Institutional Biosafety Committee New Research Submission Form

Please attach the following documents along with this submission form and email them to envhea@ewu.edu:

- Experimental Protocol or Standard Operating Procedures (SOPs)
- Your Training Records – Attach your CITI training certificate for the following trainings
  - *Training for Investigators, Staff, and Students Handling Biohazards*
  - *NIH Recombinant DNA (rDNA) Guidelines*

All personnel will be required to take the two CITI training courses before they can work on this project. Completion of training is not required prior to submission. **Send all training certificates to the IBC (envhea@ewu.edu), along with training records for in-lab training on project specifics before an individual begins working.**

Note: Eastern Washington University does not have any Biosafety Level 3 (BSL3) laboratories on campus and cannot accommodate work with Select Agents and Toxins.

Section 1 – General Information

Principle Investigator (PI): _____

Department: _____ EWU ID#: _____

Email: _____ Phone: _____

Project Title: _____

Anticipated Research Start Date: _____ Anticipated Research End Date: _____

Location(s) of Research (building and room) _____

If your project requires Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) approval, please indicate below; include approval number or status.

□ IACUC _____ □ IRB _____

Research Personnel

List all personnel who will work on this project

Name	Position (Student/Faculty/Staff)	EWU ID number

PLEASE COMPLETE THE REST OF THIS FORM USING LANGUAGE DIRECTED TO A GENERAL AUDIENCE WITH LIMITED SCIENTIFIC BACKGROUND. PLEASE DEFINE ANY TECHNICAL TERMS.

Section 2 – Description of Research

Research Involves (select all that apply):

- ☐ Potentially Infectious or Toxic Materials
- ☐ Toxic Plants
- ☐ Genetically Modified Organisms
- ☐ Recombinant DNA molecules (e.g. plasmids, viral vectors) or synthetic nucleic acids
- ☐ Human or nonhuman primate materials (e.g. blood, tissues, cell lines)

Please provide a brief description of the goals of this research project. (*Copy relevant sections of research proposal if appropriate.*)

Provide detailed information on specific experiments you will be conducting, focusing on how the biological materials will be used. *Use additional pages as necessary.*

Category of Research

According to the NIH Guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm), what is the NIH research category of your project (select all that apply)?

☐ III-D □ III-E □ III-F □ Research does not fall into an NIH category

Category	III-D (1-3)	III-D (4-7)	III-E	III-F
Definition	• Using Risk Group 2* agents as host-vector systems • rDNA/SNA from Risk Group 2* agents cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems • DNA or RNA virus work	• rDNA/SNA experiments in animals or microorganisms going into animals • rDNA/SNA experiments in weeds or exotic plants with plant pathogens • Any experiment involving more than 10L of culture • Some Influenza experiments	• Work with <2/3 of the DNA from a eukaryotic virus in tissue culture • rDNA/SNA experiments in domestic, non-weed plants or non-pathogenic organisms in plants • Transgenic mouse work requiring ABSL1	• rDNA/SNA that can't replicate in living cells or can't enter living cells • low risk rDNA/SNA already found in nature • Transposons found in nature • rDNA/SNA work in a specific list of organisms
Examples	• Cloning GFP plasmid into P. aeruginosa • CrispR-Cas9 modification of Helicobacter pylori • Using modified P. falciparum purchased from ATCC • Cloning S. typhimurium genes into E. coli BL21 • Packaging a 3rd generation lentiviral vector in HEK cells	• Modifying the Aag gene of rats • Injecting modified HeLa cells into mice • Feeding mice L. reuteri containing GFP • Growing 11L of any culture • Generating a new novel strain of influenza by combining fragments from different seasonal strains	• Modifying Arabidopsis • Adding B. subtilis with GFP to the soil of spinach • Creating transgenic mice requiring only ABSL1 • Receiving a lentiviral vector containing a gene of interest from a viral vector core • Cloning GFP into E. coli BL21	• rDNA/SNA (with less than half of any eukaryotic virus) propagated and maintained in culture • rDNA/SNA in E. coli K-12, S. cerevisiae, S. uvarum, K. lactis, or B. subtilis strains • PCR fragments from genomic DNA

Table adapted from MIT's NIH category examples table: https://ehs.mit.edu/site/biosafety/nih-guidelines#Examples

*Because there are no BSL3 laboratories on campus most experiments involving Risk Group 3 or 4 agents will not be allowed. If you believe your experiment involving a Risk Group 3 or 4 agent can be safely carried out in a BSL1 or BSL2, submit your application along with a letter explaining why your experiments can be carried out safely under a lower biosafety level.

Will your experiment involve more than 10L of culture? □ No □ Yes

If yes, what will be cultured in volumes greater than 10L?

PI Experience

Please describe the experience and qualifications you have for working with the agent(s) or using the proposed protocols.

Section 3 – Potentially Infectious or Toxic Agents

Complete this section if you are working with potentially infectious agents (regardless of the pathogenicity to humans, animals, or plants). *Duplicate this page as needed.*

Name of Agent: _____

Source of Agent: _____

Agent Host(s): _____ Agent Risk Group: _____

If the agent can infect humans, is a vaccine available? □ No □ Yes

Largest volume of agent to be cultured: _____

How will agent be inactivated? _____

_____

Will the agent be introduced to plants or animals? □ No □ Yes, plants □ Yes, animals

If yes, describe the route of administration, dose, housing/containment requirements, and disposal procedures:

Section 4 – Toxic Plants

Describe the plant and the nature of its toxicity.

Describe containment and disposal methods

Section 5 – Genetically Modified Organisms

Type of genetically modified organism to be used (select all that apply):

Macroorganisms	□ Plants/Fungus	□ Invertebrate animals	□ Vertebrate animals
Microorganisms	□ Bacteria	□ Archaea	□ Eukaryotes

Describe the organism to be modified, the type of genetic modification, the method used to alter the host genetic material, and the anticipated results. If not discussed in Section 4, describe any housing/containment requirements and disposal methods.

Section 6 – Recombinant DNA and Synthetic Nucleic Acids

□ Check this box if your experiment involves PCR amplification of genomic DNA without cloning, then proceed to Section 6.

Describe host cells or organisms:

List vectors and/or plasmids to be used (indicate if any of the vectors are capable of infecting human cells):

What gene(s) will be cloned (indicate if any genes are known or suspected oncogenes, tumor suppressors, or used to alter the cell cycle)?

What is the source of the genetic material?

If applicable, list protein(s) to be produced:

How will the materials be disposed?

Section 7 – Human or Nonhuman Primate Materials

Work with human or nonhuman primate materials may require Bloodborne Pathogen (BBP) training from Environmental Health & Safety (EH&S) and the development of a BBP Exposure Control Plan specific to your lab, contact EH&S with any questions.

Will human samples be collected as part of this experiment? □ No □ Yes

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

List any information about potential infectious risk of the material to be used (e.g. tested negative for bloodborne pathogens, known to be infected with specific agent…)

Describe disposal procedures:

Section 8 – Risk Assessment

Research will take place under (select all that apply):

□ Biosafety Level 1 □ Animal Biosafety Level 1 □ Plant Biosafety Level 1

□ Biosafety Level 2 □ Animal Biosafety Level 2 □ Plant Biosafety Level 2

Will a biosafety cabinet be used for containment? □ No □ Yes, date of last certification _____

Which procedures will take place in the biosafety cabinet?

Is there an eyewash in the lab(s)? □ No □ Yes

If no, where is the nearest eyewash and/or safety shower?

Is there a first-aid kit in the lab(s)? □ No □ Yes

If no, where is the nearest first-aid kit?

Are any vaccinations recommended or required to conduct this research? □ No □ Yes, list below

Hazards

For questions below, if the answer is yes please describe how the hazard will be controlled. Reference any lab protocols or procedures that address the question.

Will material be transported between rooms or buildings on campus? □ No □ Yes

Will material be shipped off campus? □ No □ Yes

Shipping biohazardous materials requires DOT training; attach a copy of the completion certificate for the CITI course ***Shipping and Transport of Regulated Biological Materials***.

Where and how will materials be stored (e.g. -80°C freezer in SCI 200)? *If materials will be stored in liquid nitrogen, describe the additional precautions in place.*

Will any infectious agents be used in a protocol that could create aerosols or droplets? □ No □ Yes

Will infectious material be centrifuged? □ No □ Yes

Will sealed rotors and/or buckets be used? □ No □ Yes

Where will rotors/buckets be opened?

Will biological samples be cultured in an incubator? □ No □ Yes

What type of incubator will be used (e.g. shaking or static shelf)?

Describe measures to prevent and contain any spills and procedures for spill clean-up.

Will sharps be used at any stage during this activity? □ No □ Yes

Justify their use and describe measures in place to protect users and others from injury.

Personal Protective Equipment

List personal protective equipment that will be used in this procedure (e.g. gloves, lab coat, safety goggles). Describe how the personal protective equipment will be disposed of or decontaminated.

Employee use of respirators requires enrollment in the Respiratory Protection Program, contact EH&S for more information.

Emergency Procedures

In the event of a release of materials, what is the worst-case scenario for humans and/or the environment?

Briefly describe the procedures for dealing with spills in the following locations. *Put N/A if not relevant.*

Inside a biosafety cabinet

Inside a centrifuge

Inside the general lab space

Outside of the lab (e.g. in the hallway during transport between rooms)

Describe the procedure for accidental exposure.

Describe procedure for safe exit of the lab during an emergency.

Describe any precaution in place for power outages.

Describe any other emergency related procedures.

Section 9 – Certifications

Read through and initial each statement indicating your agreement. Sign and date at the end.

PI

To the best of my knowledge, the information provided in this form and all attached documents is complete and accurate. If applicable, the information I have provided accurately reflects the research described in any associated grant applications. _____

I have read the ***EWU Biosafety Manual*** and am familiar with the ***NIH Guidelines*** and the ***Biosafety in Microbiological and Biomedical Laboratories*** (BMBL). I will conduct all research in compliance with these documents. _____

I understand that failure to comply with the ***NIH Guidelines*** may jeopardize my research grants and those of other researchers at Eastern, regardless of the funding source for my research. _____

I have completed the CITI courses ***Training for Investigators, Staff, and Students Handling Biohazards***, and ***NIH Recombinant DNA (rDNA) Guidelines*** and have included a copy of the completion certificates with this application. I will ensure that any additional people involved in this project also complete these courses and submit their completion certificates to the IBC. _____

I am trained in good microbiological techniques and I will ensure that all members of my laboratory receive appropriate training to conduct research safely. _____

I understand that I am responsible for immediately reporting any violations of the ***NIH Guidelines***, problems with containment, or significant research-related accidents or illnesses to the IBC. _____

I will notify the IBC of changes to the described research and will submit a revised IBC registration form should such changes occur. _____

PI Signature: _____ Date: _____

Print Name: _____

Department Chair

I have read the research submission; I believe that the department possesses appropriate facilities to control any biohazardous material. _____

I believe the protocols and emergency procedures are appropriate for the level of biohazard. _____

Department Chair Signature: _____ Date: _____

Print Name: _____

Dean or Designee

I have read the research submission; I believe that the department possesses appropriate facilities to control any biohazardous material. _____

I believe the protocols and emergency procedures are appropriate for the level of biohazard. _____

Dean/Designee Signature: _____ Date: _____

Print Name: _____

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