

THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Submission Deadline: Funding Range: Funding target start date:

5:00pm, Thursday September 7, 2023 Each funded up to \$25,000 October 2023

OVERVIEW and ELIGIBILITY

The Rockefeller University Center for Clinical and Translational Science (RUCCTS), The Maurice R. and Corinne P. Greenberg Center for the Study of Inflammation, Microbiome, and Metabolism, the Shapiro-Silverberg Fund for the Advancement of Translational Research, and the SNF Institute for Global Infectious Disease Research, solicit requests for pilot projects to support:

- New and innovative clinical and translational studies
- Basic or clinical research projects or innovative technologies focused on fundamental biological processes or clinical applications related to infectious diseases or immune responses to vaccines and infections
- New collaborations that are innovative and advance clinical or translational research.
- Projects from Clinical Scholars and from basic investigators that extend their studies to clinical or translational research
- Projects engaging community partners
- Translational proposals from community researchers engaging 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 with generalizable application to 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> (<u>N3C</u>))

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.

Pilot projects are expected to be completed within a 1-year time frame. A second year of funding is possible but will be determined after a progress report for the first year is submitted and the funding will be competitive with new submissions. Approximately **12** awards will be made this round. Up to **5** pilot grants will be funded by the SNF Institute for Global Infectious Disease Research and they will support basic or clinical research projects or innovative technologies focusing on fundamental biological processes and/or clinical applications related to infectious diseases or immune responses to vaccines and infections. Up to **2** awards may be made in community-engaged research, and up to **5 additional** awards in 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 for CTSA-supported, Maurice R. and Corinne P. Greenberg Center for the Study of Inflammation, Microbiome, and Metabolism, the Shapiro-Silverberg Fund for the Advancement of Translational Research, and SNF Institute for Global Infectious Disease Research pilot projects only that are directed towards a specific scientific outcome as a unique project or as a standalone 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.

PREVIOUSLY FUNDED PILOT PROJECTS: Pls of Pilot Projects funded in 2022-2023 are required to resubmit a full application if they wish to be considered for a second year of funding in 2023-2024. 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, domestic conference travel, etc. **Request for CTSA supported pilot** projects may not be used to support any 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, or institutional indirect costs.

HOW TO APPLY

Applications must be <u>received</u> on or before 5:00 PM, ET, on September 7, 2023

All applications are to be uploaded to the pilot project online submission system. You can access the system at <u>https://pilotprojects.rockefeller.edu</u> Please note you will need to register to submit your application online. Paper and email submissions will not be accepted.

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 only
- Use one-half inch margins (top, bottom, left, and right) for all pages of the FOA
- Place last, first name in the header of your application

No more than 6 pages for sections 1-5, the application 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 narrative (budget justification)
- 8. Biographical sketches (uploaded as one combined pdf)
- 9. Letter(s) of collaboration/support (uploaded as one combined pdf)
- 10. Letter of support from Head of Laboratory (HOL) and/or Department Head (required)
- 11. Letter of commitment from partnering faculty/institution (if applicable)
- 12. Use of Vertebrate Animals (if applicable)

<u>ABSTRACT</u>

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 and 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).

Although this submission is based on key elements of the PHS 398 form, the entire application should be brief, 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 a part of Research Design and Methods section.

Applicants submitting <u>research</u> proposals including human subjects research (including samples-only research) are encouraged to consult the Research Facilitation Office and submit a <u>Request for Protocol</u> <u>Assistance</u>, the IRB x8411, and the Clinical Research Support Office x8408 (kostr@rockefeller.edu) for at least preliminary discussions about feasibility and protocol design. 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 HUMAN SUBJECT PROPOSALS

If human subjects are involved in the pilot project you are proposing, in addition to the items above, please include the following:

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

FOR PROPOSALS REQUESTING THE USE OF VETEBRATE ANIMALS

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. o 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 aims 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.

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 having a positive health impact on the participating community.

AWARD ANNOUNCEMENT

Awards will be announced on or by October 2023.

TERMS OF AWARD

Prior to award, applicants will be informed of the applicable terms and conditions of award for pilot projects.

Supported in part by grant # UL1 TR001866 from the National Center for Advancing Translational Sciences (NCATS, National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program; Maurice R. and Corinne P. Greenberg Center for the Study of Inflammation, Microbiome, and Metabolism ;The Shapiro-Silverberg Fund for the Advancement of Translational Research; and the SNF Institute for Global Infectious Disease Research

Applicants awarded CTSA supported projects will be expected to expend all the funds before May 31, 2024 (8-month funding period). Do not apply for a CTSA supported award if you cannot complete the project in an 8-month period. Non CTSA supported projects will be required to expend all the funds by October 2024 (12-month funding period).

INQUIRIES

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

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

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