BROWN

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BIOLOGICAL RESEARCH AUTHORIZATION FORM

IBC # _____ Action: _____

Date _____

▲ For IBC Use Only ▲

Notes:

- Protocol approval is valid for three (3) years AND must be updated **annually** using the BRA – Annual Update, Amendment & Termination Form.
- At the end of three (3) years, a new Biological Research Authorization (BRA) must be submitted to renew an approval.
- To view submission deadlines and meeting dates for the Institutional Biosafety Committee (IBC) http://www.brown.edu/Administration/EHS/biological/

Instructions:
In the first table, mark all sections that will be applicable to your protocol. Go to those applicable sections and answer all questions.

- In the first table, mark all sections that will be applicable to your protocol. Go to those applicable sections and answer all questions.
- Access and complete referenced forms as applicable.
- Submit the electronic documents to Biosafety via biosafety@brown.edu

Select all sections that apply. This aids the reviewer in navigating thru the application

SECTION (CTRL + Click to Hyperlink to Applicable Section)	APPLICABLE	NOT APPLICABLE
Section 1: Administrative	REQUIRED	
Section 2: Project Information	REQUIRED	
Section 3: Human Materials	☐	☐
Section 4: Microorganisms / Infectious Material	☐	☐
Section 5: Animals and/or Animal Materials	☐	☐
Section 6: Arthropods	☐	☐
Section 7: Plants	☐	☐
Section 8: Biological Toxins	☐	☐
Section 9: Nanoparticles		☐
Section 10: Recombinant & Synthetic Nucleic Acid		☐
Section 11: Dual-Use Screening	ED	
Section 12: Progress Report	ED	
Section 13: Investigator's Assurance	ED	

Use these hyperlinks to jump throughout the form!

SECTION 1: ADMINISTRATIVE

GENERAL INFORMATION		
1. 1	☐ New Application ☐ 3-Year Renewal	
1. 2	Previous Biosafety Protocol# (if applicable): **ENTER PREVIOUS BRA #**	
1. 3	Protocol Title(s): **Title should reflect the work being proposed**	
1. 4	Principal Investigator (PI):	
1. 5	Department / Division:	
1. 6	PI Email:	PI Phone #:
1. 7	1st Lab Contact:	
	1st Lab Contact Email:	1st Lab Contact Phone #:
1. 8	2nd Lab Contact:	

	2nd Lab Contact Email:	2nd Lab Contact Phone #:

1. 9 List all locations where work will be conducted in the table below:

	Building(s):	*Room Number(s):*
	All buildings and rooms where work is expected to take place must be listed in this section	

Provide grant numbers as shown in COEUS

1. 10 List the funding agencies associated with this project in the table below:

Funding Agency:	*Grant Number:*	*Are you the primary awardee on the grant?*	*Grant Name:*
		☐ Yes ☐ No	
		☐ Yes ☐ No	
		☐ Yes ☐ No	
		☐ Yes ☐ No	

1. 11 List all individuals working on this protocol, including PI, collaborators, technicians, post docs, graduate students, undergraduate students, volunteers, etc. (*attach a separate page if necessary*):

➢ **TRAINING NOTES:**

- **Laboratory Safety Training:** Required for all individuals working in a laboratory. Required every five (5) years.
- **Biological Safety/Bloodborne Pathogens (BBP) Training:** Required for all individuals having occupational exposure to human blood, OPIM of human origin (cells/cell lines, unfixed tissues) or human BBP. Required annually per OSHA.
- **Biological Safety/Bloodborne Pathogens (BBP) Training:** Required for all individuals working with biohazard agents, toxins, and recombinant and synthetic nucleic acid molecule experiments or materials. Required every five (5) years.
- **NIH Guidelines Training:** The NIH requires training on biosafety and recombinant and synthetic nucleic acid molecules. Required once per NIH.

Name	*Job Title*	*Department*	*Telephone/Email Address*	***Relevant Experience:*** ***How many years? What kind of Relevant Experience? (Example: 4 years' experience in tissue culture and transfecting mammalian cells)***
				Make sure that the information provided here reflects experience related to the work proposed in the BRA. Include number of years of experience. If someone does not have experience, indicate how and by whom they will be trained.

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SECTION 2: PROJECT INFORMATION

PROJECT DESCRIPTION

DISCLAIMER:

The Institutional Biosafety Committee (IBC) is comprised of a diverse group of people. It is, therefore, important to use language that will be detailed enough for scientific evaluation, as well as, general enough to be understood by people with non-scientific backgrounds. Please provide sufficient information for committee members to evaluate the work for purposes of making a biohazard risk assessment. Grant applications will only be accepted as supporting documentation.

2. 1	**In lay language, provide a one paragraph summary of your overall research objectives:** **Provide a general summary of the project. Keep in mind that not all IBC members are scientists. Make sure this summary is written at a level that is easily understood in general terms.**
2. 2	**Explain the experimental design and research plan. Highlight the recombinant or synthetic nucleic acid methodology used and/or the use of biological materials.** **This explanation should describe the specific procedures and methods used. DO NOT GIVE AIMS FROM YOUR GRANT!** *Explain why and how specific agents are used:* *Describe the relationship between the work described in the Bio-Authorization and/or animal research in the IACUC application and human research from the IRB application (If applicable):*
2. 3	**Identify and describe the risk(s) to humans associated with the agents, recombinant materials (rDNA, RNA), toxins, and organisms (cell lines, animals, human materials) used in the experiment and methods that will be taken to prevent exposure.** *Increased risk of exposure may be associated with generation of splashes, sprays, or aerosols from centrifugation, sonication, homogenization, use of sharps (needles, glass or syringes), cage cleaning of infected animals, animal surgeries, etc. Management of these risks should be addressed in this section.* **This explanation should describe the risks associated with the work and the measures that will be taken to reduce or eliminate those risks.**

ENGINEERING CONTROLS, DECON, & WASTE

The following engineering controls must be certified annually. The certification dates listed should be within the past 12 months.

2. 4 ***Biological Safety Cabinets (BSC) –*** Will this work involve the use of a BSC? ☐ Yes* ☐ No

** If yes, list the BSCs being used in the following table.*

BSC Type (example: class II A2)	*Location (Bldg. & Rm#)*	*Certification Expiration Date*

2. 5 ***Chemical Fume Hoods (CFH) –*** Will this work involve the use of a CFH? ☐ Yes* ☐ No

** If yes, list the CFHs being used in the following table.*

Location (Bldg. & Rm#)	*Test Date*

2. 6 ***Laminar Flow Hoods (LFH)*** – Do … air bench? ☐ Yes* ☐ No

** If yes, list the LFHs being used i…*

Location (Bldg. & Rm#)	*Certification Expiration Date*

Certification & test dates are located on the front of the equipment.

2. 7 ***Biological Waste***

Mark the type(s) of biological waste that your laboratory will produce:

☐ Solid
☐ Liquid
☐ Sharps

☐ Pathological waste including infected or fixed animal carcasses e.g. rodents injected with lentivirus vectors, formalin, perfused animals, etc.
☐ Other:

2. 8 ***Method of Decontamination***

Please select the method of decontamination and waste handling that applies to this work:

☐ **In vitro decontamination procedures:** All surfaces will be disinfected using a 1:10 dilution of household bleach with water, made fresh daily, with a contact time of 15 minutes follow by 70% ethanol wipe to remove residue. All solid and semi-solid biohazardous waste will be disposed of into the Red Bag Lined Box (RBLB). All liquid biohazardous waste will be inactivated using a 1:10 dilution of household bleach with water, made fresh daily, with a contact time of 30 minutes, and then disposed of as hazardous waste per Brown University hazardous waste policies and procedures.

☐ **In vivo decontamination procedures:** All surfaces will be disinfected using one of the following disinfectants:

- 1:128 dilution of Chlorhexidine, made monthly, with a contact time of 2 minutes followed by 70% ethanol to remove residue
- 1:10 dilution of household bleach with water, made fresh daily, with a contact time of 15 minutes follow by 70% ethanol wipe to remove residue

All solid and semi-solid biohazardous waste will be disposed of into the Red Bag Lined Box (RBLB). All liquid biohazardous waste will be inactivated using a 1:10 dilution of household bleach with water, made fresh daily, with a contact time of 30 minutes, and then disposed of as hazardous waste per Brown University hazardous waste policies and procedures.

If neither of these standard methods will be used or additional procedures are required, please describe the disinfection procedures that will be used. Please see the disinfection table for assistance with selection of appropriate method of decontamination.

In this section, select what will be used. If additional procedures are needed or these standard procedures are not appropriate for your work, provide decon and waste handling procedures. Be sure to enter concentrations and contact times for disinfectants.

2. 9 ***Use of Brown Core Facilities:***

Will you be utilizing any Brown Cor…ce, breeding experiments, flow cytometry)?

☐ Yes* ☐ No

Select the core facilities that will be used then provide details regarding how they will be used

Select the Core Facility to be using:

☐ Transgenic Core – LMM 205
☐ Genomics – LMM 109
☐ Flow Cytometry – BMC 602
☐ XROMM – BMC GG 181
☐ Proteomics – LMM 339
☐ Magnetic Resonance Imaging – SFH 124
☐ Structural Biology – LMM 1st flo…
☐ Other:

** Explain what service(s) the Core Facility will provide for your project:*

2. 10 ***High Speed Cell Sorters***

Will a high speed cell sorter be used in this project? ☐ Yes* ☐ No

** If yes, list the Fluorescent Activated Cell Sorter (FACS) being used in the following table.*

Manufacturer	***Location (Bldg. & Rm#)***
If you have your own cell sorter, fill out this section. Please note that the use of a cell sorter for some materials will require the use of additional safety precautions!	

PERSONAL PROTECTIVE EQUIPMENT

Mark all PPE worn while conducting experiments under this protocol

2. 11 ***Gloves*** ☐ Nitrile ☐ Latex ☐ Thermal ☐ C…
☐ Other (list):

2. 12 ***Mucous Membrane (Face) Protection*** ☐ ANSI Approved Safety Glasses with Side…

Select all PPE that will be used. Safety GLASSES and GOGGLES are different!!! Describe how PPE will be used!

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		☐ Face Shield ☐ ANSI Approved Goggles ☐ Surgical Mask ☐ Other (list):
2. 13	***Protective Clothing***	☐ Button Front Lab Coat ☐ Tie Back Lab Coat ☐ Protective Coveralls ☐ Booties ☐ Hair Cover ☐ Scrubs ☐ Other (list):
2. 14	Please provide details regarding how PPE will be used and for which procedures:	
EMERGENCY PROCEDURES		
2. 15	***Reporting*** – Has your staff has been informed that ALL work related injuries and accidental exposures (needle sticks, aspiration of aerosolized material, etc.) shall be reported to Brown's Insurance Office using the Brown University Accident Report Form	☐ Yes ☐ No
ADMINISTRATIVE CONTROLS		
2. 16	***Lab Signage:*** Is EHS approved entry lab signage posted and up-to-date (ex: emergency contact information and hazards are current)? **Request new or revised signage by emailing the Chemical Hygiene Offic*	☐ Yes ☐ No*
2. 17	***Material Transfer:*** Does the protocol involve transferring material between Brown Univer outside the University?	o
2. 18	Do you need a Material Transfer Agreement (MTA)? *To determine if you need an MTA, refer to MTA information*	☐ Yes ☐ No
2. 19	Do you have an MTA? **If needed, use the MTA Form .*	☐ Yes* ☐ No ☐ N/A
2. 20	Will you be importing or exporting biological materials? **If yes, contact Biosafety Officer for coordination.*	
2. 21	Do you have the appropriate transport/import permits?	
2. 22	***Transportation:*** Does your protocol involve shipping biological material, or dry ice?	☐ Yes ☐ No
2. 23	Will this project involve transferring biological materials over public thoroughfares between Brown University owned or affiliated facilities? **If yes, Materials of Trade (MOT) training will be assigned by EHS.*	☐ Yes* ☐ No ☐ N/A
2. 24	***Medical Surveillance***: Are there any non-routine measures such as special vaccinations or additional health screening techniques that would potentially benefit research staff participating in or supporting this project? **If yes, select this statement:* ☐ This project involves the use of human materials. All personnel who have the potential for an occupational exposure to bloodborne pathogens have been offered the Hepatitis B vaccination. *If this does not apply, describe:*	☐ Yes* ☐ No
2. 25	***Training:*** Does this protocol involve the use of human blood, other potentially infectious material (OPIM) of human origin (cells, cell lines, unfixed tissue) or human bloodborne pathogens (BBP)? **If yes, Biosafety & Bloodborne Pathogens Training will be required annually.*	☐ Yes* ☐ No

Select all PPE that will be used. Safety GLASSES and GOGGLES are different! Describe how PPE will be used!

These questions cover the shipment of materials, covered by the BRA, to collaborators that may require an MTA and/or permits.

These questions cover the shipment or transport to other Brown buildings. May prompt the need for additional training.

SECTION 3: HUMAN MATERIALS

3. 1	Does your protocol involve the use of unfixed organs or tissues from living or dead humans (except intact skin), cell lines, blood, blood products and body fluids, including cell cultures purchased from commercial sources? ☐ Yes ☐ No – *Skip Section 3 & Go to Section 4* ***The use of human materials will require that an Exposure Control Plan be submitted with this application***	
3. 2	Does your protocol involve working with live humans?	☐ Yes ☐ No
3. 3	Do you have IRB approval or have you submitted an IRB application? **If yes, provide the information below.* *+ If no, contact the IRB to begin the application process.*	☐ Yes* ☐ No+ ☐ N/A

IRB Protocol Title	***IRB Number***	***Status***
		☐ Submitted ☐ Approved ☐ Not Submitted

3. 4	Will you be exposing live human subjects or human cells to recombinant and/or synthetic nucleic acid molecules? **If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*	☐ Yes* ☐ No

3. 5 **List all human material in the table below:** *Human material must be handled under BSL-2 conditions. Per OSHA requirements, all individuals with occupational exposure to any materials listed in the table below must complete Bloodborne Pathogen training.*
Click here for Risk Group Classification Definitions

Material *e.g. Established Cell Lines*	***Type*** *e.g. HEK Cell Line*	***Risk Group***	***Biosafety Level***	***Source*** *e.g. Human Kidney*	***Origin of Material*** *Check all that Apply*	***Known Pathogens***
		Choose Item	Choose Item		☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF)	
		Choose Item	Choose Item		☐ Other	
			em		☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
			em		☐ Commercial Vendor ☐ Clinical Specimens ☐ Field	

Fill in table with all human materials used. Do not leave anything blank

If unknown state "Human materials are known to carry bloodborne pathogens. Universal precautions will be used."

					☐ Internal (ACF) ☐ Other	
		Choose Item	Choose Item		☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
		Choose Item	Choose Item		☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
		Choose Item	Choose Item		☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	

If you are using human materials, an exposure control plan must also be submitted with the BRA!!

SECTION 4: MICROORGANISMS / INFECTIOUS MATERIAL

4. 1	Does your protocol involve the use of microorganisms/infectious wild type material (bacteria, viruses, fungi, prions, parasites)? ☐ Yes ☐ No – *Skip Section 4 & Go to [Section 5]* ****do not include genetically modified materials in this section****
4. 2	Will you introduce recombinant/synthetic nucleic acid molecules to any microorganism/infectious agent, use recombinant DNA methods to change the genetic make-up of any microorganism/infectious agent, or use DNA from any microorganism/infectious agent to perform any recombinant and/or synthetic nucleic acid experiments? ☐ Yes* ☐ No **If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*
4. 3	List each microorganism/infectious agent to be used in this protocol (inclu[illegible]) in the table below. *For more information please visit Pathogen Safety Data Sheets and Risk A[illegible] and Biomedical Laboratories* *Click here for Risk Group Classification Definitions*

Fill in this table for all microorganisms being used. Do not include viral vectors or bacteria/yeast being used for plasmid propagation unless bacteria are risk group 2 (RG-2) or higher!

Name (Genus, Species &Strain if known)	*Type*	*Risk Group*	*Biosafety Level*	*Use*	*The agent is hazardous to:*	*[illegible] via:*	*[illegible] associated with this agent:*	*Is the agent attenuated or fixed by serial passage or other means? If yes, attach procedures or verifying documents*	*Is an antibiogram available for the bacterial agents used? If yes, attach the document.*
	Choose Item	Choose Item	Choose Item	Choose Item	☐ Humans ☐ Animals ☐ Other: ☐ N/A	☐ Blood ☐ Feces ☐ Saliva/Nasal Droplets ☐ Other:		☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A
	Choose Item	Choose Item	Choose Item	Choose Item	☐ Humans ☐ Animals ☐ Other: ☐ N/A	☐ Blood ☐ Feces ☐ Saliva/Nasal Droplets ☐ Other:		☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A
	Choose Item	Choose Item	Choose Item	Choose Item	☐ Humans ☐ Animals ☐ Other: ☐ N/A	☐ Blood ☐ Feces ☐ Saliva/Nasal Droplets ☐ Other:		☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A
	Choose Item	Choose Item	Choose Item	Choose Item	☐ Humans ☐ Animals ☐ Other: ☐ N/A	☐ Blood ☐ Feces ☐ Saliva/Nasal Droplets ☐ Other:		☐ Yes ☐ No	☐ Yes ☐ No ☐ N/A

SELECT AGENTS

Definition: *pathogens or biological toxins which have been declared by the U.S. Department of Health and Human Services or by the U.S. Department of Agriculture to have the potential to pose a severe threat to public health and safety*

4. 4	Does your protocol involve any bacteria or viruses listed on the HHS/USDA Select Agents and Toxins List? ☐ Yes* ☐ No

	**If yes, please list the select agent you will be working with:*
4. 5	If you answered yes to 4.4, is the select agent you are working with an attenuated strain or permissible toxin? ☐ Yes* ☐ No ☐ N/A *Link to attenuated strain list* & *Link to permissible toxin list* **If yes, please specify the attenuated strain or permissible toxin you will be working with:*

SECTION 5: USE OF ANIMALS AND/OR ANIMAL MATERIALS

5.1 Does your protocol involve working with animals or animal materials? ☐ Yes* ☐ No– *Skip Section 5 & Go to Section 6*

**If yes, please complete the table in 5.7 to provide your IACUC information.*

This section must be completed when using live whole animals OR any animal materials such as tissues, cell lines, etc.

5.2	*IACUC Protocol Number*	*Status*	*IACUC Protocol Title*
		☐ Approved ☐ Submitted ☐ Not Submitted	

5.3 Does your protocol involve working with animals that are field caught? ☐ Yes* ☐ No

**If yes, explain*:

5.4 Will you be creating transgenic animals, breeding transgenic animals, exposing animals to recombinant /synthetic nucleic acid molecules, or purchasing /obtaining transgenic animals from a commercial vendor or collaborator? ☐ Yes* ☐ No

**If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*

5.5 ***List each animal/experiment separately in the table below:***

Biological Materials Used *Infectious Agents, vectors, or human cell lines used in live animals.*	***Animal Species***	***Animal Biosafety Level***	***Housing Location (If known)***	***Max. Infectious Dose/Units***	***Max Dose/ Animal***	***Method of Delivery*** *Check all that apply*	***Specify Route of Shedding/ Excretion of Infectious Agent*** *Check all that apply*	***Explain the measures your lab will take to prevent accidental exposure to employees, animals handlers, students, visitors and other animals***
		Choose Item				☐ Injection ☐ Intranasal ☐ Oral ☐ Other:	☐ Urine ☐ Saliva ☐ Feces ☐ Blood ☐ None ☐ Unknown ☐ Other:	
		Choose Item				☐ Injection ☐ Intranasal ☐ Oral ☐ Ocular ☐ Other:	☐ Urine ☐ Saliva ☐ Feces ☐ Blood ☐ None ☐ Unknown ☐ Other:	
		Choose Item				☐ Injection ☐ Intranasal ☐ Oral ☐ Ocular ☐ Other:	☐ Urine ☐ Saliva ☐ Feces ☐ Blood ☐ None ☐ Unknown	

Any biohazard work in live animals must be entered into this table. Fill out all columns. Do not leave anything blank.

							☐ Other:	

5.6	*List the animal cell lines, tissues, transplantable tumors, and hybridomas to be used below:*			
Material *e.g. Established Cell Lines*	***Type*** *e.g. COS-7*	***Source*** *e.g. Monkey kidney*	***Origin of Material*** *Check all that Apply*	***Known Pathogens***
			☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
			☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
			☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
			☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
			☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	
			☐ Commercial Vendor ☐ Clinical Specimens ☐ Field ☐ Internal (ACF) ☐ Other	

Animal materials (tissues, cell lines, etc.) must be entered into this table. Do not list any human cell lines. Do not leave any column(s) blank.

SECTION 6: ARTHROPODS

6. 1 Does your protocol involve arthropods? ☐ Yes ☐ No – *Skip Section 6& Go to Section 7*

6. 2 Will you be using, creating, or breeding transgenic arthropods or exposing arthropods to recombinant/synthetic nucleic acid molecules? ☐ Yes* ☐ No
**If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*

6. 3 List each arthropod used in the table below:
Refer to the BMBL 5th Edition for information on Arthropod Containment Levels (ACLs).

Arthropod	*ACL*	*Building*	*Room*	*Are USDA/APHIS/ PPQ Permits Required?*
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No

**If you answered yes, you need to complete a USDA registration form and submit it along with copies of the associated permits to biosafety@brown.edu .*

SECTION 7: PLANTS

7. 1 Does your protocol involve plants? ☐ Yes ☐ No – *Skip Section 7 & Go to Section 8*

7. 2 Will you be creating transgenic plants, exposing plants to recombinant/synthetic nucleic acid molecules, transgenic arthropods, or transgenic microorganisms/infectious agents? ☐ Yes* ☐ No
**If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*

7. 3 Indicate the plants used, the plant Biosafety level (BL-P) required for their housing, and where they will be housed below. *Refer to the BMBL 5th Edition for information on BL-Ps.*

Plant	*BL-P*	*Building*	*Room*	*Are USDA/APHIS/ PPQ Permits Required?*
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No
	Choose Item			☐ Yes* ☐ No

**If you answered yes, you need to complete a USDA registration form and submit it along with copies of the associated permits to biosafety@Brown.edu*

SECTION 8: BIOLOGICAL TOXINS

8. 1 Does your protocol involve biological toxins (e.g. picrotoxin, **tetrodotoxin**, diphtheria toxin, pertussis toxin, **botulinum toxin,** Patulin (mycotoxin)? ☐ Yes ☐ No – *Skip Section 8 & Go to Section 9*

- *Note: Select Agents are in **Bold** above. More information on HHS/USDA Select Agents may be found on the Select Agent Program Website.*

8. 2 Will you be performing experiments where you clone toxin molecules with an LD50 of 100 ng/kg or less? ☐ Yes* ☐ No
**If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*

8. 3 List each biological toxin in the table below:

Toxin	*LD50*	*Maximum Quantity on Hand*	*Building*	*Room*	*Is the toxin a HHS/USDA Select Agent or Toxin?*	*If Select Agent, list the permissible amount:*
					☐ Yes* ☐ No	
					☐ Yes* ☐ No	
					☐ Yes* ☐ No	
					☐ Yes* ☐ No	

	**If you are working with a toxin that is categorized as a select agent, are you working with it within the permissible amounts?* [Guidelines for Working with Biological Toxins]	☐ Yes ☐ No

SECTION 9: NANOPARTICLES

9. 1	Does your protocol involve nanoparticles?	☐ Yes ☐ No – *Skip Section 9 & Go to Section 10*
9. 2	Will you be using recombinant/synthetic DNA methods to create nanoparticles? **If yes, make sure you complete Section 10 – Recombinant & Synthetic Nucleic Acid Molecules.*	☐ Yes* ☐ No
9. 3	List each nanoparticle in the table below:	

Nanoparticle	***Description of the nanoparticle (structure, hazards, etc.)***	***Description of lab procedure involving the nanoparticle***

SECTION 10: RECOMBINANT & SYNTHETIC NUCLEIC ACID MOLECULES

PURPOSE: The purpose of the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (NIH Guidelines) is to specify the practices for constructing and handling:

- Recombinant nucleic acid molecules,
- Synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and
- Cells, organisms, and viruses containing such molecules.

DEFINITION: In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

i. Molecules that:
   a. Are constructed by joining nucleic acid molecules and
   b. That can replicate in a living cell, i.e., recombinant nucleic acids;

ii. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or

iii. Molecules that result from the replication of those described in (i) or (ii) above.

NOTE: *Your answers to the questions in this section will allow the IBC to determine the level of review that your experiments require.*

10. 1	Does your protocol involve recombinant or synthetic nucleic acid molecules (rDNA)?	☐ Yes – Click Here to go to NIH appendix ☐ No – *Skip Section*
General recombinant or synthetic nucleic acid molecule Questions		
10. 2	Describe the source of the DNA/synthetic nucleic acid molecules, the nature DNA/synthetic nucleic acid molecules sequences, the host(s) and vector(s) to be used, if an attempt will be made to obtain expression of a foreign gene and what protein will be produced. Be sure to account for whether or not the genes involved or expressed have potential: toxicity, allergenicity or other risk to research personnel.	**If using more than 1 construct, list each one then list the features of each.**
10. 3	Describe key features of the agent, virus or bacteria used in this project and if the experiments will result in acquisition of new characteristics e.g., enhanced virulence, infectivity, drug resistance, or change in host range. Give references if appropriate.	
10. 4	Have vector maps been submitted with this application via email? ****Vector maps must be submitted via email with this application****	☐ Yes ☐ No*
10. 5	Indicate the percent of the pathogen genome present in the vector (kilobases of the parent pathogen in the vector and packaging cell combined).	

10. 6	Will the research involve the use of antibiotic selection markers? **If yes, list the markers and microbial agents used (e.g. neomycin resistance marker in E. coli).*	☐ Yes* ☐ No
10. 7	***Use of Replication-Incompetent Virus Derived Vector Systems:*** Will you be using a virus derived vector system **If yes, explain how this has been achieved using* ***ribe how you will assure*** *that your vector material is free from contamina*	☐ Yes* ☐ No
10.8.1	Will any of the sequences code for toxins? *If yes, indicate* LD_{50}	☐ Yes ☐ No
10.8.2	If using adeno or lentivirus, will you be using third or fourth generation systems for safety?	☐ Yes ☐ No
10.8.3	Will VSV-G be used for pseudotyping and are you aware that this can increase the risk of exposure through absorption and inhalation along with injection and ingestion?	☐ Yes ☐ No
10.8.4	If using oncogene inserts, a DNA sequencing library shall be kept. Indicate the location of these records.	
Additional Gene Editing Questions		
10.8.5	Will your research involve gene editing technologies (i.e. CRISPR/Cas9, TALEN, Zinc Finger Nucleases, and Meganucleases)? **If no, skip to #10.9.*	☐ Yes ☐ No*
10.8.6	If CRISPR is involved, are the guide RNA sequence and the Cas endonuclease on the same plasmid or delivery vehicle? **If yes, can the plasmid, vector or delivery vehicle infect a human cell?*	☐ Yes* ☐ No ☐ Yes ☐ No
10.8.7	Does the use of CRISPR involve a viral vector?	☐ Yes ☐ No
10.8.8	Is this a gene drive experiment?	☐ Yes ☐ No
10.8.9	Will the research involve embryos or germ line cells (outside of standard transgenic animal protocols)? **If yes, discuss the potential for off-target effects?*	☐ Yes* ☐ No
10.8.10	How many genes have been targeted? ☐Single ☐Multiple – How many? ☐Library* * (List number, i.e. hundreds, thousands, more? Number of unique vectors associated with gene editing library? Number of gene editing sequences targeting each gene in the library (per vector)?	

If using more than 1 construct, list each one then list the features of each.

10.9	Use the table below to describe your recombinant or synthetic nucleic acid experiments. *Click here for Risk Group Classification Definitions*							
Host	***Host Risk Group Classification***	***Vector***	***Vector Risk Group Classification***	***Biosafety Level***	***Inserted recombinant or synthetic nucleic acid molecules***	***What is the largest fraction of eukaryotic viral genome contained in the recombinant or synthetic nucleic acid molecules?***	***Will a helper virus or packaging cells be used?***	***Is the virus replicative?***
	Choose Item		Choose Item	Choose Item		Choose Item	Choose Item If yes, enter name:	Choose Item
	Choose Item		Choose Item				Choose Item If yes, enter name:	Choose Item
	Choose Item		Choose Item				Choose Item If yes, enter name:	Choose Item
	Choose Item		Choose Item	Choose Item		Choose Item	Choose Item If yes, enter name:	Choose Item
	Choose Item		Choose Item	Choose Item		Choose Item	Choose Item If yes, enter name:	Choose Item

The vector is the construct. The host (animal, cell line, etc.) is what the vector will be used in. When propagating plasmids, the plasmid is the vector and the bacteria/yeast is the host.

Every host/vector combination needs to be displayed in this table. If multiple vectors are used in the same host(s) and they have the same backbone, they may be listed together in 1 row.

SECTION 11: DUAL-USE SCREENING

DISCLAIMER:
A research project is considered dual-use in nature if the methodologies, materials or results could be used for public harm. **The following questions must be answered prior to the initiation of research.** It should be noted that an affirmative answer will not delay the progress of research, but indicates that further review and consideration may be warranted as the research advances. Information regarding the dual-use dilemma in biological research may be found at http://www.serceb.org/dualuse.htm.

11. 1	Will an intermediate or final product of your research make a vaccine less effective or ineffective?	☐ Yes	☐ No
11. 2	Will the intermediate or final product of your research confer resistance to antibiotics or antivirals?	☐ Yes	☐ No
11. 3	Will your work enhance the virulence of a pathogen or render a non-pathogen virulent?	☐ Yes	☐ No
11. 4	Will the results of your work increase the transmissibility of any pathogen?	☐ Yes	☐ No
11. 5	Will your research result in the alteration of the host range of the pathogen?	☐ Yes	☐ No
11. 6	Will your research result in an intermediate or final product that may prevent or interfere with the diagnosis of infection or disease?	☐ Yes	☐ No
11. 7	Does your research enable weaponization** of an agent or toxin? ***In this context, weaponization refers to the enhanced dispersion, deliverability, survivability or pathogenesis of a potentially harmful agent or toxin.*	☐ Yes	☐ No
11. 8	Will synthetic biology[+] techniques be used to construct a pathogenic organism, toxin or **potentially harmful** intermediate product? [+]*Synthetic biology includes, but is not limited to, techniques of molecular biology, chemistry and genetics that would allow for the de novo synthesis or reverse engineering of genes, gene products or entire functional organisms.*	☐ Yes	☐ No
11. 9	**After considering your answers to 11.1 – 11.8, do you believe there is the potential for your research data/product to be readily utilized to cause public harm?**	☐ Yes	☐ No

SECTION 12: PROGRESS REPORT

12. 1	Have any adverse events occurred in the last approval period? **If yes, please provide details of the events:*	☐ Yes*	☐ No	☐ N/A
12. 2	Were these events reported to the EHS immediately following the incidents? **All accidents and injuries must be reported.*	☐ Yes	☐ No*	☐ N/A
12. 3	Have there been any accidental exposures related to this protocol, not limited to your lab staff? **If yes, please provide details of events (including notification being sent to the EHS and/or Insurance and Risk) and what was done to prevent this type of event from recurring:*	☐ Yes	☐ No*	☐ N/A
12. 4	Were these events reported to the EHS immediately following the incidents? **All accidents and injuries must be reported.*	☐ Yes	☐ No*	☐ N/A

SECTION 13: INVESTIGATOR'S ASSURANCE

13. 1	I confirm that all persons involved with this project (including my collaborators) have been adequately trained in good microbiological techniques, have received instruction on any specific hazards associated with the project and worksite, and are aware of any specific safety equipment, practices, and behaviors required while conducting project procedures and using these facilities. The IBC may review my records documenting the instruction.	☐ I Accept

13. 2	I will immediately report to Brown's Biosafety Office 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 biohazardous or toxic material.	☐ I Accept
13. 3	I confirm that any proposed changes to my work that would result in an increased level of biohazard will be reported to the EHS before the change is implemented, and a BRA – Annual Update, Amendment & Termination Form will be submitted.	☐ I Accept
13. 4	I confirm that no work that requires EHS approval will be initiated or modified until approval is received and all sponsoring agency requirements have been met.	☐ I Accept
13. 5	I will notify the EHS of all personnel changes or additions through the use of the BRA – Annual Update, Amendment & Termination Form.	☐ I Accept
13. 6	I have read and understand my responsibilities of Principal Investigator outlined in Section IV-B-7 of the NIH Guidelines and agree to comply with these responsibilities.	☐ I Accept
13. 7	I certify that the information provided within this application is accurate to the best of my knowledge. I also understand that, should I use the project described in this application as a basis for a funding proposal (either intramural or extramural), I am responsible for ensuring that the description of procedures in the funding proposal is identical in principle to that contained in this application.	☐ I Accept
13. 8	I confirm that all persons involved with this protocol will comply with all applicable environmental laws and regulations and that this project does not significantly impact the environment.	☐ I Accept

13. 9	Electronic Signature:	Date:
	Principal Investigator (By electronically signing this fo on that all items are accurate and you agree above items.) An image of the signature is acce	
Please subr Biosafety@brown.edu		

Insert an image of the PIs signature here and don't forget to add the date!

NIH Appendix

Recombinant DNA Experiment Classifications

****Select any that apply-see bottom of page for Risk Group definitions. Only answer below if you have answered "yes" to the use of recombinant DNA****

☐**Section III-F-1**: Experiments that are not in organisms or viruses.

☐**Section III-F-2**: Experiments that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, although one or more of the segments may be a synthetic equivalent.

☐**Section III-F-3**: Experiments that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

☐**Section III-F-4**: Experiments that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

☐**Section III-F-5**: Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers is prepared and periodically revised by the NIH Director and can be found at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html

☐**Section III-F-6**: Those exemptions as determined by the NIH Director to not present a significant risk to health or the environment are listed in the appendices below. **Please check all categories that apply:**

- ☐**Appendix C-I:** Recombinant DNA in Tissue Culture; Molecules Containing <1/2 of any Eukaryotic Viral Genome.
- ☐**Appendix C-II:** Escherichia coli K-12 Host-Vector Systems. 0Appendix C-III: Saccharomyces Host-Vector Systems.
- ☐**Appendix C-IV:** Kluyveromyces Host-Vector Systems.
- ☐**Appendix C-V:** Bacillus Subtillus or Bacillus Lichenformis Host-Vector Systems.
- ☐**Appendix C-VI:** Extrachromosomal Elements of Gram Positive Organisms.
- ☐**Appendix C-VII:** The Purchase or Transfer of Transgenic Rodents, BSL 1 only.
- ☐**Appendix C-VIII:** Transgenic Rodents Generated by Breeding, BSL 1 only.

☐**Section III-E**: Experiments that are not included in Sections III-A, III-B, III-C, III-D, and III-F; and experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic eukaryotes fall under Section III-E and may be conducted at **BSL-1 containment**.

☐**Section III-E-1**: Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (**BSL 1 only)**.

☐**Section III-E-2**: Experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA modified organisms associated with whole plants (**BSL 1 only)**.

☐**Section III-E-3**: Experiments involving transgenic rodents, modified by the stable introduction of genetic material. Note: This section applies to BLS 1 only; all others are classified under Section III-D-4.

☐**Section III-D-1**: Experiments using Risk Group 2, Risk Group 3, or restricted agents as host-vector systems.

Select Risk Group: ☐Risk Group 2 (RG2) ☐ Risk Group 3 (RG3) ☐ Risk Group 4 (RG4)

☐**Section III-D-2**: Experiments in which DNA from Risk Group 2, Risk Group 3, or restricted agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems.

Select Risk Group: ☐Risk Group 2 (RG2) ☐Risk Group 3 (RG3) ☐Risk Group 4 (RG4)

☐**Section III-D-3**: Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.

Select Risk Group: ☐Risk Group 2 (RG2) ☐ Risk Group 3 (RG3) ☐ Risk Group 4 (RG4)

☐**Section III-D-4**: Experiments involving whole animals (e.g., non-human vertebrate or invertebrate organism, including arthropods).

Select Section that applies: ☐ III-D-4-a: RG 1 Organisms ☐ III-D-4-b: RG 2 or 3 Organisms

☐**Section III-D-5:** Experiments involving whole plants or insects; experiments to genetically engineer plants by recombinant DNA methods, to use such plants for experimental purposes (e.g. response to stress), to propagate such plants, or to use plants together

with microorganisms or insects containing recombinant DNA (cannot be done at BSL 1).

☐**Section III-D-6:** Experiments involving more than 10 liters of culture.

Please note: This section requires NIH pre-approval. Please contact the IBC for assistance.

☐ Section III-A-1: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally. (Requires RAC review and NIH Director pre-approval)

☐ Section III-B-1: Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight. (Requires NIH pre-approval)

☐ Section III-C-1: Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants. (Requires NIH pre-approval)

Risk Group Definitions

Risk Group 1 (RG1): Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2): Agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.
Risk Group 3 (RG3): Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.
Risk Group 4 (RG4): Agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available.

Once you have completed this section, click here to return to the main application.

Disinfection Table

Sterilizer/Disinfectant	Micro-Organisms/Biologically Active Substances and Wastes													
	Spores	***Gram (-) bacteria***	***Gram (+) bacteria***	***Non-lipid or Small Viruses***	***Fungi***	***Vegetative bacteria***	***Lipid or Medium-size Viruses***	***DNA***	***Cells***	***Prions***	***Bloodborne Pathogens***	***Protozoa***	***Wastes***	***REFERENCE***
Steam Sterilization (specify temp, time, and pressure setting)														
Gaseous Disinfectants (ETO etc.)										NR				
Commercial Disinfectant/Sterilizer										NR				
Alcohols	NR			NR			NR			NR	NR	NR C.parvum		
Chlorine and Chlorine Compounds												NR C.parvum Cryptosporidium		
Formaldehyde	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Glutaraldehyde					NR Fungal ascospores	NR Some mycobacteria				NR		NR C.parvum Cryptosporidium		
Hydrogen Peroxide										NR				
Iodophores	NR				NR					NR				
Ortho-phthalaldehyde										NR				
Paracetic Acid										NR		NR C.parvum		
Paracetic Acid and Hydrogen Peroxide										NR				

= Not Recommended

Click here to return to the Engineering Controls section of the form