Falk Medical Research Trust Transformational Awards Program

2025 Application

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| **Application for:** | **Translational stage:** |
| [ ]  Catalyst Award[ ]  Transformational Award *(must be* *former Catalyst Awardee)* | [ ]  **Early** (preclinical from biomarker or target identification and validation to proof of concept up to development of a lead therapeutic)[ ]  **Late** (Lead optimization through drug candidate selection and IND-enabling studies)[ ]  **Pre-transition** (Projects that need one or more critical experiments to satisfy a transition requirement)[ ]  **Investigator-initiated trial** (Proposals for human clinical studies that are initiated, managed, and sponsored by the investigator or investigator’s institution) |
| **Requested award duration:** |  |
| [ ]  12 months [ ]  18 months [ ]  24 months[ ]  36 months *(Transformational only)* |  |
| **Research Focus** *(check all that apply)***:** |  |
| [ ]  Identification of biological markers of disease activity or progression [ ]  Identification of targets for therapeutic interventions[ ]  Development of therapeutic agents that will disrupt, arrest, or prevent the disease process |  |
| **Requested award amount:** | **$** |

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| **CERTIFICATION**: By signing this Face Sheet, the Lead Applicant and the submitting Institution certify that the statements contained in this application are true and complete to the best of their knowledge, that eligibility requirements have been met, and that the Institution has reviewed the application and approved it for submission. They also certify that the terms of the Falk Medical Research Trust Awards Programs as documented in the 2025 Guidelines are understood and agreed upon, and that the Institution will commit to appropriate oversight if the project is funded, including obtaining any animal use, human subjects, and/or other required institutional approvals. |
| **LEAD APPLICANT** | **AUTHORIZED INSTITUTIONAL REPRESENTATIVE** |
| **Printed Name:** |  | **Printed Name:** |  |
| **Title:** |  | **Title:** |  |
| **Institution:** |  | **Institution:** |  |
| **Email:** |  | **Email:** |  |
| **Signature:** | X \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Signature:** | X \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Date:** |  | **Date:** |  |

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| **Investigative Team***Please list all Key Personnel including lead applicant (PI), multiple-PIs and collaborators. Applicants may expand, re-format, and delete parts of this table as necessary.* |
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| **Role:**  | **LEAD APPLICANT** |
| Name and Degree: |  |
| Full Academic Title: |  |
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| Institution: |  |
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5. Biosketch(es)
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7. Letters(s) of Collaboration (*if applicable*)
8. Budget and Other Support

*2/2025*

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| **Project Title and Summary** |
| **Project Title** |  |
| **Project Summary** **(200 Words)** *State the project’s broad, long-term objectives and specific aims and/or milestones and benchmarks. Describe the research design and methods for achieving these goals. The section is meant to serve as a succinct and accurate description of the proposed work when separated from the application and will be posted on our website if the project is funded.* ***This statement should match the text in the corresponding field for online submission.*** |  |

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| **Performance Sites***(Institution, City, State)* |  |

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| **Non-Technical Overview***Please answer the following questions in ONE SENTENCE EACH, in terms understandable to a non-specialist.* ***This statement should match the text in the corresponding field for online submission.*** |
| What big question(s) will your work answer? |
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| Why does this question matter? |
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| How will your work answer the big question? |
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| **Non-Technical Summary** (200 words or less)*Prepare a lay-language description of the proposed research plan in terms that can be understood by the general public.* * *Do not state your specific aims verbatim*
* *Avoid technical jargon such as gene names and specialist vocabulary; use simple terms; define all essential terms.*
* *Use simple analogies and try to include everyday relevance*
* *Avoid extraneous details*
* *Review with non-scientists and make sure they understand it*

*This statement should match the text in the corresponding field for online submission.* |
| What do you plan to do if funded? |
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| **Description of Translational Potential** (350 words or less)*The Falk Research Award Programs fund high-risk, high-reward projects that address critical scientific and therapeutic roadblocks. High translational potential is an essential prerequisite to a favorable score. Please address the following within your response:** *Which stage of translation the project is at.*
* *Which critical roadblock(s) this project addresses and sufficient context for a non-subject matter expert to understand the importance of addressing this.*
* *How it will move a basic science insight toward a solution, technique, or tool that can be transferred to clinical practice in the near term.*
* *The nature of the risk involved with this project.*
* *If successful, how it would be used in clinical medicine to open a new avenue for treating or curing a disease.*

*This statement should match the text in the corresponding field for online submission.* |
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**Research Proposal**

*Arial 11 black 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. Research Proposal sections include both word count AND page limit maximums. 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.* ***Note: Please use the blue headers provided for each section below. Do not put text inside the blue headers. Italicized Instructions within each header and within this document may be deleted before final submission.***

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| **1. Resubmission Response** (if applicable, maximum 300 words)*For project resubmissions, please provide a high-level description of the issues that were raised previously by reviewers and how those concerns were addressed in the current proposal. This should not be a point-by-point rebuttal but rather a summary of how the new application addresses key issues raised by the reviewers, including changes to the overall hypothesis, specific aims, and if new preliminary data were added.* |

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| **2. Background, Significance** (Maximum 1000 words and 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.* |

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| **3. Preliminary Data** (Maximum 1000 words and 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 to explain which milestones were achieved. Critical information and metrics describing proposed markers, targets or therapeutics should be clearly described (e.g. target or marker validation, lead optimization, pharmacology and toxicology studies, etc.). Include a brief description for how the Catalyst project is ready to transition into a Transformational Award. Please include an explanation for any milestones that were not achieved, and any unanticipated outcomes or unforeseen results that led to alterations in the originally proposed research plan. The application may reference a detailed progress report from the Catalyst Award.*  |

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| **4. Specific Aims** (Maximum 500 words and 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.*  |

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| **5. Research design, experimental methods, and analytical plan** (Maximum 2000 words and 4 pages including figures) |

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| **6. Research limitations and contingencies** (Maximum 300 words) |

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| **7. Community engagement** (Maximum 250 words)*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.* |

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| **8. 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 (e.g., value compared to the nearest competitor or alternative approaches), the market potential for the proposed product, and/or any current or future plans for licensing of technology. How will the cost of the product relate to the value gained in improved quality and length of life?* |

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| **9. 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. Include how the team will bring diverse perspectives and promote diversity, equity, and inclusion within the team and/or in the research process.*  |

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| **10. 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****.*  |

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| **11. Optional Sections** (not included in page limit)*(a) Management plan – required for multiple-PI projects, optional for others.**(b) Human or animal studies considerations, as applicable.* * *Research involving Human Subjects must include the possible risks of the study (e.g. potential adverse or off target effects, complications, etc.) as well as steps planned to protect patient safety. Justification for the sample size included in the research design must be provided. Human studies must include an enrollment table that describes participant recruitment. Funded clinical research must include women and racially and ethnically diverse participants in proportions that reflect how the disease affects the population. Any exclusions within the study population need to be described and scientifically justified.*
* *Research involving Vertebrate Animals must include a description of the proposed procedures on live animals; justification for animal use and why the research cannot be accomplished using an alternative model; circumstances of, and methods to minimize animal pain and distress; and methods of euthanasia if not consistent with American Veterinary Medical Association guidelines.*

*(c) For Investigator-Initiated Trials – Explicitly state the status of or plan for obtaining FDA and/or IRB approvals.*  |

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| **12. Literature Cited** *(not included in page limit)* |