Samuel Merritt University

Biological Use Authorization

PRINCIPAL INVESTIGATOR INFORMATION:

Name _____
Last First Title

Phone _____ Fax _____ Email _____

Department _____ Building _____ Room _____

Project Title _____

Application Status: Initial ☐ Renewal of BUA ☐

OTHER PERSONNEL ASSOCIATED WITH THE PROJECT:

Use continuation page, if necessary.

Last First Phone

Name _____

Name _____

Name _____

PRINCIPAL INVESTIGATOR'S CERTIFICATION:

By signing below, I certify that I and the listed participants will abide by all Samuel Merritt University laboratory safety policies and by the policies and procedures governing the use of infectious agents, recombinant DNA, and other biological materials as outlined in CDC and NIH publication **"Biosafety in Microbiological and Biomedical Laboratories, 6th Edition, (2020)."** (https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf)

I will:

- Ensure that listed personnel receive appropriate training in safe laboratory practices and the procedures for these protocols prior to any work beginning.
- Inform the University Biosafety Officer of any significant research related accident or illness as soon as possible after its occurrence.
- Submit in writing a request for approval from the Biosafety Committee of any significant modifications to the study, facilities, or procedures.

Signature of Principal Investigator _____ Date _____

For BSC use only

☐ Biosafety Committee Approval _____
Biosafety Committee Chair

Approval Date _____ Expiration Date _____

FUNDING INFORMATION:

This study will be funded Yes ☐ No ☐

Check all that apply:

- ☐ Federal Government
- ☐ Other Government (State, City, WHO)
- ☐ Pharmaceutical/Device Company
- ☐ Other private
- ☐ Campus/University-wide programs
- ☐ Departmental

Funding source name (and grant/contract #, if known) _____

SPECIFIC LOCATIONS WHERE RESEARCH WILL BE PERFORMED:

Location(s) of biohazardous materials _____

Location(s) of biosafety cabinet(s) _____

Location(s) of autoclave(s) _____

PART A: INFECTIOUS AGENTS AND TOXINS

1. Please indicate "Yes" or "No" to each of the following. I am working with:

☐ Yes	☐ No	a. an RG1 organism.
☐ Yes	☐ No	b. an RG2 organism.
☐ Yes	☐ No	c. sheep tissue or sheep cell lines.
☐ Yes	☐ No	d. Old World primate tissues or cell lines.
☐ Yes	☐ No	e. toxins known to affect humans.
☐ Yes	☐ No	f. human genes, blood, body fluids, unfixed tissue, or cell, tissue, organ cultures derived from humans.

2. If you answered “Yes” to any of the above statements, please complete the following Infectious Agents and Toxins Information section.

Use continuation page if necessary.

Note: Information about Biosafety Risk Levels of Biologic Organisms is located at (https://my.absa.org/Riskgroups).

If you are working with human genes, blood, body fluids, unfixed tissue, or cell, tissue, or organ cultures derived from humans, list the potential blood-borne pathogens, the specific material being used, and enter "2" under Risk Group.

INFECTIOUS AGENT OR TOXIN	RISK GROUP

3. Please attach a written description for the following:

- The experimental design and goals of the research, including a brief description of the experimental procedures. Provide sufficient detail to allow the committee to assess the hazardous potential of the experiments.
- An assessment of the hazardous potential, including a brief description of the agents, its hosts, modes of transmission to humans, and pathogenicity. Also, describe the implications if the organism were to be released outside the laboratory.
- A description of your plan for biosafety for the research, including a description of the biosafety training you will provide related to this work for all personnel involved in the project.

4. Please indicate "Yes" or "No" to the following statement:

Yes ☐ No ☐ I will use one or more of the **DHHS Select Agents** in this study.

A List of DHHS Select Agents is located at:
(https://www.selectagents.gov/SelectAgentsandToxinsList.html)

If "Yes" please attach one-paragraph descriptions of the agent(s), the quantities in which you will be handling and storing them, storage locations, security precautions and mechanisms by which you will ensure their safe usage and disposal.

PART B: RECOMBINANT DNA

1. Please indicate “Yes" or "No" to each of the following.

Yes ☐ No ☐ a. I am inserting foreign DNA into a vector or organism for cloning.

Yes ☐ No ☐ b. The DNA to be cloned is from a RG3 agent, represents more than two-thirds of the genome of a RG1 or 2 organism, encodes a known oncogene, or encodes molecules known to be toxic to vertebrates at concentrations less than 1 mg/mL.

Yes ☐ No ☐ c. The vector I am using for introduction of foreign DNA into the host is from an RG3 agent, is a RG1 or 2 virus that infects eukaryotic cells and contains more than two-thirds of the viral genome.

Yes ☐ No ☐ d. The host into which I am introducing the DNA is a cell or organism other than *E. coli* K12 or its derivatives, *Saccharomyces cerevisiae*, *S. uvarum*, *Bacillus subtilis*, or *B. licheniformis*.

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2. If you indicated "Yes" to any of the above statements, please complete the following Recombinant DNA Information.

Please provide specific names: Risk Group

Host(s)

Vector(s)

Gene(s) to be cloned

DNA source(s)

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3. Please attach one paragraph descriptions of the following:

- The experimental design and goals of the research, including a brief description of the experimental procedures. Provide sufficient detail to allow the committee to assess the hazardous potential of the experiments.
- Assessment of the hazardous potential of cloning any DNA segments encoding pathogenic, oncogenic, or toxic substances.
- Containment conditions that will be implemented.

PART C: STANDARD OPERATING PROCEDURES FOR ALL APPLICANTS:

Please Initial to acknowledge agreement with each of the following:

_____ a. Decontamination Procedures: I will use 0.5% sodium hypochlorite (a 1:10 dilution of household bleach) to decontaminate equipment and work surfaces. In locations where bleach would cause corrosion, I will decontaminate with an iodophore (e.g., Wescodyne).

_____ b. Local Transport of Infectious Materials: All infectious materials transported to and from my laboratory will be enclosed in a primary container with sealed top, which will then be enclosed in a secondary leak-proof, non-breakable container (such as a Coleman cooler) appropriately labeled with the biohazard symbol.

_____ c. Storage: All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as well as the storage space (e.g., freezer, refrigerator).

_____ d. Human Origin: If I am using human genes, blood, body fluids, unfixed tissue, or cell, tissue, or organ cultures derived from humans, I will handles all such cultures under BSL2 conditions and in accordance with Blood-borne Pathogen Standards unless the Biosafety committee has specifically approved a lower level of containment.

_____ e. Shipment of Biological Materials: I will follow all applicable state, Federal, and international regulations whenever I ship biologic materials domestically and internationally. I will also obtain the proper importation or exportation permits/licenses before shipping or receiving any biologic material.

_____ f. Containment of Aerosols or Splashes: All manipulations having a potential for generating aerosols (e.g., homogenization, centrifugation, and sonication) will be conducted in a properly certified biosafety cabinet or in a centrifuge equipped with sealed rotor heads or safety cups. Screw-cap centrifuge tubes will be no more than three-fourths filled.

_____ g. Disposal: I will post in my laboratory the procedures for disposal of biologic waste, as determined by the Biosafety committee.