South Carolina Clinical & Translational Research Institute (SCTR)
Request for Full Applications (RFA) for Pilot Project Program (PPP) Grants
2010-2011

Key dates

Full Application RFA Release Date: May 21, 2010 (F)
Full Application Due/Receipt Date: June 25, 2010 (F) (Required for Funding)
Just-in-Time Due: August 4, 2010 (W)
Orientation for the Awardees: August 26, 2010 (Th)
Earliest Anticipated Start Date: September 1, 2010 (W)

I. Overview of the SCTR Pilot Project Program (PPP)

• To facilitate innovative, meaningful clinical and translational research with emphasis on diseases demonstrating significant prevalence in South Carolina
• To promote scientific interactions between many disciplines of basic scientists (such as biomedical, biobehavioral, computational, engineering, physical, social, economic, ethical and public health) and clinical scientists, and between clinicians and the community to accelerate the process from discovery, innovation, to improved patient care
• To actively promote an interdisciplinary, interactive translational research culture across Medical University of South Carolina (MUSC) and SCTR affiliated institutions (listed below)
• To provide research support for highly promising trainees and junior faculty to shorten the time to research independence because they are future of clinical and translational research, and they must be supported and encouraged in their efforts
• To support the development of new technologies and methodologies and to ensure they become widely available to investigators across SCTR, with the concept that some projects supported under this initiative may ultimately become new SCTR core facilities

SCTR Participating Institutions and Community Partners

Medical University of South Carolina
Claflin University
Clemson University
Greenville Hospital System
Greenwood Genetic Center
Health Sciences South Carolina

Palmetto Health
Ralph H. Johnson VA Medical Center
South Carolina Research Authority
Spartanburg Regional Healthcare System
University of South Carolina

II. Key Elements of the SCTR PPP Grants

The main objective of the PPP grants is to support studies that will lead to sustainable, innovative, and collaborative projects that will impact human health.
All proposed projects must:
• address an important question in human clinical and/or translational research that impacts human health
• include a collaborative, synergistic team of researchers from different institutions and/or different departments within the same institution
• propose research that is new to the team members (Please note that SCTR pilot grants do not support ongoing projects.)
• require pilot funds to generate preliminary data that will enable the investigators to obtain extramural funding to continue the project

i. Fields of Research
• Translational experiments that propose a hypothesis that will eventually require a human experiment to validate
• Clinical experiments or trials that involve human subjects or samples
• Experiments on human populations. Here, the hypotheses address the multitude of approaches that have the potential to impact the health of an individual, a population, or even global health
• If there is no human subjects involved in your proposal, please address one of the followings:
  ▪ Provide a persuasive argument that the proposed research will lead to work with human subjects within the next 3-5 years
  ▪ Is your proposed research to create infrastructure that will facilitate clinical and translational research within the next 3-5 years
• Projects outside of the traditional scientific and healthcare professions. We encourage the submission of proposals that will address issues of technology, law, ethics, policy, business, industry, and government that have the potential to impact the conduct of human experiments and/or the outcome of the health of a population

ii. Anticipated Outcomes of the SCTR PPP Include:
• generation of critical preliminary data to support new investigator-initiated clinical and translational research grants
• successful applications of extramural grant funding mechanisms using the preliminary data generated from this pilot funding to support and sustain the ongoing research
• proof-of-concept studies to move laboratory findings toward clinical applicability and/or the dissemination of clinical findings to the community
• acquisition or use of new technologies or skills
• development of new collaborations between established scientists and junior investigators as well as between basic scientists and other health-related clinical researchers
• trans-disciplinary collaborations across the SCTR region, including interactions with the private sector and community engagement

iii. Categories of the SCTR PPP Grants
The SCTR PPP funds a range of projects in three broad categories with distinct criteria to meet the need of the investigators from multiple disciplines at various career levels.

1. Discovery Grants. Discovery grants must address an unmet medical need such as identification of new therapeutic targets and agents, and may utilize the expertise and capabilities of the translational technology; a novel fundamental discovery that needs further development to bring it rapidly to a Phase I, II or III trial or that leads to large-scale dissemination/translation; a novel biomarker or clinical discovery that requires rigorous assessment to determine its potential value for large-scale clinical research; or a novel device that needs prototype development.

2. Early Career Investigator Grants. These grants are available to faculty no more than four years past postdoctoral or specialty/subspecialty training. Please see the review criteria listed under the ‘Pre-Application Review Process’. This is essentially a ‘Discovery
Grant’ where an early career investigator partners with an established researcher (for mentoring).

3. **Novel Methodologies and Technologies Grants.** These proposals must include information on the novelty of the target methodology or technology and its potential application to clinical or translational research with consideration of the types of investigators who would benefit. Plans for establishment and management as a core facility and a business plan including cost analysis and fee schedule may be required, as appropriate.

**iv. Award Details:**
The maximum period of award is 12 months, counted as of the effective funding date. The maximum amount to be awarded per application is $50,000/year, direct costs only. Indirect costs are not allowed. **Note that the funding cannot be released until all applicable human and animal subject protocols have been approved and copies sent to the SCTR PPP office.** Each award is non-renewable and non-transferable from one Principal Investigator to another. Please be advised that upon funding, additional administrative documents may be required. Approximately 10-15 pilot grants will be funded in this 2010-2011 cycle. The pilot projects funded in the previous years are listed in the SCTR web page for information purposes only. The listing does not necessarily indicate the types of projects to be funded in future cycles.

**v. Progress Reports**
Progress reports are required every six months (at 6 months and 12 months). The SCTR PPP office will send the progress report forms as each due date approaches. Please note, as the SCTR grant is a cooperative agreement with the National Institute of Health, we will continue to follow the progress of each project post-funding to determine the pilot funding success (extramural funding, publications, IND/IDE, SBIR/STTR, patents etc). You are required to provide copies of publications, any future extramural funding award notifications, and invention disclosures that occurred as a result of your pilot project funding.

Please note that you are required to acknowledge CTSA/SCTR PPP funding as shown below on any publications that would result from this award as per NIH/NCRR guidelines.
"This publication (or project) was supported by the South Carolina Clinical & Translational Research Institute, Medical University of South Carolina's CTSA, NIH/NCRR Grant Number UL1RR029882. The contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH or NCRR."

**III. Program Eligibility**

i. **Investigators**
   a. **Principal Investigators:**
      Any SCTR affiliated institute member who holds a university faculty appointment is eligible to be the Principal Investigator.
      - Individuals may serve as the Principal Investigator of only one proposal.
      - Professors, Associate Professors, Assistant Professors, Instructors
      - Undergraduates, graduate students, clinical trainees, post-doctoral and clinical fellows, visiting faculty, and individuals with pending faculty appointments cannot serve as the Principal Investigator of an application, but may serve as a Co-Investigator provided they meet the criteria listed below for Co-Investigators.
      - Since one of the goals of the SCTR Pilot Grant is to help train the next generation of clinical and translational investigators, we encourage junior investigators (i.e. prior to
promotion to Associate Professor) to submit applications. However, since experience and expertise will be criteria for funding, we encourage junior faculty to recruit pertinent senior Co-Investigator(s).

b. Co-Investigators
SCTR Pilot Grants require collaborative research that crosses divisions, departments, institutions, and/or communities. Researchers must make a substantial contribution to the project in order to be listed as Co-Investigators. Substantial contributors should have:

- helped conceive of the experimental idea, or contributed to the intellectual development of the concept
- designed the study or part thereof (scientific or technical details)

At least one Co-Investigator is required, with a limit up to ten Co-Investigators are allowed to be listed. While investigators may submit only one application as Principal Investigator, they may be listed as a Co-Investigator on multiple applications.

IV. Overview of Full Application and Review Process

i. Full Application
Due Date: Friday, June 25, 2010, 11:59am
The application consists of an on-line form and pdf uploads, similar to the pre-application but with a budget and budget justification, and more detailed proposal with a page limit of 8, and must be submitted online through the SCTR website at http://sctr.musc.edu/index.php/programs/pilot-projects

Submission of a full application is required to be considered for funding and there will be no exceptions permitted. Please allow the time before the deadline to deal with any unexpected problems submitting the application. The SCTR PPP personnel will be available until noon on the due date to help should you encounter problems submitting the application. Applications will not be able to submit after 11:59am on the due date. Any requests for application submission after due date/time will be denied. Please see the full application components below.

ii. Components of the Full Application
The application on-line form should be completed in full and any questions with an * are required an answer. The form cannot be submitted if any of the required fields are left blank. If the application is not correctly filled in or will not be submitted on time will be disqualified. The full application can be saved and return back to finish. Please fill in all the required information and uploads before submitting the full application. Once submitted, you will be able to download a pdf copy of the application but you will have no access and will not be allowed to change the application.

Principal Investigator (PI) Information
- Name*
- eRA Commons ID*

Please see your departmental administrator for information about obtaining an NIH eRA Commons ID. See also https://commons.era.nih.gov/ MUSC investigators can contact Robbie Lee, Office of Research & Sponsored Programs at 843-792-7198 or lee@musc.edu if you need to obtain an eRACommons user ID. Investigators in other institutions, please contact appropriate personnel to obtain the eRACommons ID before submitting the full application.
• PI biosketch:* (Following the new NIH 4-page requirements, including personal statement and 15 most applicable publications. NIH format, rules and page limit apply, pdf upload only)
• Degree*
• Faculty Rank*
• Home Institution*, Academic Appointment Institution*, Department* and Center Affiliation (some institutions may have Center affiliations instead of Departments), and Division within institution
• NIH Specialty Code* (Investigators on any study requesting use of the Clinical Research Unit must designate their primary area of specialty by selecting the NIH specialty code)
• Telephone number where investigator can be contacted*
• Email address*
• Physical Address* (Address 1* should be PI’s primary location. Address 2 can be used if the PI needs more space for the address or for a secondary location as necessary).
• Project Title* (Please limit to about 150 characters without space)
• Grant Category*
• PI Business Manager Name*, Phone*, email*, Physical address*
• Optional Contact Person name, phone, email, Physical address (if different from PI)
• All correspondence will be sent to PI and it will be PI’s responsibility to coordinate with the Co-Investigators. The PI can indicate one additional person (optional contact) to contact with information regarding your application.

Co-Investigator (Co-I) Information
Similar to PI's information, all Co-I's information is required.
To add information for Co-Investigators, please select the ‘Click on button to add Co-I’ on the on-line form for each Co-I. At least one Co-Investigator is required and the limit is ten.

Additional Information
• IRB*
Indicate whether the proposed research will require IRB approval. If IRB approval is required, indicate if you have already obtained this approval.
• IACUC*
Indicate whether the proposed research will require IACUC approval. If IACUC approval is required, indicate if you have already obtained this approval.
• Child health component*
Select ‘yes’ if the proposed study has a child health component, which is defined as not only studies on pediatric subjects or populations, but also maternal-fetal medicine, childhood antecedents of adult disorders, and translational studies related to diseases of children and adolescents.
• Previous collaborations with Co-I/s*
Have you ever applied for funding or published with any of your co-investigators?*
If the PI has previously collaborated with any of the Co-I’s, this should be indicated in here. A brief explanation of the previous collaboration/s and how it relates to this work should be provided (limit to 250 words).
• Upload your abstract and relevance:* (abstract limit to 250 words, relevance should be brief and limit to 150 words, PHS 398 format, 1 page limit, Arial font size 11, at least 0.5 margins, pdf only)
• Upload the detailed budget and justification (Use the PHS 398 form ‘Detailed budget for initial budget period direct costs only’ (1 page) at [http://grants.nih.gov/grants/funding/phs398/fp4.pdf](http://grants.nih.gov/grants/funding/phs398/fp4.pdf) and use continuation 1-2 extra pages as needed for the budget justification, Arial font size 11, pdf only)
• Upload your proposal:* (8 page limit for the proposal, the 8 page limit does not include the literature citations, and any recommendation and supportive letters that you may have. But the proposal, literature citations, letters, and any other supportive documents that you may have should be uploaded as a single pdf in the full application where it is indicated as ‘upload the proposal’. Arial font size 11, at least 0.5 margins, pdf only)
• In the proposal, you must include project description, background, specific aims, methods description, anticipated results, power estimates, and data analysis, significance, time table, translational potential, whether the funding would stimulate collaborations that otherwise might not have taken place, potential for extramural funding and the types of funding for which you intend to apply.

iii. Full Application Review Process:
Reviewers are faculty members from the SCTR affiliated institutions. The applications will be reviewed by a scientific review committee. The reviewers will be asked to look for following primary considerations in addition to the scientific merit:
• Does the application responsive to the RFA?
• Does the proposal address an important health problem and, if successful, will the results have a substantial impact on human health
• Does the proposal have ‘Translational Potential’?
• Is the proposal new and innovative?
• Is there an inter-departmental or inter-institutional team? Does the proposed project stimulate new collaboration across institutions? At least two of the collaborations between disciplines and/or institutions are required.
• Is the collaboration new and project roles established for the team?
• Does the funding stimulate collaborations that otherwise might not have taken place?
• Is the project focused, feasible, and achievable, and does it have a high potential to secure future extramural funding?
• Do the investigators have the requisite skills and experience to carry out the project successfully?

The reviewers will also be asked to comment on the following for the Early Career Investigator grant category:
• Clearly defined mentorship plan with a senior/established investigator
• Is adequate supervision and mentoring provided for junior faculty and trainees who will carry out the project?
• Plan for achieving research independence and potential to lead to independent funding (with a plan to submit K or R applications)
• Defined need for funding to support proposed direction of research

The reviewers will also be asked to comment on the following for the Novel Methodologies and Technologies grant category:
• Project Innovation
• Likelihood of facilitating clinical and translational research
• Potential value to multiple investigators, Number of potential users
• Potential to support extramurally-funded research projects
• Business plan, economic impact such as cost effectiveness of allowing multiple investigators to use core facilities

VIII. Allowable Costs
**Faculty Salary Support:** Faculty salary support is allowed, however you must be able to demonstrate that you can successfully accomplish your proposed Scope of Work within the budget parameters ($50K) to generate necessary preliminary data for a successful extramural grant application.

**Other Personnel Support:** Salary and fringe benefits are allowed for technical support, such as: Research Fellows, Research Assistants, Clinical Coordinators, Research Nurses, etc. However, 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), travel to research meetings, 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:** are general office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, subscription costs, mailing costs, rent, and graduate student lab costs.

**Facilities and Administrative Costs:** Facilities and administrative costs, also known as indirect costs, are not permitted.

**IX. More Information Regarding SCTR Pilot Project Program (PPP)**

We encourage your inquiries concerning SCTR PPP application process. Inquiries should be directed to Dayan Ranwala PhD, SCTR Institute, in writing at ranwala@musc.edu