COLUMBIA UNIVERSITY

INSTITUTIONAL BIOSAFETY COMMITTEE

APPLICATION FOR THE USE OF RECOMBINANT

## DNA MOLECULES IN HUMAN GENE TRANSFER

# Project Title:

# IRB Number:

1. **Name(s) of the recombinant material(s)/product(s) to be administered:**

# Principal Investigator: name, address, University e-mail, telephone number

# Sponsor: name, address, contact person and title, phone number.

1. **Source of recombinant material, if different from sponsor:**

# Is this part of a multi-center study?

# Has this Protocol been reviewed by the NIH Recombinant DNA Advisory Committee (RAC)?

**If “NO”, please fill out the: *Determination of Public RAC Review for Proposed Human Gene Transfer Studies, Addendum to the IBC Application Form***

# Limitations (e.g., required vaccinations, pregnancy, immune status) on project personnel who will handle, administer, or otherwise have exposure to the product:

# Outline the administration regimen: route, dose, frequency.

1. **Where will the material be received, stored, prepared, and administered? *(Refrigerators or freezers must be kept locked and the temperature monitored. If prepared at a site separate from administration, sealed bags containing filled syringes will be placed in a puncture proof container (e.g. “Tupper Ware”) for transport. Containers must be decontaminated after each use.)***
2. **How will the material be prepared for administration?**
3. **Will “Safe Needles” be used for injections?**

If “NO”, please explain *(Federal law requires such devices when “available and feasible”. It is presumed that for the types of procedures typical of Gene Transfer that such devices are available.)*

1. Will the same needle be used to fill syringes and administer the product? If not and needle-changing is necessary, what safe guards will be in place to reduce the risk of self-inoculation?
2. Describe the procedures in the event of spill. *(Spill response procedures for the Health Sciences Campus can be found at:* [*http://www.ehs.columbia.edu/BiologicalSpills.pdf*](http://www.ehs.columbia.edu/BiologicalSpills.pdf))
3. Provide a brief description and schematic of the vector/gene insert construct and a description of the cells in which it is produced. If the vector is designed to be replication incompetent, note how this was accomplished. *You may attach or cite the relevant page(s) from the clinical investigators' brochure to provide this information.*
4. Provide a history of testing for replication competent virus if applicable to the product. *You may attach or cite the relevant page(s) from the clinical investigators' brochure to provide this information.* Will any such testing be done as part of this project?

# Do data on localization and shedding exist? Will there be any assessment of shedding as part of this project?

1. What is the expected persistence of recombinant material and gene expression in participants? Will it be necessary for patients to limit their types of personal contacts?
2. What provisions (if any) will be effect to isolate subjects from susceptible individuals who may be present in clinical areas while viral shedding may be occurring?
3. **What criteria will be used to determine the usability of recombinant material? Will unusable material be returned to the supplier? *(If “yes” and it is not autoclaved or otherwise inactivated prior to shipment, EH&S must provide US DOT–approved training on shipping of Infectious Substances or Genetically Modified material.)***
4. **Who will be responsible (sponsor or PI) for required reporting to the NIH?**

**ADDITIONAL REQUIREMENTS**

* Attach a concise scientific abstract, no longer than one page. The abstract from the grant proposal may be used.
* Provide a copy of the Clinical Investigator’s Brochure, and the Informed Consent Application that is currently (or will be) under consideration by the University’s IRB.
* Provide of copy of the Sponsor’s NIH submittal as per Appendix M of the rDNA Guidelines, *Considerations for Human Gene Therapy*.
* Provide a copy of the NIH’s response to the aforementioned submittal. **NOTE:** Even if the ‘Outcome of the Initial Review by RAC (NIH’s Recombinant DNA Activities Committee) Members’ does not indicate that ‘In-depth Review and Public Discussion’ is required, the Outcome document may indicate that there were comments by RAC members. If this is the case, provide these comments and how these comments were/will be addressed.

Provide two hard copies and an electronic version of the information requested in the above bulleted list to the IBC Recording Secretary, Dr. Aderemi Dosunmu ([ad3241@columbia.edu](mailto:ad3241@columbia.edu)).

* Project personnel must be enrolled in the University’s Occupational Health Program (305-7590) prior to beginning work. Medical Surveillance through the Occupational Health Service will be performed annually.
* Reporting of adverse events to the Institutional Biosafety Committee (IBC) will be on an As Soon As Possible basis.
* The IBC approval is required for any protocol changes pertaining to the information above.
* The IBC will be updated annually on safety-related issues, via the Annual Safety Report that would be submitted to the NIH.

**I acknowledge and accept responsibility for the safe conduct of these activities according to NIH Guidelines for the Use of Recombinant DNA, as described in this Application, and as approved by the Institutional Biosafety Committee.**

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**PI signature Date**

Please list all project personnel who will handle the recombinant material or perform any clinical activities that may result in their exposure to it. Signatures\* will be taken to indicate that they have read and understand this Application. Information for personnel added to the protocol at future dates must be provided to EH&S as soon as possible.

# Name Title E-mail Signature\*