**INSTRUCTIONS**

This form must be filled out **completely** and sent electronically to showard@wellesley.edu. Incomplete forms will be returned.

* PI’s must receive a copy of the approved form for their records and may not start research until IBC approval, as applicable.
* The PI must notify the IBC Chair when significant changes occur in the project. Changes that require Proposal Amendments Forms include, but are not limited to, the following:
	+ - Change in personnel, including students
		- Change in laboratory location
		- Change in hazard control plans
		- Change in experimental methods
		- Change in infectious agents/ vectors
		- Use or change of human cell lines

If you need assistance or have questions concerning form completion contact the IBC Chair, Suzanne Howard in the Environmental Health and Safety Office at 7819-283-3882 or at showard@wellesley.edu.

Protocol Title:

Principal Investigator(s):

Department:

Proposed Start Date:

**1) Project Information:**

1. List all locations where research is to be conducted and the corresponding biosafety level. Please refer to the CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition for assistance in determining biosafety level of the laboratory rooms ([http://www.cdc.gov/biosafety/publications/bmbl5/index.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm))

|  |  |
| --- | --- |
| **Laboratory Room #** | **Proposed Biosafety Level** |
|  |  |
|  |  |

1. List which room number biological materials will be stored and where within the room they will be stored (i.e., freezer)

|  |  |
| --- | --- |
| **Laboratory Room #** | **Location** |
|  |  |
|  |  |

1. List all personnel associated with this project:

|  |  |
| --- | --- |
| **Personnel** | **Biosafety Training Date** |
|  |  |
|  |  |
|  |  |

**2) Project Description:**

Outline the overall goal(s) of the project. Give enough information that the techniquesused and purpose of the experiments are clear. Be as concise as possible using reasonably non-technical terms. For microorganisms, cell lines, tissues, blood, or other biological materials please list the species.

**3) Risk Assessment for Human Materials, Other Potentially Infectious Materials**

**[ ] This section is not applicable**

This section includes: **(1)** human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; **(2)** Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and **(3)** HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.), or use of *Nonhuman Primate Cells/Tissues*.

a) What Human Material(s) or OPIM will be used? Please describe.

b) What is the source of the Human Material?

c) Has the human material been genetically modified, and if so, how?

d) Will aerosol-generating procedures be used with biological agents or rDNA as part of the experiment? (e.g., centrifugation, homogenization, sonication, vortexing, pipetting)? If yes, please describe.

e) Will needles or other sharps be used? If yes, please describe.

f) Provide a brief assessment of the possible risks involved with this work. Include safety, security, environmental and perceived risks as appropriate.

• What are the potential results of an exposure to the materials used in this work?

• What procedures or processes could result in injury or exposure?

g) What strategies will you implement to reduce the risk of exposure (e.g., use of a biosafety cabinet, sealed centrifuge cups, sealed rotor)?

h) What PPE will be worn while performing this work?

i) In your estimation is medical surveillance needed?

j) In your estimation is vaccination needed?

k) What disinfectant will be used?

l) Describe decontamination/disposal procedures used for surfaces and solids/ liquid wastes.

**4) Risk Assessment for other biological material (ie. parasites, algae, fungi, bacteria, mycoplasma, rickettsiae, prions, insects etc.):**

**[ ] This section is not applicable**

a) What biological material(s) will be used? Include the species and strain.

b) Where will the biological material come from?

c) Does the biological material have any characteristics that affect its pathogenicity? (e.g. is it attenuated, drug-resistant, etc.)

d) Has the biological material been genetically modified, and if so, how?

e) Will aerosol-generating procedures be used with biological agents or rDNA as part of the experiment? (e.g., centrifugation, homogenization, sonication, vortexing, pipetting)? If yes, please describe.

f) Will needles or other sharps be used with the biological material? If yes, please describe.

g) Provide a brief assessment of the possible risks involved with this work. Include safety, security, environmental and perceived risks as appropriate.

• What are the potential results of an exposure to the materials used in this work?

• What procedures or processes could result in injury or exposure?

h) What strategies will you implement to reduce the risk of exposure (e.g., use of a biosafety cabinet, sealed centrifuge cups, sealed rotor)?

i) What PPE will be worn while performing this work?

j) In your estimation is medical surveillance needed?

k) In your estimation is vaccination needed?

l) What disinfectant will be used?

m) Describe decontamination/disposal procedures used for surfaces and solids/ liquid wastes.

**5) Please answer the questions below if your work involves recombinant or synthetic nucleic acid molecules:**

**[ ] This section is not applicable**

a) Please describe your work with recombinant or synthetic nucleic acid molecules.

b) Will this work lead to the creation of a transgenic animal or insect?

c) Will a foreign gene be expressed, and/or will genes be overexpressed/silenced? Please explain.

d) What is the nature of the gene of interest? Does it have a physiological effect or potential hazard? Do any of the sequences code for toxins? If so what is the LD50?

e) Could the experiment increase the virulence or drug resistance of a pathogenic organism?

f) Could the experiment expand the range or tropism of a pathogenic organism?

g) What vector will be used as part of this research?

h) Describe the source of the vector:

i) If using viral constructs, will replication competent virus being produced?

j) What steps will be taken to prevent replication-competent virus from being produced?

k) How probable is recombination leading to infectious viral vectors?

l) Will all viral preparations be characterized for presence or absence of replication competent virus? If not, is there appropriate preexisting data to assure us that the risk is minimal?

m) What percent of viral genome is in the construct?

n) Provide a brief assessment of the possible risks involved with this work. Include safety, security, environmental and perceived risks as appropriate.

• What are the potential results of an exposure to the materials used in this work?

• What procedures or processes could result in injury or exposure?

o) What procedures or processes could result in injury or exposure?

p) What strategies will you implement to reduce the risk of exposure (e.g., use of a biosafety cabinet, sealed centrifuge cups, sealed rotor)?

q) What PPE will be worn while performing this work?

r) Describe decontamination/disposal procedures used for surfaces and solids/ liquid wastes.

**Vectors and Host Cells:**

a) List host cells used to grow/amplify the construct.

b) List vectors used to insert construct into the cell. What are the host ranges?

c) Will the promoter(s) function in mammalian cells?

d) Please provide a restriction and gene map of vectors, inserts, promoters, and other control sequences.

**Cite the appropriate NIH Guideline section(s) for the research**. Refer to **Appendix A** for information. Contact IBC if you need assistance assessing the Guideline section that applies to your experiment. \_\_\_\_\_\_\_\_\_\_\_

**6) Use of Animals or Insects**:

1. Will animals or insects be used in this protocol? [ ] Yes [ ] No
2. List animals/insects used in the project

|  |  |  |
| --- | --- | --- |
| **Animal / Insect Species** | **Strain** | **Source (i.e., commercial vendor)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. Are any of the animals genetically modified? If so, how
2. Will biological materials or recombinant/synthetic nucleic acid molecules be administered to animals?

If yes, describe agent(s) to be administered, route of administration, and dose.

e) How will the animals/insects be accounted for?

**7) Material Transfer and Storage:**

a) Will materials be transferred from one lab and or building to another? If so, describe the procedure for transferring these materials. Include disinfection information, if needed, prior to transport.

b) Will materials be stored on campus for future use? If so, please describe where materials will be stored, how they will be labeled/inventoried.

c) Will materials be transferred to other researchers off-campus?

**8) Large Scale Research:**

Do experiments involve growth of more than 10 liters of culture at a time?

[ ] Yes [ ] No

**9) Dual Use Research Assessment**

Please read the following questions and answer below.

1. Will the experiment(s) result in acquisition of new characteristics such enhanced virulence, infectivity, stability, transmissibility, or the ability to be disseminated?
2. Will the experiment(s) result in resistance to useful prophylactic or therapeutic interventions?
3. Will the experiment(s) result in the biological agent being able to evade detection methodologies as such that the capacity to identify or provide treatment for the agent is compromised?
4. Will the experiment(s) enhance the susceptibility of a host to the biological agent?
5. Will the experiment(s) cause disruption in the immunity of the host or the effectiveness of immunization, or change the host range?
6. Will the experiment(s) generate or reconstitute a biological agent for which there are no known or widely available prophylactic or therapeutic interventions?
7. Will your research result in the development of materials or technologies with “dual use” potential?

**Are any of the above statements true? [ ] Yes [ ] No**

If yes, please indicate which question number(s) and your corresponding answer(s) below.

**Investigator’s Assurance:**

|  |
| --- |
| 1. I confirm that all persons involved with this project have been adequately trained in good microbiological techniques, have received instruction on any specific hazards associated with the project, are aware of any specific safety equipment, practices, and behaviors required while conducting project procedures and using these facilities and have the facilities and equipment to support the research at the level designated.
2. I confirm that all personnel involved in the experiment have been informed of the medical risks and know where to seek medical attention if needed.
3. I confirm that a proper risk assessment has been conducted and all risks have been mitigated as much as reasonably possible. This assessment has been shared with all involved students, faculty and staff.
4. I will immediately report to the Science Center Office and EHS any accident, injury, spill of biohazardous material, equipment or facility failure (i.e., ventilation failure), and /or any breakdown in procedure that could result in potential exposure of laboratory personnel, staff, or the public to biological material.
5. I confirm that any proposed changes to my work that would result in an increased level of biohazard will be reported to the IBC before the change is implemented.
6. I confirm that no work that requires IBC approval will be initiated or modified until approval is received.
7. I confirm that I will notify the IBC of all personnel changes or additions.
8. If using rDNA, I have read and understand my responsibilities as Principal Investigator outlined in Section IV-B-7 of the NIH Guidelines and agree to comply with these responsibilities. (<http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261589>)
9. I have reviewed the section on dual use research and understand how it may or may not apply to the research being conducted as outlined in this registration document. <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>

**The information above is accurate and complete.** |
| **PI Signature:** |  | **Date:** | . |

***For use by the Institutional Biosafety Committee (IBC) only:***

**Application Status:**

**Stipulations:**

**Laboratory Containment Level(s):**

**Animal Containment Level(s):**]

**IBC Chair Signature: Date:**

### Appendix A

### Institutional Biosafety Committee (IBC)

### NIH Guidelines Summary

### [http://oba.od.nih.gov/rdna/nih\_guidelines\_oba.html](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)

### Please contact IBC if you need assistance assessing which Guidelines sections apply to your experiments.

### (Click the section number to link to the full text of that section)

### [SECTION III-A](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261560): **Experiments Requiring IBC Registration and Approval plus RAC Review and NIH Director Approval Before Initiation.**

### [III-A-1-A](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_C.htm#_Toc7261561) Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control the disease agents in humans, veterinary medicine or agriculture.

### [SECTION III-B](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261562): **Experiments Requiring IBC Registration plus NIH/ORDA Approval Before Initiation.**

### [III-B-1](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261563) Cloning of Toxin Molecules with LD50 < 100ng/kg of body weight.

### [SECTION III-C](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261564): **Experiments Requiring IBC Registration plus IRB Approval and NIH/ORDA Registration**

### [III-C-1](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261565) Transfer of rDNA or DNA or RNA derived from rDNA into human subjects.

### [SECTION III-D](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm#_Toc7261566): **Experiments Requiring IBC Registration and approval Before Initiation**

### [III-D-1a](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261567) Introduction of rDNA into Risk Group 2 agents, BSL-2 or ABSL-2N. (See appendix B for listing)

### [III-D-1-b](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html#_Toc7261567) Introduction of rDNA into Risk Group 3 agents, BSL-3 or ABSL-3N.

### [III-D-1-c](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261567) Introduction of rDNA into Risk Group 4 agents, BSL-4 or ABSL-4N.

### [III-D-1-d](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261567) Introduction of rDNA into restricted agents requires case-by-base review by NIH/OBA and USDA permit.

### [III-D-2-a](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261568) DNA from Risk Group 2 or 3 agents transferred into nonpathogenic prokaryotes or lower eukaryotes is carried out at BSL2.

### [III-D-2-b](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261568) DNA from Risk Group 4 and restricted agents transferred into nonpathogenic prokaryotes or lower eukaryotes is reviewed by NIH/ORDA and requires an USDA permit.

### [III-D-3-a](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261569) Infectious or defective [defective eukaryotic viruses contain less than 2/3 of the genome] Risk Group 2 viruses in the presence of helper or packaging system in tissue culture handled at BSL2 or higher at IBC discretion.

### [III-D-3-b](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_C.htm#_Toc7261569) Infectious or defective Risk Group 3 viruses and prions in the presence of helper or packaging system in tissue culture handled at BSL3.

### [III-D-3-d](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261569) Infectious or defective restricted pox viruses in the presence of helper functions in tissue culture reviewed on case-by-case basis by NIH/ORDA and requires USDA permit.

### [III-D-3-e](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261569) Infectious or defective viruses in the presence of helper virus in tissue culture not covered in III-D above. IBC reserves the right to determine Risk Group Classification for novel agents.

### [III-D-4-a](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261570) Recombinant DNA or DNA or RNA molecules derived from rDNA (including the creation and use of transgenic animals) except greater than two-thirds of eukaryotic viral genome transferred to any non-human vertebrate or an invertebrate organism. Animals with sequences from viral vectors which do not lead to transmissible infection either directly or indirectly are handled at BSL-1 or BSL-1N or as appropriate to the animal. Introduction of other sequences from eukaryotic viral genomes are covered in Section III-D-4-b. rDNA modified Risk Group 2 and higher agents in animals are covered in Section V-A, V-G and V-L. Animal and plant pathogens require a USDA permit.

### [III-D-4-b](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261570) Recombinant DNA, or DNA or RNA molecules derived from rDNA involving whole animals, not covered in Section III-D-1, human or animal pathogen Risk Group 2 and higher as host vector systems, or Section III-D-4-a. Containment determined by IBC.

### [III-D-5-a](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261571) Recombinant techniques with exotic infectious agents with recognized potential for serious detrimental impact on ecosystems using whole plants. BSL-3P or BSL-2P+

### [III-D-5-b](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261571) Plants with cloned genomes of readily transmissible exotic infectious agents that may reconstitute by genomic complementation. BSL-3P or BSL2P+

### [III-D-5-c](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261571) Readily transmissible exotic infectious agents such as the soybean rust fungus, maize streak or other viruses in the presence of specific arthropod vectors. BSL-4P

### [III-D-5-d](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261571) Sequences coding vertebrate toxins (not covered by Section III-B-1) introduced into plants or associated organisms, BSL-3P

### [III-D-5-e](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261571) Microbial pathogens of insects or small animals associated with plants if the rDNA microorganism has a recognized detrimental impact on ecosystems. BSL-3P

### [III-D-6](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261572) Experiments involving more than 10 liters of culture. IBC determines containment level. (See Appendix K)

### [SECTION III-E](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261573): **Experiments Requiring IBC Registration Before Initiation**

### [III-E-1](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261574) Formation of rDNA molecules containing nor more than two-thirds of the genome of any eukaryotic virus in tissue culture, BSL-1 with no helper virus. The IBC classifies retroviral vectors with packaging system capable of infecting human cells as BSL-2.

### [III-E-2-a](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261575) rDNA modified whole plants or rDNA modified organisms not in Section III-E-2-b. BSL-1P

### [III-E-2-b](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261575) Plants modified by rDNA that are noxious weeds or can interbreed with noxious weeds. Plants with rDNA that is the complete genome of a non-exotic infectious agent. Plants associated with rDNA-modified non-exotic microorganisms with a recognized potential for serious impact on ecosystems or exotic microorganisms with no recognized potential for serious impact on ecosystems. rDNA-modified arthropods or small animals associated with plants or with arthropods or small animals associated with them if the rDNA modified microorganisms have no serious impact on ecosystems. BSL-2P

### [III-E-3](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261576) Generation of rodents with stable introduction of DNA into the animal’s genome if not covered in Section III-D-4. BSL-1.

### [SECTION III-F](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577): **Exempt experiments Requiring IBC Registration before Initiation (BSL-1)**

### [III-F-1](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) Not in organisms or viruses.

### [III-F-2](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) DNA segments from a single non-chromosomal or viral DNA source.

### [III-F-3](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_C.htm#_Toc7261577) DNA from prokaryotic host when propagated only in that host or transferred to another host by well established physiological means.

### [III-F-4](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) DNA from an eukaryotic host when propagated only in that host (or closely related host). See Appendices A-I through A-VI for a list of natural exchangers.

### [III-F-5](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) DNA segments from different species that exchange DNA by known physiological processes.

### [III-F-6](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577) Those that do not present a significant risk to health or the environment.

### [Appendix C-1](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm) Recombinant DNA (non-virus vector) in Tissue Culture (see C-IV for exceptions)

### [Appendix C-II](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm) E. coli K-12 host-vector systems. (See C-II-A for exceptions)

### [Appendix C-III](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_C.htm) Saccharomyces host-vector systems. (See C-III-A for exceptions)

### [Appendix C-VI](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm) Purchase or transfer of transgenic rodents.

### Please contact IBC if you need assistance assessing which Guidelines sections apply to your experiments.