

# **HESI THRIVE Grant Application Requirements and Guidelines**

The HESI THRIVE Research Grant Program has a two-step application process. A letter of intent is required in advance of submitting a full grant application. Only investigators who have submitted a letter of intent and have been invited to submit a formal grant application will be considered for THRIVE funding. For more

information on how to submit a letter of intent, please refer to the Letter of Intent Instructions on the HESI THRIVE website. The 2024 deadline for letters of intent is 08 April 2024. Full Submissions – if invited – are due 24 July 2024.

The following instructions are for investigators who have already submitted a letter of intent and <u>have been invited to submit a full grant application</u> to THRIVE. Funding requests are limited to a maximum of US \$50,000 total (direct costs only) for a maximum 24-month period.

### **Application Requirements**

The research grant application should be completed and submitted through <a href="https://proposalcentral.com/">https://proposalcentral.com/</a>. When preparing your application, the entire package should be no more than 14 pages in length including the application form and any figures or tables, the biographical information and publication list. The application should contain the following sections:

#### 1. Application Form (3 pages)

The provided cover sheet should be completed and signed.

#### 2. Project Abstract and Lay Person Summary (2 pages)

Briefly and clearly state the nature, objective, procedures and significance of the proposed research and explain how the study furthers how the study will aid in the characterization or prediction of when and how adverse effects may occur in patients who have received cancer treatment and/or supports the development of approaches to avoid or lessen these effects. The lay version of the abstract should be written for a non-technical person to understand. The lay summary may be used by THRIVE for communication and publicity purposes.

#### 3. Research Plan (4 pages)

The text should cover the following areas in detail:

A. Title of project

- B. Background and significance: This should provide information on the scope of the problem, summary of mechanisms, markers, or approaches to be studied, a brief evaluation of existing research and knowledge in this area, and insight into gaps in knowledge that the study intends to fill. The section should clearly indicate how the study findings might impact the prediction or treatment of adverse effects following cancer therapy.
- C. Specific Aims: The investigator should present both the broader research objectives as well as the specific study hypothesis to be tested in this project.
- D. Research Design and Methods: This should describe the experimental design and methods that are used to accomplish the specific aims. This section should describe how data will be collected, analyzed and interpreted. Any new methodology or novel cross-disciplinary (e.g., nonclinical and clinical) partnerships and their advantages over existing approaches should be mentioned. Potential difficulties and limitations of the proposed procedure along with alternative approaches should be mentioned. If the study involves human subjects, details on the study and control group criteria as well as the recruitment process should be provided.
- E. Timetable: This should specify he time required for study setup, conducting the experiment, data analysis and evaluation, and dissemination of study findings.
- F. Project personnel: Each researcher's name, title, institution, role in project and percentage of effort devoted to the project should be listed.
- G. Resources and Environment: This should describe the research facility(ies), laboratory space and major equipment needed for the study. Any materials, procedures, or situation that may be hazardous should be described along with the proposed precautions taken.

#### 4. Budget (1 page)

<u>Budget breakdown:</u> Include a total research budget for the proposed project stating the amount requested from THRIVE along with other confirmed funding sources. Individual THRIVE awards will not exceed \$50,000 USD. The budget should consist of only direct cost items such as personnel, supplies and equipment. Project personnel should be listed by name, title, time/percentage effort and requested salary. If the amount of the study exceeds what is being requested from THRIVE, please indicate other sources of funding or provide an explanation of how additional funding will be secured to complete the study.

Administrative overhead or indirect costs should not be included in the budget. THRIVE does not cover institutional construction or renovation, purchase of capital equipment other than what is needed for the proposed research, office equipment or furniture, equipment service contracts, non-study related travel, tuition fees, journal subscriptions, dues or memberships, and publication fees.

<u>Budget justification</u>: The narrative should explain the budget items and reason for the expense. For project personnel, an explanation of their role in the project should be included.

#### 5. Research Approval Letter (1 page)

Biomedical research involving human subjects or animals require an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) letter of approval from the investigator's affiliated institution. If one is not available at the time of the application, an institutional letter of support can be provided. However, grant funding will be contingent on securing an IRB or IACUC letter of approval prior to the start of the study.

# 6. Biographical Information and Publication List (appendix- additional 1-4 pages if needed)

Biographical sketches for key investigators involved with the study should include name, position, education, and training in chronological order as well as research and professional experience in chronological order. Only publications from the past 5 years that are relevant to the proposed research topic should be listed.

#### **Application Submission**

A PDF copy of the proposal should be electronically submitted to <a href="https://proposalcentral.com/">https://proposalcentral.com/</a> no later than 5:00 p.m. eastern standard time on 24 July 2024.

No extensions of the deadline can be made. Once submitted, a confirmation email will be sent by THRIVE.

For questions, please contact us at research@hesithrive.org.

#### **Application Review Process**

Applications are reviewed in detail by the THRIVE Advisory Review Board and will be discussed as a group to determine funding priority based on THRIVE's research criteria. Preference will be given to studies in which both a non-clinical and clinical researcher are engaged in either design, conduct, or analysis of the study results in ways that bring new innovation to cardio-oncology research and outcomes. Details about the grant review process can be obtained by downloading THRIVE's Grant Requirements & Guidelines document.

Each research grant is carefully evaluated on the basis of:

#### 1. Significance & Scientific Merit

- Does the study advance our ability to replicate and interrogate critical elements of treatment-induced toxicity pathways in both physiologically and pharmacologically relevant ways?
- Does the study develop models (in vivo, in vitro, in silico) of pediatric or adult drug exposure that support improved predictivity for delayed toxic effects?;
- Does the study advance understanding of the role of protective co-therapies or modified exposure protocols on the onset of toxic damage? and/or
- Does the research support the development and translational interpretation of clinically accessible biomarkers (or measures) of injury that have relevance for patient monitoring?

#### 2. Approach & Feasibility

- Are the conceptual framework, design, methods and analyses adequately developed, well integrated and appropriate to the aims of the project?
- Are potential risks and problems addressed and alternative methods recommended?
- Will the study be completed in the proposed timeframe and within the proposed budget?

#### 3. Innovation

- Are the aims original and innovative?
- Does the project involve novel interactions across non-clinical and clinical scientific researchers and/or scientific data sets?
- Does the project employ novel concepts, approaches and methods?

#### 4. Investigator Qualification & Environment

- Does the investigator have the expertise and commitment to carry out the proposed work?
- Are all the required elements such as laboratory, technology, equipment, reagents, and human or animal subjects available for the project?

#### 5. Ethical & Regulatory Adherence

- Is the study ethical and does it abide by HIPAA regulations?
- Will the study be conducted properly in accordance to IRB and IACUC regulations?

#### 6. Prospect of long-term funding

• What is the likelihood of getting subsequent NIH or other major funding to sustain the project and/or expand the research?

Final decisions on funding will be made by THRIVE's Advisory Board by 15<sup>th</sup> August 2024, and grant applicants will be notified by email. All decisions about grant applications made by THRIVE are final and are not subject to appeal. The funding period will initiate on 1<sup>st</sup> September 2024.

#### **Research Grant Terms**

Before THRIVE disburses funds to a grant recipient, the principle investigator (PI) will be asked to sign a funding agreement letter with the THRIVE program which outlines the below research grant terms:

- ➤ **Grant Period:** Grants must specify the proposed timeline and major milestones. All experimental work is to be completed within a maximum of 24 months.
- ➤ Grant Payment: Upon receipt of a signed THRIVE letter of agreement and letter of approval by the PI's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), THRIVE will disburse 75% of the funds. The remaining 25% of the award is provided upon completion of the study milestones. Exceptions may be made. Specific milestones for disbursement of funds will be specified in the funding agreement letter.
- ➤ **Grant Reporting:** Awardees will be required to provide a written study update at the 12-month mark and at completion of the study. All awardees will be provided with funding to attend the annual THRIVE network forum meeting and will be asked to provide an update on study outcomes or interim findings at that time. Awardees are highly encouraged to publish results of these studies as feasible. The THRIVE Advisory Board can assist in identifying appropriate publication venues.
- 1. **Site of Project:** THRIVE awards funding to public or private universities, hospitals and biomedical research institutions globally. The research shall take place only in the

research facility specified in the submitted research proposal. In the event the PI leaves his or her affiliated institution, the PI shall immediately notify THRIVE of the changes and submit a status report and accounting of the funds spent to date. It is the responsibility of the PI to make necessary arrangements with their institution to permit transfer of any unused THRIVE research funds to the PI's new institution.

- 2. **Expenditures:** The grant is made only for the purposes stated in the research proposal and according the proposed research budget. The grant covers direct costs only, and funds may not be used for administrative overhead, construction or renovation, purchase of capital equipment other than what is needed for the proposed research, office equipment or furniture, equipment service contracts, non-study related travel, tuition fees, journal subscriptions, dues or membership, and publication fees. At the end of the grant period, any unused funds shall be promptly returned to THRIVE.
- 3. **Grants Administration:** The grant funds shall be physically segregated, and such funds shall be shown separately on the PI's books for ease of reference and verification. Records of receipts and expenditures under the grant, as well as copies of reports submitted to THRIVE, shall be kept for a reasonable period of time following completion of such receipts and expenditures.
- 4. **Institutional Research Approval:** All THRIVE funded research projects must conform to local and federal regulation requiring that all institutions maintain appropriate policies and procedures for the protection of the rights and welfare of human subjects and the safe and humane treatment of animals used for research. A letter of approval from the PI's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) or other relevant body must be provided to THRIVE before the start of research study.
- 5. **Liability:** The PI assumes sole responsibility for conducting the research and supervising the work of co-investigators associated with the study and is therefore responsible for any negligent acts or omissions in connection with their research study. The PI and PI's institution shall indemnify and hold harmless THRIVE, its advisors, agents and partners from any claim, judgment, award, damage, settlement, liability, negligence or malpractice arising from accepting THRIVE's grant, expending or applying grant funds, or in carrying out the research study supported by the grant.
- 6. **Grant Suspension or Cancellation:** THRIVE reserves the right to suspend or cancel the funding agreement at any time at its sole discretion for failure of the PI to abide by THRIVE's grant terms. Upon receipt of a written notice of project suspension or cancellation from THRIVE, the PI should prepare and submit a project status report and accounting summary of funds expended to date. All unused funds must be returned to

THRIVE immediately upon its request. A PI may terminate a grant by sending written notice to THRIVE stating the reason and providing a project status report and accounting summary of funds expended. The PI should make arrangements to promptly return unused funds to THRIVE.

- 7. **Dissemination of Findings:** All findings resulting from research supported by THRIVE shall be made public, preferably through recognized scientific/medical meetings and peer reviewed journal articles. Any scientific data resulting from research funded by THRIVE shall be made available to other researchers and non-commercial laboratories in a timely manner at a no charge or at cost basis. If it has been determined that the findings will not be published, the PI and THRIVE shall discuss other options for dissemination of the data to the public and medical/scientific community.
- 8. **Presentation and Publication Acknowledgement:** All presentations and publications related to research funded in part or in whole by THRIVE's research grant must cite the HESI THRIVE Initiative as a source of funding. THRIVE shall be notified when a presentation or publication related to the funded research has been confirmed, and a PDF file of the final abstract or publication shall be forwarded to THRIVE when available.
- 9. **References to Work:** Both THRIVE and the PI may include general, non-confidential information about the research grant in announcements to the general public and their constituents. For specific print or internet references, such as communication materials or press releases, the PI or PI's institution must acknowledge THRIVE's involvement and notify the THRIVE before distribution. Similarly, announcements about the study findings must be reviewed by the PI before distribution by THRIVE.

All submissions will occur through proposal central (<a href="https://proposalcentral.com/">https://proposalcentral.com/</a>). The online submission portal will prompt you for the information outline in the next 3 pages. You are <a href="mailto:no longer required">no longer required</a> to e-mail your submission to research@hesithrive.org

**Research Information** 



## 2023-2024 Application for THRIVE Research Grant

# Title of Research Project:

Type of Research: Involvement:	<ul><li>□ Basic</li><li>□ Human Subjects</li></ul>	<ul><li>☐ Clinical</li><li>☐ Animal Subjects</li></ul>	<ul><li>☐ Translational Research</li><li>☐ Biohazards</li></ul>	
APPLICANT INFORM	ATION			
Principal Investigator	Name (First, MI, Last)			
Title	Degree(s)			
Institution	Division/Department			
Mailing				
Address				
Phone	Fax	Email		
Institution and Supe	rvisor Information			
If research is to be co	onducted at a different	t site:		
Institution			on/Department	
Mailing				
Address				
Phone	Fax	Email		

This form should be completed on: <a href="https://proposalcentral.com/">https://proposalcentral.com/</a>

If a supervisor or co-Investigator is involved:	
Supervisor Name	Title/Degree(s)
Supervisor's Phone	E-mail
Co-investigator Name	Title
Institution	Division/Department
Co-investigator's Phone	Email
Total research project budget:	
TURN'S for diagrams and (CSO 000 USD marines)	
THRIVE funding requested (\$50,000 USD maximum):	<del></del>
Timeline to complete funded research (maximum 24 mo	nths)
Grant payment check should be made payable to:	
Grant payment check should be mailed to (i.e. grants ad	ministration office):

This form should be completed on: <a href="https://proposalcentral.com/">https://proposalcentral.com/</a>

## APPLICANT STATEMENT

I certify that of the information contained in this grant application is accurate and not misleading. I agree to accept responsibility for the scientific direction, conduct, and financial and legal oversight of this project. I certify that I have read THRIVE's research grant terms and understand the grant requirements if awarded funding by THRIVE.
requirements if awarded fulfullig by THRIVE.
Applicant's Signature:
Date:
APPLICATION CHECK-LIST
☐ Application form
☐ Project abstract
☐ Lay person summary
☐ Research Plan
☐ Budget
☐ Biographical sketches
☐ Human subject IRB or Animal IACUC approvals