Dr. Ralph and Marian Falk Medical Research Trust Awards Programs Catalyst Award

Frequently Asked Questions

Grant Cycle 2024

<u>General</u>

What is the goal of the Falk Trust Catalyst Award?

The Catalyst Research Award Program provides one to two years of seed funding to support translational research projects that address critical scientific and therapeutic roadblocks. The program is designed to enable planning and development of projects, teams, tools, techniques, and management infrastructure necessary to successfully compete for a two- to three-year award through the Transformational Research Award Program.

What types of proposals will be most competitive?

The Falk Trust is interested in transformational efforts to cure disease and reduce suffering. Therefore, proposals that seek to move a basic science insight toward a solution, technique, or tool that can be transferred to clinical practice *in the near term* will be most competitive. Catalyst Award proposals that establish milestones that effectively test the clinical utility of science-based innovation, and that may realistically result in products or ideas that will move to the next step in commercial development by the end of the Catalyst/Transformational awards cycle are most likely to gather positive reviews. The reviewers include professionals with translational expertise such as academic researchers, venture capital investors, and biotech executives. For those investigators who have previous experience with NIH awards, this is more similar to the small business innovation research award program than to an R01 mechanism.

How do lapply?

Please go to <u>https://hria.org/tmf/FalkCAP</u> and download the Guidelines and Instructions. To start a new application, please use the following link: https://www.GrantRequest.com/SID_738?SA=SNA&FID=35089.

Eligibility

Can I apply if my institution is not on the invite list?

In order to apply, the Lead Applicant or principal investigator (PI) must hold a full-time faculty appointment at an eligible institution on the invited institutions list. The project must also be nominated by the institution. We encourage those investigators who are not eligible to apply to identify ways to partner with a PI from an eligible institution.

Can I request that my institution get added to the invite list?

Invited institutions have been selected in line with the wishes of the Trust's founder. The eligibility list focuses on research institutions located in the Midwestern United States with a

few exceptions for historical reasons. The number of institutions invited is constrained by reviewer capacity and efforts to keep the application success rate at a reasonable level.

I am based at an institution outside of the United States. Am I eligible?

Lead applicants do not have to be U.S. citizens, but they must hold a faculty appointment at an invited non-profit, academic, medical, or research institution in the United States.

Is there a limit on how many applications may be submitted from one institution? Select institutions may internally nominate up to two applicants for submission to the Program.

Must the lead applicant be nominated by their institution? Yes.

Am I eligible to apply if I hold an appointment at an invited institution but am employed by another institution? To be eligible, the administrative lead must be based at and hold a full-time faculty appointment at the nominating institution. We consider the entity where the lead applicant's research will be conducted to be the nominating institution, and the nominating institution must be the primary funding recipient if the application is awarded.

Is there a limit on how many applications in one cycle may be submitted from one applicant? Yes, one application per Principal Investigator (PI) or multi-PI.

May I apply with a Co-Principal Investigator and/or a Co-Investigator?

Yes, although we no longer use these terms. One principal investigator (Applicant) must be identified as the lead or administrative PI of the award. The administrative PI will be responsible for all grant reporting and fiscal management. For other key personnel, please describe their roles using the terminology given in the Guidelines (multi-PI and collaborator), and do not use terms such as Co-PI and Co-I as these are not recognized by this program.

May a Pl on one grant also be part of another grant submission?

Yes. A PI on one grant may be listed as personnel on someone else's grant but not in a major role such as multi-PI. It is acceptable to have a role as collaborator or other personnel within the same cycle.

May a Pl on one grant also be multi-Pl on another grant?

No, only one application as PI or multi-PI is permitted per cycle.

I am Adjunct Faculty at my institution. May I apply as a lead applicant?

No. The program only accepts applications from full-time independent faculty members.

I would like to apply as a multi-PI. Both the administrative PI and I are from different eligible institutions. Would I be considered one of my institution's two nominees?

No, each institution is allowed to nominate two projects led by principal investigators at their institution. Multi-Pls and sub-contracted individuals from other eligible institutions on those projects are not counted as one of the two nominees from their own institution.



My research topic is related to human health and improving health care services. Am I eligible?

Research projects supported by the Falk program must be within three areas of focus: 1) identification of biological markers of disease activity and progression, 2) identification of targets for therapeutic interventions, and 3) development of therapeutic agents that will disrupt, arrest, or prevent the disease process. These are typically biomedical research projects, thus health systems or public health research projects are not normally within the scope of work supported. For specific questions regarding whether a research topic is eligible, please email us at FalkAwards@hria.org.

My research topic is related to device development. Am I eligible?

As of 2023, projects relating to the development of medical devices will be eligible. The project must still speak to the mission of the trust and be within one of the three areas of focus. For specific questions regarding whether a research topic is eligible, please email us at FalkAwards@hria.org.

My research topic is related to model validation. Am I eligible?

You may be eligible, however, in general these types of projects are not successful unless tied to a specific research question and can be clearly translated into clinical development within a reasonable time frame.

Proposal Application

May I submit a project that involves human subjects?

Yes. Investigator-initiated trials are allowed under strict criteria. Please see the Research Focus section of the guidelines for more information. Additionally, basic research projects using human specimens are eligible.

Are there formatting rules for the Research Proposal?

Yes - please refer to the Guidelines and application form template for specific instructions.

Should the references be placed after the Research Proposal?

Yes, please add any references cited after the research proposal. The bibliography of references related to the project are excluded from the word count and page limit maximums.

Are the section headings mentioned in the Research Proposal portion required or may other headings be included?

Please prepare your proposal using the headings in the Guidelines and application form template.

Do you have a Biosketch form I should use? Use the current NIH form for your Biographical Sketch (https://grants.nih.gov/grants/forms/biosketch.htm).



I have a multi-PI. Should their Biosketch be included in the Attachment?

Yes - please include Biosketch(es) for any multi-Pls.

How should the multi-PIs be reflected in the proposal?

In addition to the list of key personnel on the application cover page and the multi-Pls' Biosketch(es) in the PDF upload, all of the key personnel should be listed with their roles in the "Investigative team" section of the research proposal. The information should also be included in the "management plan" page at the end of the proposal. Current and pending support for all multi-Pls should also be provided within the budget spreadsheet.

Where do I find the Application Form templates?

The Application form templates are downloadable documents found at: https://hria.org/tmf/FalkCAP.

Can the start date of the award be adjusted?

Yes, an award recipient may postpone the start date for up to three months. Longer delays must be approved and will only be allowed under exceptional circumstances.

May I use the NIH Current and Pending Support Form?

For each source of funding, please transfer the information from the NIH form to the Other Support section of the Budget Form provided with the application. Please include current and pending support for the Lead Pl and any multi-Pls, and for any collaborators who are Key Personnel and have funding related to the proposed project.

How much money will be given each year of the award and how should I budget accordingly?

We typically encourage applicants to evenly split the budget evenly between award years. However, the Applicant may request more money in a particular year of the award if they have a justifiable reason. This information will be available to the reviewers so a detailed justification should be made explaining why this is necessary.

Is the project budget subject to the NIH salary cap requirements?

Yes. The compensation for individuals funded by Falk awards cannot exceed the NIH salary cap. For individuals whose institutional salary exceeds the applicable rate, the amount of salary charged to the Falk award must be limited to their percent effort multiplied by the salary cap rate. Salaries must be in proportion to the percent effort on the research project; however, percent effort may exceed the percent of total salary support requested from the Program. If the requested salary for any personnel listed on the proposal exceeds the NIH salary cap the application will not be processed.

Is tuition for graduate students an allowable expense under this program?

Tuition for graduate students is an allowable expense. This expense should be in proportion to the student's time on the project and should be listed in the Other Expenses category and on the Budget Justification tab of the Budget Template Form.



Are subcontracts allowed to a collaborator at a non-invited institution? How much of the award can be subcontracted?

Yes, subcontracts are allowed to institutions not on the invited institution list. Only the administrative PI needs to have a primary appointment at an eligible institution. The majority of awarded funding should be used to support research at the nominating institution. Budgets for large sub-contracts (amounts greater than what is budgeted for at the recipient institution) will be heavily scrutinized and must be properly justified.

What is the difference between the Authorized Institutional Representative and the Institutional Officer to Receive Funds?

Depending on the institution, the Office of Sponsored Programs (or similar grants management department) will sign off on the application to ensure that the statements contained in the application are true and complete, that the terms of the award are understood, and that you and the Institution have met the eligibility requirements. The Institutional Officer to Receive Funds is typically within the finance or accounting office. Please check with your institution to determine who should certify the application.

Online Application

Where do I find my Institution's Tax ID?

Please contact your Office of Sponsored Programs for this number.

How do laccess the Online Application?

Use this link to begin a NEW application:

https://www.GrantRequest.com/SID_738?SA=SNA&FID=35089

I have started and saved an Online Application. However, when I try to log-in, I cannot find my previous application. Do I need to start a new one?

No – there is a separate log-in link for applicants who have already started and saved an application. Please be sure to click the link titled, "Return to a Saved Online Application" to access your previous form.

Return to a SAVED application:

https://www.GrantRequest.com/SID_738?SA=AM

What will be asked in the Online Application?

Your Institution's Tax ID number, an Eligibility Quiz, followed by Contact Information, Educational Background, Institutional information, Key Personnel, Project Title, Keywords, Project Summary, Non-technical Summary and Overview, Experimental Systems, Translational Stage, Description of Translational Potential, Applicant's initials to certify the accuracy of submitted information, acceptance of Terms of Award, and accuracy of submitted information.



Post Award

If I am offered the Award but cannot accept it, may it be transferred to a collaborator or other individual significantly involved in the project?

No. The grant can only be awarded to the Pl or multi-Pls who originally submitted the grant application.

If I apply and do not receive an Award, may I apply in future years? Will I be at a disadvantage if I reapply?

Yes. You may apply again if your institution is invited to apply in future years and your proposal is nominated. There is no inherent disadvantage in applicants reapplying, however we would encourage any resubmissions to carefully consider and address any concerns noted in the Reviewer feedback.

As a Catalyst Awardee, when am I eligible to apply for the Transformational Program?

Catalyst Awardees are encouraged to apply for the Transformational Award if the proposed benchmarks and milestones outlined in their Catalyst Awards have been successfully achieved. To maintain momentum, Catalyst Awardees with grants in progress who have hit their Catalyst milestones and benchmarks earlier than the official end date, or who are clearly on track to hit these, are welcome to apply. Otherwise, Applicants may apply during the final year of their Catalyst Award, or the year following, and must not have previously applied for a Transformational Award. For example, Applicants will be eligible to apply for the 2024 Falk Transformational Program if their Catalyst Award ends between November 2023 and February 2025.

What happens if my Catalyst Award does not go as planned? If I don't achieve my proposed milestones can I still apply for the Transformational Award?

This program is designed to support high-risk, high-reward projects. As such, many projects do not achieve the proposed milestones as planned. We applaud Applicants and Awardees for taking on such high-risk projects and see all progress as a positive outcome. However, if milestones and benchmarks have not been met and there is not enough preliminary data or rationale for further support through the Transformational Award, Awardee's are encouraged to consider re-applying for another Catalyst Award.

I was given more funding than I had budgeted. How should I proceed with spending on my award?

On occasion, payments may be greater than the original budgeted amount to meet disbursement requirements of the Funder. However, Awardees are still expected to make expenditures in alignment with their original budget, not the actual payment made. Awardees will not need to count the extra funds as carryover into subsequent years.

Contact

FalkAwards@hria.org

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