Registration Document for Biological Research (New and Five Year Renewal)

Rev. March 2015

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

Research requiring Registration

Use this form to register research with:

- Potentially infectious agents (regardless of pathogenicity to humans) (e.g., bacteria, viruses, fungi, parasites, prions, rickettsias, yeasts, etc.)
- Recombinant DNA molecules, exempt or non-exempt from NIH Guidelines (e.g., recombinant or attenuated viral vectors, use of rDNA to create transgenic plants or animals)
- Human and nonhuman primate materials, including blood, tissues, and cell lines (primary and established)
- Biological toxins subject to the Select Agent Regulations

Form Submittal

Submit via IRBNet the following:

- This Registration 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 OS.
- 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

IBC Review and Approval Cycle

All IBC approvals require a renewal at their five year expiration. For renewals, submit an updated **Registration Document for Biological Research (New and Five Year Renewal).**

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 874-7993.

IBC Registration Document Completion Checklist

The checklist provided is an optional tool for researchers that clearly defines the requirements for IBC registration document submission. Use this to make sure all of the required documents are being uploaded to IRBNet and all personnel associated with your project receive the necessary training.

- ☐ Completed Registration Document for Biological Research. **Please try to limit your answers to the space provided and focus on the biological research**. (Upload separate document if you believe additional information is valuable to the committee. Refer to specific questions you are addressing).
- ☐ Attach an inventory sheet of all biological research materials you will be using for this protocol. Provide the location where each material will be stored.
- ☐ Attach information detailing how you will obtain the biological materials for this protocol (e.g., commerical vendor)
- ☐ Attach copies of your laboratory's Standard Operating Procedures (SOPs).
- ☐ All personal are required to attend an in-person biosafety training class with Connie Heird, Chemical Hygiene/ Biosafety Officer, Environmental Health & Safety Office. After the initial training, **annual training is required** and can be completed by attending further trainings with Connie Heird, or taking the CITI training modules (www.citiprogram.org) relevant to your research. The following modules are offered:

  Basic Biosafety Training
  Animal Biosafety Training
  Shipping and Transport of Regulated Biological Materials
  OSHA Bloodborne Pathogens

- ☐ Attach relevant thesis, dissertation, or grant proposals.
- ☐ Attach signed Proposal Approval form, if part of a thesis/dissertation.

In-person biosafety training classes are offered all year round. Participants must visit the Environmental Health & Safety Training Schedules and Handouts page for training dates and registration information.

Questions?

- Contact the Office of Research Integrity at 401-874-4328
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- For information on biosafety training, contact URI EH&S Office at 874-7019.

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Section 1 - Administrative Information

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.

a. Principal Investigator

b. College / Department

c. Email

d. Phone Number

e. Project Title

f. Type of application ◯ New Registration ◯ Five Year Renewal

If Renewal, list Protocol (BI #)

g. Anticipated Research Start Date

Anticipated Research End Date

h. What sponsored research projects support this research? List the title(s), sponsor, URI Project ID # , current period of performance.

i. Where will the research take place? (Include Building/Room number(s)

j. Date of Biosafety Training

Collaboration

k. Does this project involve collaboration with another institution? ◯ Yes ◯ No

If yes, please be clear in Section 3 what portions of the work will not be conducted at URI.

This Registration Document for Biological Research is for work involving:

(More than one category may apply)

☐ Potentially infectous agents	Complete Sections 2, 3, 4, 5, and 9
☐ Recombinant DNA molecules (e.g., plasmids, viral vectors) or synthetic nucleic acids	Complete Sections 2, 3, 4, 6, and 9
☐ Human or nonhuman primate materials (e.g., blood, tissue, cell lines)	Complete Sections 2, 3, 4, 7, and 9
☐ Biological toxins subject to the Select Agent Regulations	Complete Sections 2, 3, 4, 8 and 9

Associated Approvals:

Committee	Description	Approval Number or Review Status (e.g., pending, under review)
IACUC	Conducting Biological Research with animals (e.g., introducing infectious agent, viral vector) require IACUC approval	
IRB	Collecting biological specimens from human subjects (e.g., blood draws) require IRB approval	

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Section 2 - Personnel

List all personnel associated with the project

a. Co-investigator

Name | Department

Email | Phone Number

Date of Biosafety Training

b. Student Researcher

Name | Department

Email | Phone Number

Date of Biosafety Training

Will this project be used as a thesis or dissertation proposal, directed research, independent study or research paper?

◯ Yes
◯ No

If yes, submit an electronic copy of that proposal/paper as part of the IRBnet package

c. Other Personnel

All personnel should complete biosafety training offered by URI EHS.

Name	Position	Date of Biosafety Training

Describe any relevant experience for key personnel

Section 3 - Description of Research

a. Please provide a brief description of the goals of the Biological Research. Write for non-specialists.

b. Provide a detailed description of specific experiments you will be conducting, focusing how the infectious agent, rDNA materials, human or nonhuman primate materials, or toxin will be used. **If conducting more than one experiment, list them as A, B, C, etc. in order for the committee to easily distinguish between the procedures.**

Use the space provided below to continue your answer to question b if necessary.

Section 4 - 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. Work will be performed at:

- ☐ Biosafety Level 1
- ☐ Animal Biosafety Level 1
- ☐ Biosafety Level 2
- ☐ Animal Biosafety Level 2

Comments

c. Will a biosafety cabinet be used for containment?

- ◯ Yes
- ◯ No

List date of last BSC certification:

BSCs must be certified annually.

If yes, which procedures specifically?

d. Describe personal protective equipment being used for this research (e.g., gloves, eye protection, lab coat)

e. Are any vaccinations require to conduct this research (e.g., hepatitis B vaccine)

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Section 5 - Research with Potentially Infectious Agents

Complete this section if you are working with potentially infectious agents (regardless of the pathogenicity to humans or animals). Provide the information requested below for each agent.

a. Name of agent(s):

b. Source of agent(s)

c. Is antibiotic resistance expressed? ◯ Yes ◯ No — If yes, describe:

d. Is toxin produced? ◯ Yes ◯ No — If yes, describe:

e. Largest volume of agent cultured?

f. Is agent concentrated? ◯ Yes ◯ No — If yes, what is the highest concentration?

g. Describe how agent(s) will be inactivated (e.g., bleach, autoclave). Describe specific parameters (e.g., disinfectant concentration)

h. Will the agent be introduced into animals? ◯ Yes ◯ No

Don't forget to upload your spill protocol and other relevant SOPs.

i. If yes to h, describe administration of agent to animal including route of administration (e.g., IM, IP, IV), dose, and any special housing requirements.

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Section 6 - rDNA / Synthetic Nucleic Acids Research

NIH requires that Principal Investigators indicate the Section of the NIH Guidelines that covers their research. For specific language from the NIH, refer to the NIH Guidelines.

NIH Guideline Section	Example(s)
☐ Section III-A	Transfer of a drug resistant gene into a microorganisms that do not acquire the gene naturally that could compromise the use of the drug to control disease in humans, veterinary medicine or agriculture.
☐ Section III-B	Cloning of genes for toxins with LD50 of > 10 ng/kg body weight.
☐ Section III-C	Deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (human gene transfer)
☐ Section III-D	Introduction of rDNA or synthetic nucleic acid molecules into risk group 2 agents. rDNA from Risk Group 2, 3, 4 or restricted agents or use as host vector systems. Some experiments involving whole animals or plants. Large scale experiments. (e.g, use of adenoviral vectors, lentiviral vectors, retroviral vectors)
☐ Section III-E	Experiments involving formation of rDNA or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any eukaryotic virus. Some experiments with whole plants. Creation of transgenic rodents that require BSL1 containment.
☐ Section III-F	Experiments involving rDNA that are not in organisms or viruses.

Generation and Use of Non-viral rDNA

Briefly list specific host(s), vector(s), DNA and proteins that will be produced. Typically this work falls under Section III-E or III-F of the NIH Guidelines. Please ensure that Section C describes their use

a. Describe host cells (e.g., E.coli K12)

b. List vectors/plasmids:

c. What genes will be inserted DNA?

d. What are the gene product effects? (e.g., physiological activity, oncogenic potential)

e. Protein produced (if applicable)

f. Other Information (e.g., introducing rDNA to animals)

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Section 6 - rDNA / Synthetic Nucleic Acids Research

*Complete this section if you are **generating and/or using viral vectors** in your laboratory. Typically this work falls under Section III-D of the NIH Guidelines*

g. Identify Vector System

☐ Adeno-associated virus ☐ Adenovirus ☐ Other (e.g., vaccinia, HSV)

☐ Retrovirus ☐ Lentivirus

Provide full name(s) of vectors (include all associated plasmids)

h. List host cell line or packaging cells for vector propagation:

i. Source of vector system (e.g., vendor)

j. Is the vector capable of infecting human cells? (e.g., VSVg pseudotyped lentivirus) ◯ Yes ◯ No

k Describe the function and activity of the transgene(s). If you are planning on using an extensive number of transgenes, list classes or submit a separate file. If you are using a genome wide approach, describe library.

l. Are the expressed transgenes known or suspected to be oncogenic, potentially oncogenic, a tumor suppressor, or, to alter the cell cycle? ◯ Yes ◯ No

If yes, please describe:

m. Source of gene(s) (genus/species)

n. Describe how agent will be inactivated (e.g., bleach, autoclave). Describe specific parameters (e.g., disinfectant concentration)

o. Will the agent be introduced into animals? ◯ Yes ◯ No

Use of live animals also requires IACUC approval.

If **yes**, describe administration of agent including route of administration (e.g., IM, IP, IV), dose, and any special housing requirements.

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Section 7 - Research with Human or Nonhuman Primate Materials

Complete this section if you are working with human or nonhuman primate materials (e.g., blood, tissue, cell lines, other potentially infectious materials as defined by OSHA)

a. Identify the type (e.g., blood, cell line, tissue) and source (e.g., vendor, colleague)of the materials to be used. For cell lines, indicate if the cells are established or primary.

b. List any information that may be relevant to the infectious risk of the materials to be used (e.g., known to be infected with specific agent, known to be tested for presence of bloodborne pathogens)

c. Will sharps be used with the materials? ◯ Yes ◯ No

If yes, describe:

d. Describe how agent will be inactivated (e.g., bleach, autoclave). Describe specific parameters (e.g., disinfectant concentration)

e. Will the human or nonhuman primate material be introduced into animals? ◯ Yes ◯ No

Don't forget to upload your spill protocol and other relevant SOPs.

f. If yes to e, describe administration of material to animal including route of administration (e.g., IM, IP, IV), dose, and any special housing requirements.

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Section 8 - Research with Biological Toxins

Complete this section if you are working with a toxin of biological origin, subject to the Select Agent Regulations.

a. Identify the toxin, source (e.g., vendor, colleague), and largest quantity of toxin in use and stored.	
b. Describe how the toxin will be stored.	
c. Describe the toxin deactivation/disposal procedures.	

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Section 9 - 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

Print the form for your records

Print Form