UNIVERSITY OF MIAMI
Human Gene Transfer
Submission form 2017
Institutional Biosafety Committee

(305)243-2311 Fax:(305)243-2853
http://uresearch.miami.edu/regulatory-compliance-service/ibc

Please send all submissions to
IBCsupport@miami.edu

COMMITTEE USE ONLY

APPROVAL NUMBER

APPROVAL DATE

EXPIRATION DATE

STUDY DURATION

Section 1. Application Information

Title of project:

Same Title for IRB? Yes ☐ No ☐ IRB#:

PI name: C#:

School/College: Department/Center:

Email Address: UM Phone #:

Primary Contact:

Submission type (new or 3 year renewal): NEW Funded by:

Is UM the initial/only study site?: Yes ☐ No ☐ Sponsor:

Section 2: Purpose and Rationale

*Explain in Lay terms (**for community members and the public**) the rationale for the study. What is to be learned from this study and the significance of this study?*

2a. Provide Scientific Overview

2b. Describe the experimental approach involving the rDNA.

2c. What kind of vector system is involved in this study?

Section 3: Risk Groups

List the risk group for your vector (e.g. RG1, RG2). See section II-A of NIH guidelines for research involving recombinant DNA molecules for risk group guidance.

3a. This study fall under Risk Group Select

Section 4: Biosafety Levels

Biosafety levels are defined and described in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, which is located at the following website: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf and see Section II-B of the NIH Guidelines for Research Involving Recombinant DNA Molecules for containment guidance to evaluate the biosafety level(s) your study falls under.

4a. This study fall under Biosafety Level BL Select

Section 5: Procedures

Please check and identify the organisms/viruses that apply to your experiments:

5a. Viral particles: Yes ☐ No ☐

If "Yes", please check what type of viral particles: Retro ☐ Lenti ☐ Adeno Adeno-Associated ☐ Other ☐

5b. Viral Vectors: Yes ☐ No ☐

If "Yes", maps must be provided, otherwise the submission is not complete and the study cannot be reviewed.

5c. In vitro work: Yes ☐ No ☐

If "Yes", please indicate what culture is being used:

5d. Prokaryotes: Yes ☐ No ☐

5e. Other: Yes ☐ No ☐

If "Yes", please describe:

5f. Will cell sorting be conducted in these experiments? Yes ☐ No ☐

If "Yes", what is the Cell sorting facility name?

If "Yes" in question 5f, please specify the sorting that will be performed, including the cell types, infectious potential, any genetic manipulation (transduction / transfection) of the cells, and any biohazard containment that will be utilized:

5g. Will flow cytometry analysis (not sorting) be conducted in these experiments? Yes ☐ No ☐

If "Yes", what is the flow cytometry analyzer name?

If "Yes" in question 5g, please specify the analysis that will be performed, including the cells types, infectious potential, any genetic manipulation (transduction/transfection) of the cells, and any biohazard containment that will be utilized (e.g., if a fixation procedure is used, please describe it):

5h. Please describe what physical methods (injection, electroporation, transfection, infection, "gene gun", etc.) will be used in the gene transfer.

5i. Please describe the vectors that are involved in this study (organisms and cells lines).

List all vectors (DNA prokaryotic and eukaryotic)

5j. List all genes to be expressed.

5k. Name and describe the nature of inserted DNA sequence (specify whether cDNA, genomic, PCR fragment, synthetic, etc) and the species of origin.

Section 6: Viral Constructs

For any work dealing with viral constructs, please provide vector maps as the project will not be reviewed by the IBC without the maps.

6a. Do experiment involve the use or formation of rDNA molecules containing ≥2/3 of the genome of a eukaryotic virus? Yes ☐ No ☐

6b. Do the experiments involve murine retroviruses? Yes ☐ No ☐

If "Yes" in question 6b, what type of envelope are you using?

6d. List all genes to be transferred. Please define abbreviations.

Gene Name	Species of origin

6e. Is the virus replication deficient? Yes ☐ No ☐

6f. Do experiments involve the use of defective animal viruses in the presence of a helper virus? Yes ☐ No ☐

If Yes in question 6f, describe the experiments which involve the use of defective animal viruses in the presence of a helper virus.

6g. For retrovirus vector preparation, indicate the number of different plasmids required to produce virus particles.

6h. Do experiments involve the use of a lentiviruses? Yes ☐ No ☐

If "Yes" in question 6h, will there be 2nd or 3rd generation vectors?

6i. Do experiments involve the use of infectious human, animal, that can propagate in the absence of a helper virus? Yes ☐ No ☐

If "Yes" in question 6j, describe the experiments which involve the use of infectious human viruses that can propagate in the absence of a helper virus.

6k. Provide a brief description of the potential for exposure hazards (ex. aerosol generation when transferring) and the safety practices and precautions are you taking when handling this agent(s) to minimize risk and prevent release of infectious agents (ex. protective clothing, use of biosafety cabinet, sharps disposal procedures, biomedical waste disposal procedures, etc.) as per: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf and University policy.

Please note that all associates involved in the experiments must take the biosafety seminar before the work begins (please contact 305-243-3400).

Section 7: Principal Investigator Certification

Check all below to indicate your agreement

☐ If any of the information described above is to be changed, I will submit an amendment / revised form as appropriate. For experiments that require prior approval, I will not implement the changes before receiving IBC approval.

☐ I agree that all work on this project will be conducted according to NIH Guidelines for Research Involving Recombinant DNA Molecules and using the appropriate biosafety practices described in the CDC/NIH Biosafety in Biomedical and Microbiological Laboratories (BMBL) http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf.

☐ Any serious adverse event that is fatal or life-threatening, that is unexpected, and associated with the use of the gene transfer product must be reported to the NIH OBA and the UM IBC as soon as possible, but not later than 7 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA).

☐ Serious adverse events that are unexpected and associated with the use of the gene transfer product, but are not fatal or life-threatening, must be reported to the NIH OBA and the UM IBC as soon as possible, but not later than 15 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA).

☐ Changes in this schedule are permitted only where, under the FDA IND regulations [21 CFR 312(c)(3)], changes in this reporting schedule have been approved by the FDA and are reflected in the protocol.

☐ If, after further evaluation, an adverse event initially considered not to be associated with the use of the gene transfer product is subsequently determined to be associated, then the event must be reported to the NIH OBA and the UM IBC within 15 days of the determination.

☐ Relevant additional clinical and laboratory data may become available following the initial serious adverse event report. Any follow-up information relevant to a serious adverse event must be reported within 15 calendar days of the sponsor's receipt of the information. If a serious adverse event occurs after the end of a clinical trial and is determined to be associated with the use of the gene transfer product, that event shall be reported to the NIH OBA and the UM IBC within 15 calendar days of the determination.

☐ Any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity must be reported as soon as possible to the NIH OBA and the UM IBC, but not later than 15 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA).

☐ If there are any changes in the clinical protocol (e.g., Investigator's Brochure), the new IB, and a memo outlining what was originally approved and what has now changed must be sent to the UM IBC.

☐ If there are any changes in personnel working on the project, the IBC should be informed.

☐ Please submit a copy of the documents that will be sent to OBA within 20 working days after enrollment of the first trial participant.

☐ I understand that additional requirements may be stipulated by the IBC after the review of this submission.

Signature of Principal Investigator	Date: