Southeast Missouri State University Biosafety Form

Shaded Areas for EHSC Use Only

Form Reviewed by:_____ Date:_____ Form Routed to:_____ Date:_____

1. Protocol Title: _____

2. Principal Investigator _____ E-mail Address _____
Department _____ Title _____
Campus Address _____ Campus Phone _____

Co-Investigator _____ E-mail Address _____
Department _____ Title _____
Campus Address _____ Campus Phone _____

3. Application Type ☐ New ☐ Amendment ☐ Renewal

4. Dates of Proposed Research _____ to _____

5. Primary Research Locations and Multiuser Rooms

Building	Room #	Biosafety Level	Shared Room	Inspected
			☐	
			☐	

6. Research Storage and Biosafety Cabinet locations

Biohazardous Agent	Building	Room #	Storage/Biosafety Cabinet	Shared	Secured	Inspected
				☐	☐	
				☐	☐	
				☐	☐	

7. Research Animal or Plant Locations

Animal/Plant	Building/Farm	Room #	Biosafety Level	Shared
				☐
				☐

8. Research Personnel

Name	Employee ID Or Student ID	E-mail	Title/Role	Training Class			
				Biosafety	Training Date	BBP	Training Date
				☐		☐	
				☐		☐	
				☐		☐	
				☐		☐	
				☐		☐	
				☐		☐	

9. Protocol Risk Assessment

Answer all sub-questions to any question that is answered Yes.

a. **Use of (receiving) biohazardous or recombinant material (i.e. animal, plant, human tissue) from outside source?** ☐ Yes ☐ No

i. Collaborator information

_____

b. **Use of Recombinant or Synthetic Nucleic Acid Molecules?** ☐ Yes ☐ No

i. Source of cloned molecules

_____

ii. Nature of inserted molecules

_____

iii. Vector(s) Used: Page (Vectors Used)

_____

Plasmids (conjugative/non-conjugative)

_____

iv. Viral Component(s) sequence(s) present?

_____

v. Host organism(s) for foreign sequences?

_____

vi. Will an attempt be made to obtain expression of a foreign gene? ☐ Yes ☐ No

(a) What Protein will be produced? _____

(b) Indicate possible toxicity or other hazards, if any:_____

vii. Is this experiment expressly exempt from NIH rDNA guidelines? ☐ Yes ☐ No

(If no, approval from EHSC is required BEFORE initiating experiments.)

c. **Use of Biological Organisms/Agents?** ☐ Yes ☐ No

i. Identify Biological Organisms/Agents to be used in conjunction with this protocol and their risk level

_____

_____

_____

_____

d. **Use of Select Agent/Toxin?** ☐ Yes ☐ No

i. Identify all Select Agents/Toxins to be used in conjunction with this protocol

_____

_____

e. **Use of Radioactive Materials?** ☐ Yes ☐ No
   i. Type of Isotope(s) to be Used _____
   ii. Date of Radiation Safety Committee Approval _____ ☐ Pending Approval
f. **Use of Research Animal Subjects?** ☐ Yes ☐ No
   i. Genus/Species of Animal _____
   ii. Transgenic Animal ☐ Yes ☐ No
      (a) Genetic Alteration _____
g. **Use of Animal Blood/Tissue (OPIM—Zoonotic)?** ☐ Yes ☐ No
   i. Genus/Species of Animal _____
   ii. Other Potentially Infectious Material (OPIM) ☐ Yes ☐ No
      (a) Identify Zoonotic Disease (OPIM) _____
h. **Use of Whole Plants?** ☐ Yes ☐ No
   i. Genus/Species of Plant _____
   ii. Transgenic Plant ☐ Yes ☐ No
      (a) Genetic Alteration _____
   iii. Any rDNA derived from a plant pathogen? ☐ Yes ☐ No
i. **Use of Human Blood, Tissues, Cell Lines or OPIM?** ☐ Yes ☐ No
   i. Are you using human subjects in this research? ☐ Yes ☐ No
   ii. Human Subjects Committee Approval Date _____ ☐ Pending Approval
j. **Conducting Gene Therapy or Vaccine Trial?** ☐ Yes ☐ No
k. **Will over 10 Liters of Material be possessed at any one time?** ☐ Yes ☐ No

10. Proposed Biosafety Level ☐ BL-1 ☐ BL-2 ☐ BL-3

11. Mitigation Assessment

a. What PPE Devices will be used? ☐ Gloves ☐ Safety Glasses ☐ Lab Coat ☐ Respirator/Mask ☐ Other: _____
b. Will access to the laboratory be controlled? ☐ Yes ☐ No
   i. How so? _____
c. Is a Biological Safety Cabinet available for use? ☐ Yes ☐ No ☐ N/A
   i. Location? _____
d. Have Emergency Procedures been developed to respond to an incident? ☐ Yes ☐ No
   i. Date of Creation or Last Review? _____
e. Has an Exposure Control Plan been developed for Laboratory Workers? ☐ Yes ☐ No
   i. Date of Creation or Last Review? _____
f. Has Emergency Notification and Biohazard signage been posted? ☐ Yes ☐ No
   i. Date of Creation or Last Review? _____
g. Have all personnel been offered vaccination/titer check for all material to be used in your research? ☐ Yes ☐ No

12. Scope of Work

a. Purpose of the experiment:

_____

b. Rationale for the use of the agent:

_____

c. Description of the experimental procedures

_____

d. Assessment of risk for your (specific) research protocol

_____

e. The experimental amplification risk

_____

f. The use of whole transgenic plants and/or animals

_____

g. Human research participants used and/or laboratory animal subjects used

_____

h. Waste disposal protocols

_____

Statement of Agreement

1. I certify that the information contained in the completed application form, date_____, is accurate to the best of my knowledge. I agree to comply with all EHSC requirements with regard to the use, handling, storage and disposal of biohazardous agents and recombinant or synthetic nucleic acid molecules. I also agree to follow the current NIH *Guidelines for the Use of Recombinant or Synthetic Nucleic Acid Molecules*, the CDC recommendations from the CDC/NIH handbook, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition* and all Southeast Missouri State University Biosafety Guidelines and Regulations.
2. I further attest that all research personnel under my supervision on this project, have attended all appropriate biosafety training sessions and that they are familiar with the hazards and symptoms of exposure relevant to the biological materials used within the laboratory. All laboratory personnel have been briefed on emergency procedures, good laboratory work practices, and the safe operation of laboratory equipment prior to the initiation of experimental work.
3. I will select and provide personal protective equipment to all laboratory workers as recommended by NIH, CDC, and/or Southeast Missouri State University that is necessary for experimental procedures. All required biosafety cabinets shall be certified annually and maintained properly. Any vaccinations or medical surveillance requirements recommended by the EHSC will also be met prior to the initiation of experimental work.
4. I will complete all required forms and approvals for any human subject research and any animal subject research prior to initiation of experimental work.
5. I will notify the EHSC and the respective departmental chair in the event of any of the following:
   a. Any accident that results in inoculation, ingestion, and inhalation of biohazardous agents or recombinant DNA or any incident causing serious exposure of personnel or danger of environmental contamination.
   b. Any problem pertaining to the operation of biological and physical containment safety equipment such as a biosafety cabinet or a facility failure such as a power outage which may compromise building engineering controls and consequently, the safety of the workers in the lab.
6. I will notify EHSC when the experimental work has been completed and/or I am leaving Southeast Missouri State University, after which a close-out inspection will be conducted at least two weeks before the date of departure/completion.
7. I will not proceed with the experiment until I have received an official notice of approval from the EHSC unless otherwise specified or exempted. I acknowledge EHSC approval granted by this application is non-transferable to any other Southeast Missouri State University researcher.
8. I acknowledge and understand that failure to comply with any of the above items, as well as the failure to comply with Federal and/or State statues and their associated regulations will be reported to the EHSC. Further, that the EHSC has the power and authority to take appropriate actions to rectify any non-compliance, including but not limited to letters of reprimand, sanctions against the Principal Investigator, suspension of research activities of Principal Investigator, and revocation of all EHSC research protocols.

Principal Investigator _____ Date: _____

Co-Investigator _____ Date: _____