project description, including objectives and methodology):

 **D.** Host organism (List the Biosafety Level or Name and Strain of organism):      \_\_\_\_\_\_\_\_\_\_\_\_

 If *E. coli*, is it Enteropathogenic, Entertoxigenic, Enteroinvasive or a strain bearing K1 antigen?

 [ ]  Yes [ ]  No - If yes, it is a Risk Group 2 agent, requiring BL2.

 **E.** Describe the vectors and sources:

 **F.** Does this project qualify for an exemption from the NIH Guidelines? [ ]  Yes [ ]  No

 If yes, on what basis (please cite the sections of the Guidelines that establish the exemption)?

 **G.** Proposed Containment Level (Specify Physical level, Biological level or combination levels):

 **H.** List Disposal Method:

 **I.** Locations – List the names of the buildings and the room numbers of all laboratories in which the experiments will be conducted:

 **J.** Personnel – List the names and titles of all individuals engaged in the experiments:

 **K.** Training – Indicate the steps taken to ensure that laboratory personnel identified above are familiar with the NIH Guidelines, laboratory policies and procedures associated with work on this project and with the procedures to be followed in case of accident:

**III. Assurance by Principal Investigator (PI):**

The information provided in this Memorandum of Agreement is accurate and complete. I am familiar with and agree to abide by the relevant portions of the current NIH Guidelines and other specific instructions from NIH and the IBC pertaining to the proposed project. No changes in my research protocol will be implemented without prior review and approval of the Institutional Biosafety Committee.

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Submit the memorandum (hard copy) to the **Institutional Biosafety Committee, 102 Life Sciences** and e-mail electronic copy to **jbarans@bgsu.edu**

**Note: Do not submit this or any of the following pages with your MUA.**

 **Steps in the Process of Review by the Institutional Biosafety Committee**

1. A signed original and an electronic version of the completed Memorandum of Understanding and Agreement (MUA) are submitted to the Office of Research Compliance – 310 Hayes Hall.
2. Research Compliance Office distributes the MUA to IBC members for review at a convened meeting of the Committee.
3. The IBC reviews the information contained in the MUA and makes a determination regarding the proposed research:
	1. Declare it to be exempt from the federal guidelines
	2. Approve the research as submitted
	3. Approve the research subject to modifications
	4. Disapprove the research
	5. Defer action on the proposed research pending receipt of additional information
4. The Office of Research Compliance communicates the results of the review to the researcher.

The following definition is taken from the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*

*"Recombinant DNA Molecules”* means either (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i). Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines.* Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transposon itself contains recombinant DNA.