

Application Instructions & FAQs SCTR Translational Science Challenge Pilot Project Grant

Please read these instructions carefully before beginning your application. The entire application package must be completed and successfully submitted through the InfoReady application portal by the deadline to be considered for funding. Incomplete and/or late applications will not be accepted for any reason.

What is translational science?

Translational science (i.e., the Science of Doing Science) is defined by NIH's National Center for Advancing Translational Sciences (NCATS) as the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.¹

Examples of translational science that may be supported by this opportunity include:

- Development of new research methodology and/or technologies/tools/resources that will advance CTS and thus increase the efficiency and effectiveness of translation
- Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock
- Demonstration in (a) particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient
- Dissemination of effective tools, methods, processes, and training paradigms
- Feasibility/proof of concept studies to support future CTS projects
- Secondary analysis of existing data (e.g., projects using the National COVID Cohort Collaborative (N3C) Data Enclave)

I'm still not sure if my idea is a fit for the Translational Science Challenge. How can I learn more?

SCTR is hosting an Informational Session on April 13, 2022 from 4:00-5:00pm. <u>Click here to join the meeting</u> on Microsoft Teams. You are encouraged to send general questions ahead of time to SCTR's Science Development Office.

KEY DATES

RFA Release Date: 3/30/2022

• Informational Session: 4/13/2022, 4:00-5:00 pm, Join the meeting on Microsoft Teams.

Concept Proposal*(required): 5/2/2022
 Full Application (by Invitation): 7/1/2022
 Earliest Anticipated Funding Date: 9/1/2022

ELIGIBILITY

- Principal Investigators (PIs) must have a primary faculty appointment as Assistant Professor or above at MUSC.
- Faculty from other academic institutions are encouraged to partner as Co-Investigators and/or collaborators on collaborative applications with MUSC faculty.
- Undergraduates, graduate students, clinical trainees, post-doctoral and clinical fellows, visiting faculty, and individuals with pending faculty appointments may serve as a Co-Investigator (Co-I) or collaborator.
- PIs/Co-PIs with an active SCTR pilot award are not eligible to apply as PI or Co-PI. Current SCTR pilot PIs may serve as a Co-I or collaborator on a Translational Science Challenge application.

^{*}Concept proposals will be reviewed for responsiveness. Selected applicants will be invited to submit a Full Application; non-responsive concept applicants will also be notified.

¹ https://ncats.nih.gov/training-education/translational-science-principles Translational Science Challenge Application Instructions & FAQs- Updated 3/30/2022

I am currently funded through the SCTR Pilot project program. Can I apply for this opportunity?

No, a PI and/or Co-PI can have only one active award from SCTR at any given time including a SCTR pilot project award, Career Development (KL2) award, or Community Engaged Scholar award. This restriction does not apply to SCTR Vouchers.

I was a previous recipient of SCTR Pilot project program funding. Can I apply for this opportunity?

Yes, prior awardees are eligible to apply. If your pilot award ended between 4/1/2020 and 3/31/2022, you will be required to provide a brief progress update. The report will be evaluated to determine the progress/stewardship of the previous SCTR award.

OTHER REQUIREMENTS

- Collaborations informed by expertise from multiple disciplines are needed to advance translational science. Thus, only applications from investigative teams representing two or more disciplines will be accepted.
- Projects must be feasible within the proposed one-year timeframe, have high methodological and scientific quality.
- Translational research proposals, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, will be considered non-responsive. This mechanism is not intended for large projects by established investigators that would otherwise be submitted as research grant applications.

APPLICATION INSTRUCTIONS

How do I apply for this funding opportunity?

The Concept Proposal application process has two steps:

- 1) Obtain a Study ID for the proposed project through SPARCRequest (https://sparc.musc.edu)
 - → If you have existing study in SPARC that is directly related to the proposed study, you will need to add the Translational Science Challenge funding opportunity to your existing study.
 - → If your study is NOT already in SPARC, you will need to create a study to obtain a Study ID for your proposed study.
 - Note: in step 2, select "Pending Funding" under <u>Proposal Funding Status</u> and select "Internally Funded Pilot Project" as the <u>Potential Funding Source</u>, and indicate "SCTR" when asked for <u>Sponsor Name</u>.
 - → Detailed information about the steps to obtain a SPARC Study ID can be found on the <u>Translational Science</u> <u>Challenge webpage</u> under "How to Apply".

For additional assistance with SPARCRequest, contact the SCTR SUCCESS Center at success@musc.edu

No application materials should be uploaded in the SPARCRequest system.

2) Complete the InfoReady application, upload all required documents where indicated, check your application for errors and omissions, and SUBMIT your proposal in InfoReady.

APPLICATION DOCUMENTS & REQUIREMENTS

- → Format: All documents must be uploaded as PDF files.
- → Font: Arial, 11-point or larger. Smaller text in figures and tables is acceptable, provided it is readable when the page is viewed at 100%. Ensure that final PDF documents comply with font size requirements.
- → Margins: A minimum of one-half inch (0.5") on all sides is allowable.
- → NIH (eRA) Commons ID: PIs will be required to include their eRA commons ID on the InfoReady application form.
 - o To set up an eRA commons ID, visit the MUSC Office of Research & Sponsored Programs at https://research.musc.edu/resources/orsp and click the link for "Need and NIH Commons Account?"
- → ORCID: PIs will also be required to provide their ORCID on the InfoReady application form.
 - Visit https://orcid.org/ to create an ORCID

CONCEPT PROPOSAL REQUIREMENTS

Applicants are required to upload the following documents in InfoReady when submitting a Concept Proposal.

Concept Proposal Document Checklist	Page Limit
 Specific Aims identify the translational science challenge/barrier the project addresses concisely state the specific aims of the proposed project summarize the expected outcome(s) 	1 page
 describe the generalizability and potential impact on translational research efficiency 	
Plan for Future Funding • describe how the data obtained during the pilot project will support (a) future extramural grant application(s)	1 page
Translational Science Team Description • describe succinctly the expertise and role of each member of the project team • summarize the unique qualifications of the team to address the identified challenge	1 page
Literature Cited (if applicable), does not count towards the page limits	N/A
Combine the Specific Aims, Plan for Future Funding, and Translational Science Team Description and Literature cited into a single PDF file to be uploaded in the InfoReady application	
 Early-Stage Investigator PIS PIs who meet the NIH-criteria for an early-stage investigator (ESI) must also include a letter of support from a qualified senior co-investigator who will serve as a mentor for the project. describe planned ESI/mentor interactions, frequency of meetings, and plan for achieving research independence, additional resources etc. this letter will not count toward page limits 	N/A
 Biographical Sketches current NIH-formatted biosketch for each investigator CV/resume may be used for any non-academic investigator or community member Combine all biosketches together in a single PDF file, beginning with the PI and followed by other project team members in the order listed on the InfoReady application. If a consultant(s) is involved, include their name(s) and role on the project in the Translational Science Team description in lieu of a biographical sketch. Consultants are not required to be listed on the InfoReady application. 	5-pages per investigator
 Progress Report Pls or Co-Pls who have been previously funded via a SCTR award (e.g., pilot project, KL2 award, Community Engaged Scholars) that ended between 4/1/2020 and 3/31/2022, must also submit a brief Progress Report → Follow this REDCap link to provide the necessary information for the progress report. → Once you complete the REDCap, download a PDF file of the information you provided and attach the document to the InfoReady application. 	3 pages

What happens after I submit the Concept Proposal?

Concept proposals will be reviewed to determine whether the concept qualifies as a translational science innovation and progresses to a Full Application. Investigators submitting a Concept Proposal will be notified of the review panel's decision to proceed to or not to proceed to a Full Application.

FULL APPLICATION REQUIREMENTS

Invited Full Applications will be pre-populated with the SPARC Study ID, application information, and files submitted as part of the Concept Proposal.

Will I be able to modify the information and/or documents that were part of my Concept Proposal?

Yes, applicants may update this information and upload revised documents as needed prior to submission of the Full Application.

Applicants are required to include the following materials when submitting a Full Application.

Full Proposal Document Checklist	Page Limit
Specific Aims (as mentioned above, will auto-populate, 1-page limit)	1 page
Plan for Future Funding (as mentioned above, will auto-population, 1 page limit)	1 page
Translational Science Team Description (as mentioned above, will auto-populate, 1-page limit)	1 page
Literature Cited (if applicable) (does not count towards the page limit, will auto-populate)	N/A
Early-Stage Investigator PIs (Letter of Support as mentioned above, will auto-populate)	N/A
Biographical Sketches (as mentioned above, will auto-populate)	5 pages/ investigator
Progress Report (as mentioned above, will auto-populate)	3 pages
Research Proposal (Research Strategy)	4 pages
• follow the NIH style	
 → Prepare a detailed budget: The PHS 398 Form Page 4 (Detailed Budget for Initial Budget Period) is required. https://grants.nih.gov/grants/funding/phs398/fp4.PDF → Prepare a detailed budget justification: Allowable and unallowable costs are listed below. Each budget line item must be clearly justified. → Combine the budget form page and justification pages and upload as a single PDF file 	N/A
 → Obtain a Biostatistical Consultation for this proposal using SPARCRequest. Add the consultation to the Study ID you created for this application. → Ensure that the consultation is completed no later than Friday, June 17, 2022. → Upload a statement indicating that the consult was completed in the space indicated on the InfoReady application. 	1 page

BUDGET AND ALLOWABLE COSTS

Allowable costs

It should be noted that salary requests and all other budget item requests should be clearly justified and appropriate to conduct the proposed project properly.

- **Faculty Salary Support.** Faculty members' pilot project effort must be clearly listed in the budget. Support of faculty salary and fringe benefits is allowed up to 5% effort for each faculty member subject to the NIH salary cap.
- Effort Reporting. SCTR Pilot Projects are funded by MUSC Institutional funds. It is the PI's responsibility to ensure all faculty effort listed in the budget complies with their institutional effort policy. Investigators are not required to accommodate their effort on the pilot project budget. However, they must comply with their respective institution's effort policy should they choose to charge the effort to other funding sources.
- Other Personnel Support. Salary and fringe benefits are allowed for technical support, such as: Research Fellows, Research Assistants/Coordinators, Research Nurses, etc.
- **Non-personnel Research Expenses.** Some allowable expenses are supplies, equipment (under limited circumstances), animal purchase cost and care, study subject compensation, study subject transportation costs, in-and out-patient care costs, and statistical and computational services including personnel and computer time. All expenses must be directly related to the proposed research.
- **Subawards.** Please indicate potential subaward(s) to other institutions clearly on the budget. No signed documents from subaward institution(s) are needed at the time of application submission. The SCTR Finance Office can assist the PIs and their Business Managers to establish subawards once an application is approved for funding.

Unallowable Costs

- **Students.** SCTR pilot project funds cannot be used to cover student tuition, fees, or health insurance costs, either directly or indirectly as a stipend. If an application proposes a student stipend as undergraduate or graduate student research assistant, funding support will be deemed inappropriate and not funded. If an application proposes a graduate student as a research assistant, you must provide a justification as to why a student is included in the proposed project and how work on this pilot project is related to the student's thesis/dissertation research project. Proposed student(s) undergraduate and graduate must be identified by first name and last name (i.e., TBD/TBN is not allowed).
- Ancillary Personnel. Salary support for ancillary personnel (e.g., Mentors and Administrative Assistants) is not allowed.
- General office supplies and equipment, computers, and laptops (unless specifically requested and justified), membership dues and fees, travel costs to conferences/meetings, publication and subscription costs, mailing costs, and rent are not permitted.
- Facilities & Administrative Costs (F&AC). F&AC, also known as indirect/overhead costs, are not permitted.

BUSINESS MANAGER RESPONSIBILITIES

The PI's Department/Division Business Manager is responsible for all human resources, subaward (if applicable), procurement and reconciliation activities, and providing proper finance reports as requested for the funded project account(s).

APPLICATION REVIEW PROCESS

Concept Proposal Review

Each concept proposal will be reviewed by two members of a special translational science review panel to determine whether the concept qualifies as a translational science innovation and progresses to a Full Application. Investigators submitting a Concept Proposal will be notified of the review panel's decision to proceed or not to proceed.

Full Application Review

Full applications will undergo an NIH-style peer review with attention to the criteria listed below. Applications will also be reviewed by a biostatistician. Review critiques of the Full Applications will be sent to the appropriate PIs.

Review Criteria:

- 1. Significance of the project to advance clinical and translational science methods and processes
- 2. Innovation
- 3. Relevance to translational science
- 4. Multidisciplinary Team
- 5. Potential for future external funding or intellectual property development
- 6. Soundness of the design and proposed methods
- 7. Feasibility of accomplishing the project goals in one-year project period
- 8. Level of community engagement (when applicable)
- 9. Utilization of SCTR Resources and services

AWARD DETAILS

- Notice of Award (NOA) and funding cannot be released until all requested just-in-time (JIT) information and required
 regulatory documents have been approved and copies submitted to the SCTR Pilot Project Program during the JIT
 period.
- SCTR is funded through a cooperative agreement with the NIH. Therefore, the SCTR Pilot Project Program office will continue to follow longitudinal progress of the projects for up to 5 years from the project start date.

Who may I contact for more information?

Questions regarding the application process may be directed to <u>Dayan Ranwala</u>, <u>PhD by email</u>.

Questions about Translational Science may be emailed to <u>SCTR's Office of Science Development</u>. We will respond directly to specific inquiries and compile general questions for discussion during the informational session.