

FOR IBC USE ONLY  
Date received: \_\_\_\_\_

**IBC HUMAN GENE TRANSFER  
PROTOCOL:  
PATIENT ENROLLMENT  
NOTIFICATION FORM**

**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: \_\_\_\_\_  
Title\*: \_\_\_\_\_  
**\*If not faculty, have co-responsible faculty also sign this form**  
College/Department: \_\_\_\_\_  
Campus address: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_
2. Co-Principal Investigator (Co-PI) name and degree: \_\_\_\_\_  
Title: \_\_\_\_\_  
**\*If not faculty, have co-responsible faculty also sign this form**  
College/Department: \_\_\_\_\_  
Campus address: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_  
**If there are additional Co-PI(s) on this project, please attach a separate sheet with same information on all additional Co-PI(s)**
3. Project title: \_\_\_\_\_
4. Funding agency: \_\_\_\_\_
5. Date of enrollment of first patient: \_\_\_\_\_

**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 Administration, Toxin Administration* must be submitted.

Principal Investigator signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Co-responsible faculty name (required if PI is not an OUHSC faculty member): \_\_\_\_\_  
Co-responsible faculty signature: \_\_\_\_\_  
Date: \_\_\_\_\_

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