

THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Submission Deadline: 5:00pm, Friday April 19, 2024 Funding Range: Each funded up to \$25,000

Funding target start date: June 2024

OVERVIEW and ELIGIBILITY

The Rockefeller University Center for Clinical and Translational Science (RUCCTS), solicit requests for pilot projects to support:

- New and innovative clinical and translational studies.
- New and existing collaborations that are innovative and advance clinical or translational science and research.
- Projects from Clinical Scholars and from basic investigators who extend their studies to translational science and clinical research.
- Projects engaging community partners.
- Translational science proposals from community researchers in collaboration with Rockefeller scientists.
- Pilot projects that utilize CTSA Program resources and The Rockefeller University Hospital.
- Development of new research methodology and/or new technologies/tools/resources that will advance the RUCCTS and thus increase the efficiency and effectiveness of translation.
- Early-stage development of new therapy/technology or procedures with generalizable application to overcome an identified translational roadblock.
- Development and dissemination of effective tools, methods, processes, and training paradigms
- Secondary analysis of existing data ((e.g., projects using the <u>National COVID Cohort Collaborative</u> (N3C).
- Priority will be given to studies that include a human participant protocol that includes studying research participants in the Rockefeller University Hospital.

In the event a trainee submits a proposal, the Background and Significance section should explain how the supported research will advance the career and training goals of that individual. A letter of support from the trainee's mentor, specific to the project, is a required element of the application.

Pilot projects are expected to be completed within a 1-year timeframe. A second year of funding is possible but will depend on progress in the first year and the funding will be competitive with new submissions. Approximately 8 awards will be made this round. Up to 2 awards may be made in community-engaged research, and up to 6 additional awards in translational science and/or translational research. A statement regarding the potential public health impact of the research is required for all proposals.

NEW APPLICATION REQUIREMENTS

Please note this announcement is only for CTSA-supported pilot projects that are directed towards a specific scientific outcome as a unique project or as a stand-alone aim of a larger project. Pilot project support is not intended for large projects by established investigators that would otherwise be submitted as separate research applications. Translational science projects in this round should be

focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. An announcement will go out in July to support global infectious disease, digestive disease, basic science, and additional translational projects.

One criterion to assess whether a project meets the definition of Translational Science is whether the answers to the two following questions are "yes." 1. Will the results of your research lead to a tool, process, or intervention that is generalizable, that is, can be adapted to a broad range of research questions and/or diseases, and adopted by other investigators at other sites? 2. Will the results of your research overcome a current barrier to conducting clinical and translational research?

PREVIOUSLY FUNDED PILOT PROJECTS: Pls of Pilot Projects funded in 2023-2024 are required to resubmit a full application if they wish to be considered for a second year of funding in 2024-2025. In addition to the information listed above, these applications must include a summary of progress during the first year and a description of efforts (planned or already made) to obtain external funding to continue the project.

FUNDING and EXPENDITURE

A maximum of \$25,000 in direct costs can be requested. Pilot projects that propose more than \$25,000 in direct cost will be reviewed and considered on a case-by-case basis. Funding may be used to support other than personnel costs such as materials, laboratory supplies, assays, animal costs, consultants, recruitment costs, participant compensation, cost for use of shared resources, domestic conference travel, etc. CTSA-supported pilot projects may not be used to support clinical trials beyond Phase IIB except for Phase III clinical trials for the treatment of rare diseases. Funding may not be used to support salary, time/effort, remodeling costs, or institutional indirect costs. While pilot funding may not provide salary support, any named individuals working on the project must indicate a non-zero amount of effort committed to the project for effort reporting purposes.

A maximum of two applications from a given Laboratory will be funded within a given funding cycle. Rare exceptions may be granted by consensus of the Review Committee.

HOW TO APPLY

Applications must be received by 5:00 PM, EDT on April 19, 2024.

All applications are to be uploaded to the Pilot Project Online Submission System, as well as in RAS. You can access the system at https://pilotprojects.rockefeller.edu Please note that you will need to register to submit your application online. Paper and email submissions will not be accepted. You can access RAS at RAS-Grants Log-In. Work with your Sponsored Projects Officer to create the Funding Proposal in RAS. Utilize the sponsor "Rockefeller University Pilot Grant" in the application phase.

A confirmation e-mail will be sent when your submission is successfully received.

CONTENT AND FORM OF APPLICATION

FORMAT SPECIFICATIONS

Follow format and font specifications as outlined below. Applications that do not follow instructions will be deemed non-responsive to this FOA.

- Use Arial typeface and a font size of 11 point.
- Use one-half inch margins (top, bottom, left, and right) for all pages. Place last, first name in the header of your application.

Sections 1-5 must occupy no more than 6 pages and should contain the following: (Applications longer than 6 pages will be deemed non-responsive to this Funding Opportunity

Announcement)

- 1. Specific Aims.
- 2. Background and Significance.
- 3. Preliminary Studies, if relevant.
- 4. Research Design and Methods.
- 5. Project Timeline.
- 6. Literature Citations.
- 7. Budget and budget justification (narrative). This must include the names of RU personnel working on the project, along with their effort commitment.
- 8. Biographical sketches (uploaded as one combined pdf).
- 9. Letter(s) of collaboration/support; trainees must include a letter from their HOL/Mentor (uploaded as one combined pdf).
- 10. Letter of commitment from partnering faculty/institution (if applicable).
- 11. Use of Vertebrate Animals (if applicable).

ABSTRACT

The application should include a brief abstract. That abstract should contain an explanation of how the proposed project will accelerate the development of a clinical or translational project, how the proposed research will address an issue of significance to human health, and what impact it may have on population health. **Your abstract should be no longer than 1500 characters (including spaces).** The abstract is no part of the 6-page maximum length.

Although this submission is based on key elements of the PHS 398 form, the entire application should be no longer than **6 pages**. If the study involves a design where statistical methods are used to determine the number of subjects that need to be studied, that statistical information should be included as part of Research Design and Methods section.

FOR HUMAN SUBJECT PROPOSALS

If human subjects are involved in the pilot project you are proposing, please add the following:

A Protection of Human Subjects section that clearly describes the risk, protections, benefits, and importance of the knowledge to be gained by the activities outlined in your pilot project application.

Inclusion Plan for Women, Minorities and Children.

Targeted Enrollment Table or Inclusion Data Record (IDR) –See Pilot project submission system for form download.

Data and Safety and Monitoring plan (DSMP) if applicable.

Applicants submitting research proposals including human subjects research (including samples-only research) are encouraged to consult the Research Facilitation Office and submit a Request for Protocol Assistance, to undergo at least an initial Navigation Meeting led by the Research Facilitation Office. The IRB x8411 and the Clinical Research Support Office x8408 (kostr@rockefeller.edu) participate in Navigation and can provide preliminary discussions about feasibility and protocol design. If a pilot project that includes human subjects research is recommended for funding with a CTSA-supported pilot award, the related human research protocol will have to be IRB-approved before the funding will be finally approved. If a study involves vertebrate animals, the five points detailed below should be included but will not count towards the 6-page length. Plans to use core resources of the Center for Clinical and Translational Science are highly encouraged and should be explained in Research Design and Methods, if relevant.

FOR TRANSLATIONAL SCIENCE PROPOSALS

Translational Science (TS) proposals should focus on identifying generalizable principles or processes that lower barriers to the successful conduct of translation. As such, it is not disease specific. Projects can be considered TS if they address a translational research (TR) question in a particular disease or intervention development/dissemination context if they also provide generalizable innovations or insights that can be applied to other translational research projects and thereby increase the overall efficiency or effectiveness of Translation. Both TS and TR investigations can be applied anywhere along the Translation spectrum, from basic science to public health. If you are submitting a translational science proposal, in addition to the items above please include responses to the following questions:

- 1) Will the results of your research lead to a tool, process, or intervention that is generalizable, that is, can be adapted to a broad range of research questions and/or diseases and adopted by other investigators at other sites? If so, how?
- 2) Will the results of your research overcome a current barrier to conducting clinical and translational research? If yes, which barrier and how will the barrier be overcome?

FOR PROPOSALS REQUESTING THE USE OF VETEBRATE ANIMALS (including Custom Antibodies) Applications involving live vertebrate animals must address the following criteria:

- 1. **Description of Procedures**. Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
- 2. **Justifications**. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- 3. **Minimization of Pain and Distress.** Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.
- 4. **Method of Euthanasia.** Provide a justification for methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If answer is "No" to the question "Is method consistent with AVMA guidelines?", describe the method and provide scientific justification in the text field provided.

If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used.

FOR COMMUNITY- ENGAGED RESEARCH PROPOSALS

The Rockefeller University Center for Clinical and Translational Science (RUCCTS) and the SNF Institute for Global Infectious Disease Research aim to increase access to research in communities by supporting community/academic research partnerships and collaborations that are both relevant and responsive to the health needs of the community. Research projects must be designed with input from the community, to enhance practical as well as theoretical understanding of community health issues and include creative strategies for addressing community-identified problems by bringing together academic and community partners. In addition to the content and form of the application above, proposals should include a brief description of the problem under investigation as identified with a community partner, provide a description of procedures for conducting the community-based research study, and include a timeline. Proposals should describe the importance and significance of the results or findings that are likely from the research and its benefit to the community. The proposal should outline plans for publication and presentation of the results once the project is completed, including dissemination to and with the relevant community partners and stakeholders.

REVIEW CRITERIA

Projects will be evaluated based on scientific and technical merit and clinical and translational impact, as well as the potential of the research to advance the career of a trainee. The applications will be reviewed by the Oversight of Pilot and Collaborative Translational and Clinical Studies subcommittee of the Advisory Committee for Clinical and Translational Science (ACCTS) and presented to the ACCTS for final determination of funding. Once a project is evaluated for its scientific and technical content and recommended for funding, funding will be contingent on the investigator obtaining ACCTS and IRB approval for human subjects' protocols and ACCTS and IACUC approval for studies involving vertebrate animals. For community-engaged research projects applicants must provide a letter of commitment from the partnering faculty/institution. Proposals in this category must incorporate community involvement in the design, and where appropriate, focus on health equity and having a positive health impact on the participating community.

AWARD ANNOUNCEMENT

Awards will be announced on or by June 2024.

TERMS OF AWARD

Prior to award, applicants will be informed of the applicable terms and conditions of award for pilot projects. Applicants awarded CTSA-supported projects will be expected to expend all the funds before May 31, 2025.

INQUIRIES

Address inquiries to Maija Neville-Williams, Administrative Director at mwilliams@rockefeller.edu.

<u>Please share this announcement with Rockefeller University faculty colleagues who may be interested</u> in submitting a proposal.