

The University of Rhode Island (URI) Institutional Biosafety Committee (IBC) serves as the IBC for the URI. The mission of the IBC is to promote safety and minimize the risks of performing Biological Research to URI investigators, study participants, the community, and the environment by providing scientific review and oversight to Biological Research at URI. The IBC is committed to following the letter and the spirit of biosafety guidelines, guidance, and regulations. The IBC shall operate in full compliance with all applicable federal, state, and local regulations.

## **Instructions**

### ***Amendment Procedures***

Amendments to approved research are required for administrative changes (e.g., changes to staff, laboratory location, funding source, and title) and scientific changes. Scientific changes that require amendments include i) addition of new Biological Agents (including new strains or subtypes), rDNA, or Biological Toxins, ii) addition or changes to laboratory procedures, iii) additional of new animal studies, iv) anything that alters the risk of the biosafety assessment.

### ***Form Submittal***

Submit via IRBnet the following:

- This Amendment Document
- Any attachments
- Relevant thesis, dissertation, or grant proposals

### **Adobe Forms**

- Check that you have installed the latest version of Adobe Acrobat or Reader. The link to install Adobe Reader is: <http://get.adobe.com/reader>
- Download the IBC Registration Document
- Mac and iOS Users, open the file using Adobe Reader rather than the Preview function built into your Mac.
- Windows users, open the file using Adobe Acrobat or Reader rather than using a web browser.
- Save the form once you have entered your information. Then submit the form for IBC review via IRBnet

### ***Timetable***

Refer to the IBC meeting schedule on the URI Research Integrity [website](#) for submission deadlines. Administrative changes and some scientific changes do not need to be reviewed by the full committee. For more information, contact the Office of Research Integrity or refer to the IBC Policy of Defining Review Procedures for Categories of Biological Research within the URI Governance and Operating Policies.

### ***IBC Review and Approval Cycle***

- All IBC approvals require annual renewals. For annual renewals, submit a completed annual renewal form.
- All Registrations must be completely resubmitted every 5 years

### ***Questions?***

- Contact the Office of Research Integrity at 401-874-4328
- For training materials on IRBnet, refer to the Office of Research Integrity [website](#)
- For information on biosafety training, contact [URI EH&S Office](#) at 874-7019.

REMINDER FOR MAC USERS: Complete form in Adobe Reader, not the Preview function in MAC OS. Using the Preview function will disable parts of the form.

**Section 1 - Administrative Information**

a. Principal Investigator

b. Department

c. Phone Number

d. Email

e. Project Title

f. IBC Protocol Number (BI#)  g. IRBNet Number

**Section 2 - Administrative Changes**

a. Has the funding source changed?  Yes  No If yes, describe change and list the title(s), sponsor, award number, current period of performance.

b. Has the location of this research changed?  Yes  No If yes, where will the research take place? (Include Building/Room number(s))

c. Has the personnel changed?  Yes  No If yes, fill in information in table below for new personnel, including date of Biosafety Training as offered by URI's Environmental Health and Safety Office.

Name	Position	Date of Biosafety Training
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

If yes, list any personnel removed from protocol.

### Section 3 - Scientific Change

- a. Please provide a brief description of the proposed changes to the Biological Research, specifically describe new procedures and what, if any, additional infectious agent, rDNA materials, human or nonhuman primate materials, or toxin will be used. Ensure that all questions addressed on Registration Document for the new materials are addressed here (e. g., source of infectious agents, transgene expressed).

### Risk Assessment

NIH requires Principal Investigators make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines

- b. Does the proposed scientific change affect the current biosafety level of the original Registration?

Yes

No

If yes, describe change and why change is necessary.

Describe any other relevant information that will assist the IBC in their evaluation.

#### Section 4 - Certifications and Endorsements by Principal Investigator

To indicate agreement, check each statement and sign below

- To the best of my knowledge the information provided in this protocol form is complete and accurate and that this application accurately and completely reflects the Biological Research described in my full grant applications (if applicable).
- I am familiar with and agree to abide by the University's policies for research with potentially biohazardous materials, as based on the provisions of the *NIH Guidelines* and the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition.
- I understand that failure to comply with the *NIH Guidelines*, may jeopardize my research grants and those of others at the University regardless of the funding sources for my research.
- I am trained in good microbiological techniques and will ensure that all laboratory staff involved with this research are adequately trained and have completed University sponsored biosafety training and laboratory and project specific training and any additional training, instruction, and supervision needed to work safely with the biological agents and materials involved.
- I understand that I am responsible to report immediately to the IBC any significant violations of the NIH Guidelines, problems with containment, and any significant research-related accidents or illnesses.
- I agree to notify the IBC of changes in the research described in the application and will submit a revised IBC Registration to the IBC for review.

#### Principal Investigator Sign-Off

Please print name