Dr. Ralph and Marian Falk Medical Research Trust Awards Program
Transformational Award

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

Request for Applications and Application Guidelines   Grant Cycle 2022

SUBMISSION DEADLINE: Thursday, June 16 2:00 PM, Eastern Time	Terms of the Award Application Instructions

	CATALYST AWARD	TRANSFORMATIONAL AWARD
AWARD DURATION:	12 - 24 months	24 – 36 months
MAXIMUM AWARD AMOUNT:	Up to $300,000 (inclusive of 10% indirect costs)	Up to $1,000,000 (inclusive of 10% indirect costs)
AWARD START DATE:	November 30, 2022	November 30, 2022
ELIGIBLE CANDIDATES:	Invited institutions may nominate up to two projects.	Prior Catalyst awardees who meet eligibility criteria described below

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 created the Trust to support **"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. This program provides support to move 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 seed funding over one to two years, 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 to three years of additional research funding to support successful projects funded by a Catalyst Award and help them move a healthcare innovation toward the next step in commercial development. Applications will be accepted only from prior Catalyst awardees who 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 Dr. Ralph and Marian Falk Medical Research Trust Awards Programs are administered by Health Resources in Action (the Administrator), on behalf of the Trustee, Bank of America, N.A. (the Funder). HRiA is a nonprofit public health organization dedicated to promoting individual and community health and health equity through prevention, health promotion, policy, and support of medical research.

RESEARCH FOCUS

This program is designed to support high-risk, high-reward projects that address critical scientific and therapeutic roadblocks. If successful, these projects 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.

Applications should be responsive to one of the three principal areas of Research Focus and have high translational potential. Proposals that are not responsive to the mission of the Trust will not be reviewed and the nominating institution may be removed from eligibility. Applications must include clear, achievable milestones that will lead to outcomes expected to have high impact on improving the lives of individuals suffering from disease. Applications for clinical trials will not be accepted.

All stages of the translational research pipeline are eligible for Falk funding. Applicants will be asked to make clear in the application which stage of translation the proposal is targeting.

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.)

TRANSFORMATIONAL AWARD GUIDANCE TO APPLICANTS

The Transformational Research Award Program will provide two to three 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 Transformational Award.

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.

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.

ELIGIBILITY CRITERIA

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

- Applicants must have a Catalyst Award completion date <u>no earlier</u> than July 1, 2021, and must not previously have applied for a Transformational Award.
- The proposed benchmarks and milestones outlined in the Catalyst Award proposal must 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.
- The administrative lead applicant (Principal Investigator) must hold a full-time faculty appointment.
- PIs and multi-PIs must be independent investigator(s) with demonstrated institutional support and the specialized space and facilities needed to conduct the proposed research.
- Applicants and key personnel 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 for a Transformational Award.

COLLABORATIONS

The Trust encourages investigative teams that involve synergistic collaborations between industry, government, academic and disease-advocacy organizations. Collaborations are encouraged to integrate teams horizontally across different disciplines, to involve both PhD and MD researchers, and to integrate teams vertically in terms of investigator seniority.

Collaborations should combine complementary expertise capable of addressing roadblocks and accelerating achievement of critical research objectives. Proposals may extend or apply such ongoing collaborations or establish new ones.

Awards will be made via a contract awarded to a single invited 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.

KEY PERSONNEL, DEFINITIONS:

- **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.
- **Multiple Principal Investigators (Multi-PIs):** Multi-PIs may be proposed for projects that involve a team science leadership approach. The application should describe the need and management plan for multiple PI leadership.
- **Collaborators:** Collaborators may share Award funding.

DURATION AND AWARD AMOUNT

We have seen in previous cycles that the duration and award amount of the Falk awards is not always well-matched to the science proposed. For example, while projects in the later stage of translation or based in large well-staffed labs may be well-positioned to begin immediately upon receipt of funding and may progress quickly, other projects at earlier stages and/or based in smaller groups where additional staff need to be hired sometimes need more time. To address this issue, *we will allow applicants flexibility to select the most appropriate duration and budget for their work, up to the stated limits*.

Given the variety of scientific approaches and types of research that could address the goals of this program, we expect proposals to be of varying duration and cost. Only proposals in which the award duration and budget accurately reflect the needs of the project will advance to the final stage of review. **To ensure the best chance of receiving funding, applicants should request the amount of time and budget that is essential to the proposed research, and clearly justify these choices in the application and budget justification section.** Due to the increased flexibility in the award duration, proposed timelines and milestones should be realistic, and No Cost Extensions will only be approved in exceptional cases.

Falk Catalyst and Transformational funding is intended to support the time-limited project proposed, not the long-term general infrastructure of the institution. If institutions do not have the required equipment to conduct a project, researchers should seek collaborators to help them access it. Plans to purchase equipment with Falk funding will be scrutinized, and equipment requests may be disallowed without opportunity to re-budget.

REVIEW CRITERIA

Translational Potential	Project moves a basic science insight toward a solution, technique, or tool that can be transferred to clinical practice in the near term. *Transformational Award* projects must have achieved their *Catalyst Award* benchmarks and milestones and should move an exciting healthcare innovation toward the next step in commercial development.
Impact	The proposed research project addresses a critical scientific or therapeutic roadblock, will open a new avenue for treating or curing a disease, and will have high impact on improving the lives of patients, if successful. May be high risk.
Investigative Team	The investigative team has the right combination of expertise and high potential to successfully carry out the project, and access to necessary infrastructure. Collaboration with synergistic industry, government, academic, or disease-advocacy organizations that integrate complementary expertise is an additional, but not required, positive factor. Completion of the Catalyst project on time and on budget will be considered favorably.
Project	The proposed work is based on sound precedents and a clear rationale. Objectives are technically feasible. Research methodology is realistic and sufficiently powered. Requested budget and duration are appropriate for the research proposed. *The application may include or reference a detailed progress report from the prior Catalyst award, referencing or updating the summary table from the original application. If unforeseen results resulted in a change in strategy that led to alterations in the originally proposed research plan, this should be noted and described.*

PROPOSAL WRITING TIPS

Applicants are strongly encouraged to prioritize good grant writing in drafting their applications to maximize their chances of being funded. The quality of the written proposal is an important factor in the scoring of proposals, in addition to the quality of the science and the team, and the impact the work will have on patients. The Review Committee is composed of a multi-disciplinary group of professionals such as venture capital investors, biotech executives, and academic researchers, with translational expertise and the ability to assess a wide range of proposal topics. Characteristics of a well-written proposal include the following:

- Main points are communicated clearly and concisely. The big picture of what will be done, why it is important, and how it will advance a project to the next stage of translation is clear.
- The language is understandable to a general scientific audience. When jargon must be used, it is clearly explained, and complex technical points are put in context.
- Concise/essential background, aims, experiments, milestones, and analysis plan are connected using clear logic, and key choices are justified.
- For products that aim to enter a competitive environment, the proposal makes clear how the eventual product will be differentiated in a way that supports commercialization.
- Goals and metrics of success are well-defined.
- The impact of the work and how it will lead to a substantial advance in translational research should be clear.
- Any scientific or budgetary overlap with other current or pending support is clearly described, including a plan to avoid duplication of funding.
- Budgets should reflect the amount needed to conduct the proposed research. The maximum budget should not be requested unless it is genuinely needed.
- The timeline should be feasible, as no cost extensions will only be awarded in exceptional cases.

Applicants are encouraged to seek feedback on their proposals within their institutions and externally. Examples of successful proposals can be found in the grant-writing tip sheets for NIH research grants. Institutions and colleagues may also be willing to provide examples of well-written and successful grant applications.

Suggested resources:

Secrets to Writing a Winning Grant: https://www.nature.com/articles/d41586-019-03914-5

NIH grant writing tips:

https://www.nlm.nih.gov/ep/Tutorial.html

https://www.nimh.nih.gov/funding/grant-writing-and-application-process/grant-writing-tips.shtml

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm#Important%20Writing%20Tips

NOTIFICATION SCHEDULE:

Final notification to applicants will occur in mid-October for the November 30th funding start date. Applicant ranking and scores will not be provided. Key points from reviewer feedback will be provided.

HISTORICAL SUCCESS RATE:

Historical Statistics	2021	2020	2019	2018	2017	2016	2015
Catalyst Submissions	45	44	43	35	40	40	44
Catalyst Award Recipients	16	11	12	11	10	10	9
Transformational Submissions	7	6	9	10	5	6	8
Transformational Award Recipients	3	3	4	3	4	3	5

Terms of the Award

Award Amount and Funding Period: Awards are made according to the stated schedule. Recipients may postpone the start date for up to three (3) months without an approval, but the revised date must be noted either on the signature page of this Agreement or by an email notification to the Administrator. Longer delays must be approved by the Administrator. A delayed start date will not reduce the total award period but will adjust the schedule out to include the entire period.

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

COVID-19 Related Research Disturbances: Upon award funding recommendation notification, the Recipient or recommended principal investigator ("PI") if not the Recipient and the Institution shall confirm that the Recipient's laboratory (and any laboratories/facilities/staff included in the proposed Project) will be operational, and able to start the work described in the Project's research proposal by funding start date or within the standard three (3) month delayed start timeframe. Start dates beyond the three (3) month timeframe will be considered with assurances from the Institution.

Institutional Assurances: Recipients must adhere to all federal, state, and local regulations regarding the use of human subjects, animals, radioactive or hazardous materials, and recombinant DNA in this Project. It is the responsibility of the Recipient's Institution to ensure that all approvals (IRB, IACUC, other) are in place prior to releasing any award funds. The confirmation of the representative of the Institution on the application forms confirms this oversight.

Liability: Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, agents, or directors, to the extent allowed by law.

Research Misconduct: Institution certifies that it has established administrative policies as required by Public Health Service Policies on Research Misconduct, 42 CFR § 93, and will comply with the policies and requirements (collectively, the "Policy") set forth therein. In the unlikely event that a Recipient is involved in an investigation of research and/or financial misconduct directly related to the Project, he or she will be subject to the procedures in place at the Institution as applicable. According to the Policy, research misconduct is defined as the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or difference of opinion."

To the extent legally permissible, the Institution must notify the Administrator of a finding of research and/or financial misconduct related to the Project. Research misconduct may affect the Recipient's continued eligibility for support for the Project.

Other Funding: Neither the Institution nor the Recipient will accept funding from another source which will result in an overlap of funding for this Project or result in greater than 100% effort of the Recipient or Key Personnel. The Institution and the Recipient are responsible for determining whether acceptance of this award will jeopardize support they may receive from other sources and ensuring that the Recipient has the capacity required to perform the Project within the proposed timeline. The Recipient will immediately report to the Administrator any additional funding available for activities related to this Project.

Use of the Award Funds: The laws of the United States place certain restrictions on the way funds awarded by charitable trusts and foundations may be expended. **Award funds and any interest earned may be used only for the research project and budget as submitted in the Recipient's Project proposal**. Funds may not be expended for any other purpose without the prior written approval of the Administrator.

The Recipient Institution must exercise proper stewardship over award funds and ensure that costs charged to the award are allowable, allocable, reasonable, necessary, and consistently applied in line with the Project's accepted proposal and budget. The Institution shall be liable for reimbursement to the Funder of any award funds associated with any inappropriate or unauthorized expenditures or fraudulent or improper conduct involving the use of award funds. The grant monies which have been awarded, including any interest earned therein, may only be used for the purposes stated in this Agreement.

Expenses eligible for support include the Recipient's salary and fringe benefits; salaries and fringe benefits of personnel essential to the Project for only their work as it directly relates to the Project; publication of scientific data; travel to scientific meetings; laboratory and data processing supplies; and other direct expenses such as equipment essential to the Project. Award funds may only be used for salaries in proportion to the percent effort on the Project. However, percent effort may exceed the percent of total remuneration requested.

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. Research-related expenses not directly related to the Project, general office supplies, individual institutional administrative charges in addition to indirect costs (e.g. telephone, other electronic communication, IT network), professional membership dues, and pre-award charges are **not** allowable expenses.

Indirect Costs (institutional overhead): Indirect costs may not exceed 10% of direct costs. In instances where there is a subcontract, the combined dollar amount for indirects taken by both the Recipient Institution and the contracting institution may not exceed total allowed indirects of the accepted budget.

Re-Budgeting: Expenditures are expected to be within reasonable range of the Project budget as accepted by the Administrator. All requests for re-budgeting or reallocation of grant funds over $20,000 must be clearly justified in the annual financial report or conveyed in an update to the report to the Administrator a minimum of thirty (30) days prior to the requested effective date of change. The request must include the current allocation of resources along with specific detail and justification for the reallocation. If the Institution makes a request for re-budgeting or reallocation outside of the annual progress reporting process, Institution must contact Program Staff to obtain the required forms.

Financial Responsibilities of Award Recipient Institution: The Institution will keep systematic records of all expenditures relating to the Project. Vouchers consisting of bills, invoices, cancelled checks, receipts, etc. will be retained by the Institution for three (3) years after the close of the award period and will be available for inspection by representatives of Funder during normal business hours and upon reasonable notice throughout this period. The Funder may, at their expense, examine, audit, or have audited the records of the Institution insofar as they relate to Project activities supported by this award.

Carry Forward of Funds: All requests to carry forward unspent funding from one year's budget to the next must be clearly justified in the annual financial report. Amounts greater than $50,000 will be scrutinized and may be disallowed if adequate justification is not provided.

No-Cost Extension (NCE): A no-cost extension for up to twelve (12) months may be granted upon receipt and approval of a no-cost extension request. The NCE request form must be submitted between 30 and 90 days prior to the end of the award period. Incomplete forms will not be processed. The NCE request form includes a section for justifying the extension, the unexpended balance, and a timeline for expenditure of the remaining funds. A final scientific report is due at the completion of the extension period. Any portion of the award not expended at the conclusion of the extended period must be returned to the Administrator within sixty (60) days. ***Due to the increased flexibility given to applicants beginning in 2021 regarding the award duration, for awards beginning in 2021 and subsequent years, NCEs will only be granted in exceptional circumstances.***

Changes in Award Status: Any changes in the Project's research design including changes to/omission of specific aims described in the Recipient's accepted Project proposal require a formal written request and prior approval before implementation. Changing of Project plans without prior approval may result in the suspension of payments, early termination of the award, and/or reimbursement to the Funder of any expended or unexpended funds. Any change in percent effort of the Recipient, or other personnel providing a substantial intellectual contribution to the Project (collectively, the "Key Personnel") requires prior written request and approval. Requests should include the reason for the change and a description of how the change will affect the scope of work, implementation, and timeline of the Project. All requests for changes to the Project design, aims, or percent effort of the Recipient or Key Personnel must be received by the Administrator at least thirty (30) days prior to the desired effective date of the change.

Transfer or Termination of Award: Awards are made to the Institution where the named Recipient is conducting research. If the Recipient plans on moving to another non-profit academic, medical, non-governmental or research institution during the award period, Recipient will notify and seek approval from the Administrator to continue the Project at the Recipient's new institution. If approved, the Institution will return unexpended Project funds, subject to allowable costs and non-cancelable obligations, to the Administrator to coordinate the transfer of unexpended funds to the new institution.

In the event of early termination of this Agreement, for any reason, Institution will be reimbursed for allowable costs and non-cancellable obligations incurred prior to the date of termination.

If the Recipient is not continuing the Project in another nonprofit research setting, the award will be canceled, and unused funds must be returned within sixty (60) days. Transfer of the award to another PI, if applicable, is not permitted. Disposition of and title to any equipment purchased by the Recipient with award funds will be evaluated on a case-by-case basis. If the Project is terminated for any reason, any unused funds, subject to allowable costs and non-cancelable commitments incurred in the performance of the Project but not yet paid for, must be returned to the Administrator within sixty (60) days. Performance under this Agreement may be terminated by either party upon thirty (30) days written notice to the other.

It is the responsibility of the Recipient as well as the Institution to notify the Administrator of any change in employment status of the Recipient in a timely manner and usually not less than thirty (30) days prior to such change.

Unused Funds and Reversion: Should any of the following events occur, the Administrator, on behalf of the Funder, may demand repayment of all unexpended portions of the award; moreover, all unpaid installments may be cancelled. The 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 United States Internal Revenue Service that the award does not constitute a qualifying distribution.
- The Institution fails to perform any of its duties, in the judgment of the Funder, the Administrator, or its Scientific Review Committee, required by this Agreement. In such cases, the Administrator 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 Institution ceases to be exempt from income taxes under the 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.

Unexpended Funds: Any unspent funds remaining at the close of an extended Project period must be returned to the Administrator within sixty (60) days.

Medical and Family Leave: The Recipient may continue to expend any award funds allocated to salary during medical or parental leave consistent with the Institution's policies.

Reporting Requirements and Payment Schedules: Final scientific and financial reports are due sixty (60) days following conclusion of the award period. Progress reports are due six (6) months after the award start date for one-year awards and on September 30 for multi-year awards, regardless of award start date. The Recipient will receive access to the required online report forms by email approximately three (3) weeks prior to their due dates. It is the responsibility of the Recipient to email the financial report form to the Institution's Financial Officer and ensure that the Administrator receives this completed form. The Funder and Administrator reserve the right to place a hold on funds where the Recipient is non-compliant with these reporting requirements.

Requests for a no-cost extension or re-budgeting should be made to the Administrator a minimum of thirty (30) days and a maximum of ninety (90) days prior to requested effective date of change. In cases where an extension has been granted, Recipients may be required to file an interim status report.

Patents, Copyright, and Intellectual Property: The Recipient should follow the Institution's policies regarding discoveries or any other intellectual property that results from research conducted under this Project. Neither the Administrator nor the Funder of this Project will retain any rights to intellectual property including patents, copyrights, trademarks, or other proprietary rights that result from the Project.

Confidentiality and Third-Party Release: Application materials as well as scientific progress and final reports are considered confidential. The Administrator engages third parties who have the necessary expertise to review the submitted materials and evaluate each project. Although the Administrator endeavors to protect the confidentiality of the reports by requiring reviewers to sign confidentiality agreements, confidentiality cannot be guaranteed. The Administrator and the Funder are not responsible for any consequences resulting from the disclosure of the content of these materials to such third parties.

The Administrator and the Funder reserve the right to public acknowledgement of Project information (Recipient Name, Institution, Project title and research summary). This information will be made available through the website of the Administrator (www.tmfgrants.org/Falk) and may be posted on other affiliated organization websites, publicly accessible databases of privately funded awards, or published in print form or other media. As noted in the application guidelines, the Project summary submitted with the application will be posted on the Administrator's website if the Project is funded

Scientific Poster Sessions and Events: The Recipient is expected to share research findings in a timely manner through professional meetings and/or publications.

Acknowledgements: Professional publications or presentations resulting from Project work supported by the award must acknowledge**,** the **Dr. Ralph and Marian Falk Medical Research Trust, Bank of America, Private Bank.**

Post Award: Recipient shall make good faith efforts to respond to the Administrator's reasonable requests for information on his/her research progress, new position, affiliation, or contact information (especially email address) following the award period. The Recipient may be requested to provide a current Biosketch or update information in an online database. The Recipient understands that this obligation survives the award period.

APPLICATION INSTRUCTIONS

Use this link to begin a NEW application:
https://www.GrantRequest.com/SID_738?SA=SNA&FID=35094

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 **multi-PIs**, one must be designated as the "Administrative or Lead" PI and only that person will complete the Face Sheet.
- ☐ **Key Personnel**: Multi-PI and Collaborator names and institutional affiliations should be supplied in the Key Personnel fields, if applicable.
- ☐ **Research Proposal**: Project Title, Keywords, Project Summary, Non-technical Summary and Overview, Experimental Systems, Translational Stage, Description of Translational Potential, and Applicant's initials to certify the accuracy of submitted information.
- ☐ **Institutional Certification:** Complete Institutional Contact fields. The Institutional Representative administratively responsible for the oversight of the project must certify that the eligibility requirements have been met, that the Institution has reviewed the application and approved it for submission, and that the Institution understands the Terms of the Award. Endorsement by the Institutional Representative confirms that the Institution will commit to appropriate oversight if the project is funded, including ensuring that the Lead Applicant has obtained any required human subjects (IRB), animal use (IACUC), or institutional equivalent approvals.
- ☐ **Attachments**: **Two Uploads are required-** please name the files:
  1. LastName, FirstName 2022T.pdf - **Application Form** should include the items listed below combined into PDF for upload. On the final PDF, make sure all pages are numbered sequentially starting with the Application Cover Sheet as page #1. This PDF must be named LastName, FirstName 2022T.pdf (for example, Doe, Jane 2022T.pdf).
  2. LastName, FirstName 2022T_Budget.xlsx – **Budget and Other Support Form**

    Templates for Application Form (Word), Budget Form (Excel): https://hria.org/tmf/FalkTAP

Application Form (PDF):

A. **Cover Page:** Requested duration, amount requested, translational stage, certification, and investigative team.

B. **Table of Contents:** Follow the Table of Contents template and number all pages sequentially.

C. **Project Title and Summary, Performance Sites, Non-Technical Overview and Summary, and Description of Translational Potential:** Follow the instructions in the application form template for each section.

D. **Research Proposal:** 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 1-inch margins on all four sides. Figure legends do not count towards word limits, however any figures, graphs, tables or pictures, including their legends must fit within the indicated page limits for each section. 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.

Utilize headings provided in the application template. Include these sections:
1) **Background and Significance (maximum 1000 words, 2 pages including figures):** 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. Include sufficient background information to allow non-subject matter experts to assess the proposal.
2) **Preliminary data (maximum 1000 words, 3 pages including figures):** Describe the results of the Catalyst award that have informed this proposal, referencing the project milestones table from the original Catalyst application.
3) **Specific Aims (maximum 500 words, 1 page including figures):** These should be specific, measurable, and necessary preliminary steps 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.
4) **Research design, experimental methods, and analytical plan (maximum 2000 words, 4 pages including figures)**
5) **Research limitations and contingencies (maximum 300 words)**
6) **Community engagement (maximum 250 words):** Briefly explain how the patient and payer voice has been involved in developing the project if relevant. Explain how you intend to include patient input going forward including any plans for patient or community engagement and dissemination of results. Please note that award funding may be budgeted for this purpose.
7) **Commercialization potential (maximum 250 words):** Briefly explain how the eventual product will be used in clinical medicine if successful. If relevant, explain the value proposition in the context of the competitive environment, and the market potential for the proposed product. How will the cost of the product relate to the value gained in improved quality and length of life?
8) **Investigative team (maximum 200 words):** Briefly describe how the team will function including the relevant qualifications of the investigative team and how the team members, including collaborators, will contribute to the project. If relevant, include how the team will bring diverse

perspectives and promote diversity, equity, and inclusion within the team and/or in the research process. This section can include the management plan.

9) **Transformational Project Milestones and Research Plan Table (maximum 1 page):** 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. ***Due to the increased flexibility in the award duration, proposed timelines and milestones should be realistic, and No Cost Extensions will only be approved in exceptional cases***.

10) **Optional Sections, not included in page limit**: (a) management plan – required for multiple-PI projects, optional for others (if not included in the Investigative Team section above). (b) Human or animal studies considerations, as applicable. For human studies, include an enrollment table that describes recruitment of women and racially and ethnically diverse participants in proportions that reflect how the disease affects the population.

11) **Literature Cited (not included in page limit)**

E. **Biosketch of PI/Applicant (use the latest NIH biosketch, max 5 pages)**: If applicable, please also include Multi-PI Biographical Sketch(es) to the upload. It is not necessary to include a collaborator's biosketch unless they are key personnel.

F. **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 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. The letter should include a section summarizing the institution's commitment to diversifying the research workforce, and should provide evidence of how the institution prioritizes diversity, equity, and inclusion as core values.

G. **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.

Budget and Other Support Form (Excel)

A. **Budget, Summary, and Justification:** Complete each tab in the Excel spreadsheet template as indicated in the instructions on tab 1. Indirect costs (institutional overhead) may not exceed 10% of direct costs. In instances where there is a subcontract, the subcontract budget must be included and combined dollar amount for indirects taken by both the Award Recipient Institution and the contracting institution may not exceed total allowed indirects per award. Budgets should reflect only the amount needed to conduct the proposed research. The maximum budget should not be requested unless it is genuinely needed. The justification for all budget items must be explained. The compensation for personnel funded by Falk awards cannot exceed the NIH salary cap. For personnel 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.

B. **Other Support Page:** Using the Other Support tab in the Excel spreadsheet 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 multi-PIs/key personnel.**

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: https://hria.org/tmf/falktap/

Or email FalkAwards@hria.org

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