

Expansion Award

Augmenting the depth and breadth of scientific research & technologies for single ventricle

2023 Request for Proposals

Proposal Deadline: May 4, 2023 (8 PM EDT)



TABLE OF CONTENTS

EXPANSION AWARD PROGRAM OVERVIEW	3
2023 KEY DATES	3
SCIENTIFIC FOCUS AREA	3
AWARD DETAILS	4
ELIGIBILITY REQUIREMENTS	5
ADDITIONAL IMPACT CONSIDERATIONS	5
APPLICATION INSTRUCTIONS	6
OVERVIEW OF PROPOSAL COMPONENTS	е
REVIEW PROCESS	7
ACTIVITIES AND DELIVERABLES	7
COVID-19 POLICY AND SUPPORT	8
TERMS OF GRANT AND USE OF FUNDS	8
QUESTIONS?	8
AROLIT ADDITIONAL VENTURES	Q



EXPANSION AWARD OVERVIEW

The Additional Ventures Expansion Award enables teams to add new **single ventricle-focused** approaches and directions to their current work by providing a one-time, 12-month award of \$50,000. The Expansion Award supports investigators, both established and new to the single ventricle field, in achieving:

- 1. The **expansion** of existing studies within the single ventricle research community, as well as
- 2. The addition of single ventricle-directed aims to an ongoing study within any adjacent field.

These awards fill a gap in existing funding opportunities to promote scientific advancement of teams with a documented history of award success in and adjacent to the single ventricle research community.

All application materials will be accepted electronically via the online <u>ProposalCentral</u> portal, in accordance with the timeline below. *Please carefully review eligibility requirements on page 5 and proposal components on pages 6-7.*

2023 KEY DATES

Application Portal Opens	February 6, 2023
Proposal Due	May 4, 2023, 8 PM Eastern Time
Notification of Award	June 8, 2023
Funding Begins	July 1, 2023

Note: Deadlines are subject to change at the discretion of Additional Ventures in response to nationally or globally relevant events, including the COVID-19 pandemic.

SCIENTIFIC FOCUS AREA

Single ventricle heart disease is an understudied and underfunded area that requires a multi-disciplinary approach from a research and clinical care perspective.

What is Single Ventricle Heart Disease?

In human hearts, four distinct chambers form during development: two atria and two ventricles. However, in some individuals, one ventricle does not form properly and is either smaller, underdeveloped, or is missing a valve. Such conditions are referred to as single ventricle heart defects, which encompass a spectrum of diagnoses, including but not limited to pulmonary atresia with intact ventricular septum, hypoplastic left heart syndrome, and tricuspid atresia.

Additional Ventures aims to accelerate research that will lead to both improved care and novel treatments for single ventricle based on a mechanistic understanding of the disease. In September 2020, our organization published a Research Roadmap, which was developed in partnership with investigators across disciplines to identify strategic solutions to address these gaps and challenges. The Research Roadmap is intended to guide a decade's worth of research efforts and serve as a framework for coordinating global resources to advance single ventricle research and clinical care.

For more information on single ventricle and our Research Roadmap, visit our website.



The 2023 cycle of the Expansion Award welcomes research efforts relevant to single ventricle heart disease and aligned with our Research Roadmap in Focus Areas II through V (bolded) and strategic topics (nested) related to each one (see below). Registry builds and proposals within Focus Area I will not be considered. Investigators are encouraged to propose research projects with relevance to multiple types of single ventricle.

II. Understand the Origins of Single Ventricle Disease

- II-1. Deep phenotype-genotype
- II-2. Model organisms
- II-3. Non-genetic and modifiable risk factors
- II-4. Normal cardiac development

IV. Effectively Predict, Prevent, and Address Clinical Sequelae

- IV-1. End-Organ trajectory, mapping, and biomarkers
- IV-2. Personalized medicine approaches
- IV-3. Alternative interventions
- IV-4. Learning networks

III. Define Biological Mechanisms of Outcomes

- III-1. Outcome origins
- III-2. Substrate-outcome relationship
- III-3. Predictive models
- III-4. Early detection

V. Focus on Functional Cures, Not Palliative Approaches

- V-1. Enabling technologies
- V-2. Standardization and scale
- V-3. Cross-disciplinary teams
- V-4. Bionic, regenerative, and transplant approaches

AWARD DETAILS

The Additional Ventures Expansion Award program supports the expansion of scientific research related to single ventricle and the use of enabling technologies within the field. Each 12-month award will provide up to \$50,000 USD in funding to support ongoing research.

Expansion Award funds can be used to expand upon the scope, impact, or breadth of currently funded projects ("parent projects"), active through December 31, 2023, to achieve the following:

- A) Expansion of existing single ventricle studies through the use of additive technology, approaches, or tools. Open to investigators with current, ongoing studies focused on understanding or treating single ventricle heart defects and/or their related sequelae. Previous awardees in this category have proposed to support the following:
 - Equipment acquisition (e.g., bioreactors, microscopes, 3D printers, computers)
 - Expansion of clinical studies to additional study sites
 - o Computational tool or software development
 - Sample preparation, data storage or processing (e.g., for large scale sequencing, proteomic, or computational projects)
- **B)** Addition of single ventricle-directed aims to ongoing studies. Open to investigators with current awards in any adjacent field seeking to apply technology or findings to single ventricle for the first time. Previous awardees in this category have proposed the following:
 - Assessment of gene or molecular candidates in the context of single ventricle (after identification in other studies)
 - Application of computational tools for single ventricle populations (after validation for other patient populations)
 - Assessment of novel biomarker or intervention for single ventricle populations (after validation for other populations)



In 2023, we anticipate funding approximately ten (10) grants; however, we reserve the right to fund any number of grants based on both the quality and quantity of the applications received. Previous Expansion awardee project abstracts can be viewed in our awards database.

Competitive applications are expected to provide a credible and realistic discussion of how the award will expand the scope, expediate time to completion, or otherwise increase the scientific interest or impact of an existing parent project. Details regarding eligibility can be found in the Eligibility Requirements section below.

ELIGIBILITY REQUIREMENTS

- 1. Principal Investigator(s) (PIs) must hold doctoral degrees (e.g., PhD, MD, PsyD, or equivalent). Applications are welcome from early career investigators and those in instructor or postdoctoral roles, so long as they meet all other eligibility criteria.
- 2. Applicants must be currently affiliated with a nonprofit academic or research institution, including:
 - Domestic and international nonprofit organizations,
 - Domestic and international public/private academic universities or institutions of higher learning (colleges, medical schools, and other related academic research institutions), and
 - o Governmental agencies with active biomedical research programs.
- 3. Applicants must be listed as a PI on the existing parent project with concurrent funding (through at least December 31, 2023).
- 4. Proposed expansion plans must have demonstrated relevance to single ventricle heart defects.
- Pls may only submit one application per cycle, and may not currently hold an active Expansion Award from another award cycle. Pls funded by Additional Ventures through other mechanisms <u>are</u> still eligible to apply for Expansion Awards.

ADDITIONAL IMPACT CONSIDERATIONS

Additional Ventures strives to support a scientific community that is diverse, collaborative, and forward thinking. As such, Additional Ventures recognizes the deep inequalities inherent in academia and strives to include those who have been historically excluded and underrepresented. When evaluating the overall impact of submissions, Additional Ventures will take into consideration:

- The **diversity of the expertise and background** of project leads and team members, including underrepresented racial and ethnic groups, sexual and gender minorities, and persons with disabilities.
- Proposals from investigators new to single ventricle and associated conditions.
 - For the purposes of this RFP, "new to single ventricle and associated conditions" identifies a principal investigator who has not authored a publication relating to single ventricle and associated conditions and has not been the PI on a grant related to single ventricle and associated conditions awarded from a grant-making agency, nonprofit, foundation, or other grant-awarding organization.
- Proposals from early career investigators and those in instructor or postdoctoral roles.
 - For purposes of this RFP, an "early career investigator" is an individual that has had an independent lab or clinical research position for no longer than seven (7) years past their postdoctoral position or medical fellow position. If an investigator has achieved independence



- directly following graduate school, an "early career investigator" is considered one who has had an independent research position for ten (10) years or less.
- Exceptions to this timeline include, and are not limited to: 1) Childbirth or adoption (one (1) year automatic extension), 2) Extenuating circumstances related to child, elder, or family care, 3) Periods of part-time work or leave, 4) Period of time after receipt of terminal degree requirements when the investigator was not conducting research (including required clinical training/activities, or time away due to family care, medical issues, military service, or natural disasters), and 5) Significant change in field of study.

Applicants are not required to disclose the information above. Responses will be visible only to Additional Ventures; outside reviewers will not have access to this information.

APPLICATION INSTRUCTIONS

Interested candidates who meet eligibility criteria are invited to submit a proposal through <u>Additional Ventures' online grant portal, ProposalCentral</u>, by **Thursday, May 4, 2023, 8 PM EDT**.

All application materials should be completed within the portal and prepared from provided templates, when appropriate. All uploaded application materials should be submitted as a **PDF** and formatted in a **sans-serif**, **11-point font** with **1-inch margins** and **single-spaced**, except where provided templates or fillable forms apply; elements should not exceed the page or character limit, where applicable.

Please visit ProposalCentral to access the application portal and apply:

- 1. Log in (or create an account) as an 'Applicant or Awardee' to start your application.
- 2. Within the portal, Additional Ventures' open programs are listed under the 'Grant Opportunities' tab.
- 3. Click 'Apply Now' to begin your application. To revisit an existing application, select your draft under the 'Proposals' tab.

OVERVIEW OF PROPOSAL COMPONENTS

Application instructions can be found in ProposalCentral; a formal proposal detailing the intended project must be submitted as part of the application and will contain the following elements:

- Title page
- Eligibility criteria certification
- Investigator information
 - o Principal Investigator (PI) name, institution, degree(s), academic rank, contact information
 - o Co-Investigator contact information (limited to three (3) per proposal)
 - o Investigator biosketches (template provided; five (5) page maximum, each)
- Primary institution information & contacts
- Project summary
 - o Lay summary & Technical abstract (2100 character maximum, each)
 - Succinct summaries written for the general public and technical audiences, respectively, describing the project's aims and goals, including how the completion of the study expansion will impact the field of single ventricle research and/or care.

Please visit the <u>application portal</u> for the most up-to-date application guidelines and requirements.

Requirements are subject to change at Additional Ventures' discretion; any changes will be reflected in real time within the application portal.



 Selection of <u>Research Roadmap</u> Focus Area and Strategic Topic reflective of the proposal's scientific focus area

Budget

- Itemized budget (fillable form, in USD) supplemented with narrative budget justification (3000 character maximum)
 - For non-US applicants: All grants will be made in USD, and Additional Ventures is not responsible for any changes in conversion rates.
- Acceptable expenditures include, but are not limited to: equipment, reagents, software and compute time, patient recruitment, project-related travel.
- Support for up to 20% effort for one non-PI individual. Use of this award for indirect costs or PI salary is not permitted.
- If more than one institution will be involved in the project, one should be proposed as the applicant organization, and the other(s) included as a sub-grantee. Please submit individual budgets and budget justifications for each institute.

• Parent project award information

- Source of parent project award or grant, title of project, start/end dates, annual costs, abstract
- Uploaded documents (PDF format)
 - Background/Preliminary Results (two (2) page maximum)
 - A technical summary of relevant research currently underway, the methodology used in pursuit of the project, including discussion of relevant results or expected findings.
 - Expansion Plan (two (2) pages maximum)
 - A technical narrative describing the limitation or problem within the parent project that the award will address, including discussion of rationale, goals, and impact of findings. Include a sufficient description of the significance of the application, including how the award will positively impact the scope, rate, or interest of the parent project, and its impact on our understanding or treatment of single ventricle.
 - References Cited (no page limit)
 - Timeline & Milestones (template provided; two (2) pages maximum)
 - A timeline indicating expected scientific milestones and products achieved, post-award.
 - Letters of support from collaborators (if applicable)
- Applicant demographics optional and confidential

REVIEW PROCESS

Upon receipt of complete proposals, Additional Ventures review committees will evaluate proposals based on scientific and technical merit, realism of cost and implementation, overall impact, and context of the proposal within existing scientific investments. Additional Ventures will provide context of the decision for all proposals not selected for funding.

ACTIVITIES AND DELIVERABLES

Grantees funded by this effort will be expected to report to Additional Ventures the progress and results of awards in a **final report: a two (2) page summary of research progress**, including a description of scientific



impact and use of funds; submitted to Additional Ventures within three (3) months of the conclusion of the award term.

Additional Ventures may make reporting inquiries and request responses relating & not limited to: publications and presentations, patents, collaborations, external award of additional funding, students and postdoctoral associates trained in association with work funded by Additional Ventures.

Grantees are invited to engage in the following (optional, but strongly encouraged) activities:

- Attendance at the biannual (every 2 years) <u>Additional Ventures Investigator Meeting</u>; when possible, presentations are encouraged to be made by postdoctoral or pre-doctoral researchers.
- Active participation in <u>Additional Ventures-led meetings or workshops</u> that bring together grantees to share progress and results amongst the single ventricle and cardiovascular research communities.
- Active participation in leadership and mentorship activities throughout the grant award period.

COVID-19 POLICY AND SUPPORT

As a foundation, Additional Ventures is deeply committed to the support of our scientific and research communities. We are sensitive to the ongoing effects of the COVID-19 pandemic on the wellbeing of our scientific, clinician, and academic colleagues.

We recognize that COVID-19 can cause delays and changes to planned research activities, through the introduction of both professional and personal difficulties. The Additional Ventures team is cognizant that no standard plan will work for all grantees or apply to all situations; as such, we are willing to work with our grantees on a personal basis to discuss options and find appropriate solutions. Contact our team to discuss how we can help; we know that allowing flexibility means a greater chance of success.

TERMS OF GRANT AND USE OF FUNDS

Each funded organization will be required to sign and agree to the Additional Ventures grant terms within thirty (30) days from receipt of notice of the award and prior to award funds being released. Full agreement terms will be distributed following notice of award; a summary of the Terms and Conditions can be found here.

Award funds for proposals selected for funding will be made payable to the applicant organization; under no circumstances will payment be made to an individual. Responding to this RFP and/or submitting a proposal does not entitle any individual or institution to receive funding from Additional Ventures. Funding, if any, is provided at Additional Ventures' sole discretion pursuant to the Terms and Conditions of a written grant agreement executed by Additional Ventures and the selected grantee organization, the terms of which Additional Ventures may require to be acknowledged by the PI.

QUESTIONS?

Please contact our team with any inquiries you may have at grants@additionalventures.org.

ABOUT ADDITIONAL VENTURES

Additional Ventures is a nonprofit foundation that aims to accelerate research progress and improve clinical care for children born with complex congenital heart defects so that they have a normal duration and quality of life. Although one in one hundred children are born with a congenital heart defect, there are limited options



for those with the most complex forms, including single ventricle heart defects. For these children, there is no cure. With rapid advances in areas like genomics, single-cell technologies, and tissue engineering, now is the time to coordinate concerted efforts to understand how to overcome this devastating, complex disease.