**LIMR BIOSAFETY/RECOMBINANT DNA COMMITTEE**

 **For Protocols Involving Recombinant or Synthetic Nucleic Acid Molecules, Microorganism Usage, Biological Toxins, or Human Blood/Tissue/Fluid/Materials/Cells/Cell Cultures**

**Annual Renewal 2018**

**Principal Investigator Name:** **Laboratory #:**

**Biosafety Protocol No.:**

**Biosafety Protocol Title:**

**Current Protocol Information**

**Please respond to all questions. Indicate N/A when appropriate.**

1. **This protocol is:** a. [ ]  Activeb. [ ]  Terminated (if terminated, go directly the signature section on page 2)

 c. Other, please explain:

1. **The Biosafety containment level used for this protocol is:** (BSL 1, 2 or ABSL-1, ABSL-2)
2. **List current funding sources for protocol. Include all sources of funding in the space below.**

1. **Have your research objectives and/or protocol, pathogenic organisms, or agents changed since approval of this protocol which have not been submitted for review?**

#  [ ]  NO [ ]  YES\*  If yes, all changes must be submitted as an addendum and approved by the Committee.

# Do you use recombinant or synthetic nucleic acid molecules and/or viral vectors?

#  [ ]  NO [ ]  YES\*

# \*If yes, list those used in your protocol which are not exempt from the NIH Guidelines <http://www.limr.org/doc/Page.asp?PageID=DOC001206>.

# Are live animals involved in this research project?

#  [ ]  NO [ ]  YES\*  If yes, please list the IACUC protocol number(s):

# Do you use human derived materials (human blood, tissue, fluid, materials, cells, and/or cell cultures) in

#  your research?

#  [ ]  NO [ ]  YES\*  If yes, please list. Indicate the approved IRB protocol number(s) when applicable:

# Do you use fixed non-human primate (NHP) cells, fluids and/or cell lines in your research (Please note that use of NHP non-fixed primary tissue derived materials and macaque materials are prohibited)?

#  [ ]  NO [ ]  YES\*  If yes, please list source:

# Do you use viruses, bacterial or other prokaryotes, biological toxins, or other pathogens in your research? [ ]  NO [ ]  YES\* \*If yes, please list:

# Do you use radiation and/or radioactive isotopes in your protocol?

 [ ]  NO [ ]  YES\*
 \*If yes, please describe:

# Do you use Select Agents?

 [ ]  NO [ ]  YES\* (Include all select agents, regardless of quantity)
 If yes, please describe and include quantity:

# List the current laboratory personnel who are involved in this study and indicate if they have been

#  trained to safely conduct the procedures in the study. (*The required Biosafety Training can be completed by logging on to* [*www.citiprogram.org*](http://www.citiprogram.org) *and any questions regarding specific courses can be directed to the Office of Research Protections.*)

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#

# List personnel in your lab who are not involved in this study and indicate if they have informed of all

#  risks involved in this work.

#

# Indicate any recombinant or synthetic nucleic acid molecules, microorganism usage, biological toxin, or human blood/tissue/fluid/materials/cells/cell cultures described in your original protocol that will no longer be used in your laboratory and why. Proper disposal is required.

#

# Please describe any protocol deviations and/or unanticipated problems/adverse events (e.g., unexpected health issues or exposures to biohazards, significant spills, injuries or side effects) that have occurred in the laboratory. In your description, please explain how the problem/adverse event was resolved. If there were no problems/adverse events, please indicate “NONE” in the space provided.

#

1. **a.** **[ ]  I foresee no changes to my protocol in the coming year.**

 **b.** **[ ]  I will amend my protocol if necessary.**

 **c.** **[ ]  Other, please describe:**

**RECERTIFICATION OF THE PRINCIPAL INVESTIGATOR**

The following signature certifies that the Principal Investigator will continue to conduct this research in accordance with the policy and procedures of the Lankenau Institute for Medical Research Laboratory Safety Manual and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

[ ]  I agree to comply with federal, state, and institutional requirements pertaining to handling, shipment, transfer, and disposal of biological materials.

[ ]  I agree to accept responsibility for the training of all personnel involved in this research and certify that all personnel have been trained. I agree to ensure all required training is completed for personnel in my laboratory.

[ ]  I understand that all changes in agents, procedures/practices, and facilities must be reported to the Institutional Biosafety Committee (IBC) and approval shall be obtained prior to implementation of these changes.

[ ]  I agree to no unauthorized uses of recombinant or synthetic nucleic acid molecules, microorganisms, select agents, biological toxins, regulated and particularly hazardous chemicals or deviation from an approved IBC protocol.

[ ]  I understand that IBC approval is required to obtain IACUC approval for studies using live vertebrate animals if recombinant or synthetic nucleic acid molecules, microorganisms, select agents, and/or biological toxins are involved.

[ ]  All protocol deviations must be reported to the IBC. A protocol deviation occurs when there is an inconsistency in a research study between the protocol that has been reviewed and approved by the IBC, and the actual activities being done.

**When working with Synthetic or Nucleic Acid Molecules:**

[ ]  I am aware of and have read the relevant sections of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,* <http://www.limr.org/doc/Page.asp?PageID=DOC001207>.

[ ]  I will report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC within 2 business days of occurrence. <https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/>

Principal Investigator (Printed Name)

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Principal Investigator (Signature) Date

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Signature of Biosafety Committee Chairperson Date

Training Pending for:

Training Completed for:

Training Verified by ORP:

**To be completed by ORA Personnel:**