South Carolina Clinical & Translational Research Institute (SCTR)
Request for Applications (RFA) for Pilot Project Program Grants
2015-2016 Funding Cycle

RFA Release Date: August 05, 2015

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). Further, we encourage patient-centered and community-engaged applications and those focused on implementation science, dissemination science and studies designed to eliminate roadblocks to clinical and translational research. We also provide pilot funding support for highly promising early career 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.

- **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 4 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 Instructor level 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.
- **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 with Previous SCTR Funding:** PIs 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 section (see page 6 of the RFA for more instructions). The report will be evaluated to determine the progress/stewardship of the previous SCTR award.
- **Human Subjects Recruitment Tracking:** Once funded, studies designed to recruit human subjects are required to track referral resources and report enrollment information via a SCTR-provided form with the Notice of Award (NOA).

Questions:
Contact Dayan Ranwala, PhD
SCTR Pilot Project Program Manager
Email: ranwala@musc.edu
- **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 UL1TR000062.”

---

**THREE GRANT CATEGORIES**

<table>
<thead>
<tr>
<th>Grant Categories</th>
<th>Discovery Pilot Projects</th>
<th>Translational Roadblock Pilot Projects</th>
<th>High Innovation – High Reward Pilot Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Facilitate high-impact translational research (from basic to clinical to community/population health) with emphasis on diseases of significant prevalence in South Carolina – especially special populations, integrated team science, health disparities, proof of concept &amp; feasibility projects, and methods to engage rural patients</td>
<td>Investigate solutions to root causes of problems preventing translation of discoveries into practice (e.g., new recruitment methodology, accelerated regulatory approvals, effective dissemination methods, health literacy, cultural competency and public trust, CDW use)</td>
<td>Stimulate innovative collaborations leading to substantial development of intellectual property and/or commercialization opportunities.</td>
</tr>
<tr>
<td><strong>Funds Available</strong></td>
<td>• Up to $25,000 (Total – indirect costs are not allowed)</td>
<td>• Up to $25,000 (Total – indirect costs are not allowed)</td>
<td>• Up to $10,000 (Total – indirect costs are not allowed)</td>
</tr>
<tr>
<td></td>
<td>• Award term is 12 months</td>
<td>• Award term is 12 months</td>
<td>• Award term is 12 months</td>
</tr>
<tr>
<td></td>
<td>• 2 application cycles per year</td>
<td>• 2 application cycles per year</td>
<td>• 12-MONTH ROLLING SUBMISSION</td>
</tr>
<tr>
<td><strong>Special Requirements</strong></td>
<td>• Data projects must receive a Clinical Data Warehouse (CDW) Feasibility Consult prior to submission</td>
<td>• Emphasis placed on applications with community co-investigators and/or patient advocates</td>
<td>• Must receive a biostatistical consult prior to submission</td>
</tr>
<tr>
<td></td>
<td>• Must receive a biostat consult prior to submission</td>
<td>• Progress reports required at 6-month intervals to facilitate go/no-go decisions</td>
<td>• All disclosures pertaining to your application must be listed separately in the Literature Cited Section - disclosures include: abstracts, posters, platform presentations, theses &amp; 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 ago</td>
</tr>
</tbody>
</table>

---

**FOR ALL PROJECTS**

- Projects must be interdisciplinary and include at least one co-investigator
- Early Career Faculty must include an Individual Development Plan with mentor’s signature, mentoring plan and mentor support letter(s) – see page 4 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 after project closing for NIH reporting
SUGGESTED FREE PRE-APPLICATION CONSULTATIONS
The following free consultations are available to help strengthen your pilot project (and other) applications. Visit http://sparc.musc.edu to view consult descriptions and request those of interest:

- Biostatistics and Research Design
- Budget & Justification
- Study Feasibility & Recruitment (for clinical trials)
- Community Engagement & Dissemination Science, Special Populations, Cultural Sensitivity
- Technology Development and Intellectual Property, if applicable
- Clinical Data Warehouse, if applicable
- Collaborator Matching Assistance – Palmetto Profiles web page at https://profiles.healthsciencessc.org/profiles/search/ is a great resource for finding collaborators.

KEY DATES

For Discovery Projects and Translational Roadblock Projects

CYCLE 1
Pre-application Submission Open Date: Wednesday, August 05, 2015
Pre-application (REQUIRED): No later than Noon on Monday, August 31, 2015
Pre-Application Scientific Review: Wednesday, September 16, 2015*
Full Application Due: No later than Noon on October 15, 2015
Full App Scientific Review: Wednesday, November 18, 2015
Earliest Anticipated Date: December 1, 2015

*Selected applicants will be notified to submit the full applications by the end of day on Friday, September 18, 2015.

CYCLE 2 – dates will be announced in December, 2015

For High Innovation – High Reward Projects

- Applications are accepted on a rolling basis.
- NOTE: As soon as an application is submitted for this category, notify Dayan Ranwala via email at ranwala@musc.edu
- The applications will be reviewed within 3-4 weeks of submission.

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)

- Investigators may serve as the PI of only one application or SCTR-funded award at any given time.
- 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.
- 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 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.

**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 member's effort, related to the proposed pilot project, must be clearly listed in the budget. Support of faculty salary is allowed up to 5% efforts subject to the NIH salary cap.
- **Cost Share to Federal Grant.** SCTR pilot projects are cost share to a federal grant and must comply with federal and institutional regulations/policies related to effort reporting for federal grants.
- **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.
  - Please note that 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.
  - In compliance with the MUSC effort policy, MUSC PIs who plan to charge investigators’ efforts to other funding sources will have to provide the appropriate UDAKs during the Just-in-Time period. Please note that “other sponsored projects” or “in-kind support” cannot be used to cover the efforts. The MUSC policy can be found at: [http://academicdepartments.musc.edu/vpfa/policies/grants/4-5.02.htm](http://academicdepartments.musc.edu/vpfa/policies/grants/4-5.02.htm).
• **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 as inappropriate. 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, 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.

• **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).

**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. If the required documents are not available at the time of the JIT information is due, only those documents should be sent to the SCTR Pilot Project Program office to Dayan Ranwala, PhD at ranwala@musc.edu.

- Please note that the SCTR grant is a cooperative agreement with the NIH, and the Pilot Project Program office will continue to follow longitudinal progress. Progress reports are due at 6-month intervals while the project is active. Brief annual progress follow-ups are due for 5 years after project closing for NIH reporting.

- All the questions/communications should be sent in writing to Dayan Ranwala, PhD via email at ranwala@musc.edu
THE APPLICATION PROCESS

- Access SCTR Pilot Project website (http://academicdepartments.musc.edu/sctr/programs/pilot_projects) and click the appropriate “Apply” link to fill out the online application form.

- **Incomplete or Late applications will not be reviewed.**

- NIH biosketches for all investigators are required in the **new 5-page format** (General Biographical Sketch Format Page – Forms Version C) 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.

- 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** 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 Project Title/s and each Project Begin/End Dates
  o Funding Mechanism (i.e., pilot award, KL2 award, and/or Community Engaged Scholars)
  o Brief Summary of each project Findings/Results
  o 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 awarded.
  o Publications listing (include PMCIDs and/or NIHMS Manuscript IDs, PMIDs, journal name)
  o If applicable, intellectual property record of invention listing and iEdison number

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 PHS 398 PDF fillable forms, you must use the MS WORD template and convert the document to a PDF since it is not compatible with the SCTR application system)
- **Link to PHS 398 Forms** http://grants.nih.gov/grants/funding/phs398/phs398.pdf

FOR HIGH INNOVATION HIGH REWARD (HIHR) APPLICATIONS

- Make sure your application addresses the required criteria for HIHR applications on page 2 of this RFA (see the Grant Categories table).

  The Application consists of four uploads:
  1) Each Investigator’s biosketch in the new 5-page limit 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 with an exception for EC investigators - see below for details

- **NIH biosketches** for all investigators are required in the new 5-page format (General Biographical Sketch Format Page – Forms Version C) 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.
  
  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.

• **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 (3-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 (2-page limit).
  
  o **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.
  
  o **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).
  
  o 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.
  
  o **Early Career (EC) PIs** must include the required additional information detailed on page 4 of this RFA under Program Eligibility – Early Career Principal Investigators; and address the additional/special review criteria on page 9 of this RFA. **One extra page** is allowed to address the additional required EC information (hence 1-page for Specific Aims and 3-pages for Research Strategy). **NOTE:** include mentor(s) support letters after the Literature Cited page(s) and upload as a single, combined Research Proposal document
  
  o **Literature Cited** should be included at the end of the Research Proposal and is not counted towards the Research Proposal page limit.
  
  o **EC Mentor Support Letter(s)** should follow the Literature Cited section and is not counted towards the Research Proposal page limit.
  
  o **Updated Progress Report from the PIs with Previous SCTR Awards** should come next and is not counted towards the Research Proposal page limit – however the report itself has a **2-page limit.** See instructions on page 6 of this RFA.
FOR DISCOVERY OR TRANSLATIONAL ROADBLOCK APPLICATIONS
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.

- Make sure your application addresses the required criteria for Discovery or Translational Roadblock applications on page 2 of this RFA, as appropriate (see the Grant Categories table).

- 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 new 5-page format (General Biographical Sketch Format Page – Forms Version C) 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); 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 4 of this RFA under Program Eligibility – Early Career Principal Investigators; and address the additional/special review criteria on page 9 of this RFA. One extra page is allowed to address the additional required EC information (hence 2-pages for the Pre-proposal). NOTE: include mentor(s) support letters in the single, combined Research Proposal document after the Literature Cited page(s).
  - 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 and is not counted towards the Research Proposal page limit.
  - Updated Progress Report from the PIs with Previous SCTR Awards should come next and is not counted towards the Research Proposal page limit – however the report itself has a 2-page limit. See instructions on page 6 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).
INSTRUCTIONS: For Investigators Invited to Submit Full Applications
(Notification will be sent via email to the PIs who have submitted a Pre-application within 2 business days of the pre-application scientific review committee meeting.)

- Follow the instructions for **High Innovation – High Reward Applications** on Page 6 of this RFA to submit the full application.
- Make sure your application addresses the required criteria for **Discovery or Translational Roadblock applications** on page 2 of this RFA, as appropriate (see the Grant Categories table).
- **NOTE ON PAGE LIMITS – DIFFERENT FROM HIHR APPLICATIONS:** Discovery and Translational Roadblock Research Proposals have a 5-page limit (1 page for Specific Aims and 4 pages for Research Strategy). Similar to HIHR applications, Early Career (EC) applicants may have one additional page to address the required EC information (hence: 1 page for Specific Aims and 5 pages for Research Strategy).

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 for High Innovation-High Reward proposals and all other full-application proposals will be sent to the appropriate PIs. There will be no review critiques for the pre-applications.

**Review Criteria for Scoring**

**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

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.