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

SCTR High Innovation - High Reward (HIHR) Grant Applications RFA
Release Date: February 12, 2016

Applications eligible under this RFA are ONLY the HIHR Grant Applications.
Separate RFA has been released for the Discovery Grant Category related applications on 2/1/2016.

PURPOSE:
The purpose of this RFA is to support new and interdisciplinary pilot projects that propose substantial development of intellectual property 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/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.

- **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 Pre-
proposal page (for the Pre-applications) and Research Proposal (for the Full applications, see pages 7 & 8, respectively, of the RFA for more instructions). 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.

- **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).

- **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. Visit [http://sparc.musc.edu](http://sparc.musc.edu) to view consult descriptions and request those of interest:

- Science Consults
- Intellectual Property and Commercialization Resources
- Biostatistics and Research Design
- Via SCTR SUCCESS Center: Budget & Justification Development, Regulatory, Recruitment Consults
- Self-service Research Data & Feasibility
- Community Engagement & Research
- Nexus Research Opportunities and Management
- Mobile Health and Novel Technologies
- Research Data Requests

### 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 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.

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.

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 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 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.
- 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.

- **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 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).

### APPLICATION PROCESS

- Access SCTR Pilot Project website at 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.
- **Link to PHS 398 Forms** http://grants.nih.gov/grants/funding/phs398/phs398.pdf
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 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

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).
  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 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).
  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 Literature Cited should be included at the end of the Research Proposal and is not counted towards the Research Proposal page limit.
  o 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.
  o 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 6 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.

- **EC Mentor Support Letter(s)** should be included at the end of the above page to upload. The letters are 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. 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 PMCID 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**

**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?
  - Is there a timetable for becoming independent and a plan for achieving research independence?
  - If established, has he/she 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?
- **Potential for successful 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. The SCTR Pilot Project Program office will continue to follow longitudinal progress of the funded projects to report to NIH. 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 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.