

PROPOSAL APPLICATION REQUIREMENTS

APPLICATION INFORMATION

PRINCIPAL INVESTIGATOR:

INSTITUTION:

PROJECT TITLE:

THERAPEUTIC TYPE:

MOLECULAR PATHWAY/TARGET:

SCIENTIFIC NARRATIVE

PROJECT PROPOSAL

Combine as one PDF document including all attachments. Send budget attachment separately.

- Scientific Narrative
- Literature Citations
- Detailed Budget
- Budget Justification
- Other Funding Sources
- Other Figures and/or Photographs
- Relevant Articles

ADMINISTRATIVE INFORMATION

All documents must be in English. If not relevant, make note of it within the application.

- Institutional Approval (principle investigator only)
- Relevant IRB/IACUC Approval Letters (principal investigator only)
- Letters of Intent from Drug Supplier or Manufacturer (if relevant)
- Informational Brochure for Repositioned Drugs (if relevant)
- Copies of Relevant FDA Meeting Minutes, Correspondence, or "May Proceed" Letter (if relevant)
- Biographical Sketches
- Letters of Collaboration (collaborators only)
- IP Acknowledgement Letters (collaborators only)
- Financial Statements (for-profit organizations only)

GENERAL FORMATTING GUIDELINES

- Use letter-size pages (8.5 x 11 inches)
- Minimum of one-inch margins on the top, bottom, and both sides of every page
- 11-point font
- You may delete instructional text

SCIENTIFIC NARRATIVE

SPECIFIC FORMATTING GUIDELINES

Page limits:

- Project Goal & Study Plan – 5 pages
- Project Timeline/Milestones– 2 pages
- Therapeutic Profile – 2 pages
- Literature Citations – 2 pages

PROJECT GOAL

Provide a concise statement describing your proposed project.

STUDY PLAN

- Summarize about the therapeutic(s) and experimental plan. The narrative should include a pre-clinical package that justifies your therapeutic moving to the clinical stage. At a minimum, narrative should include rationale for therapeutic development of selected compound.
- In addition, please summarize trial design and methods, including rationale for the particular design and outcome measures/endpoints used.
- Include detailed information on sample size including power, significant level, effect size and outcome measures considered during the calculation. In addition, list the statistical methods to be used to analyze the data.

PROJECT TIMELINE/MILESTONES

Detail your milestones in a decision-tree/flowchart format. This should clearly explain which milestones lead into each other, and what happens with the project if the work in a particular milestone doesn't go as planned. Be sure to include the timing for each milestone. You may use the format of your choice.

THERAPEUTIC PROFILE

For therapeutic programs involving a small molecule or biologic, complete the included template for the lead compound or series which you would like to pursue as a mitochondrial disease therapeutic.

LITERATURE CITATIONS

You may use number formatting to reduce word count.

BUDGET

STUDY BUDGET

Complete the included budget template and insert directly into the Scientific Narrative PDF document. All budget information should be denominated in United States Dollars (USD).

Indirect Costs:

- All costs must be justified and approved by the Foundation. Academic institutions may request up to 25% of direct costs.
- In the event of a collaboration between multiple institutions, indirect costs are only paid once – either to the PI's institution as a percent of total direct costs or, in the case of multiple PIs, to each PI's institution as a percent of each institution's total direct costs.

Please copy and complete the budget template for each year or milestone, as appropriate.

List all significant aspects of the project, including but not limited to:

- Personnel, base salaries, and requested salaries, including percentage effort. The maximum base salary for an individual applying to a Foundation funded grant is \$203,700.
- Supplies and materials
- Travel reimbursement/compensation for study participants

The following may NOT be included in your budget

- Funds may not be used for equipment purchases (including computers or software upgrades).
- Funds may not be used for abstract fees, publication costs or general office supplies.
- Funds may not be used for travel or related costs for scientific meetings and conferences.

BUDGET JUSTIFICATION

Provide a brief description of the role and responsibility(s) of each key personnel on the project. Provide justification of key budget items, specifying their relevance to the project (for example, recruitment and retention costs, etc.).

OTHER FUNDING SOURCES

Required for the Principal Investigator (PI) and any individual on the grant receiving funds through this award. Include both current and pending funding sources. For each grant include the title, a brief abstract, annual amount of grant, funding period, and percentage effort of the investigator. Applicants whose total time commitment exceeds 100% must explain in detail. Specifically state whether or not there is scientific overlap with the current application; and where there is overlap, please explain. If an individual has no other funding (current or pending), a statement should be included to specify this.

SUPPORTING MATERIALS

FIGURES AND/OR PHOTOGRAPHS

You may attach one additional page of figures, photographs or other supporting data.

RELEVANT ARTICLES

You may attach any relevant articles referenced in the scientific narrative that are published or “in press” at the time of application submission.