Gene Therapy Resource Program

Funded by the National Heart, Lung, and Blood Institute

To access this RSA form, please use one of the following links:

- Approved GTRP investigators - https://www.gtrp.org/Public/RSA/Default.aspx
- All other investigators - https://www.gtrp.org/Public/InvestigatorRegistration/

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.

Guidance to Investigators

The GTRP Clinical Coordinating Center (CCC) will accept multiple Request for Service Applications (RSAs) from approved investigators. The project associated with each RSA must fall within the mission of the NHLBI and the scope of GTRP services.

A separate form must be completed for each type of assistance activity requested. This will allow each service request to be individually evaluated for approval/disapproval by the GTRP, and it will facilitate the CCC's ability to assign appropriate staff for approved requests. For tracking purposes, the GTRP database will assign an RSA number to each request.

The scope of regulatory assistance services potentially available through the CCC is broad. Some examples include:

- General regulatory assistance
  - Assist with INTERACT (INitial Targeted Engagement for Regulatory Advice on CBER ProducTs) and Pre-IND meeting scheduling and package compilation and submission to FDA as well as IND preparation and submission to FDA.
  - Assist in the preparation and submission of materials to IBCs, IRBs, NHLBI and/or the NIH Office of Science Policy (OSP)
  - Provide guidance in compilation of the clinical protocol and other relevant documents required for review by the local IBC(s) and IRB(s), including relevant communications from FDA, NHLBI, and the NIH-OSP
  - Arrange for expert scientific advice in preclinical and clinical study design
  - Assist in securing an IBC if the institution does not have a standing IBC
- Clinical trial start-up – assistance with site management and regulatory compliance tools
  - Assist sites with preparation of a study-specific Manual of Procedures (MOP) and a Regulatory Binder including tips on organization and content
  - Assist sites with schedule planning to ensure submission of documents, reports and other materials to oversight bodies
  - Assist sites in development of study/site-specific required forms and providing review of drafted CRFs
- For investigators whose clinical protocol is partially GTRP funded
  - Assistance with site readiness assessments
  - Guidance on GCP training
  - Guidance regarding clinical site monitoring

Section II - Description of the Request

Instructions

* Indicates a required field.

Do not exit your browser without saving your RSA information using one of the save buttons at the bottom of this Section (following item 7)!

If you need to copy information from another RSA, open a new browser window to access that RSA. To navigate between initiated RSAs use the "minimize" and "maximize" buttons. **Do not** use the forward/back browser buttons.

1. * Please provide a brief description of the project related to the service you are requesting.

2. Provide a description of the regulatory service you are requesting.

3. Provide information regarding the timeline, including anticipated start and completion dates, for accomplishing this regulatory service. Include any factors that influence the timeline.

4. Provide a description of any contact you have had with FDA regarding the project and any other regulatory status information regarding your project.

5. The Clinical Coordinating Center may request that you upload documents that are relevant to assessing and accomplishing this service. Please upload any requested documents in this section. File names should make the document readily identifiable. (5 uploads maximum)

Browse... Upload

Note: To save and upload a document, select the *Upload* button.

6. If you have initiated other regulatory RSAs that pertain to the same project – and have uploaded documents (as in item 5 above) that are relevant to this request please indicate below:

2019
2040

Add
Remove

7. Have you initiated other RSAs (e.g., for vector production, pharmacology/toxicology services or clinical trial funding assistance) that are associated with this Regulatory Support request? If so, please indicate below.

2007
2008
2009
2010
2011

Add
Remove

RSA ID:

Save and Continue

Section III - Study Specific Funding Support

Instructions

Do not exit your browser without saving your RSA information using one of the save buttons at the bottom of this Section!

If you need to copy information from another RSA, open a new browser window to access that RSA. To navigate between initiated RSAs use the "minimize" and "maximize" buttons. **Do not** use the forward/back browser buttons.

Please provide information on your current and pending funding for this research project.

Note: If any of the NIH or NHLBI grant funds are allocated for regulatory support (e.g., clinical site monitoring), please indicate the amount.

☑ NHLBI Funding

☑ Other NIH Funding

☑ Other Funding (Institutional, Foundation, Industry, etc.)

☑ No Funding Secured

What are your plans for securing funding for your project?

RSA ID: 2044

Submit Final RSA