OVERVIEW
SCTR’s Pilot Project Program aims to facilitate new and innovative, high-impact translational research. 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 team 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 and research team’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). Further, we encourage submission of applications that may have emanated as a result of SCTR Scientific retreat/s, patient-centered and community-engaged applications, and those focused on implementation and dissemination science. 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.

• Triage Triggers: Incomplete applications; late applications; applications with no interdisciplinary teams (i.e., single investigator applications, investigators working in the same lab); and/or Early Career applications missing required components (i.e., mentoring plan, support letters – see page 3 of the RFA) are considered not responsive to the RFA and will not be reviewed. There will be no exceptions.

• Principal Investigator (PI) Eligibility: PIs must have a primary faculty appointment at MUSC (at the Assistant Professor level or above). Faculty from other academic institutions are encouraged to partner with MUSC faculty on collaborative applications as a Co-PI or Co-I as appropriate. Palmetto Profiles web page at https://profiles.healthsciencessc.org/profiles/search/ is a resource for finding collaborators. Please contact the SCTR SUCCESS Center for assistance with collaborator matching at success@musc.edu or 843-792-8300.

• 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 the project close out progress report is submitted.
• **Investigators with Previous SCTR Funding:** All investigators, who have been previously funded via a SCTR award and if the project is closed, must submit an updated progress report as an appendix to the new pilot project’s Pre-proposal page (for the Pre-applications) and Research Proposal (for the Full applications). Please see Page 5 of the RFA for more instructions. **This applies to all the investigators in the current application regardless of whether it is the PI, Co-PI or Co-I in the current application.** 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.

• **Resubmissions of Full Applications:** Applicants will have the opportunity to submit one revised full application. Those applicants are not required to submit another Pre-application. Instead they should submit the revised full application addressing the prior review critique as listed in the Page 9 of the RFA. However, those PIs should contact the SCTR Pilot Project Program Office (Dayan Ranwala at ranwala@musc.edu) via emails to inform their intentions and to receive the application submission link.

• **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.”

### DISCOVERY GRANT CATEGORY

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<th>Purpose</th>
<th>Funds Available</th>
<th>Special Requirements</th>
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| Facilitate new and high-impact translational research (from basic to clinical to community/population health) with emphasis on diseases of significant prevalence in South Carolina – especially proof of concept & feasibility projects, special populations, integrated team science and health disparities. | Up to $25,000 in direct costs (indirect costs are not allowed)  
Award term is 12 months from the date the NOA is issued | Projects must be new and interdisciplinary, and include at least one co-investigator  
A biostat consult prior to submission of the full applications is strongly recommended (from your respective Department or SCTR Institute via SPARC)  
Early Career Faculty must include an Individual Development Plan with mentor’s signature, mentoring plan and mentor support letter(s) – see page 3 of the RFA for additional requirements  
Progress reports at 6-month intervals while the project is active  
Brief annual progress follow-ups for up to 5 years from the project start date for NIH reporting |

### 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
• Comparative Effectiveness and Data Analytics Research Resource (CEDAR)
• 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

KEY DATES
Pre-application Submission (REQUIRED): by noon on Friday (EST), August 11, 2017
Selected applicants notified to submit full applications: Friday, September 8
Full Application Due: by noon on Friday, September 29
Scientific Review: Wednesday, October 25, 2017
Earliest Anticipated Date: November 1, 2017

APPLICATION WEBSITE
Access the SCTR Pilot Project website to submit your application at:
http://academicdepartments.musc.edu/sctr/programs/pilot_projects

PROGRAM ELIGIBILITY

Principal Investigator (PI)
• Faculty members may serve as the PI or Co-PI of only one application or SCTR-funded award at any given time.
• Faculty members from other institutions can be a Co-PI or Co-I as appropriate. However, the primary PI should have an appointment at MUSC.
• Undergraduates, graduate students, clinical trainees, post-doctoral and clinical fellows, instructors, 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.
• EC investigators who are submitting applications as PIs should identify them as ‘EC’ where it is indicated on the online application form and submit all the required information/documents below. Incomplete EC PIs applications will not be reviewed.

Early Career Principal Investigators (PI)
Early career PIs must include the following in their application:
• Qualified senior co-investigator(s) as mentor(s) must be identified in the research proposal - include the mentor(s) name, biosketch and support letter(s)
• List the mentor as a co-investigator on the online application and indicate them as a mentor by their last name by entering (Mentor) within parentheses
• Strong mentorship plan – include details of EC/mentor interactions, frequency of meetings, additional resources, etc.*
• Timetable and plan for achieving research independence*
• Potential of the project to lead to independent funding with a plan to submit a K-series or R-series application *
*Early Career PIs are allowed to submit one additional page in their research proposal to address these additional requirements. The support letter/s can be extra pages and will not be counted towards the page limit.

**NOTE:** Please carefully read ‘Review Criteria for Scoring’ for special criteria related to EC applications.

**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.

**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 members’ effort, related to the proposed pilot project, 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. It should be noted that 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 the PI’s responsibility to make sure all faculty effort listed in the budget is in compliance with their institutional effort policy. Investigators are not required to accommodate their effort 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.
- **Students.** The 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, such as Mentors 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 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.
• Unallowable costs. General office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, travel 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. If needed, the SCTR Finance Office can assist PIs and their Business Managers to establish subawards once an application is approved for funding. However, the PI and PI's department will be responsible for establishing the subaward on time to start the project without delay, and managing it. If the subaward is not processed on time and delay is due to the negligence by the PI and PI's department, SCTR may deny the funding for your project.

• 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 PROCESS
• For Pre-applications: Access SCTR Pilot Project website at http://academicdepartments.musc.edu/sctr/programs/pilot_projects and click the appropriate “Apply” link to fill out and submit the online application form.

• For Full Applications (by invitation only): The application submission web link will be sent to each PI who has been selected to submit a full application after the Pre-application Scientific Review Committee meeting.

• NIH biosketches for all investigators are required in the new 5-page format at 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.

• Investigators who have been previously funded via a SCTR award (i.e., pilot project, KL2 award, Community Engaged Scholars) must submit an Updated Progress Report, regardless whether those investigators serve as a PI, Co-PI or a Co-I in the current application. The report should be submitted as an appendix to the new pilot project’s Research Proposal section (additional 2 pages allowed; combine files into a single PDF to upload). The updated progress report will be evaluated to determine the progress/stewardship of the previous SCTR award. The progress report should include the following:
  o Funded Project Title/s and each Project Begin/End Dates.
  o SCTR Funding Mechanism (i.e., pilot award, KL2 award, and/or Community Engaged Scholars).
  o Brief Summary of each project including the specific aims, and findings/results of each specific aim, overall results and conclusions.
  o Extramural Funding Activities resulted from the SCTR award: Please use the subheadings as: Applied, Pending, Awarded etc., as appropriate, and include each grant information in the following order. Name of the funding agency, project title, form of funding (R01, R21 etc.), investigators/team members names, award amount and duration, grant number – if funds are awarded.
Publications resulted: Please use the subheadings as: Published, Under review, Submitted etc., as appropriate, and include each publication information in the following order. Title of publication/s, Authors, Journal Name, Year, PMCID(s) (and/or NIHMS Manuscript IDs, PMID(s) as applicable) and whether you have acknowledged SCTR support/SCTR Grant number(s) in the publication.

If applicable, intellectual property rights such as record of invention disclosure to MUSC Foundation for Research Development, Patent and iEdison number etc.

FOR ALL DOCUMENTS
- **Font Type and Size**: Arial, 11pt.
- **Page Margins**: No less than 0.5” on all sides (one-half inch)
- **Document Type**: PDF (DO NOT use the PHS 398 PDF editable or fillable forms, you must use the MS WORD template and convert the document/s to PDF file/s since they are not compatible with the SCTR application system)
- **Link to PHS 398 Forms**: http://grants.nih.gov/grants/funding/phs398/phs398.pdf

PRE-APPLICATION INSTRUCTIONS: PIs are REQUIRED to submit pre-applications. SCTR will review the pre-applications and invite only selected applicants to submit full applications.

- **The pre-application consists of three 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. Pre-proposal Page: 1-page limit with an exception for EC investigators - see below for details
- **NIH biosketches** for all investigators are required in the PHS 398 new 5-page format. Please see the details at http://grants.nih.gov/grants/funding/424/index.htm#format
- **Description: Project Summary and Relevance** *(1-page limit)*. Follow PHS 398 instructions for content, and combine the Project Summary and Relevance onto 1 page.
  - 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.
  - The Relevance should state, in lay language, how the research is relevant to public health
- **The Pre-proposal Page** must include* *(1-page limit)*:
  - Brief description of the hypothesis and aims and include each team member’s name and role; how the project will stimulate new and interdisciplinary collaborations that would otherwise might not have taken place; translational potential of the proposed research; address potential impact on special populations (e.g., rural, geriatrics, women, children) as applicable; plans/potential to secure future extramural funding including funding agency and mechanism (R, P, U, other).
  - Early Career (EC) PIs must include the required additional information detailed on page 3 of this RFA under Program Eligibility – Early Career Principal Investigators; and address the additional/special review criteria on page 8 of this RFA. **One extra page** is allowed to address the additional required EC information (hence 2-pages for the Pre-proposal).
  - Literature Cited should be included at the end of the Research Proposal and is not counted towards the Research Proposal page limit.
  - EC Mentor Support Letter(s) should follow the Literature Cited section.
Updated Progress Report from the investigators with Previous SCTR Awards - 2-page limit. See instructions on page 5 of this RFA.

* Please note that the one-page Project Description and one-page Pre-proposal page will be reviewed together as a blended proposal (since the SCTR application system will combine your uploaded files). The mentor(s) support letters, Literature Cited page(s), and the Updated progress report pages are not counted towards the research proposal page limit. However, they should be uploaded as a single, combined Research Proposal document.

**INSTRUCTIONS: For Investigators Invited to Submit Full Applications**

- The Full Application consists of four uploads:
  1) Each Investigator's biosketch in the new 5-page limit NIH biosketch format (as listed above)
  2) Description: Project Summary and Relevance Page, 1-page limit (as listed above)
  3) Budget and Justification: PHS 398 format
  4) Research Proposal: 5-page limit with an exception for EC investigators - see below for details

- The **Budget and Justification** (discussed above in **BUDGET AND ALLOWABLE COSTS**). Applicants must use the PHS 398 Form Page 4: Detailed Budget for Initial Budget Period for the budget page, and use the 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** (5-page limit) – combine all of the following sub-bullets into a single combined PDF document. Follow PHS 398 instructions for **Specific Aims** (1-page limit), and **Research Strategy** (4-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 that otherwise might not have taken place; translational potential of the proposed research; address potential impact on special populations (e.g., rural, geriatrics, women, children); plans/potential to secure future extramural funding including funding agency and mechanism (R, P, U, other).
  - **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.
  - **Early Career (EC) PIs** must include the required additional information detailed on page 3 of this RFA under Program Eligibility – Early Career Principal Investigators; and address the additional/special review criteria on page 8 of this RFA. **One extra page** is allowed to address the additional required EC information (i.e. a total of 6 pages are allowed for the EC PIs as: 1-page for Specific Aims, 4-pages for Research Strategy, and 1 extra page for EC components as described in the page 3 of this RFA). **NOTE**: include mentor(s) support letters after the Literature Cited page(s) and upload as a single, combined Research Proposal document
  - **Literature Cited** should be included at the end of the Research Proposal.
  - **EC Mentor Support Letter(s)** should follow the Literature Cited section.
- Updated Progress Report from the investigators with Previous SCTR Awards - should come next. Two page limit. See instructions on page 5 of this RFA.

Note: The mentor(s) support letters, Literature Cited page(s), and the Updated progress report pages are not counted towards the research proposal page limit. However, they should be uploaded as a single, combined Research Proposal document.

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. Review critique of full applications 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 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html

Additional/Special Review Criteria
- **Early Career Investigator**
  - If Early Stage Investigators or New Investigators, do they have appropriate experience and training?
  - If Early Stage Investigators, is there a defined mentorship plan with a senior/established investigator (PI is required to submit)?
  - Are there a timetable for becoming independent and a plan for achieving research independence?
  - If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
  - If the project is collaborative, do the investigators have complementary and integrated expertise; is their organizational structure appropriate for the project?

- **Innovation**
  - If the proposed project is related to a Novel Methodology or Technology, is there a potential value to multiple investigators facilitating clinical & translational research and supporting extramurally-funded research projects?
  - Is there an adequate business plan and cost effectiveness of allowing multiple investigators to use core facilities?

- **Potential of successful extramural grant applications** that may generate from the proposed research

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 via a REDCap Survey during the JIT period.
- You are strongly encouraged to use the free SCTR regulatory consultation services to facilitate the submission process. Significant delays on your part in obtaining required regulatory approvals (i.e. more than 2 months of receipt of the JIT notice) may result in SCTR denying the funding for your project.
• SCTR grant is a cooperative agreement with the NIH. Therefore, the SCTR Pilot Project Program office will continue to follow longitudinal progress. Progress reports are due at 6-month intervals while the project is active. Then brief annual progress follow-ups are due for 5 years from the project start date for the NIH reporting.

RESUBMISSION OF FULL APPLICATION
• Applicants will have the opportunity to submit one revised application. Those applicants are not required to submit another Pre-application. Instead they should submit the revised full application as listed below. However, those PIs should contact the SCTR Pilot Project Program Office (Dayan Ranwala at ranwala@musc.edu) via emails to inform their intentions and to receive the application submission link.

• The resubmission, similar to the NIH guidelines, should thoroughly address all prior 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.