South Carolina Clinical & Translational Research Institute (SCTR)
Request for Applications (RFA) for Pilot Project Program Grants

SCTR High Innovation - High Reward (HIHR) Grant Applications RFA

Applications are accepted on a rolling basis.
Since applications are accepted on a rolling basis you are required to inform the SCTR Pilot Project Program Office via email to Dayan Ranwala, PhD, at ranwala@musc.edu as soon as an application is submitted to process it accordingly.

PURPOSE:
The purpose of this RFA is to support new and interdisciplinary pilot projects that propose substantial development of intellectual property (IP) and/or commercialization opportunities.

AWARD AMOUNT: Up to $10,000 direct costs for a 12 month period from the date Notice of Award is issued.

OVERVIEW
SCTR's Pilot Project Program aims to facilitate new and innovative, high-impact translational research with emphasis on diseases demonstrating significant prevalence in South Carolina. The primary objectives of pilot funding are to support new and innovative, scientifically meritorious projects to collect critical preliminary data for submission of extramural grant applications and to publish research findings. We place a premium on interdisciplinary team science and new collaborations. Therefore if you are applying for this grant mechanism it is required to have an interdisciplinary collaboration with at least one Co-Investigator/Collaborator from a different discipline. This RFA does not preclude submitting new and innovative project ideas from existing investigator teams even if it is not a new collaboration, but the novelty of the research direction needs to be clearly distinguished from the PI's past and current research. The existing investigator teams still have to be interdisciplinary (i.e. should not be made of investigators who are working in the same lab such as an investigator and a post-doctoral fellow from the same lab). We also provide pilot funding support for highly promising early career investigators, as Principal Investigators, who are faculty members within 10 years of completing their terminal research degree, medical residency or specialty training to shorten the time to research independence. However the investigative team still has to be interdisciplinary.

• Triage Triggers: Incomplete applications; late applications; applications with no interdisciplinary teams (i.e., single investigator applications, investigators working in the same lab); and resubmitted applications that do not address previous review critique are considered not responsive to the RFA and will not be reviewed. There will be no exceptions.
• Single SCTR Concurrent Award: Please note that a PI can have only one active award from SCTR at any given time (i.e., pilot project award, KL2 award or Community Engaged Scholars award) – this restriction does not apply to SCTR Vouchers. PIs with an active SCTR award are not eligible to apply until the currently awarded project is complete and a final progress report for the project is submitted.
• PIs and Co-Is with Previous SCTR Funding: PIs and/or Co-Is who have been previously funded via a SCTR award (and the project is closed) must submit an updated progress report as an appendix to the
new pilot project’s Research Proposal). The report will be evaluated to determine the progress/stewardship of the previous SCTR award. Failure to do so will result in the application being triaged.

- **Acknowledgement of NIH/NCATS CTSA Grant:** By accepting SCTR funds and support, you acknowledge the requirement to cite the National Institute of Health’s (NIH) National Center for Advancing Translational Sciences (NCATS) grant support in each publication, press release or any other document(s) and presentations similar to the following:

  “This publication (or project) was supported in whole or in part by the South Carolina Clinical & Translational Research (SCTR) Institute, with an academic home at the Medical University of South Carolina through NIH/NCATS Grant Number UL1 TR001450.”

### FREE CONSULTATIONS

The following free consultations are available from the SCTR Institute to help strengthen your pilot project (and other) applications. Please visit [http://sparc.musc.edu](http://sparc.musc.edu) to view consult descriptions and request those of interest. They are listed under the MUSC tab, and then under the SCTR tab to you left.

- Biostatistics, Design & Epidemiology
- Community Engagement & Research
- Via SCTR SUCCESS Center: Grant Forms & Budget Services, Regulatory Services, Recruitment Services and Special Populations Navigation
- Nexus Research Coordination and Management
- Self-service Research Data & Feasibility
- Mobile Health and TACHL Center
- Research Data Requests
- Biomedical Informatics Center
- Intellectual Property and Commercialization Resources

Palmetto Profiles web page at [https://profiles.healthsciencessc.org/profiles/search/](https://profiles.healthsciencessc.org/profiles/search/) is a great resource for finding collaborators.

### KEY DATES

- Applications are accepted on a rolling basis.
- **Since applications are accepted on a rolling basis, you are required to inform the SCTR Pilot Project Program Office via email (to Dayan Ranwala, PhD, at ranwala@musc.edu) as soon as an application is submitted.**
- Applications will be reviewed within 3-4 weeks of submission.

### PROGRAM ELIGIBILITY

**Principal Investigator (PI)**

- **Eligibility:** PIs must have a primary faculty appointment at MUSC (at the level of Assistant Professor or above). Faculty from other academic institutions are encouraged to partner with MUSC faculty on collaborative applications. Please contact the SCTR SUCCESS Center for assistance with collaborator matching at success@musc.edu or 843-792-8300.

Early Career (EC) Investigators are encouraged to submit proposals as PIs. EC investigators are faculty members with no more than ten years past postdoctoral or specialty/subspecialty training as similar to the NIH guidelines.

- **EC investigators who are submitting applications as PIs should identify them as ‘EC’ where it is indicated on the online application.**
• Undergraduates, graduate students, clinical trainees, post-doctoral and clinical fellows, visiting faculty, and individuals with pending faculty appointments cannot serve as the PI of an application, but may serve as a Co-Investigator (Co-I) provided they meet the criteria listed below for Co-Is.

Co-Investigator (Co-I)
• Co-Is should have helped conceive of the experimental idea, contributed to the intellectual development of the concept, and/or designed the study or part thereof (scientific or technical details).
• At least one Co-I, who should be from a different discipline than that of the PI, is required.
• Co-Is that are community members or Co-Is without an eRACommons user name should enter “N/A” in the appropriate box on the online application.
• Co-Is that are community members and who may not have a NIH biosketch can submit their resume/CV as appropriate where it is indicated as the ‘biosketch’ upload in the application.
• If an application proposes an undergraduate or graduate student as a Co-I or research assistant, the PI must provide a justification as to why a student is included in the proposed project and how work on the proposed pilot project is related to the student’s thesis/dissertation research project. Proposed student(s) – undergraduate and/or graduate – must be identified by first name and last name (i.e., TBD/TBN is not allowed).

Consultants
• Please include consultant(s) names and their roles/duties in the research proposal. You do not have to include their information on the online submission form.

BUDGET AND ALLOWABLE COSTS
• Faculty Salary Support. Faculty member’s effort, related to the proposed pilot project, must be clearly listed in the budget. Support of faculty salary and fringe benefits are allowed up to 5% efforts for each member subject to the NIH salary cap. It should be noted that the personnel salary requests and all other budget item requests should be clearly justified and appropriate to conduct the proposed research properly.
• Effort Reporting. For federal/institutional compliance purposes, it is PI’s responsibility to make sure all the investigators efforts listed in the budget are in compliance with their institutional effort policy. Investigators’ are not required to accommodate their efforts on the pilot project budget. However, they have to be in compliance 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. Please confirm fringe benefit rates on your respective institution’s Sponsored Awards Office website.
• Students. The SCTR pilot project funds cannot be used to cover student tuition fees or health insurance costs in any way directly or indirectly as a stipend. If an application proposes a student stipend as undergraduate or graduate student research assistant, we will deny funding support. If an application proposes a student as a Co-I or research assistant, the PI 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, such as Mentors, Secretaries, and Administrative Assistants, is not allowed.
• Non-personnel Research Expenses. Some allowable expenses are: supplies, equipment (under limited circumstances), animal purchase cost and care, study subjects stipends, study subjects 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.

- **Unallowable costs.** General office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, traveling costs to meetings, publication and subscription costs, mailing costs, and rent.

- **Facilities & Administrative (Overhead/Indirect) Costs.** Facilities and administrative costs, also known as indirect/overhead costs, are not permitted.

- **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 will work with PIs and their Business Managers to establish subawards once an application is approved for funding. However, the PI’s Department/Division will be responsible for establishing and managing all subawards.

- **Business Manager Responsibilities.** PI’s Department/Division Business Manager shall be responsible for all human resource, procurement and reconciliation activities for the funded project account(s).

**APPLICATION PROCESS**

- Access SCTR Pilot Project website at [http://academicdepartments.musc.edu/sctr/programs/pilot_projects](http://academicdepartments.musc.edu/sctr/programs/pilot_projects) and click the appropriate “Apply” link listed under the ‘HIHR Grants’ to fill out the online application form.

**FOR ALL DOCUMENTS**

- **Font Type and Size** Arial, 11pt.
- **Page Margins** No less than 0.5” on all sides (one-half inch)
- **Document Type** Please DO NOT use the PHS 398 PDF fillable forms since they are not compatible with the SCTR online application system. You must use the MS WORD template and convert the document to a PDF file to upload.

**APPLICATION INSTRUCTIONS:** The application consists of four uploads:

1) Each Investigator’s biosketch in the new 5-page NIH biosketch format  
2) Description: Project Summary and Relevance Page, 1-page limit  
3) Budget and Justification: PHS 398 format  
4) Research Proposal: 3-page limit. Please indicate if a Record of Invention has been submitted to MUSC Foundation for Research (FRD).

- **NIH biosketches** for all investigators are required in the new 5-page format (Biographical Sketch Format Page – Forms Version D) at [http://grants.nih.gov/grants/funding/424/index.htm#format](http://grants.nih.gov/grants/funding/424/index.htm#format)  
**NOTE:** If your project team has community members as investigators, they do not need to have the eRACommons user names or NIH biosketches. On the online form, indicate ‘Not Applicable’ for their eRACommons User Name and upload a PDF version of their resume or CV in place of a biosketch.

- **Description: Project Summary and Relevance* (1-page limit).** Please follow PHS 398 instructions for content, and combine the Project Summary and Relevance onto 1 page.  
  o Project Summary should serve as a succinct and accurate description of the proposed work when separated from the application. State the application’s broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to others working in the same or related fields and understandable to a scientifically or technically literate reader.
  o The Relevance should state, in lay language, how the research is relevant to public health
- **Budget and Justification**: Applicants must use the PHS 398 Form Page 4: Detailed Budget for Initial Budget Period for the budget page, and use Continuation Format Page for the budget justification. **Each budget line item must be clearly justified.** Combine your budget and justification into a single PDF file to submit via the online application.

- The **Research Proposal (3-page limit)** – combine all of the following sub-bullets into a single PDF document to upload as the ‘Proposal’. Follow PHS 398 instructions for **Specific Aims** (1-page limit), and **Research Strategy** (2-page limit).
  - **Specific Aims** should state concisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposal, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new technology.
  - **SCTR-specific instructions** (not in PHS 398 guide) – on the remainder of the Specific Aims page, include how the project will stimulate new and multidisciplinary collaborations and plan for the substantial development of IP and Commercialization (as appropriate for the HIHR grant applications) plans/potential to secure future extramural funding including funding agency and mechanism (R, SBIR, STTR).
  - The **Research Strategy** should be informative enough for reviewers to understand the proposed research without any supporting documents. Follow PHS 398 instructions and standard review criteria for this section which includes Significance, Innovation and Approach. Be sure to explain the roles/duties of each team member.
  - **Literature Cited** should be included at the end of the Research Proposal and is not counted towards the Research Proposal page limit.
  - All intellectual property disclosures pertaining to your application must be listed separately at the end of the Literature Cited Section - disclosures include: abstracts, posters, platform presentations, theses & dissertations, funded grant applications, and manuscripts. Foreign patent rights are lost immediately upon one of the foregoing and US rights are gone if it is more than one year old.
  - **Updated Progress Report** from the PIs and Co-Is with Previous SCTR Awards should come next and is not counted towards the Research Proposal page limit. PIs who have been previously funded via a SCTR award (i.e., pilot project, KL2 award, Community Engaged Scholars) must submit an updated progress report (additional 2-3 pages allowed). The updated progress report will be evaluated to determine the progress/stewardship of the previous SCTR award. The progress report should include the following:
    - Project Title/s and each Project Begin/End Dates
    - Funding Mechanism (i.e., pilot award, KL2 award, and/or Community Engaged Scholars)
    - Brief Summary of each project Findings/Results
    - Extramural Funding Activity resulting from the SCTR award (applied, pending, awarded)
    - Include name of the funding agency, project title, award amount and duration, grant number – if funds have been awarded.
    - Publications listing (include PMCsIds and/or NIHMS Manuscript IDs, PMIDs, journal name)
    - If applicable, intellectual property record of invention listing and iEdison number

**APPLICATION REVIEW CRITERIA AND PROCESS**

**Overview**
A minimum of two SCTR Scientific Review Committee (SRC) members, and/or an approved ad hoc reviewer, and a biostatistician will review the applications. SRC review critiques will be sent to the appropriate PIs.
Review Criteria for Scoring
SCTR utilizes the standard NIH Review Criteria for extramural research applications. A link to those review criteria is: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html

Additional/Special Review Criteria
- Potential for successful IP and commercialization, and extramural grant applications that may generate from the proposed research

AWARD DETAILS
- Pilot project funding cannot be released until all required regulatory documents have been approved and copies submitted to SCTR Pilot Project Program via a REDCap Survey during the just-in-time (JIT) period.
- Please note that the SCTR grant is a cooperative agreement with the NIH/NCATS. The SCTR Pilot Project Program office will continue to follow longitudinal progress of the funded projects to report to NIH/NCATS. Project Progress reports are due at 6-month intervals while the project is active. Thereafter brief annual progress reports will be requested for 5 years after project closing date for NIH/NCATS reporting.
- Your project will be evaluated at the 6-month of project start date to determine the progress and viability.

RESUBMISSION OF AN APPLICATION
- Applicants will have the opportunity to submit one revised application.
- The resubmission, similar to the NIH guidelines, should thoroughly address the SRC review critiques using up to 2 additional pages in the front of the application.
- The revisions to the body of the proposal should be highlighted throughout to facilitate the re-review process and facilitate assessment of responsiveness to the critiques.