

Dr. Ralph and Marian Falk Medical Research Trust Awards Programs

Transformational Award

*A program of the Dr. Ralph and Marian Falk Medical Research Trust
U.S. Trust, Bank of America, N.A., Trustee*

Application Guidelines

Grant Cycle 2019

Submission Deadline:

July 25, 2019

2:00 PM, Eastern Daylight Time

Award Period: 11/30/19 – 11/29/21

Award Amount: Two-year awards of up to \$1,000,000 (\$500,000 each year)

The number of Transformational Awards available will be determined by the Trustee each year, depending on the availability of funds and the merit of the applications received.

Applicants: Only Catalyst Awardees meeting the eligibility requirements are permitted to apply for a Transformational Award

Program Overview and Statement of Purpose:

The Dr. Ralph and Marian Falk Medical Research Trust was created by Marian Falk in 1979, and was fully funded upon her death in 1991. Mrs. Falk had very strong views on how best to support biomedical research. She sought out brilliant investigators and supported them, as well as the young investigators who worked with them, by funding **“medical research to improve treatments of the past and eventually find cures for diseases for which no definite cure is known.”**

In 2014, the Falk Medical Research Trust launched a new program to fund transformational research focused on increasing the impact of its funding. These new award programs provide support in moving insights gained from basic science into clinical practice. In keeping with the intention to fund breakthrough research designed to overcome roadblocks in scientific progress, there are two separate linked awards:

- The ***Catalyst Research Award*** provides one-year seed funding to help investigators lay the foundation for the Transformational Award. Select institutions are invited to submit up to two applications per grant cycle.
- The ***Transformational Research Award*** provides two years of additional research funding to support successful projects funded by a Catalyst Award and help them achieve their final goals. Applications will be accepted only from prior Catalyst awardees that have successfully achieved the proposed benchmarks and milestones outlined in their Catalyst Award proposals. Catalyst Awardees may only apply for a Transformational Award once.

The Catalyst Awards provide an opportunity to conduct preliminary work on high-risk, high-reward research addressing a wide variety of clinical disease areas. The target of the Falk Catalyst's funding are projects at the intersection of technology and clinical science, intended to move from insights gained from basic science towards creating solutions, techniques and tools that can be transferred to clinical practice in the near term. The Catalyst Awards are a stepping stone to eligibility for the Falk Transformational Awards Program. Catalyst research projects must describe specific **milestones and benchmarks** that if successfully met, would then enable recipients to apply for additional funding through the two-year Transformational Awards program.

The Dr. Ralph and Marian Falk Medical Research Trust, Bank of America, N.A., Trustee, works with The Medical Foundation at *Health Resources in Action* (HRiA), to select the most qualified applicants. HRiA is a nonprofit organization in Boston, MA that advances public health and medical research through the creation and oversight of biomedical research grant programs.

Research Focus:

This program is designed to support high-risk, high-reward projects that address critical scientific and therapeutic roadblocks. The Transformational Award provides a bridge to the technology transfer process for moving an exciting health care innovation to the next step in commercial development.

If successful, these project will open new avenues for treating and curing disease. The Program has three principal 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.

This request for proposals pertains to the *Transformational Research Award*.

The Transformational Research Award Program will provide two years of funding to complete the research program started, and supported by the Catalyst Award. Successful applications will summarize the results of their Catalyst Award project and describe the transformative research program that will be conducted and completed within the two year Transformational Award.

Applications should address at least one of the three principle areas of focus of this research program, listed above.

Transformational Awards will be granted based on both scientific merit and having successfully attained the proposed milestones and benchmarks of the Catalyst Award, thus demonstrating its successful execution within the proposed budget and projected timeframe.

Eligibility Requirements:

Only Catalyst Awardees are eligible to apply for a Transformational Award:

- Received a Catalyst Award in 2017 (with approved NCE) or 2018 and not previously applied for a Transformational Award
- Successfully achieved the proposed benchmarks and milestones outlined in their Catalyst Award proposal
- Hold a full-time faculty appointment
- Are independent investigator(s) with demonstrated institutional support and the specialized space and facilities needed to conduct the proposed research
- Applicants may not have funding for a similar project
- United States citizenship is not required; visa documentation is not required.
- Each PI may submit only one application

Collaborations:

The Trust encourages the use of synergistic collaborations between industry, government, academic and disease-advocacy organizations that integrate complementary expertise capable of addressing roadblocks and accelerating achievement of critical research objectives. Proposals that extend or apply such ongoing collaborations are encouraged, as are those that establish new ones. Awards will be made via a contract awarded to a single institution responsible for satisfying the administration, performance and reporting requirement of the contract. Other collaborating organizations, both non-profit and for-profit, may be sub-contracted to the lead institution and must designate a lead principal investigator who is responsible for performance under the contract.

In support of this collaborative approach, the Transformational Program may provide funding to investigators for:

- Identifying any competencies necessary to complete the project that are not available within the applicant institution,
- Identifying collaborators who will provide those competencies,
- Building relationships and negotiating contracts between institutions,
- Internal development of critical expertise or tools that are not available from external sources, and
- Building the management infrastructure to support future project proposals.

Project Key Personnel:

- **Principal Investigator (PI):** One principal investigator (Applicant) must be identified as the lead or administrative PI of the award, who will be responsible for all grant reporting and fiscal management. The lead or administrative PI will be the main contact for budget and reporting management.
- **Co-Principal Investigator (Co-PI)** Up to one Co-Principle Investigator may be identified; the application should describe the need for a Co-PI and multiple PI management coordination.

- **Co-Investigators:** Co-Investigators must provide a major intellectual contribution to the project. Co-Investigators may share Award funding.

Review Criteria:

- How well has the applicant met the milestones and benchmarks of the Catalyst award?
Note that this application may include, or reference, a detailed progress report of the prior catalyst award, referencing or updating the summary table from the original application. In the event that unforeseen results resulted in a change in strategy that led to alterations in the originally proposed research plan, this should be noted and described.
- Are the *specific aims* measurable and feasible within the timeline proposed?
- Are the proposed *methods* sound and, when appropriate, are proper statistical analyses provided?
- Is the *team* capable of carrying out the proposed research, and do they have the necessary infrastructure, experience and support to do so?
- Overall, will the proposed research program achieve high *impact* in addressing human disease?
- *Applicants should be mindful of proper formatting and general proof reading standards and review proposals thoroughly before submitting.*

Notification to Candidates:

Receipt of submitted applications will be acknowledged by automated email from the online system. Final notification to applicants will occur by October for the November 30th funding start date, upon completion of the approval process.

Terms of the Award

Overview: Awards are made to non-profit academic, medical or research institutions in the United States on behalf of the Award Recipients. The Award Recipient Institution is responsible for the administrative and financial management of the project, including any subcontracts, and maintaining adequate supporting records and receipts of expenditures.

The Falk Trust Awards Programs is managed by The Medical Foundation, *at Health Resources in Action* (HRiA). HRiA is a nonprofit organization in Boston that advances public health and medical research.

Award Amount and Funding Period: Two-year awards totaling up to \$1,000,000 (\$500,000 per year) will be awarded for the funding period. The start date of the Award may be postponed for up to three months without a formal request. Any longer delays must be approved by The Medical Foundation. A delayed start date will not reduce the total Award Period (i.e., a project start date of February 28th will revise the project end date to February 27th).

Institutional Assurances: The Award Recipient must adhere to all federal, state, and local regulations regarding the use of human subjects (including informed consent), animals, radioactive or hazardous materials, and recombinant DNA in this research project. It is the

Institution's responsibility to ensure that all approvals have been secured prior to releasing the Award funds. An Authorized Institutional Representative must acknowledge understanding of these responsibilities on the submitted Application and the Institutional Officer must confirm this oversight before award funds are released.

Liability: The Dr. Ralph and Marian Falk Trust and The Medical Foundation at HRiA, do not assume, and are exonerated from, any liability or responsibility for activities supported by this Award including, without limitation, incidents or accidents involving the undersigned whether on travel, in the laboratory or classroom or elsewhere.

Scientific Misconduct: The Medical Foundation also requires that the appropriate federal, state, and local guidelines with regard to scientific misconduct are in place and enforced at the Award Recipient Institution. In the unlikely event that an Award Recipient is involved in an investigation of scientific and/or financial misconduct, he or she will be subject to the procedures in place at the Institution. The Institution must notify The Medical Foundation of both the investigation and the procedures that the Institution will follow.

According to the NIH/U.S. Department of Health and Human Services, research misconduct is defined as the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." A finding of scientific and/or financial misconduct must be reported to The Medical Foundation and may affect the Award Recipient's continued eligibility for support under this Program.

Use of the Award Funds: The laws of the United States place certain restrictions on the manner in which funds awarded to organizations by charitable trusts and foundations may be expended. The award from the Falk Trust may be used to support the Award Recipient's salary and fringe benefits; salaries and fringe benefits of postdoctoral fellows, technicians or graduate students; publication of scientific data; travel to scientific meetings; laboratory and data processing supplies; and other direct expenses such as equipment essential to the project. 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 Falk Trust.

Funds may not be used for new construction, the renovation of existing facilities, fundraising projects or endowments. Funds may not be used for any political activity, accumulated deficits, or for any other purpose prohibited by the Internal Revenue Service Code. Funds awarded for the direct costs of the project may not be used for general operating costs. The grant monies which have been awarded, including any interest earned therein, may only be used for the purposes stated in this agreement.

Indirect costs (institutional overhead): Indirect Costs may not exceed 10% of direct costs or \$90,909 total, or \$45,454 in either year. In instances where there is a subcontract, the combined dollar amount for indirects taken by both the Award Recipient Institution and the contracting institution may not exceed \$90,909 per award.

Re-budgeting: Expenditures are expected to be within reasonable range of the Budget that was submitted with the grant application. All requests for re-budgeting or reallocation of grant funds *over \$20,000* must be conveyed by email to The Medical Foundation Program Staff. The request must include the current and revised allocation of resources along with specific detail and justification for the reallocation.

Financial Responsibilities of Award Recipient Institution: The Institution will keep systematic records of all expenditures relating to this Award. Vouchers consisting of bills, invoices, cancelled checks, receipts, etc. will be retained by the Award Recipient Institution for three (3) years after the close of the Award Period and will be available for inspection by representatives of the Falk Trust during normal business hours and upon reasonable notice throughout this period. The Falk Trust may, at its own expense, examine, audit, or have audited the records of the Institution insofar as they relate to activities supported by this Award. When requested, the Award recipient institution must be able to provide IRS form 990 tax returns and audited financial statements for the last three years.

No-Cost Extension: Before the end of the Award Period, a no-cost extension for up to nine months may be requested via email notification to the Program Staff. The Award Recipient shall provide an explanation for the extension, the unexpended balance, and a timeline for completing the project. Any funds remaining at the close of the extended project period must be returned to The Medical Foundation within sixty (60) days. Final Scientific and Fiscal Reports will be due at the completion of the extension.

Transfer or Termination of Award: Awards are made to the Institution where the named Award Recipient is conducting research. If the Award Recipient is planning a move to another nonprofit research institution during the Award Period, transfer of funds to continue the project must be requested via email to the Program Staff. This communication must include a letter from the new Department Chair confirming the availability of resources to continue the project as well as a Fiscal Report stating the remaining fund balance. If the transfer is approved, the Award Recipient and the new Institution will be responsible for notifying The Medical Foundation of the new payee information and coordinating the fund transfer.

If the Award Recipient is not continuing the research in another nonprofit research setting, the Award will be cancelled and unused funds must be returned within sixty (60) days. Disposition of any equipment purchased by the Award Recipient with Falk Trust Award funds will be evaluated on a case by case basis. Transfer of the Falk Trust Award to another PI is not permitted.

Change in Award Recipient Status: It is also the responsibility of the Award Recipient as well as the Award Recipient Institution to notify The Medical Foundation of any change in employment status of the Award Recipient **at least 30 days prior to such change.**

Unused Funds and Reversion: Should any of the following events occur, The Medical Foundation on behalf of the Falk Trust, may demand repayment of all unexpended portions of the Award; moreover, all unpaid installments may be cancelled. The Award Recipient Institution is also required to give written notice if there is a change in the Institution's status as noted below:

- A determination, preliminary or otherwise, is made by the U.S. Internal Revenue Service that the grant does not constitute a qualifying distribution.
- The Institution fails to perform any of its duties, in the judgment of The Medical Foundation or its Scientific Review Committee, required by the terms of this Award. In such cases, the Foundation shall provide no less than thirty (30) days termination notice in writing to the Institution, upon which the Institution shall have an additional thirty (30) days following receipt of such notice within which to cure any deemed failures.
- The Award Recipient Institution ceases to be exempt from income taxes under the U.S. Internal Revenue Service Code or becomes a private foundation.
- There is a material change in the purpose, character, or method of operation of the Institution such as to jeopardize its tax status.

Medical and Family Leave: The Award Recipient may continue to expend any Award funds allocated to salary during medical or parental leave consistent with the Institutional level of paid leave for such purposes.

Reporting Requirements: A Progress Narrative and Financial Report is due 60 days prior to the start of year two of funding. The Award Recipient will receive an email notice and forms for these reports, approximately three weeks prior to their due dates. Final Narrative and Fiscal reports are due sixty (60) days following conclusion of the Award Period. The Falk Trust and The Medical Foundation reserve the right to place a hold on funds in cases where the Award Recipient is non-compliant with these Reporting Requirements.

Patents, Copyright and Intellectual Property: Award Recipients should follow their Institutions' patent, copyright, and intellectual property policies regarding discoveries or any other intellectual property that result from research conducted under this Award. The Falk Trust and The Medical Foundation will not retain any rights to intellectual property including patents, copyrights, trademarks, or other proprietary rights that result from the research.

Confidentiality and Third Party Release: Application Materials, as well as Scientific Progress and Final reports, are considered confidential. The Medical Foundation engages contracted third parties who have the necessary expertise to review the submitted materials and evaluate the project. Although The Medical Foundation endeavors to protect the confidentiality of the reports by requiring reviewers to sign confidentiality agreements, confidentiality cannot be guaranteed. The Medical Foundation or the Falk Trust will not be responsible for any consequences or damages resulting from the disclosure of the content of these materials to such third parties.

The Medical Foundation and the Falk Trust reserve the right to public acknowledgement of Award information (Award Recipient Name, Award Recipient Institution, Project Title and Research Project Summary). This information will be made available through the website of The Medical Foundation at Health Resources in Action (<https://hria.org/tmf/FalkTAP>) and may be posted on other affiliated organization websites, publicly accessible databases of privately funded awards, or published in print form or other media.

Scientific Meetings: Awardees will be expected to share ideas and present research findings throughout the Award period at scientific meetings or symposiums.

Additional Support: Awards from the Falk Trust are made for the specified award period. In making this Award, the Falk Trust assumes no obligation to provide additional support to the Award Recipient beyond the original award period.

Scientific Publications: Publications or presentations resulting from research supported by this Award must acknowledge the **Dr. Ralph and Marian Falk Medical Research Trust Awards Programs**.

Acknowledgements: The Award Recipient and Institution are encouraged to announce receipt of this Award entitled, the **Dr. Ralph and Marian Falk Medical Research Trust Transformational Awards Program** and credit financial support to the Dr. Ralph and Marian Falk Medical Research Trust. Disclosure of additional details regarding the Falk Trust must be approved by the Falk Trust.

Post Award Reporting: The Award Recipient will respond to The Medical Foundation's requests for information on his/her research progress following the Award Period and may be requested to provide a current Curriculum Vitae or update information in an online database. The Recipient understands that this obligation survives the Award Period.

ONLINE APPLICATION INSTRUCTIONS

Use one of the following links to begin or continue the application process:

Begin a NEW application: https://www.GrantRequest.com/SID_738?SA=SNA&FID=35094

Account page to return to a SAVED application: https://www.GrantRequest.com/SID_738?SA=AM

Sharing/Transferring your application with your Institutional Representative (s) for Certification

- The Applicant is considered the “Owner” of this request. The Applicant/Owner is required to secure sign off from their Institutional Representatives, such as OSP and Finance, by “transferring ownership” temporarily to complete the Institutional Representative Information
- Transfer takes place on the applicant’s account page
https://www.GrantRequest.com/SID_738?SA=AM
- All contacts must have an Account to share applications
- New users will Create an Account with their own email and password
- Use the transfer  icon under the **Action** heading to transfer ownership
- The Institutional Representative will transfer ownership back to the Applicant prior to submission

Please complete the following tabs in the online form:

- Institution’s Tax ID Number**
- Eligibility Quiz**
- Applicant Data:** Institution, Contact, and Educational background information. Provide the PI’s ORCID identification number, if available. If there are two **Co-PIs**, one must be designated as the “Administrative or Lead” PI and only that person will complete the Face Sheet.
- Key Personnel:** Co-PI and Co-Investigator’s name and institutional affiliation should be supplied in the Key Personnel fields, if applicable.
- Research Project:** Project Title, Keywords, Project Summary, Non-technical Summary and Applicant’s initials to certify the accuracy of submitted information
- Institutional Contact Information:** Complete Institutional Contact fields. Certification by the Institutional Representative on the application will acknowledge understanding of the terms of the Program, and that the proposal has been reviewed and has been approved for submission to the Program.
- Attachments:** All items must be combined into ONE PDF for upload to the Online Application. Upload the **Transformational Proposal** which includes the following forms and documents. On the final PDF, make sure all pages are numbered sequentially starting with the Application Face Sheet as page #1. This PDF must be named LastName, FirstName 2019T.pdf (for example, Doe, Jane 2019T.pdf).
- Templates are provided for items A-C (Word), D and E (Excel):**
<https://hria.org/tmf/FalkTAP>

- A. Face Sheet:** The Face Sheet (Form A) template must be completed by the Applicant and the Office of Sponsored Programs or the Institutional Officer administratively responsible for the oversight of the project. The Applicant on the Face Sheet confirms their responsibility for obtaining any required human subjects (IRB), animal use (IACUC), or institutional equivalent approvals. In addition, the Institutional Officer confirms that all eligibility requirements have been met. Endorsement by the Institutional Officer confirms that the Institution will commit to appropriate oversight if the project is funded. The Face Sheet is used as page 1.
- B. Table of Contents** (Form B): Follow the Table of Contents template and number all pages sequentially.
- C. Project Summary** (Form C): Copy the Project Summary from the Online Form into the Project Summary template. The 400-word summary should state the project's broad, long-term objectives and specific aims.
- D. Budget, Summary, and Justification** (Form D): Complete each tab in the Excel spreadsheet template. Indirect costs (institutional overhead) may not exceed 10% of direct costs or \$90,909 total or \$45,454 in either year. In instances where there is a subcontract, the combined dollar amount for indirects taken by both the Award Recipient Institution and the contracting institution may not exceed total allowed indirects per award.
- E. Other Support Page** (Form E): Using the Other Support template:
- PI/Applicant should list all active and pending support, addressing potential overlap for each at the level of the specific aims with the submission.
 - Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.
 - Effort devoted to projects must be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.
 - Guidance regarding the type and extent of information requested is included within the template. Please delete the example before submission.
 - **If applicable, please also provide grant overlap for co-investigator's/key personnel.**
- F. Research Proposal (maximum of nine pages, excluding references cited):** Outline succinctly how the proposed research project addresses critical scientific and therapeutic roadblocks that may open new avenues for treating and curing disease.

Research Proposal Format: Arial 11 font and size must be used in the text of the research proposal section. Use single spacing within paragraphs, double spacing between paragraphs and ½ inch or larger margins on all four sides. Any figures, graphs, tables or pictures must be included within the nine-page limit. For these visuals, the minimum is an 8 point-font size. Supplementary material (e.g. reprints of publications, appendices, and additional data) are not permitted.

Within the page limit, include these sections:

- 1) **Background and Significance:** summarize the previously approved, detailed rationale for the entire transformational research program. Be sure to include any new advances since the Catalyst Award application was written.
- 2) **Specific Aims (*maximum one page*):** These should be specific, measurable, and necessary aims for the overall research effort. These should be based on those in the original Catalyst Awards, but may be modified to reflect the results of the Catalyst award or accumulating knowledge in the field.
- 3) **Preliminary data:** Describe the results of the Catalyst award that have informed this proposal, referencing the summary table from the original Catalyst application
- 4) **Research design, experimental methods and analytical plan**
- 5) **Research limitations and contingencies**
- 6) **Transformational Project Milestones and Research Plan:** Create a summary table, based on the specific aims of the original Catalyst project, which describes the proposed milestones and benchmarks. The successful completion of these activities **will form the basis of measuring achievement of the project goals**. Please include specific data, methods, and benchmarks that will demonstrate achievement of the milestone. Quantitative benchmarks must include statistical methods including sample size justification. *Note:* (1) All personnel and collaborations should be related to the achievement of milestones. (2) Please include a milestone that describes plans for dissemination of results.
- 7) **Optional Sections, not included in page limit:** (a) management plan – required for multiple co-PI projects, optional for others. (b) Human or animal studies considerations, as applicable. For human studies, include an enrollment table that describes recruitment of women and minority participants.
- 8) **Literature Cited (not included in page limit)**

G. Biosketch of PI/Applicant (use the latest NIH biosketch, max 5 pages): If applicable, please also include Co-Investigator Biographical Sketch(es) to the upload. It is not necessary to include a Collaborators biosketch unless they are key personnel.

H. Department or Division Chair's Letter: This letter (forwarded to the Applicant for upload) must address the applicant's qualifications to conduct the proposed research independently as well as note the space and equipment available for the completion of the project. If the applicant is Chair of his/her department, a letter of recommendation from the Dean should be submitted.

I. Letter(s) of Collaboration (if applicable): When applicable, letters confirming the availability of resources outside the Applicant's institution or letters confirming any significant collaboration may be included (forwarded to the Applicant for upload). These are not additional letters of recommendation.

Out of fairness to applicants who adhere to the Guidelines, applications that do not conform to the stated instructions will be rejected.

Frequently Asked Questions: Please review the FAQs: <https://hria.org/tmf/FalkTAP>

Or Email: grants@hria.org