Yale EHS IBC Human Gene Transfer (HGT) Registration Form ('Protocol Profile')

If this information is already detailed in one of your existing documents, please provide the document title and page number(s) in the applicable spaces below

Principal Investigator	Sponsor: Manufacturer (of product):
Title of Protocol	
FDA IND #: Yale HIC#:	Sponsor Protocol #:
Targeted Disease or Clinical Aim of Project:	
Summary of preclinical studies conducted in support of the proposed clinical trial or reference to the specific section of the protocol providing this information.	
Product description	
Derivation of the delivery vector system including the source (e.g., viral, bacterial, plasmid), associated modifications (i.e., deletions to attenuate or self-inactivate, encapsulation in any synthetic complex, changes to tropisms), and previous clinical experience with the system	

Genetic content of the transgene or nucleic acid delivered, including the species source of the sequence, and whether any modifications have been made (e.g., mutations, deletions, truncations)
Any other material to be used in preparation of the agent (vector and transgene) to be administered to research participants (e.g., helper virus, packaging cell line, carrier particles)?
Intended *ex vivo* or *in vivo* target cells and transduction efficiency
Gene transfer agent delivery method
Methods for replication-competent virus testing 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:

Please outline the procedures that will be followed in the event of a spill of the investigational agent: Please outline the procedures that will be followed in the event of a staff member's exposure to the investigational agent:
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:

Note: Any application submitted shall not contain any document that is designated as 'confidential' in its entirety. If a determination has been made that a specific portion of a document should be considered proprietary or trade secret, each specific portion shall be clearly identified as such. If a specific portion of the submission is identified to be proprietary or trade secret, the submission to the Yale IBC must contain a letter that: (1) clearly indicates what select portions of the application contain information considered as proprietary or trade secret, and (2) provides justification as to why this information is proprietary or trade secret. The justification must be able to demonstrate with specificity how release of that information will reveal a trade secret or will result in substantial competitive harm.