

HUMAN GENE THERAPY AGENTS APPLICATION

BIOSAFETY COMMITTEE
ENVIRONMENTAL HEALTH AND SAFETY
 ✧ WAKE FOREST UNIVERSITY ✧ WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE ✧
 ✧ WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER ✧
TELEPHONE 716-6440
FAX 716-0588

1. APPLICANT INFORMATION

Protocol Title	
First and Last Name	
Degree (Check All That Apply)	Ph.D. <input type="checkbox"/> M.D. <input type="checkbox"/> D.V.M. <input type="checkbox"/> D.Sc. <input type="checkbox"/> Pharm.D. <input type="checkbox"/> Other <input type="checkbox"/> _____
Division/Department	
Department #	
Office Telephone Number	
Lab Telephone Number	
Fax Number	
E-mail Address	
Type of Application (Check One)	New Protocol <input type="checkbox"/> Renewal <input type="checkbox"/>

2. TYPES OF HUMAN GENE THERAPY AGENT USED

Please indicate the type of Human Gene Therapy Agent that you intend to use.

If you will be sharing space with another Authorized Investigator, please include the User's name in COMMENTS.

Chemical Transfection	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Electroporation	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Microinjection	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Ballistic barrage	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Bacteria/bacteriophage	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Viral Mediated	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Virus-like particles	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Other Agent (Please describe)				

3. RISK ASSESSMENT			
a. Can this organism or agent infect or insert into human cells	YES <input type="checkbox"/>	NO <input type="checkbox"/>	If Yes, what kind of symptoms and/or disease may results?
b. What is the greatest concentration (titer) and volume of this organism or agent that you expect to have on-hand at any one-time?			
c. Denote the personal protective clothing and equipment you intend to use:			
<input type="checkbox"/> Eye protection	<input type="checkbox"/>	Automatic pipettors (required)	
<input type="checkbox"/> Head Cover	<input type="checkbox"/>	Safety centrifuge/Blender	
<input type="checkbox"/> Shoe covers	<input type="checkbox"/>	95% efficient respirator	
<input type="checkbox"/> Double glove	<input type="checkbox"/>	HEPA respirator (99%)	
<input type="checkbox"/> Lab coat	Note: A surgical mask is not considered protective equipment		
<input type="checkbox"/> Lab gown	<input type="checkbox"/>	Other - Explain	
<input type="checkbox"/> Tyvek/Disposable gowns or suits			
d. Explain the methods used for disposal of biohazardous waste such as contaminated cultures vessels, animal tissues, blood and body fluid, etc.			
e. Indicate the containment equipment and the Biosafety Level of the rooms in which you plan to handle the viable organism			
Room Number	Fume Hood Present	Number of Biosafety hoods? Which type?	Facility Biosafety Level
	<input type="checkbox"/>		<input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL3
	<input type="checkbox"/>		<input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL3
	<input type="checkbox"/>		<input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL3
	<input type="checkbox"/>		<input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL3
	<input type="checkbox"/>		<input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL3
An inspection of the facilities and equipment will be made prior to approval of this application			
f. Indicate the Biosafety Level of practices you propose to use when working with the recombinant DNA products Please include a justification in your project summary	<input type="checkbox"/> Biosafety Level 1 Practices <input type="checkbox"/> Biosafety Level 2 Practices <input type="checkbox"/> Biosafety Level 3 Practices <input type="checkbox"/> Biosafety Level 4 Practices		

<p>4. DESCRIPTION OF THE PROJECT</p> <p>Please attach a short summary of the project, <i>in lay language</i>, for review by the Institutional Biosafety Committee. Please include the following points:</p> <ul style="list-style-type: none"> ▪ Describe the proposed use of recombinant DNA (therapeutic or other purposes?). ▪ Why is the disease selected for treatment by gene therapy a good candidate for such treatment? ▪ Describe the anticipated risks and benefits of this project. 	
<p>Please provide the following about the study:</p>	
1) Who is the study chair?	
2) Who is the study sponsor?	
<p>3) Has this protocol been submitted to NIH Office of Biotechnology Activity for registration YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>If you are the study chair, attach a copy of your responses to the information required in Appendix M of the NIH Guidelines</p> <p>INDICATE: NIH OBA Registration Number RAC Date:</p>	
<p>4) Has an IND been filed with US FDA? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, please attach the Investigators Brochure from the IND.</p>	
<p>5) Has the Institutional Review Board approved this project? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, please attach any correspondence.</p>	
6) Where will the Human Gene Therapy Agent be stored?	
7) Where will the Human Gene Therapy Agent be prepared for administration to patients?	
8) How will the Human Gene Therapy Agent be transported from the place of storage?	
9) Where will Human Gene Therapy Agent be administered to patients?	
10) Will patients be isolated, what type of isolation, for what duration?	
11) How and where will patient specimens be obtained, transported, stored?	
<p>12) Has EH&S been contacted to review the facilities where the above activities will take place? YES <input type="checkbox"/> NO <input type="checkbox"/></p>	
<p>5. FOR NEW APPLICANTS ONLY NOT APPLICABLE <input type="checkbox"/></p> <p>PREVIOUS TRAINING AND WORK EXPERIENCE WITH HUMAN GENE THERAPY</p> <p>Please describe any previous training (formal courses or on-the-job) you have completed. If you have been approved previously as an Authorized User of Human Gene Therapy at another institution, please include the name of the facility and the date of your approval. You may attach to this application any Certificates of Training you have received from other institutions.</p>	
Previous Authorized User	YES <input type="checkbox"/> NO <input type="checkbox"/>
Institution	
Address (City and State)	
Date(s) of Authorization	

COURSE	DATE	TYPE OF TRAINING
Principles of Biological Safety		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> NONE <input type="checkbox"/>
Infection Control		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> NONE <input type="checkbox"/>
Bloodborne pathogens		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> NONE <input type="checkbox"/>
Clinical Research Investigator/Coordinator Training/Certification Program		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> NONE <input type="checkbox"/>

Please list the biohazardous materials (and typical quantities) with which you have previous experience. If you have no previous experience, please check **NONE**. NONE

Biohazardous Material	Typical Quantity	Biohazardous Material	Typical Quantity

6. LOCATION OF DOCUMENTATION

All biosafety and chemical safety program records (including correspondence regarding your Human Gene Therapy Application and Memorandum of Understanding, Inventory, Certifications of Training, and survey results) must be available for review by EH&S Industrial Hygiene and Biosafety. Please indicate the location of your Human Gene Therapy program documentation.

7. EMPLOYEES **NOT APPLICABLE**

Please list the individuals working with biohazardous and chemical materials in your laboratory under your supervision. (Attach Additional Sheets As Needed.) Please indicate any individuals who are under 18 years of age. You are required to submit to the Biosafety Officer a completed *Certification of Training* (located at the end of this application) for each employee.

EMPLOYEE FIRST AND LAST NAME	EMPLOYEE FIRST AND LAST NAME
1. Under 18 <input type="checkbox"/>	2. Under 18 <input type="checkbox"/>
3. Under 18 <input type="checkbox"/>	4. Under 18 <input type="checkbox"/>

9. PROTOCOL-SPECIFIC SAFETY TRAINING

Please describe your protocol-specific training program for employees working with Human Gene Therapy Agents under your supervision. Include the name of the individual(s) who will provide training, frequency of training (such as “upon hiring” or “annual update”) and any methods used to evaluate staff prior to handling materials.

If you designate someone to provide training on your behalf to other staff members, please include the name of the individual and a *brief* description of his/her qualifications. (You must also submit a **CERTIFICATION OF HUMAN GENE THERAPY TRAINING** for this designee.)

Training topics should include (but not be limited to):

- Hazards associated with the human gene therapy agent;
- Storage locations of human gene therapy agent;
- Procedures to minimize biohazardous exposure;
- Purpose and function of protective devices;
- Contamination control;
- Decontamination methods;
- Appropriate responses to unusual occurrences (spills, contamination incidents, etc.);
- Location of human gene therapy documentation.

The completed **CERTIFICATION OF HUMAN GENE THERAPY TRAINING** serves as documentation of employee training. Although you must submit to the Industrial Hygienist a form for each employee, you must also maintain a copy of the Certification in your files. (This item will be reviewed during the EH&S periodic audits of your laboratory.)

Person(s) providing training	
If designee(s) will provide training, <i>briefly</i> describe his/her (their) qualifications	
Frequency of training	
Evaluation method(s)	
Additional Comments (such as intended use of videotapes for general biological safety training)	

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.
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.

Signature of Principal Investigator

Date

The facilities and procedures referred to above have been reviewed by the Biosafety Committee of Wake Forest University School of Medicine of Wake Forest University. The committee judges them to be adequate to meet State, Federal, Local and Institutional Guidelines.

Biosafety Committee Chairperson

Date

Director of EH&S

Date

CERTIFICATION OF HUMAN GENE THERAPY TRAINING

This Form Should Be Retained in the Human Gene Therapy Records and
Available For Review By EH&S Industrial Hygiene.

Please submit a copy of this form to:

**BIOSAFETY OFFICER
ENVIRONMENTAL HEALTH AND SAFETY
WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE
TELEPHONE 716-6440
FAX 716-0588**

AUTHORIZED USER INFORMATION

Authorized User	
Division/Department	

EMPLOYEE INFORMATION

First and Last Name	
Work Telephone Number	

PREVIOUS TRAINING WITH BIOHAZARDOUS AND CHEMICAL MATERIALS

Please describe any previous training (formal courses or on-the-job) you have completed.

Course	Date	Type of Training
Principles of Biological Safety		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> None <input type="checkbox"/>
Infection Control		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> None <input type="checkbox"/>
Bloodborne Pathogens		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> None <input type="checkbox"/>
Clinical Research Investigator/Coordinator Training/Certification Program		Formal Course <input type="checkbox"/> On-the-Job <input type="checkbox"/> None <input type="checkbox"/>

PREVIOUS WORK EXPERIENCE WITH BIOHAZARDOUS MATERIALS

Please list the Biohazardous Materials and typical quantities per experiment with which you have work previous experience.

If you have no previous experience, please indicate NONE. NONE

BIOHAZARDOUS MATERIALS	Typical Quantity	BIOHAZARDOUS MATERIALS	Typical Quantity

SIGNATURES

These signatures verify that the employee has received lab-specific biosafety safety training from the Authorized User or designee.

The employee may now work with Biohazardous materials under the supervision of the Authorized User.

EMPLOYEE:

DATE:

AUTHORIZED USER:

DATE:

INSTRUCTIONS FOR SUBMITTING AN APPLICATION TO ENVIRONMENTAL HEALTH & SAFETY:

Please save this document and send one paper copy with signatures to Environmental Health & Safety and send one copy via e-mail as an attachment to ehs@wfubmc.edu. If you do not have access to e-mail, please save to a disk and send interoffice to EH&S.

If you need further instructions on sending an e-mail, please access the link below or contact EH&S at 716-9375:

<http://intranet.wfubmc.edu/netscape/email/sending.html>