Request for Letters of Intent to Apply for Grant Funding

Request for Proposals for Novel Approaches to Improve the Availability and/or the Quality of Pediatric Donor Hearts

LOI Submission Deadline: August 15th, 2019

Full Proposal Deadline: November 1st, 2019

About Enduring Hearts: Enduring Hearts launched in 2013 with a mission to fund research to increase the longevity of pediatric heart transplants and improve the quality of life for pediatric heart transplant recipients.

Goal: Enduring Hearts in partnership with the Hoffmann-Schroepfer Foundation announces new funding to stimulate research focusing on improving the quality of donor hearts worldwide and the utilization, allocation, and matching of pediatric donor hearts.

Background: While the waitlist mortality for children listed for heart transplantation is unacceptably high, the number of pediatric organ donors has declined in the recent era. This is compounded by the rejection of over 40% of pediatric donor hearts offered for transplantation. While the reasons for this are multifactorial, there is significant variability in donor acceptance practices across centers and heart transplant providers and limited evidence to guide clinical practices regarding optimal donor selection and donor-to-recipient matching. In addition, we have a limited understanding of how to optimize transport conditions or other novel preservation to improve the longevity and/or quality of donor hearts.

Grant Opportunity: Enduring Hearts’ Scientific Advisory Committee seeks to fund projects up to 2 years and $300,000 with an optional third year based on progress that has a combination of the best science, innovation, and potential for clinical impact. Specific areas of research requested for the current proposal include:

1. Increasing donor availability
   a. Increasing pediatric organ donation rates
   b. Expanding use of donation after circulatory death (DCD)
2. Improving donor quality
   a. Improving donor management
   b. Ex-vivo perfusion and new technologies
   c. Novel preservation strategies
3. Improving utilization and acceptance of potentially usable pediatric donor hearts
   a. Improving evidence of pediatric-specific donor co-morbidities
   b. Improving utilization of high-risk or marginal donors
c. Projects addressing the impact of regulatory oversight on donor acceptance
4. Improving donor-to-recipient matching
   a. Strategies surrounding recipient sensitization
   b. Novel techniques for donor-to-recipient size matching

Eligibility

1. Each applicant organization must be a non-profit academic or research institution, including domestic and non-U.S. non-profit organizations, domestic and non-U.S. public/private academic universities or institutions of higher learning (including colleges, universities, medical schools, and other related academic research institutions); certain qualified governmental agencies with active biomedical research programs may also apply.

   All proposed research projects must be led by a Principal Investigator (PI) who holds a doctorate (e.g., Ph.D., M.D.) or related research degree. PIs must be an independent investigator.

2. Applicants may apply to multiple grants but can only be the PI on one application.

3. Eligible Institutions: Academic or research institution, including, but not limited to domestic non-profit organizations, public/private institutions, and certain US federal agencies.

Application Process: As part of a preliminary discovery, investigators must submit an initial LOI no later than August 15th, 2019 to determine if their proposal is aligned with the funding priorities and the scope of the grant. Applicants will then be invited to submit a complete application and proposed budget.

Applications must be submitted to: Grants@enduringhearts.org

Letter of Intent (LOI) should include the following:

- Page 1
  - The name(s) and academic affiliations of the primary investigator and key collaborating investigators
  - List the Enduring Hearts targeted research area that the proposal addresses
  - A regular language summary (250 words)
- Page 2
  - A structured abstract of the research concept including:
    - Background rationale and hypothesis
    - Specific aims
    - Research methods
    - Anticipated results including clinical significance
- Page 3
  - Supporting documentation such as key references. A maximum of three pages will be accepted.
What will be required for the full proposal?

- **Cover Page including:**
  - Project title (a short title identifying the project and its intended area of focus)
  - The PI’s name and the applicant organization’s name
  - Technical abstract
- **Aims and milestones** (summary of what the project aims to accomplish and the major milestones the PI anticipates the project will complete in the process of meeting said project aims). Major milestones should include estimated timeframe of completion. One (1) page or less.
- **Full research proposal** (6 pages maximum)
  - Significance
  - Approach and Specific Aims
  - Innovation
- **Team capabilities** (statement outlining the research group’s ability to address the research question, support the research, and manage patients, if applicable, and identification of any key personnel in addition to the PI). One (1) page or less.
- **References cited**. One (1) page or less.

Full proposals should be **no longer than 11 pages**

**Additional documentation shall include:**

- Information about the applicant organization and the lead investigator it has selected, including contact information for the lead investigator and the authorized representative of the applicant organization which will receive the grant correspondence and funds.
- Lay summary (succinct summary describing the project’s aims, goals, any previous accomplishments, and how it will benefit the scientific field. One (1) page or less
- Budget (described below). Up to one (1) page.
- NIH bio sketch from primary investigators
- Institution letter of commitment stating that applicant organization will be able to support the research led by the PI.

**What is permissible to include in the budget request?**

- **Total Budget of up to $300,000**
- Budget should include a narrative summary and justification for each item, including how the PI intends to spend his/her time on the project). Acceptable expenditures will include: salary, equipment, software, patient recruitment, fringe benefits, salary for hired personnel, project-related travel, publication costs, and up to 10% indirect expenses to support institutional infrastructure.
- No awards will be made for projects that receive overlapping funding from other sources (unless supplementary in nature) or that duplicate other projects already funded.
• Award periods may not last longer than two years.

What are the requirements for the investigator to receive the award?

• Primary Investigator agrees to provide Enduring Hearts a biannual scientific progress reports with an accompanying lay summary. Information shall be treated as confidential, unless otherwise discussed/agreed upon.

• Acknowledgment of Enduring Hearts/ Hoffmann Schropfer support should be made in any publication or presentation resulting from this award, with logo as appropriate. Acknowledgement should read as follows: “This work was supported by an Award from Enduring Hearts and the Hoffmann Schropfer Foundation.” We would encourage providing Enduring Hearts with notification of presentations made. A copy of any publications should be sent to our grant’s administrators via e-mail: (grants@enduringhearts.org).

• Enduring Hearts may publish your name, project title and institutional affiliation except in purchased media advertising.

• The Principal Investigator is strongly encouraged to submit, copy Enduring Hearts, at least one abstract and/or manuscript during this project and related to this project as proposed.

• If any member of the Enduring Hearts Scientific Advisory Committee should become materially involved with this research, your institution should provide an acceptable conflict of interest mitigation plan for review to the officers on Enduring Hearts. This plan should address whether the doctor(s) involved with Enduring Hearts that are also participating in the research will receive any other non-monetary benefits because from their participation in the research; it should address the process or procedure the institution will use in overseeing the proposed conflict of interest mitigation plan, if applicable.

For more information, please visit our website at https://www.enduringhearts.org/research/for-investigators/

Email: Grants@enduringhearts.org