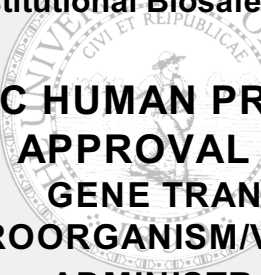


**UNIVERSITY OF OKLAHOMA  
HEALTH SCIENCES CENTER  
Institutional Biosafety Committee**



**IBC HUMAN PROTOCOL  
APPROVAL FORM:  
GENE TRANSFER,  
MICROORGANISM/VIRUS/TOXIN  
ADMINISTRATION**

**FOR IBC USE ONLY**

Date received: \_\_\_\_\_

Experiment class determination:

III-C Requires IBC and IRB approvals and RAC review before research participant enrollment

N/A

Biosafety level (BSL) required:  BSL1  BSL2  BSL3  BSL4

Approved/Disapproved IBC #: \_\_\_\_\_

Date approved: \_\_\_\_\_

IBC signature: \_\_\_\_\_

**NOTE: All protocols involving the transfer of recombinant DNA molecules into one or more human research participants requires IBC and IRB approvals and RAC review before research participant enrollment.**

1. Principal Investigator (PI) name and degree\*: \_\_\_\_\_  
**\*If Post-Doctoral Fellow, identify faculty mentor in item 2. below and have faculty mentor also sign this form on page 5.**  
 Title: \_\_\_\_\_  
 College/department: \_\_\_\_\_  
 Campus address: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_
2. Co-Investigator name and degree (if applicable): \_\_\_\_\_  
 Title: \_\_\_\_\_  
 College/department: \_\_\_\_\_  
 Campus address: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_
3. Project title: \_\_\_\_\_  
 Project location (building and room #): \_\_\_\_\_
4. Funding agency: \_\_\_\_\_
5. Dates of project: From: \_\_\_\_\_ To: \_\_\_\_\_
6. RAC Approval Number: \_\_\_\_\_
7. IND Number: \_\_\_\_\_
8. IRB Number: \_\_\_\_\_
9. Biosafety level required:  BSL1  BSL2  BSL3  BSL4
10. Identify personnel conducting the experiments (including students and temporary staff). Specify project responsibilities, applicable training and experience including duration, e.g., 2 years. If additional personnel need to be listed, please attach an additional sheet.

Name	Project Responsibilities	Relevant Training/Experience
PI*:		

\*Attach an abbreviated biosketch, similar to that submitted with grants to NIH, for the PI and any Co-Investigator(s)

11. Attach standard operating procedures (SOPs) developed, signed and dated by the PI indicating training, safety precautions, and vaccinations/medical monitoring procedures for employees; whether agent shedding from patients will occur; whether special handling and disposal of excreta is required and what those special protocols will be; and study agent handling and accountability procedures, including ordering, shipping, receipt and storage, dispensing, and disposition of unused material.

12. In the following space, please briefly describe your project with respect to microorganism/virus/toxin administration or recombinant DNA/human gene transfer. Provide a summary statement of the intent of the proposal.

**If the project involves human gene transfer, also answer the following questions.**

13. Describe the gene (genomic, cDNA or oligonucleotides) of the cloned DNA that will be used and its function: \_\_\_\_\_

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14. Describe the bacterial plasmid or phage vector construct, including regulatory element(s): \_\_\_\_\_

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15. Describe the delivery vector (if any): \_\_\_\_\_

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16. Describe the preparation, structure, and composition of the materials to be given to the patient.  
**If DNA**, describe the purity (both in terms of being a single DNA species and in terms of other contaminants), the tests which have been used to verify purity, and the sensitivity of the tests: \_\_\_\_\_

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**If a virus**, describe how it is prepared from the DNA construct, in what cells the virus is grown (any special features), what medium and serum are used, how the virus is purified, what the structure and purity is of the virus, and what steps are being taken to detect and eliminate any contaminating materials (for example, VL30 RNA, other nucleic acids or proteins) or contaminating viruses (both replication-competant or replication-defective) or other organisms in the cells or serum used for preparation of the virus stock including any contaminants that may have biological effects: \_\_\_\_\_

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**If cocultivation is employed**, describe the kinds of cells being used for co-cultivation, what steps are being taken (and assays used with their sensitivity) to detect and eliminate any contaminating materials, and what tests are being conducted to assess the material to be returned to the patient for the presence of live or killed donor cells or other non-vector materials (for example, VL30 sequences) originating from those cells: \_\_\_\_\_

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17. Describe the likelihood of generating replication competent virus, either in production or *in vivo*: \_\_\_\_\_

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18. Does the study meet all of the following characteristics?  Yes  No

- a. Induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal.
- b. Such immune response has been demonstrated in model systems.
- c. The persistence of the vector-encoded immunogen is not expected.

**If yes indicate the route of delivery:** \_\_\_\_\_

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**Attach information addressing all aspects of Appendix M, "Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Research Participants," of the NIH Guidelines for Research Involving Recombinant DNA Molecules found at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.**

**CERTIFICATION AND SIGNATURE**

The above information is accurate and complete. As Principal Investigator, I agree to comply with federal, state and university requirements pertaining to handling, shipment and transfer, and administration of biological materials. I agree to accept responsibility for the training of all workers involved in this project. I agree to not enroll any research participant until IBC and IRB approvals and RAC review has been obtained. I agree to notify the IBC and the IRB of any adverse events and the IRB, IBC, and NIH of any serious adverse events. If changes in any item(s) occur(s), such as gene, vector, location of project, standard operating procedures, etc., I understand that a completed *IBC Human Protocol Approval Form: Gene Transfer, Microorganism/Virus/Toxin Administration* must be submitted.

Principal Investigator signature: \_\_\_\_\_

Date: \_\_\_\_\_

Co-Investigator/Faculty Mentor signature: \_\_\_\_\_  
(if applicable)

Date: \_\_\_\_\_

**Please send this form to the IBC Office, BMSB 207.**

NOTE: If changes in information provided on this application occur, a revised form must be submitted.