



Section II: Regulatory Support Study Information



Gene Therapy Resource Program
National Heart, Lung, and Blood Institute



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Section II - REGULATORY SUPPORT STUDY INFORMATION

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*** Denotes Required Fields**

Disclaimer: The Clinical Coordinating Center of the NHLBI Gene Therapy Resource Program does not and will not hold the IND or serve as Study Sponsor in any capacity. Further, when providing assistance to an NHLBI-approved investigator in the preparation of any regulatory or regulatory-related document(s), the responsibilities of the IND-Sponsor and/or the Principal Investigator of the study cannot be delegated or assigned in any way to the Clinical Coordinating Center.

Type of study related to your request for assistance (Check one):

Clinical Preclinical

Study Title (maximum 250 characters): *

  Department of Health and Human Services  National Institutes of Health

Section III: Regulatory Support Regulatory Information

Gene Therapy Resource Program
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Section III - REGULATORY SUPPORT REGULATORY INFORMATION

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For Preclinical studies

Provide information regarding your study and regulatory milestones:

1. Has your **Institutional Biosafety Committee (IBC)** reviewed this study? *

Yes No

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Section IV: Study Specific Funding Support

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Section IV - STUDY-SPECIFIC FUNDING SUPPORT

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Please provide information on your current and pending funding for this research study.
Specify funding number(s), amount of funding, and funding period.

NIH Funding (maximum 1000 characters):

NHLBI Funding (maximum 1000 characters):


Other (Institution, Industry, etc) (maximum 1000 characters):


No Funding Secured

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Section V: Type of Regulatory Assistance Required



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Section V - TYPE OF REGULATORY ASSISTANCE REQUESTED

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Check all that apply:

1. Assistance with Institutional Biosafety Committee (IBC) related activities
Check all that apply:

- a. Assistance in securing an IBC
- b. Assistance with registration of an existing IBC with NIH Office of Biotechnology Activities (OBA)
- c. Assistance in compiling documents required for IBC review
- d. Assistance in responding to IBC comments, modifications and recommendations
- e. Assistance with submission of annual reports for IBC review
- f. Assistance with submission of IBC annual reports for NIH OBA review

2. Assistance with Institutional Review Board (IRB) related activities
Check all that apply:

- a. Assistance in compiling documents required for IRB review
- b. Assistance with submission of serious and unexpected adverse events to the IRB
- c. Assistance with submission of annual reports for IRB review

3. Administrative assistance with Food and Drug Administration (FDA) related activities
Check all that apply:

- a. Assistance with preparation of Investigational New Drug Application (IND) submission
- b. Assistance with submission of serious and unexpected adverse events to the FDA
- c. Assistance with submission of IND annual report for FDA review
- d. Assistance with other FDA-related issues

4. Assistance with NHLBI related activities
Check all that apply:

- a. Assistance with submission of final, approved clinical protocol to NHLBI
- b. Assistance with submission of serious and unexpected adverse events to NHLBI
- c. Assistance with submission of NHLBI-required study reports to NHLBI



5. Assistance with NIH-OBA related activities
Check all that apply:

- a. Assistance with preparation of materials (e.g. materials for RAC submission) prior to NIH-OBA submission
- b. Assistance with submission of final, approved clinical protocol to NIH-OBA
- c. Assistance with submission of serious and unexpected adverse events to NIH-OBA
- d. Assistance with submission of annual report to NIH-OBA

6. Assistance with Data Safety Monitoring Board (DSMB) related activities
Check all that apply:

- a. Assistance in compiling documents required for DSMB review
- b. Assistance with submission of serious and unexpected adverse events to DSMB
- c. Assistance with planning/designing of reports for DSMB to be prepared by data management/statistical group for study

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