

Dr. Ralph and Marian Falk Medical Research Trust

Catalyst and Transformational Awards Programs

Office Hours

March 2, 2026



HRiA partners with individuals, organizations, and communities to transform the practices, policies, and systems that improve health and advance equity.



Agenda

- Program Goals
- Research Focus and Stage
- New in 2026
- Program Overview
- Eligibility
- Review Criteria
- Review Process
- Features of Successful Projects
- Pitfalls to Avoid
- Application Tips and New Award Manager
- Q & A



The Falk Trust was created to support:

“medical research to improve treatments of the past and eventually find cures for diseases for which no definite cure is known.”



Program Goals

To move insights gained from basic science into clinical practice and support high-risk, high-reward projects that address critical scientific and therapeutic roadblocks.

If successful, these projects will have high impact outcomes that open new avenues for treating, curing, and improving the lives of individuals suffering from disease.

There are two separate but linked awards:



Research Focus and Stage

Principal Areas of Focus:

1. Identification of **biological markers** of disease and activity progression
2. Identification of **targets** for therapeutic interventions
3. Development of **therapeutic agents** that will disrupt, arrest, or prevent the disease process



Early stage	Early preclinical development from biomarker or target identification and validation to proof of concept, up to development of a lead therapeutic
Late stage	Lead optimization through drug candidate selection and IND-enabling studies
Pre-transition	Late-stage projects that need one or more critical experiments (e.g., lead candidate testing in non-human primates) to satisfy a transition requirement (i.e., FDA IND filing, venture capital investment, etc.)
Investigator-initiated trial	Proposals for human clinical studies that are initiated, managed, and sponsored by the investigator or investigator's institution

New in 2026

- New Award Manager
 - Slight changes to application format and instructions

Program Overview

Catalyst Award

Transformational Award

Award Duration:

1 – 2 years

2 – 3 years

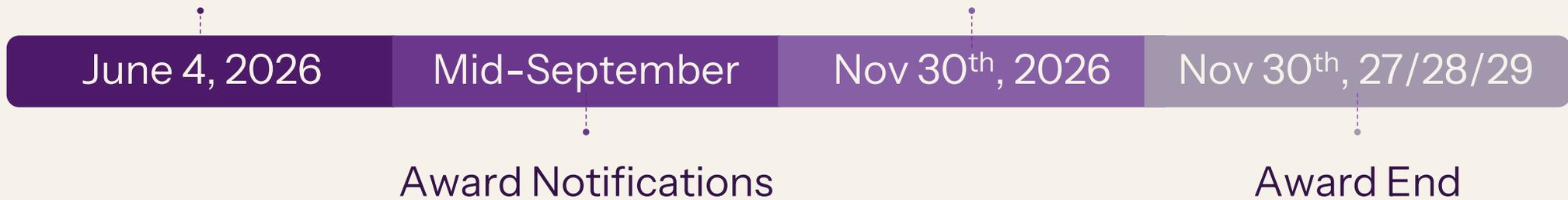
Maximum Award Amount:
(including 10% indirect costs)

Up to \$350,000

Up to \$1,000,000

Application Deadline

Award Start



Eligibility

Catalyst Award

Invited Institutions may nominate 2 projects each cycle

Transformational Award

Applicants may apply during the final year of their Catalyst Award or the year following. 1 resubmission allowed in the subsequent cycle.

Must have successfully achieved milestones & benchmarks



- Administrative PI must be full time faculty and conducting research at nominating institution
- One application per PI
- Investigative team may involve shared leadership and multiple PIs
- Nominating institution must be the primary funding recipient if awarded
- PI(s) must have institutional support
- PI(s) may not have funding for similar project
- Current awardees may not apply. Former awardees may apply, but only with a new project.

Review Process



Review Criteria

Translational Potential

- Can be transferred to clinical practice in the near term

Impact

- Addresses a critical scientific roadblock and will have high impact on patient lives if successful

Investigative Team

- Right combination of expertise and infrastructure to successfully carry out the project

Project

- Based on sound precedents and clear rationale
- Feasible, realistic & powered methodology
- Appropriate budget and timeline

Common Features of Successful Projects

- **High impact:** High potential to improve the lives of those suffering from a disease
- **Fill an unmet need** or improve upon existing products
- Translational in the **near term**
- **Clear strategic path** to a \$1M Transformational award or the next step of commercial development.
- Combination of **expertise and infrastructure** in relevant areas (i.e. pharmacology, drug delivery, clinical trials, scaling & manufacturing, commercialization, specific techniques, etc.)
- **Solid project:** Sound precedents, preliminary data, and clear rationale; feasible and sufficiently powered; alternative approaches; appropriate and realistic budget and timeline.
- **Grantsmanship:** Clear language and hypothesis understandable to a general audience and appropriate use of jargon and abbreviations.

Common Pitfalls

- Impact/critical need are lacking
- Project is heavily mechanistic and far from clinical practice
- Unclear path forward (to Transformational Award and beyond to clinical practice)
- Idea lacks innovation (e.g. therapeutic in a competitive commercial space without a plan for differentiation)
- Lacking the correct expertise
- Lacking in preliminary data or alternative approaches
- Poor grantsmanship, proposals include much jargon and are not understandable to a general audience.

Application Tips

- Recruit the right team: Include appropriate collaborations and/or shared leadership if it benefits the project
- Be realistic (in timeline, budgets, etc.)
- Avoid jargon and abbreviations; should be understandable to scientific generalists such as venture capital investors
- Be concise and clear (make it easy to read!)
- Include contingencies
- Know the competitive landscape
- Seek feedback (internally, externally, and across disciplines)

Example Reviewer Feedback

Translational Potential

- “Although innovative, this project is in its very early stages, without clear preliminary evidence that these treatments will be superior to current therapies, and thus transformational potential is somewhat limited. Also, somewhat limited by the lack of mechanistic understanding.”
- “There are concerns with overlap with ongoing commercialization approaches. It is not apparent how the proposed study is different from previous studies.”
- “Multiple efforts to target XYZ are ongoing, several a bit more sophisticated.”
- “Implementation and uptake by the end user would be a significant challenge. Consultation with physicians might be helpful to generate data required for clinicians to adopt the technology.”

Impact

- “The likelihood that the proposed therapeutic will eventually have significant clinical impact is uncertain.”
- “This seems like a ‘too safe bet’ for Falk, a project that is very likely to succeed, likely to be funded by others, and not likely to create groundbreaking headlines when the results are known.”
- “Project focuses on an ultrarare disease with very low prevalence.”

Example Reviewer Feedback

Experimental approach

- “The proposed technique has been used in prior models with limited success and there is no discussion of how it might eventually prove to be a useful approach.”
- “A more comprehensive data package involving multiple model organisms beyond mice would strengthen confidence in the approach.”
- “Because of the previous clinical trial failures in this space the authors should spend time in assessing the clinical trial applications in parallel with the development of the lead compounds.”
- “Weaknesses include a lack of clarity regarding whether the proposed sample size is sufficient to support robust model validation.”
- “One would expect local patient communities to be guiding the development of the therapeutic such that it has patient centered properties (targeted to specific quality of life challenges patients want to address such as pill formulations that affect # of times taken per day or pill size, side effects that are undesirable, etc.), as well as endpoints.”
- “Potential variability across populations is not fully addressed, which may limit generalizability.”
- “Recruitment feasibility may be affected by patient reluctance.”
- “The timeline is aggressive and involves optimizing multiple formulations and assessing stability in 6 months. This is a substantial undertaking that could easily be delayed. This could have a cascading effect on the subsequent aims.”

Example Reviewer Feedback

Investigative Team

- “This grant utilizes numerous novel techniques. While innovative, it is not clear that the PI has the resources, experience or collaborators for all of the novel techniques described.”
- “Lack of understanding of what is needed to move to clinical development.”
- “I am concerned that the team might not have the expertise to make the project work within the timeline suggested.”
- “Weaknesses include the absence of a regulatory and/or commercial expertise/plan”

Project and Grantsmanship

- “Densely written proposal with many crowded, small figures. It is not easy to read!”
- “The grant is not hypothesis-driven and there are concerns about feasibility that limit the transformational potential.”
- “Contingencies and alternative plans should be addressed.”
- “lack of experimental details and methods for validation/assessment of results”
- “Much of the proposal is early stage and unlikely to be ready for a Transformational award in 2 years.”
- “It is hard to determine the precedent and rationale from the description.”
- “The project is based on a single agent with an indirect mechanism of action, tested in an artificial context.”
- “One of the figures appears to have data panels missing as it does not line up with the figure legend and proposal text.”

New online system: HRiA Award Manager – Key Changes

1. Individual Attachments rather than one PDF upload

2. Using the Invitations feature

Role Name	Permissions/Requirements
Authorized Institutional Representative (pre-award)	Required to Certify application
Institutional Officer (post-award)	Required to submit ACH if funded
Collaborator (grant writing staff; project personnel/co-investigator/Multi-PI)	Has edit access

Invitations Feature – Request ASAP!

HEALTH RESOURCES IN ACTION Applicant Home

6 of 7

Logs

Main

Invitations 1

2025-2156 Test Organization

Authorized Institutional Representative
You are **required** to invite an Authorized Institutional Representative who must "Accept" the invitation and complete the "Certification" tab prior to your submission.

- Biomedical research applicants - The Authorized Institutional Representative is responsible for research oversight and is often in the Office of Sponsored Programs. This person signs off on the application to ensure that you and the Institution have met the eligibility requirements.
- Community-based organization applicants - The Authorized Institutional Representative may be the Chief Executive Officer/Executive Director or other senior leader and signs off on the application to ensure that the lead applicant and project team have met the eligibility requirements.

Institutional Officer
You are **required** to invite an Institutional Officer who must "Accept" the invitation prior to your submission. The Institutional Officer is typically the Fiscal Officer and receives award payments, prepares fiscal reports and oversees other financial requirements of your grant. If your project is funded, this individual will be responsible for submitting banking information.

Collaborator/Multi-PI
Users added as this role will be able to make changes to the application but will not be able to submit.

- Collaborators: Collaborators include anyone who will help you write/edit this grant. This may include grantwriting/pre-award staff and/or project personnel.
- Multi-PI: If you are applying for a biomedical grant, please refer to the Program Guidelines for further information on use of these roles, as some HRIA grant programs do not recognize a multi-PI.

Prefix	First Name	Last Name	Email	Role	Status
	Test	Test	LWilliams+TESTAIR3@hria.org	Authorized Institutional Representative	Accepted

+

Save Invite

Questions?

Contact Us:

FalkAwards@hria.org

Catalyst Award:

<https://hria.org/grants/falkcap/>

Transformational Award:

<https://hria.org/grants/falktap/>



Q&A – Research Focus

- **Is the trust looking to fund projects focused on a specific disease?**
 - No, the Falk Program does not have a specific disease focus.
- **Is the award limited to drug development or clinical trials, or are all types of interventions considered?**
 - No, the award is not limited. As long as the research involves “the development of a therapeutic agent that will disrupt, arrest, or prevent the disease process”, it would be considered.
- **Is the award open to drug discovery tools or platform technologies with the potential to identify novel therapeutics?**
 - The program is not designed to support projects where the main goal is tool or model development. In general, these projects are not successful unless tied to a specific research question that can be clearly translated into clinical development within a reasonable time frame.
- **What kind of investigator initiated trials are supported?**
 - Investigator initiated trials are considered if they are original, hypothesis driven, sufficiently powered, and supported by strong preliminary data. In addition, investigators need to ensure feasibility by having a plan in place to acquire the necessary regulatory and safety approvals, as well as having a robust participant recruitment plan. Applicants are encouraged to reach out to program staff to determine the eligibility of proposed investigator initiated trials.

Q&A – Eligibility & Application

- **Does a Multi-PI on an Award have to be from an eligible institution?**
 - No, only the Administrative PI is required to be from an eligible institution.
- **Is preliminary data required to apply?**
 - It is not required, but highly encouraged. A project lacking enough preliminary data to support the project rationale is unlikely to be funded.
- **Do resubmissions have any additional documentation/criteria required?**
 - Yes, project resubmissions will be required to include a Resubmission Response (300 words max) that provide a high-level description of the issues raised by reviewers and how those were addressed in the current proposal.
- **Do you have to reapply consecutively, or can years pass in between doing so?**
 - Applicants can reapply to the Catalyst program at any time - there is no limit. However, Catalyst awardees have a limited time to apply to the Transformational program (they can apply the year the award ends or 1 year after, and are allowed one resubmission).
- **Can funds be used to cover expenses of a foreign co-investigator, collaborator, or service?**
 - Yes. There are no limitations on international use of funds.

Q&A – Transformational Application/Award

- **Is Institutional nomination required for the Transformational application?**

- Only successful Catalyst Awardees are eligible to apply for the Transformational Award. Nominations are required for the Catalyst Award, but a second nomination is not required for the Transformational.

- **Can I apply for a Transformational award without having a Catalyst award?**

- No. Only prior Catalyst awardees (in their final year or the year following) are eligible.

- **Can the Transformational Award go in a new direction from what was proposed in the Catalyst Award?**

- The Transformational Award is intended to continue to build upon the aims and disease focus from the Catalyst Award to move a healthcare innovation toward the next step in commercial development. If the Catalyst was not successful, awardees should consider reapplying to the Catalyst program with a new project. It may be acceptable for the Transformational Award to have a new specific aim. In this case, we encourage applicants to reach out to Program Staff to confirm eligibility.

Office Hours Recording Link



View the Office Hours Recording
HERE