UNIVERSITY OF VIRGINIA
Gene Transfer Study
HIC/IBC Application Form

HIC, Box 800483, Barringer, Room 4362, Phone: 924-9634
IBC, Box 441, Jordan Hall, Room 7-85, Phone: 982-1597

Principal Investigator (printed):_____

The following documents are included with this submission (please check all that apply):

TO HIC

_____ One original and 16 copies of this form (HIC/IBC Application Form)
____ One original and 16 copies of the signed Protocol and Consent Form per HIC template.
(Templates can be found on the HIC website under "Submission Process".)
_____ 16 copies of the Attachment M Protocol Submission Package *
http://www4.od.nih.gov/oba/guidelines.html
_____ One copy of the Investigator's Brochure, if applicable
_____ One copy of the draft Investigational New Drug Application (IND), if a UVA physician sponsored IND. This must include the Safety Monitoring Plan.
_____ One copy of the sponsors protocol (if sponsored by an outside company)

TO IBC

_____ One original and 9 copies of this form (HIC/IBC Application Form)
_____ 10 copies of HIC protocol and consent form
_____ 10 copies of the Attachment M Protocol Submission Package *

Note: **Each Protocol, Consent Form and Attachment M must be stapled together in this order. The use of two-sided copies is encouraged!**

*Attachment M is part of the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules." The RAC application requires information about the disease under study, vector being used, and the nature of the proposal (in addition to other items). The NIH review process is open to the public so proprietary information should be withheld.

Sponsor Protocol #_____(If Applicable)

HIC Protocol Title:_____

Are you using radioactive materials in this study?

Yes No If yes, Authorized User Number:_____

Is this protocol part of a Grant Application?
Yes No If Yes, GHIC# for Approved Grant _____

Is this protocol part of a UVA Physician-sponsored Investigational New Drug application (IND)?
Yes No If Yes, IND#_____

Is this protocol part of an extra-murally sponsored IND?
Yes No If Yes, IND#_____

Does this study involve an investigational device or use of an approved device for an unapproved indication?
Yes No If Yes, IDE#_____

Is there an inclusion criterion for this study stating the participants must have cancer?
Yes No If Yes, and the study is not sponsored by NIH, ACS, DOD, NSF or a Cancer Cooperative Group, Cancer Center Protocol Review approval is required.

To avoid any conflict of interest are any IBC or HIC members/alternates listed on the protocol or 1572 form?
Yes No If Yes, please list names below.

_____

_____

Conflict of Interest Information:
The questions below pertain to the Principal Investigator, sub investigators or any member of their household.

1. Yes No Is anyone listed above a director, officer or member of an advisory board with a sponsoring company?
2. Yes No Does anyone listed above receive direct or indirect income from cash payment, stock, stock options or a consulting agreement etc. totalling greater than $10,000 in personal income /year (excluding salary support from study budget) from the sponsor?

PRINCIPAL INVESTIGATOR'S STATEMENT OF AGREEMENT FOR HUMAN SUBJECT PROTECTION INVOLVING HUMAN GENE TRANSFER EXPERIMENTS

HUMAN INVESTIGATION COMMITTEE OF THE UNIVERSITY OF VIRGINIA
INVESTIGATOR AGREEMENT

Title of Study: _____

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR AGREES:

1. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed HHS-310 form.
2. That any modifications of the protocol or consent form will not be initiated without prior written approval from the HIC, except when necessary to eliminate immediate hazards to the subjects.
3. That any deviation from the protocol and/or consent form, adverse events that are serious occurring during the study will be reported promptly to the HIC and other required committees or agencies in writing.(See UVA Medical Center Policy # and SAE Form)
4. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
5. That if this study involves any funding or resources from an outside source that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
6. That all subjects will sign a copy of the consent form that has a non-expired HIC approval stamp.
7. That the HIC office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.

_____	_____	_____
Principal Investigator (Name Printed)	Principal Investigator (Signature)	Date

BY SIGNING THIS DOCUMENT, THE CHAIRMAN AGREES:

1. To assume overall responsibility for the conduct of this investigator.
2. To work with the investigator, and with the Committee, as needed, in maintaining compliance with this agreement.
3. That the Principal Investigator is qualified to perform this study.

_____	_____	_____
Department Chairman/Division Head* (Name Printed) *(Cannot be Principal Investigator)	Department Chairman/Division Head (Signature)	Date

The Committee reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

For Administrative Purposes Only HIC# _____

Personnel

The list of personnel should include all those who will engage directly in the conduct of the experiment and others for whom a potential risk exists by virtue of their presence within the treatment facility. Approval of the project is given only for the identified personnel.
The HIC and IBC must be notified of any new personnel.

Principal Investigator:

First _____ Last_____Degree_____

Phone_____ Email_____ Messenger Mail Address_____

Department_____Division_____

Study Coordinator:

First _____ Last_____Degree_____

Phone_____ Email_____ Messenger Mail Address_____

Department_____Division_____

Department Contact:
First _____ Last_____Degree_____

Phone_____ Email_____ Messenger Mail Address_____

Department_____Division_____

Sponsor Information:

Company: _____

Address: _____

Phone: _____ Fax: _____

Sub-Investigators

Sub-Investigator:
First _____ **Last** _____ **Degree** _____

Phone _____ **Email** _____ **Messenger Mail Address** _____

Department _____ **Division** _____

Sub-Investigator:
First _____ **Last** _____ **Degree** _____

Phone _____ **Email** _____ **Messenger Mail Address** _____

Department _____ **Division** _____

Sub-Investigator:
First _____ **Last** _____ **Degree** _____

Phone _____ **Email** _____ **Messenger Mail Address** _____

Department _____ **Division** _____

Sub-Investigator:
First _____ **Last** _____ **Degree** _____

Phone _____ **Email** _____ **Messenger Mail Address** _____

Department _____ **Division** _____

Sub-Investigator:
First _____ **Last** _____ **Degree** _____

Phone _____ **Email** _____ **Messenger Mail Address** _____

Department _____ **Division** _____

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Are there additional sub-investigators? Yes No If Yes, additional pages.

PRINCIPAL INVESTIGATOR'S STATEMENT OF AGREEMENT FOR BIOSAFETY PRECAUTIONS INVOLVING HUMAN GENE TRANSFER EXPERIMENTS

(Must Be Typed):

Principal Investigator: _____Telephone Number _____

Messenger Mail Address _____

I attest that the information contained in the attached application, dated_____, is accurate and complete. I agree to comply with the requirements pertaining to shipment and transfer of biohazardous materials and/or recombinant DNA. I am familiar with and agree to abide by the provisions of the current NIH Guidelines and other specific granting agency instructions pertaining to the proposed research.

I attest further that all research personnel are familiar with and understand the potential biohazards, proposed precautions, and appropriate emergency procedures, and that the practices and techniques required to ensure safety will be followed. I agree to accept responsibility for training of all support personnel involved in the research.

Written reports will be submitted to the Institutional Biosafety Committee concerning:

1. Any accident that results in inoculation, ingestion, and inhalation of biohazardous materials or recombinant DNA or any incident causing serious exposure of personnel or danger of environmental contamination. This includes any Serious Adverse Events experienced by experimental subjects as specified at the University of Virginia web site, *http://keats.admin.virginia.edu/gene/home.html*.

2. Any problems pertaining to operation and implementation of biological and physical containment safety procedures or equipment or facility failure, and,

3. Any new information bearing on the Guidelines such as technical information relating to hazards and safety procedures or innovations.

Principal Investigator:_____ Date:_____
(Signature - no *per* signature)

IBC Gene Transfer Protocol Number:_____

For Administrative Use Only:

Last Laboratory Audit Date:_____ Approval Date:_____

LOCATIONS OF EXPERIMENTS, STORAGE OF MATERIALS, AND TRANSPORTATION

Approval of the proposed experiments is given only for the designated location. It is the Principal Investigator's responsibility to notify the Institutional Biosafety Committee if the designated locations of the experiment or the storage of materials change. Discuss the details of the safe transport of the materials to, from and within the University of Virginia in part F of the Project Description.

	Building	Room	Biosafety Level
Location(s) Where the Agent is Dispensed or Administered			
Other Patient Contact Areas			
Location(s) Where the Materials are Stored			

PHYSICAL CONTAINMENT EQUIPMENT [*BIOLOGICAL SAFETY CABINETS*]

BUILDING_____ ROOM_____ CLASS_____ TYPE_____
SERIAL # _____ DATE OF CERTIFICATION_____
Consult the Biosafety Manual or contact the University of Virginia Biologic Safety Officer at 982-4909 for recommended practices if you plan to use volatile radioactive isotopes in work involving viable biohazardous materials at Biosafety Level 2 or above.

Biohazardous Agent(s) Used_____
_____

Biosafety Level of Biological Materials (per CDC Guidelines)_____

DESCRIPTION OF THE PROJECT

Please attach a short (1-page) summary of the project *in lay language* for review by the Institutional Biosafety Committee. Specifics to be included for each type of work are listed below. If the work involves both recombinant DNA *and* biohazardous agents and/or human specimens, include the appropriate elements from each list.

PROJECT DESIGN

State the overall objectives and rationale of the project.

a) Describe the proposed use of recombinant DNA (therapeutic or other purposes?).
b) Why is the disease selected for treatment by gene therapy a good candidate for such treatment?
c) Documentation of appropriate training (Universal Precautions, Institutional Biosafety, etc.).
d) Describe the anticipated risks and benefits of this project.

FOR RECOMBINANT DNA

Pertains only to recombinant DNA molecules and organisms and viruses containing recombinant DNA molecules, exclusive of naturally occurring biohazardous materials.

a) Sources of DNA (species, organ or tissue, etc.).
b) Nature of the inserted DNA sequence.
c) Describe vectors and hosts.
d) Biosafety level specified in the NIH Recombinant DNA Guidelines.
e) Procedures for storage, transport (both within and outside U.Va.), and disposal.
f) Describe the containment capabilities and a brief assessment of the risk involved
i) Review of the medical surveillance practices recommended in the agent summary statement of the CDC-NIH Biosafety Manual for personnel at risk.

FOR BIOHAZARDOUS AGENTS

Pertains only to Class 2 or 3 agents, exclusive of recombinant DNA constructs.

a) Name of the agent(s).
b) Source of the agent (from where the agent was acquired).
c) Biosafety level (relevant sections of the CDC-NIH Guidelines to be cited).
d) Purpose of the project and procedures.
e) Hazard assessment (nature of the hazards to personnel - sections of the CDC-NIH Guidelines must be cited when relevant), including use of radiological hazards in conjunction with biohazardous agents.
f) Procedures for storage, transport (both within and outside U.Va.), and disposal.
g) Describe the containment capabilities and a brief assessment of the risk involved.
h) Concentration and amount of agents to be generated.
i) Review of the medical surveillance practices recommended in the agent summary statement of the CDC-NIH Biosafety Manual for personnel at risk.