



ENDURING HEARTS DIRECT GRANT PROGRAM Application Instructions

Thank you for considering Enduring Hearts for your research's support. Enduring Hearts Direct Grant program has two funding cycles, one in the spring and a second in the summer. Please visit our Web site at <https://enduringhearts.org/> for the specific deadlines each year for the **Letter of Intent** and **Detailed Proposal**. Both the **Letter of Intent** and the **Detailed Proposal** should be submitted directly to grants@enduringhearts.org.

LETTER of INTENT (LOI)

An initial LOI should be submitted up to one (1) month prior to the deadline for the Detailed Proposal. The LOI will determine if a proposed study addresses the funding priorities of Enduring Hearts. Enduring Hearts funding priorities for the 2023 Direct Program are: 1) to increase longevity of post heart transplant life by reducing/eliminating and the early and non-invasive detection of rejection and Cardiac Allograft Vasculopathy (CAV); and 2) evidence-based strategies to improve longevity of adolescent recipients. You will be notified if their research study is within these funding priorities. If so, you will be invited to submit a Detailed Proposal and proposed budget. For any additional questions, please email grants@enduringhearts.org. Your LOI will be reviewed, and you should expect to receive our email response, usually within 7 days.

The LOI should include the following:

Page 1

Listing of the name(s) and academic affiliations of the Primary Investigator (PI) and key collaborating investigators with the following: a list of ten (10) selected publications that the investigator deems relevant to the proposal.

A structured abstract (\leq 250 words) of your research proposal that would include the following sections: a **background** section that includes the rationale, an **approach** section that includes the hypothesis, the specific aims, and the anticipated methods to address the aims; and an **anticipated results** section that includes significance, and alignment with EH priority(s) listed below. Check the aligned priority(s).

- Improving longevity and quality of post heart transplant life by reducing/eliminating rejection and cardiac allograft vasculopathy (CAV).
- Development of evidence-based strategies to improve longevity of adolescent recipients.

Page 2

- Provide up to 12 key reference citations and their links. Please include at least one relevant and current review article(s) including an open access citation of a recent review(s) of the scientific area most closely related to your research concept.
- A graphical depiction of your proposed research approach.

LETTER OF INTENT should not include proprietary information as it will be made available to members of the EH Board



ENDURING HEARTS DIRECT GRANT PROGRAM Application Instructions

DETAILED PROPOSAL

Page 1

- Project title (title identifying the project and its intended area of focus)
- Short running title
- The name of the Primary Investigator (PI) and the name of the applicant's organization
- Structured technical abstract (250 words maximum) formatted as follows:
 - "Rationale"
 - "Specific Aims"
 - "Methods/Approach"
 - "Major milestones"

Pages 2 – 9

Research Proposal (7 pages maximum) structured as follows:

- **General Audience Summary** (≤ 250 words; Flesch–Kincaid readability grade ≤ 12) Describe the project's aims, goals, and how it will benefit pediatric heart transplant candidates and/or recipients. Note that Enduring Hearts may publish this General Audience Summary, along with the PI's name, project title and institutional affiliation for parent, recipients and supporters excluding purchased media advertising.
- **Rationale** for the proposed project and its alignment with stated Enduring Hearts 2022 Research priorities listed below.
- **Approach** to include Specific Aim(s) with major milestones with estimated timeframe of completion of each specific aim.
- **Innovation and Significance** to include a detailed description of how achieving the aims of the proposed project addresses a priority, or priorities, of Enduring Hearts.
- **Team and Team Capabilities** Provide a statement outlining the research group's ability to address the research question, support the research, and manage patients, if applicable. Identify any key personnel in addition to the PI. Specify the time commitment of the PI to the project. Include any relevant citations from the Team on the Key Reference list (page 10) below. The commitment of the PI is supported by anticipating at least one abstract and/or manuscript during this project and related to this project as proposed.
- **Graphical depiction of the proposed project.**

Pages 10 – 11

Key References

- To include open access recent review article(s).
- Additional documentation such as information about the applicant organization and the PI; contact information for the PI and the authorized representative of the applicant organization which would receive the grant correspondence and funds.

Page 12

Line-item Budget and Justification

- Total awards range between \$25,000-\$150,000 including indirect costs. Indirect costs should be limited to less than 5%.
- 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 of up to two years. Optional third year for clinical studies. Third year option must be applied for and reviewed at time of application.
- Acceptable expenditures, small equipment, software, patient recruitment, fringe benefits and salary for hired personnel, and publication costs.
- Provide a narrative summary and justification for partial salary support.



ENDURING HEARTS DIRECT GRANT PROGRAM Application Instructions

Review Process

- Applications will be confidentially reviewed by members of the Enduring Hearts Scientific Advisory Committee (SAC) and Expert Reviewers without conflicts of interest. Our SAC/Expert and ad hoc reviewers, along with our Board of Directors Scientific Liaison will review each application. Applications are scored based on scientific merit (e.g., significance, feasibility, approach, innovation, investigators/collaborators, and environment/inclusiveness) and alignment with, and anticipated impact on, Enduring Hearts priorities. Grants are ranked by their scores. Occasionally, the SAC will ask investigators for further clarification or to amend a grant that they believe has merit to meet specific recommendations. Notifications will be communicated to all applicants via email.

Additional Information

- Primary Investigator must agree to the following:
 - That performing medical research involving human subjects, including identifiable material or data will adhere to the ethical principles defined in the Declaration of Helsinki and that national or international ethical, legal or regulatory requirements should not reduce or eliminate any of the protections for research subjects set forth in this Declaration. (Holm et al. 2022)
 - To acknowledge and submit on stated dates, biannual scientific progress reports with an accompanying General Audience Summary.
 - Timely notification of presentations and a copy of any publications sent to grants@enduringhearts.org.
 - To provide a virtual presentation to Enduring Hearts as a summary of the funded proposals findings and how they will impact the priorities of Enduring Hearts.
 - To acknowledge Enduring Hearts support 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.**
 - That Enduring Hearts may publish your professional title, your project title, and your institutional affiliation except in any purchased media advertising.
 - To return all unused funds to Enduring Hearts.
- Enduring Hearts encourages the use of Open Access

Dispersal of Funds

Approved funding will be dispersed in three installments

- 20% will be disbursed to the recipient upon approved receipt of:
 - Letter of acceptance signed by the PI and by the appropriate institutional representative.
 - Letter of exemption or approval by the Institutional Review Board (IRB).
 - Signed PI Permission Form (this gives Enduring Hearts permission to use your information for the purpose of obtaining donations restricted to research).
 - A General Audience Summary of the project that would be understandable by parents of pediatric heart recipients; a clear enumeration of the research progress that would be anticipated.
 - An invoice for the first installment amount.
- 40% will be disbursed to the recipient once all previous steps are completed and upon approved receipt of:
 - Mid-term progress report with a General Audience Summary.
 - An invoice for the second installment amount.
- 40% will be disbursed to the recipient once all previous steps are completed and upon approved receipt of:
 - Final written progress report and General Audience Summary.
 - A short virtual presentation following oral abstract formatting with a brief Q&A period to follow by the Scientific Advisory Committee and Board of Directors of Enduring Hearts.
 - Invoice for the final installment amount.



ENDURING HEARTS DIRECT GRANT PROGRAM Application Instructions

- A line-item budget reconciliation of the research project.
- All work is to be completed within the awarded time frame. Any extensions require approval.
- Funding will be retracted if completion and or reporting is delayed.

2023 RESEARCH PRIORITIES of ENDURING HEARTS that will be considered for funding

Enduring Hearts seeks to fund projects for up to 2 years that have a combination of the best science, innovation, and potential for impact on our priorities. Specific areas of research that would align with the mission of Enduring Hearts include the following:

1. Improving longevity and quality of post heart transplant life by reducing/eliminating rejection and cardiac allograft vasculopathy (CAV) by:
 - 1.1. Integrating accurate non-invasive surveillance methods, technologies and/or biomarkers for recipient care strategies and EARLY identification of the onset of acute cellular rejection (ACR), antibody-mediated rejection (AMR) and/or cardiac allograft vasculopathy (CAV).
 - 1.2. Developing improved therapeutics and/or therapeutic strategies for acute cellular rejection (ACR), antibody-mediated rejection (AMR) and/or cardiac allograft vasculopathy (CAV).
 - 1.3. Developing novel immunotherapies, identification of novel targets for immunosuppression, improving methods for monitoring and determining the optimal level of immunosuppression to prevent ACR, AMR, and/or CAV while reducing/eliminating secondary conditions that may arise due to immunosuppression (e.g., renal; infectious).
 - 1.4. Developing and validating experimental models to study the underlying mechanisms, therapies, and/or prevention of CAV.
 - 1.5. Developing more evidence-based person-centered post-transplant care guidelines, including nutrition and exercise guidelines.
2. Development of evidence-based strategies to improve longevity of adolescent recipients including:
 - 2.1. Improving transitioning from pediatric to adult care/medication adherence.
 - 2.2. Development of evidence-based tools for improving pediatric heart recipient and family education related to heart transplantation.
 - 2.3. Improving evidence-based diverse psycho-social support methods including technologies, hosted peer action groups, virtual visit models and remote metrics.

In addition to a proposal's alignment with the above listed priorities, additional weighting is afforded to the impact of a proposed research study as evidenced by: its potential to translate within the next five years; directly involving pediatric heart transplant recipients and/or their families; and its potential to promote equity as well as standardization of post-transplant care of pediatric heart recipients.

Enduring Hearts, Inc. is a registered 501(c)(3) charitable organization. 1205 Johnson Ferry Rd · Suite 136-329 · Marietta, GA 30068

References.

Holm, A. M., et al. (2022), 'International society for heart and lung transplantation statement on transplant ethics', *J Heart Lung Transplant*, 41 (10), 1307-08.