

EOHSS registration number:

Assigned Biosafety Level:



Institutional Biosafety Committee

**IBC REGISTRATION FORM
Clinical Research**

	Principal/Responsible Investigator	Alternate Contact Person
Name		
Phone		
Fax		
Email		
Department		
Office/ Laboratory Locations		
Previous IBC Protocols Associated with this Research		
Project Title		
Sponsor Name/ Address Contact Person/ address, Telephone, Fax and Email		
Study Site Contact (name, mailing address, phone, email and fax)		
IRB Number		
IND Number (if applicable)		
IBC Submission Date		
Multicenter study?		
Phase of Study	I	II III
The following documents must be provided with this application: Investigator Brochure Consent Form Sponsor Brochure Parental Permission IRB Protocol face sheet and approval letter RAC letter, Appendix M- points to consider Clinical protocol Any other pertinent information		

OVERVIEW:

The Newark Campus IBC reviews research protocols to ensure compliance with the CDC/NIH guidelines for rDNA and biosafety and OSHA guidelines for bloodborne pathogens in research laboratories. In completing this form you must convey to the Institutional Biosafety Committee (IBC) that you: understand the potential hazards of the proposed research, have designed the experiments to minimize potential hazards, and have communicated potential hazards to others who may come in contact with the products you propose to use or generate. Please be sure to complete all applicable sections of the form and contact the biosafety officers listed below with any questions/ concerns.

INSTRUCTIONS:

In some cases it is acceptable to combine multiple experiments or organisms in the same registration form. Please contact the Biosafety Officer (listed below) if you have questions about use of this form. Email the completed form to Jessica McCormick, Ph.D., Sr. Biosafety Officer, Jessica.mccormick@umdnj.edu and Tamara McNair, Biosafety Officer, mcnairta@umdnj.edu. Once the biosafety officers have performed a preliminary review, the protocol will be distributed to the IBC members. All IBC members will have one week to review the protocol and submit concerns. The biosafety officer will compile the comments and forward them to the PI. The PI will be responsible for making the appropriate revisions and re-submitting the application to the IBC for further review. Once the protocol has been approved the PI must mail a signed hard copy to the biosafety officer. The biosafety officer will prepare an approval letter that is sent to the PI. Protocol applications should be submitted as soon as possible. The IBC meets the second Tuesday of each month, and formal approval is granted at these meetings.

QUESTIONS? Contact Jessica McCormick, Ph.D., Senior Biosafety Officer, Jessica.Mccormick@umdnj.edu, 973/972-8424, or Tamara McNair, Biosafety Officer, mcnairta@umdnj.edu, 973-972-8419, fax 973/972-3694 or Marta Figueroa, Assistant Director, figuerma@umdnj.edu, 973-972-5901.

Please complete the following sections to describe your experiment. Indicate the possible adverse effects of the DNA, quantity of culture, and a description of the experiment. Also, provide detailed information regarding the DNA inserts, vectors and host cells being used in your rDNA system. (Vector maps are also helpful)	YES	NO
1. Specify source and nature of the DNA sequence(s) to be inserted (genus, species, gene name):		
a. Will the inserted gene(s) be expressed?		
b. If yes, what are the gene product effects? Specifically identify its toxicity, physiological activity, allergenicity, environmental stability, oncogenic potential or ability to alter cell cycle:		
Location in which the rDNA research is to be conducted (building and room number)		
2. Does the donor rDNA, RNA, cDNA source or its vector have any recognized or anticipated pathogenic, toxigenic or virulence potential for animals, plants or humans?		
a. If yes, explain:		
b. If no, please provide a reference to support your conclusion:		
3. Describe the virus, phage and/or plasmid used for constructing your recombinants (prokaryotic, eukaryotic). If possible, provide a diagram or map illustrating the construct. If appropriate, include Entrez Gene nomenclature (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene).		

4. Identify host cell(s) or packaging cell line in which recombinant vector will be amplified:		
5. Is the vector replication competent?		
6. Are any viral component(s)/sequence(s) present?		
If yes, specify the nature of the viral component(s):		
7. Does the insert contain >2/3 of a eukaryotic viral genome?		
8. Is helper virus used?		
If yes, specify type		
9. Will these experiments involve human gene therapy?		
10. What are the target cells/ area for this therapy? What is the function of this therapy?		
11. Provide a flow sheet to describe your experiment. Provide enough information to describe project's specific aims, the packaging vector, cell lines used, and the function of the rDNA in the context of the overall project.		

Part B: SAFETY MEASURES

Research will be conducted at **Biosafety Level** _____ Contact EOHSS if you need assistance in determining the appropriate classification. Reference the CDC/NIH BMBL5th Edition available at: <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>.

1. How will the material be administered to patients?		
Intravenous		
Subcutaneous		
Ingestion		
Inhalation		
Other (please describe):		
2. How much of the drug will be administered to patients?		
		YES NO
3. Will syringes, scalpels, glass or other sharps be used?		
a. Has the research been reviewed to eliminate to minimize the use of sharps where possible?		
b. Are sharps with integrated safety devices/ mechanism available and used?		
If yes, please describe the safety device (Type, Model, Brand)		
c. Has training on this safety device been provided to the staff?		
Who provided this training?		
What was the date of this training?		
4. Will this material arrive ready to administer to patients, or will the laboratory staff need to prepare it?		
If the product needs to be prepared, what is the procedure?		
Will the same needle be used to draw up and administer the product or will a new needle be needed?		
If a new needle is needed please describe the process for changing it.		
5. Is this agent likely to shed from patients?		
a. Are there any special practices for handling/ disposing of excretion from patients? If yes, please describe:		

b. Will any provisions be made to isolate the patient from the other susceptible individuals present in the clinic/ home? If yes, please describe.		
c. If special provisions are required how will they be conveyed? Please attach a copy of the instructions		
<p>6. Indicate the personal protective equipment required to prepare the drug for administration (check all that apply):</p> <p>Not applicable (we will not be preparing drug):</p> <p>Tyvek suit or coverall</p> <p>Lab coat</p> <p>Apron or rear fastening gown with sleeves</p> <p>Apron or rear fastening gown w/o sleeves</p> <p>Bonnet or hair cover</p> <p>Powered Air Purifying Respirator (PAPR)</p> <p>N-95 respirator</p> <p>N-100 respirator</p> <p>Surgical mask</p> <p>Shoe covers</p> <p>Cover sleeves</p> <p>Safety glasses</p> <p>Gloves: non-powdered latex nitrile vinyl other</p>		
<p>7. Indicare the personal protective equipment required to administer the product to the patient:</p> <p>Tyvek suit or coverall</p> <p>Lab coat</p> <p>Apron or rear fastening gown with sleeves</p> <p>Apron or rear fastening gown w/o sleeves</p> <p>Bonnet or hair cover</p> <p>Powered Air Purifying Respirator (PAPR)</p> <p>N-95 respirator</p> <p>N-100 respirator</p> <p>Surgical mask</p> <p>Shoe covers</p> <p>Cover sleeves</p> <p>Safety glasses</p> <p>Gloves: non-powdered latex nitrile vinyl other</p>		

8. Decontamination/Disinfection

- a. Indicate the disinfection method (*see columns to the right*). Mark the applicable boxes with an “X.”

For Decontamination and Disinfection information, see the EOHSS Fact sheet <http://www2.umdj.edu/eohssweb/publications/disinfection.pdf>.

1. Autoclave
2. 1/10 bleach solution
3. Povidone-iodine product e.g. Betadine ®
4. 70% ethanol
5. Phenolic product e.g. Vesphene ®
6. Chlorine dioxide product e.g. Clidox ®
7. Quaternary ammonium product e.g. Quatricide ®

Routine cleaning	Spill cleanup	Solid waste	Liquid waste

8. Please indicate the location for appropriate spill cleanup materials.

9. Principal Investigator's Assessment of Risk

<p>a. What are the adverse event(s) you can foresee as a result of an exposure to this product? (For example: recombination, employee exposure, environmental release, activation of latent virus, etc.) All adverse events must be immediately reported to the IBC and in the annual report on study progress.</p>
<p>b. How did you determine the appropriate biosafety level for this protocol?</p>
<p>c. Please list the following information about your most recent literature search on the safety of the organisms, reagents and experimental procedures used in this protocol. <i>Note: Literature search must have been conducted within one month of submission to the IBC.</i></p>
<p>i. What is the timeframe of your most recent search?</p>
<p>ii. Which databases did you search?</p>
<p>iii. What keywords did you use?</p>
<p>iv. Please describe any pertinent safety or hazard analysis findings:</p>

d. Is there a significant potential for this material to be contaminated with an organism requiring a higher biosafety level? (e.g., a live virus/ bacterium contaminating a preparation of dead virus/ bacteria)		
i. How would you determine if the material was contaminated with an organism requiring a higher biosafety level?		
ii. Is your lab equipped to perform such an evaluation?		
iii. If your lab cannot perform such an evaluation, what steps will be taken to ensure the safety of staff and students working with the material?		
e. What was the source of this material?		
i. Can the sender provide background information or quality control data on the material? If possible, please include information on the types of infectious microorganisms screened for in these samples.		
f. Are there any preexisting patient conditions that may amplify the risks of using this vector/ microorganism, etc?		
If yes, what types of precautions need to be taken?		

10. Dual Use Research

<p>According to the 2007 Fink Report (http://www.nap.edu/books/0309089778/html) and the National Science Advisory Board for Biosecurity (http://oba.od.nih.gov/biosecurity/biosecurity.html), research with a legitimate scientific purpose that could be misused to pose a biological threat to public health and/or national security is considered “dual use research”. All research performed at UMDNJ will be assessed for dual use potential. Please read the following and acknowledge that you understand the definition of dual use experiments. If you have any questions you can contact Jessica McCormick, Senior Biosafety Officer at 973-972-8424 or Nancy Connell, IBC Chair, at 973-972-3759.</p> <p>Do you understand that dual use research includes the following:</p>	Yes	No
a. Disrupting immunity or the effectiveness of an immunization? (This applies to both human and animal vaccines)		
b. Enhancing the harmful consequences of a biological agent or toxin (i.e. increase virulence, pathogenicity)?		
c. Conferring to a biological agent or toxin, resistance to clinically and/ or agriculturally prophylactic or therapeutic interventions?		
d. Conferring the ability of a biological agent to evade detection methodologies?		
e. Increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin? This includes the environmental stabilization of pathogens.		

f. Altering the host range and/ or tropism for a biological agent?		
g. Enhancing the susceptibility of a host population to illness by a biological agent or toxin?		
h. Generating a novel pathogenic agent or toxin, or reconstitute an eradicated biological agent?		

11. Medical Surveillance and Training Requirements

a. All personnel who are potentially exposed to human blood, human body fluids or human cell lines have received Hepatitis B vaccine or proven immunity (required for work with human and non human primate cell lines, blood and tissues).		
b. All personnel who are potentially exposed to <i>Mycobacterium tuberculosis</i> have completed baseline TB surveillance (either TB skin test or gamma interferon release assay) and will undergo TB surveillance every 6 months for BSL3 users.		

11. Project Personnel: Use the following table to list all personnel (including any students) in your laboratory who handle or may otherwise be exposed to any of the rDNA, human cell lines, or microorganisms listed in this protocol. *Principal investigators must be included on this table, but please specify as to whether they will be performing experiments for this protocol.*

Will the PI be performing experiments included in this protocol? Yes No

Name	Project Responsibilities	Relevant Safety Training (list all that are pertinent to this protocol)	Handling of human or non human primate cell lines, blood or tissues? (Yes/ No)**	Signature*

* Indicates person who signed this form has been informed of potential hazards and safe work practices

** If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination from Occupational Medicine Services or Student Health Services and the PI must notify the IBC prior to starting work.

Part C: AFFIRMATION

I accept responsibility for the safe conduct of work with this material. I accept responsibility for ensuring that all personnel associated with this work have received the appropriate training on the hazards and the level of containment required to perform this research safely. I will report to the Biological Safety Officer any accident, incident, or adverse event that results in a potentially toxic exposure to personnel or any incident releasing recombinant DNA or other potentially hazardous materials into the environment.

Principal/Responsible Investigator: _____

Signature: _____

Date: _____

Grant Agency: _____

Award #: _____

FOR COMMITTEE USE

Approval: Yes Yes, approved with modifications *(see notes below) No

Committee's Determination of Required Biological Containment-Biosafety Level: _____

Signatures

IBC Chairman / Representative: _____ Date: _____

Biological Safety Officer (EOHSS): _____ Date: _____

Department Chairperson (as appropriate): _____ Date: _____

Occupational Medicine Physician (as appropriate): _____ Date: _____

Veterinarian (as appropriate): _____ Date: _____

Modifications: