Application for Human Gene Transfer Clinical Trials at Yale University
To initiate the review of a proposed human gene transfer clinical trial, please submit a description of your protocol in the format described in Appendix M of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), April 2016. To obtain a copy of the NIH Guidelines, access the NIH OSP web site or contact the Biosafety Office at (203)785-3550. Send a copy of your completed Appendix M, along with the additional documents detailed below to:

The Yale Biological Safety Committee
C/O Biosafety Office
Yale Office of Environmental Health & Safety
135 College Street, Suite 100
New Haven, CT 06510
Contact person: Biosafety Officer, (203) 785-3550

Yale Biological Safety Committee Submission Requirements for the Review of Human Gene Transfer Protocols
Only complete protocols will be sent to Committee members for review. Specifically, we'll need:

- The Yale Biological Safety Committee Human Gene Transfer Registration Form (Protocol Profile)
- Scientific abstract
- Non-technical abstract
- Your responses to Appendix M-I
- Your response to Adverse Event reporting requirements detailed in Appendix M-II
- A copy of your HIC clinical protocol (your IND Submission)
- A copy of the HIC approved Informed Consent Document
- Sponsor's Protocol
- Principal Investigator's Brochure
- Curricula vitae (2 pages) for each key professional in biographical sketch format
- The proposed location for vector production and description of the Good Manufacturing or Good Clinical Practices that will be utilized to prepare the vector
- A copy of the Certificate of Analysis (CoA) for sterility for each lot of vector made at Yale or sent to the University for this experiment

Additional responsibilities of the Principal Investigator conducting a rDNA experiment are detailed in Section IV-B-7, Roles and Responsibilities of the NIH Guidelines. The full set of PI responsibilities can be accessed at: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948334

Yale Biological Safety Committee Human Gene Transfer Registration Form
(Protocol Profile)

Principal Investigator	**Sponsor:**	
Title of Protocol		
FDA IND #:	**Sponsor Protocol #:**	**NIH OBA/OSP #:**
Targeted Disease or Clinical Aim of Project:		
Description of the Vector or Recombinant Molecule:		
Certificate of Analysis for adventitious agents and replication competency (if applicable) must be provided for each lot of study drug used at Yale.		
Other Clinical Trial Sites approved for the project: **Other sites proposed for the study?** **Total number of subjects enrolled to date:**		
□ YES □ NO **Has the determination of need for NIH Recombinant DNA Advisor Committee review been made by the initial site for this study?**		
If Yes to the above question, was RAC review required? **If Yes, please attach the results of the RAC review for the Committee and any comments from the NIH OBA or OSP provided to the Sponsor, Principal Investigator or initial trial site.**		
What supporting safety data (cell culture, animal model, etc.) was utilized to move forward with research involving human subjects? Please provide safety data for the recombinant		

molecule and other study drugs involved.
Describe the dosing regimen for the recombinant molecule and other study drugs (please include starting dose, maximum allowable dose, and the study administration schedule).
How many cycles are allowed for study subjects:
Provide any history of use of the recombinant molecule in other studies (include the total number of subjects, and numbers of Adverse Events and Serious Adverse Events)
Please provide the proposed study location (where the drug will be administered)? **Has the Principal Investigator confirmed participation by a suitable number of healthcare workers to participate in all required aspects of the study?**
Will the YNHH Pharmacy been involved? **Have Pharmacy personnel confirmed their participation in the study?**
Please provide the date the study presentation was provided by the sponsor to the potential study participants at YNHH: