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

<table>
<thead>
<tr>
<th>Building</th>
<th>Room #</th>
<th>Biosafety Level</th>
<th>Shared Room</th>
<th>Inspected</th>
</tr>
</thead>
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6. Research Storage and Biosafety Cabinet locations

<table>
<thead>
<tr>
<th>Biohazardous Agent</th>
<th>Building</th>
<th>Room #</th>
<th>Storage/Biosafety Cabinet</th>
<th>Shared</th>
<th>Secured</th>
<th>Inspected</th>
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</table>

7. Research Animal or Plant Locations

<table>
<thead>
<tr>
<th>Animal/Plant</th>
<th>Building/Farm</th>
<th>Room #</th>
<th>Biosafety Level</th>
<th>Shared</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
8. Research Personnel

<table>
<thead>
<tr>
<th>Name</th>
<th>Employee ID Or Student ID</th>
<th>E-mail</th>
<th>Title/Role</th>
<th>Training Class</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>Biosafety Training Date</td>
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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
   ____
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td><strong>Use of Radioactive Materials?</strong></td>
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<tr>
<td>i. Type of Isotope(s) to be Used</td>
<td></td>
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<tr>
<td>ii. Date of Radiation Safety Committee Approval</td>
<td></td>
<td>Pending Approval</td>
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<tr>
<td><strong>Use of Research Animal Subjects?</strong></td>
<td></td>
<td></td>
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<tr>
<td>i. Genus/Species of Animal</td>
<td></td>
<td></td>
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<tr>
<td>ii. Transgenic Animal</td>
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<td></td>
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<tr>
<td>(a) Genetic Alteration</td>
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<tr>
<td><strong>Use of Animal Blood/Tissue (OPIM—Zoonotic)?</strong></td>
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<tr>
<td>i. Genus/Species of Animal</td>
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<tr>
<td>ii. Other Potentially Infectious Material (OPIM)</td>
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<tr>
<td>(a) Identify Zoonotic Disease (OPIM)</td>
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<td><strong>Use of Whole Plants?</strong></td>
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<tr>
<td>i. Genus/Species of Plant</td>
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<tr>
<td>ii. Transgenic Plant</td>
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<tr>
<td>(a) Genetic Alteration</td>
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<tr>
<td>iii. Any rDNA derived from a plant pathogen?</td>
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<tr>
<td><strong>Use of Human Blood, Tissues, Cell Lines or OPIM?</strong></td>
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<tr>
<td>i. Are you using human subjects in this research?</td>
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<tr>
<td>ii. Human Subjects Committee Approval Date</td>
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<td>Pending Approval</td>
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<tr>
<td><strong>Conducting Gene Therapy or Vaccine Trial?</strong></td>
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<tr>
<td><strong>Will over 10 Liters of Material be possessed at any one time?</strong></td>
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</table>

**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
    - How so? __________
- c. Is a Biological Safety Cabinet available for use?
  - Yes
  - No
  - N/A
    - Location? __________
- d. Have Emergency Procedures been developed to respond to an incident?
  - Yes
  - No
    - Date of Creation or Last Review? __________
- e. Has an Exposure Control Plan been developed for Laboratory Workers?
  - Yes
  - No
    - Date of Creation or Last Review? __________
- f. Has Emergency Notification and Biohazard signage been posted?
  - Yes
  - No
    - 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
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: __________________________