

Request for Proposals

Clinical & Translational Science Research Project

NIH/NCATS Clinical & Translational Science Award (CTSA)

Application Deadlines

Release Date	Friday, July 22, 2022
Application Deadline	Friday, September 9, 2022
Anticipated Notification of Acceptance	Friday, September 30, 2022

Background

The Medical University of South Carolina established the South Carolina Clinical & Translational Research Institute (SCTR) in 2006 in response to the NIH Clinical and Translational Science Award (CTSA) Program. The CTSA Program is charged with developing and implementing innovative solutions to improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic, and community into therapies and clinical practices that improve individual and population health.

For more than a decade, SCTR has been successful in changing the culture of biomedical research, breaking down barriers, facilitating sharing of resources and expertise, and streamlining research-related processes across the translational science spectrum (Figure 1). These efforts have enabled large-scale change in the clinical and translational research efforts at MUSC and throughout South Carolina and resulted in the adoption and dissemination of numerous innovative and generalizable solutions to accelerate translational research locally and across the CTSA consortium.

The SCTR Institute is **planning a competing renewal application to be submitted in December 2023**. As part of this competing renewal, proposals for **Clinical and Translational Science (CTS) Research Projects** are being sought for inclusion in the renewal application.

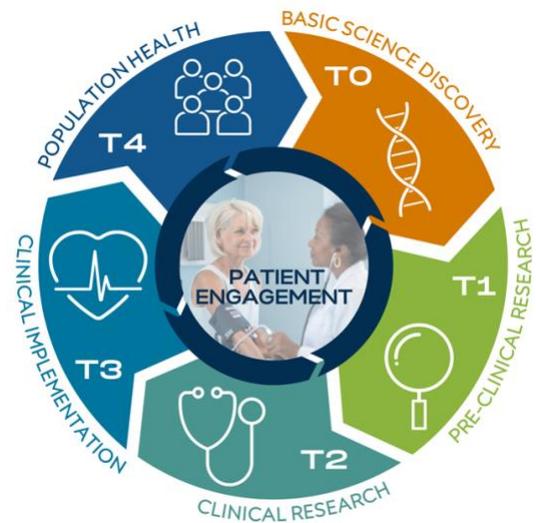


Figure 1. Translational science spectrum

Translational Research Versus Translational Science

NCATS has made a major shift in the type of project that CTSA’s should support, emphasizing the support of Translational Science rather than Translational Research. NCATS defines **Translational Research** as “the endeavor to traverse a particular step of the translational process for a particular target or disease.”

Example Translational Research Question- Is one drug better than another in improving outcomes in diabetes?

To study this, one might propose a randomized clinical trial comparing the efficacy of new drug to an FDA approved medication in controlling blood glucose in a representative population of patients with Type 2 diabetes.

Translational Science (the focus of this request for proposals) is the “field of investigation focused on understanding the scientific & operational principles underlying each step in the translational process.” Applicants are encouraged to review the [scientific and operational principles](#) underlying the translational process in developing their proposal.

Example Translational Science Question- What are the barriers to recruiting representative populations to clinical trials?

To study this, one may propose research comparing the efficiency and efficacy of a novel recruitment strategy to a standard recruitment strategy in achieving full recruitment of a representative population of patients with Type 2 diabetes invited to participate in a medication study evaluating blood glucose control.

Are there aspects of your disease/condition focused research program that address one or more of these scientific or operational principles?

How might you expand existing work to address a translational science barrier or roadblock that would have impact across multiple diseases/conditions?

Contact Tammy Loucks at louckst@MUSC.edu to arrange a time to discuss an idea.

Request for Applications

This announcement is a request for applications from eligible MUSC faculty to contribute a CTS research project, focused on Translational Science, that will make up the Clinical and Translational Science Research Program element in SCTR’s grant renewal.

Applications will be reviewed by internal and external advisors who will make recommendations to SCTR leadership who will then choose one or two projects for inclusion with the competing renewal application.

Because the award period of the planned renewal is seven years and CTS research projects may be 2-3 years in duration, we anticipate future calls to add new projects to this program element as the initial projects are completed.

Responsive Proposals

Responsive proposals **must be Translational Science projects that address a truly significant barrier or roadblock in the conduct of CTS** that if successful would have **generalizable application** to accelerate translational research. Also, CTS Research Projects need to be **feasible** given the resources available and substantial prior experience of the study team. Because expertise from **multiple disciplines** is needed to advance translational science, only applications from investigative teams representing two or more disciplines will be accepted. Proposals will document community stakeholder engagement in the design, conduct, and dissemination activities.

Funds and Duration

Funding for each CTS Research Project will be approximately **\$125,000 direct costs*** per year for a period of **2-3 years**. SCTR Administration and Finance leadership will work with you to determine the appropriate amount of funding related to needs of the project.

*funds may not be used to support any clinical trial beyond phase IIB except for phase III trials for treatment of rare diseases

Eligibility

The Principal Investigator (PI)/ Project Director (PD) must:

- hold a **PhD, MD, DO or other equivalent** degree.
- have a full-time faculty appointment at MUSC at the **Assistant Professor, Associate Professor, or Professor** level.
- have received and maintained extramural research-related funding throughout their career.
- have proven expertise and research experience to enable the proposed work.

Faculty from other academic institutions may partner as Co-Investigators and/or collaborators on applications with MUSC faculty.

Multi-PI projects led by investigators from two different disciplines are strongly encouraged.

Personnel & Required Effort

Effort for the PI/PD (or MPI team) cannot exceed 20%, i.e., most of the funds should be budgeted for programmatic needs.

Application Instructions

Font Type and Size	Arial, 11pt, single spaced
Page Margins	No less than 0.5” on all sides (one-half inch)
File Upload Type	PDF

The application consists of the following information and documents:

- **Title** of proposed Research Project
- **Key Personnel**- Provide a **Biosketch** in the new NIH format for each investigator.
- **Specific Aims**, 1 page
- **Approach**, 1 page
- **Sustainability, Dissemination, and Impact**, 1 page
- **Budget** pages (PHS 398 pages 4 and 5) and **detailed budget justification**
- **COMBINE ALL DOCUMENTS INTO ONE PDF FILE**

Key Personnel - The following information will be requested for all key personnel

- NIH- formatted biographical sketch
- Assemble beginning with the PI/MPIs

Specific Aims (1-page limit)

- The Specific Aims should:
 - state concisely the goals of the proposed research project and summarize the expected outcomes over the 2–3-year award period.
 - explain how the proposed project addresses a significant problem or barrier in the field of clinical and translational science.
 - describe how the project will be innovative and collaborative in addressing barriers and problems in clinical and translational research at MUSC and beyond.

Approach (1-page limit)

- In this section describe succinctly:
 - the scientific approach taken.
 - rational for the methods selected.
 - anticipated outcomes and analysis plan.

Sustainability, Dissemination, and Impact (1-page limit)

- The Sustainability, Dissemination, and Impact section should:
 - state concisely how the project will provide sustainable, generalizable innovations or

- insights that increase the overall efficiency or effectiveness of translation. Sustainability may also include establishing the foundation for the next research question.
- describe a plan for dissemination of the expected innovations or insights.
 - describe the impact on CTS should the proposed project ultimately be successful.

Submission Process

Complete the investigator information fields and combine and submit all documents in **one PDF file via this [REDCap link](#)**.

Review Criteria

Each application will be reviewed by **SCTR leadership, program directors and advisors with appropriate expertise**. Reviews will focus on the following areas:

- Does the project **address a critical problem or barrier in the field of clinical and translational science**?
- Does the project team have a **strong record of clinical and translational research** with achievements in useful methods, procedures, or processes leading to improved diagnoses, treatments, and strategies to solve critical translational science problems and barriers?
- Are the specific aims of the project **well-reasoned, feasible, and appropriate in terms of overall strategy, methodology and analysis**?
- Does the project challenge to **seek and shift current research, clinical practice, or implementation paradigms** by utilizing novel concepts, approaches, or methodologies?
- Does the project have the potential to provide **sustainable, generalizable** innovations or insights that increase the overall efficiency or effectiveness of translation?
- Can the project team **develop and maintain effective collaborations** with other SCTR programs and CTSA Program hubs?

Additional Information

- NIH NCATS Clinical and Translational Science Award RFA
<https://grants.nih.gov/grants/guide/pa-files/PAR-21-293.html>
- [Austin CP. Opportunities and challenges in translational science. Clin Transl Sci 2021; 00:1-19. PMC8504824](#)
- South Carolina Clinical & Translational Research (SCTR) Institute Website
<https://research.musc.edu/resources/sctr>
- NIH National Center for Advancing Translational Sciences (NCATS)
<https://ncats.nih.gov/>
- Budget pages, PHS 398 form pages 4 (initial) and 5 (project period)
<https://grants.nih.gov/Grants/Funding/Phs398/fp4.pdf>
<https://grants.nih.gov/Grants/Funding/Phs398/fp5.pdf>
- NIH Biographical Sketch Template
<https://grants.nih.gov/grants/forms/biosketch.htm>

Questions

For questions related to this opportunity or to request a **consult**, contact Tammy Loucks, MPH, DrPH at louckst@musc.edu.