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?
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 Principal Investigator Date
(Name Printed) (Signature)

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

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# ____________________________

Revision Date: March 13, 2001 Page 3 of 8
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__________________

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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.

<table>
<thead>
<tr>
<th>Building</th>
<th>Room</th>
<th>Biosafety Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location(s) Where the Agent is Dispensed or Administered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Patient Contact Areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location(s) Where the Materials are Stored</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>PROJECT DESIGN</th>
</tr>
</thead>
<tbody>
<tr>
<td>State the overall objectives and rationale of the project.</td>
</tr>
<tr>
<td>a) Describe the proposed use of recombinant DNA (therapeutic or other purposes?).</td>
</tr>
<tr>
<td>b) Why is the disease selected for treatment by gene therapy a good candidate for such treatment?</td>
</tr>
<tr>
<td>c) Documentation of appropriate training (Universal Precautions, Institutional Biosafety, etc.).</td>
</tr>
<tr>
<td>d) Describe the anticipated risks and benefits of this project.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOR RECOMBINANT DNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertains only to recombinant DNA molecules and organisms and viruses containing recombinant DNA molecules, exclusive of naturally occurring biohazardous materials.</td>
</tr>
<tr>
<td>a) Sources of DNA (species, organ or tissue, etc.).</td>
</tr>
<tr>
<td>b) Nature of the inserted DNA sequence.</td>
</tr>
<tr>
<td>c) Describe vectors and hosts.</td>
</tr>
<tr>
<td>d) Biosafety level specified in the NIH Recombinant DNA Guidelines.</td>
</tr>
<tr>
<td>e) Procedures for storage, transport (both within and outside U.Va.), and disposal.</td>
</tr>
<tr>
<td>f) Describe the containment capabilities and a brief assessment of the risk involved</td>
</tr>
<tr>
<td>i) Review of the medical surveillance practices recommended in the agent summary statement of the CDC-NIH Biosafety Manual for personnel at risk.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOR BIOHAZARDOUS AGENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertains only to Class 2 or 3 agents, exclusive of recombinant DNA constructs.</td>
</tr>
<tr>
<td>a) Name of the agent(s).</td>
</tr>
<tr>
<td>b) Source of the agent (from where the agent was acquired).</td>
</tr>
<tr>
<td>c) Biosafety level (relevant sections of the CDC-NIH Guidelines to be cited).</td>
</tr>
<tr>
<td>d) Purpose of the project and procedures.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>f) Procedures for storage, transport (both within and outside U.Va.), and disposal.</td>
</tr>
<tr>
<td>g) Describe the containment capabilities and a brief assessment of the risk involved.</td>
</tr>
<tr>
<td>h) Concentration and amount of agents to be generated.</td>
</tr>
<tr>
<td>i) Review of the medical surveillance practices recommended in the agent summary statement of the CDC-NIH Biosafety Manual for personnel at risk.</td>
</tr>
</tbody>
</table>