PILOT PROJECT PROGRAM
REQUEST FOR APPLICATIONS (RFA) and SUBMISSION GUIDELINES
2015-2016 FUNDING CYCLE

KEY DATES
RFA Release Date: June 1, 2015
Letter of Intent Due Date: June 15, 2015
Application Due Date: July 15, 2015
Earliest Anticipated Funding Date: December 1, 2015

OVERVIEW
SCRCRS's Pilot Project Program aims to attract additional junior and senior investigators into the field of stroke recovery research, promote utilization of the scientific cores, develop new collaborations and mentoring relationships, and stimulate new programmatic activities to build long-term sustainability of the Center.

PILOT PROJECT CATEGORIES
The SCRCRS Pilot Project Program will include various types of awards, modeled on SCTR's categories, as shown below.

<table>
<thead>
<tr>
<th>Grant Categories</th>
<th>Brief Description</th>
<th>Award Amount</th>
<th>Award Duration</th>
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</thead>
<tbody>
<tr>
<td>Fast Forward</td>
<td>Generate critical preliminary data for a planned submission/resubmission of an extramural grant application within 6 months.</td>
<td>Up to $10,000</td>
<td>Up to 1 year</td>
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<tr>
<td>Mentored Investigator (Choose Early Career on SCTR website)</td>
<td>Provide mentored research experiences for junior investigators who will use the cores and may become candidates to replace current COBRE Junior Investigators (JIs) as they graduate.</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
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<tr>
<td>Discovery Awards</td>
<td>Provide strategic support to explore the feasibility of projects that might become collaborative R01s or center grants.</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
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<tr>
<td>Novel Methods &amp; Technologies</td>
<td>Provide support for new equipment or techniques to ensure that core capabilities continue to be current and innovative.</td>
<td>Up to $50,000</td>
<td>Up to 1 year</td>
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TO APPLY
Access the application submission portal at: http://academicdepartments.musc.edu/sctr/programs/pilot_projects

PROGRAM QUESTIONS
Dr. Naren Banik
Email: baniknl@musc.edu

ADMINISTRATIVE QUESTIONS
LuAnne Harley
Email: harleylu@musc.edu
Phone: 843-792-3320

SCIENTIFIC SCOPE AND CORES
http://academicdepartments.musc.edu/srrc
KEY ELEMENTS OF THE SCRCRS PILOT PROJECT PROGRAM

The main objective of the program is to promote the growth of the SCRCRS through the development of new extramural funding and the utilization, enhancement and advancement of critical technologies and SCRCRS core services. The pilot project program is not designed to provide ongoing support for a long-term project or to provide supplemental support to ongoing funded research projects.

PILOT PROJECTS MUST AIM TO:

- Address an important question in basic, translational and/or clinical research that impacts recovery from stroke (ALL Grant Categories).
- Generate critical preliminary data to support submission of a competitive extramural grant application that will directly utilize one or more of the SCRCRS Cores (Fast Forward, Mentored Investigator and Discovery Grants).
- Develop or acquire a new method or technology that will directly enhance, advance or replace one or more functions or services within a designated SCRCRS Core (Novel Methods & Technologies Grants).

PILOT GRANT CATEGORIES

Pilot project grants will support four general categories of pilot projects associated with SCRCRS: Fast Forward Pilot Grants, Mentored Investigator Pilot Grants, new translationally-based Discovery Pilot Grants, and Pilot Grants for Novel Methods and Technologies. They will not be used to provide ongoing support for a project or provide bridge funding. Indirect costs (F&A) will not follow pilot project subawards; pilot project budgets will fund direct costs only. Funds may be requested for standard allowable expense categories such as key personnel and technical support (including fringe benefits at institutionally established rates), research supplies, professional travel directly beneficial to the proposed research, and other direct costs such as laboratory animal costs, research subject compensation, and data analysis/statistical support. Funds for research equipment (> $5,000) may be requested only in Category 4, Pilot Projects for Novel Methods and Technologies. Pilot project funds may not be used for general purpose equipment (e.g., computers), supplies, administrative support, publication costs, subscriptions or memberships. No pilot project funds may be used for renovations or alterations.

(1) Fast Forward Pilot Grants will be available to research faculty members who can generate preliminary data for a planned submission/resubmission of an extramural grant within 6 months. Multiple Principal Investigators (MPIs) are permitted if/as consistent with the planned extramural submission. Special consideration will be given to applications supporting resubmissions that generate new data in response to prior review. Investigators will be required to submit their summary statement for evaluation of responsiveness of proposed work to reviewers’ comments.

(2) Mentored Investigator Pilot Grants will be available to research faculty members who qualify as an NIH New Investigator (he/she has not previously competed successfully as PD/PI for a substantial NIH independent research award or its equivalent) who wish to develop an independent program of research that complements the focus of SCRCRS. Applications in this category must include a Pilot Project Mentor who will provide a detailed letter of commitment describing the mentoring arrangements (e.g., frequency of meetings, access to space and/or equipment) and focal areas (knowledge, techniques or skills) critical to the project’s outcome and the pilot investigator’s research career development. The Mentored Investigator must be named as the PI of the pilot project; MPIs are not allowed in this category. Mentored Investigator Pilot Grants may request funds for protected time for
the Investigator to conduct the proposed research, technical support (postdoctoral stipend, research assistant salary), research supplies, statistical support, animal models (purchase, per diem costs), research subject compensation and transportation, and/or other allowable direct costs of conducting the proposed study.

(3) **Discovery Pilot Grants** will be available to faculty members of any rank whose proposal is translationally-based and directly relevant to the SCRCRS theme. Proposals in this category must include a compelling rationale that clearly establishes direct relevance to the SCRCRS mission and objectives in stroke recovery, the Principal Investigator's qualifications to undertake this line of investigation, and a viable plan for obtaining competitive extramural grant funding. MPIs are permitted if/as consistent with planning for future extramural submission(s). Discovery Pilot Grants may request funds for an appropriate level of effort for the PI/Project Director, collaborator(s) and/or co-investigator(s), technical support, research supplies, and other allowable direct costs of conducting the proposed study, as described above, with the same constraints for equipment and/or professional travel.

(4) **Pilot Grants for Novel Methods and Technologies** will be available to faculty members of any rank who are in a position to carry out a feasibility study to demonstrate the utility, practicality and potential advantages of an innovative methodology or technology that would directly enhance, advance or replace one or more functions or services of a designated COBRE Research Core. MPIs are not allowed in this category. Proposals in this category must include information on the novelty of the target method or technology and its potential application to the field of stroke recovery as well as data supporting the potential advantages (e.g., efficiency, cost-saving, time-saving, accuracy, resolution, etc.). Since it is expected that the new method or technology will be included in an existing COBRE Scientific Core or non-COBRE institutional core facility, the proposal should include a supporting letter from the respective Core Director describing how the proposal methodology or technology would be incorporated and managed, including a pro forma cost analysis and fee schedule, if appropriate. If the proposal envisions establishing a new shared resource, the application must describe business, management and governance plans for the potential new entity, including documentation of institutional commitment and long-term operating support. Pilot project funds in this category may be used to purchase instrumentation and/or licenses necessary to implement and test the proposed method(s) or technology. If the cost exceeds $50,000, the PI must contact Dr. Banik for pre-approval to exceed the limit. The application must include details about total costs of acquisition, installation, maintenance and training, as appropriate, vendor quote(s), and letters of support and commitment to document all sources of support, if total costs exceed $5,000. If not required for acquisition, funds may be used for personnel, supplies, training and other appropriate core expenses directly applicable and allocable to the new technology. Funds may not be used to support routine maintenance, repairs or operating costs of the research core hosting the proposed methodology or technology. Proposals in this category should include an advisory group of internal and at least one external member with scientific and technological expertise to provide objective, critical, constructive evaluation and advice regarding the use and effectiveness of the proposed methodology/technology.

**PROGRAM ELIGIBILITY**

- Investigators may submit only one application as PI or MPI in any pilot project category per annual funding cycle. In addition, investigators may serve as Mentor for only one Mentored Investigator Pilot Grant per annual funding cycle. Investigators may serve as co-investigator on multiple applications.
• The PI of a pilot project proposal in any category must be a full-time faculty member in good standing at the Medical University of South Carolina and must have a doctoral degree. Collaboration with investigators at other institutions is encouraged in roles such as co-investigator, consultant, collaborator, advisory member, mentor or co-mentor, as appropriate. Individuals who are not US citizens or permanent residents are eligible to apply as PI if the terms and conditions of their faculty appointment and commitments are conducive to successful completion of the pilot project grant and support the probability of sustaining the COBRE center’s growth and development through future extramural research funding and/or core resource enhancements.

• Applicants for Mentored Investigator Pilot Grants may not have been or currently be PI of an NIH R01, P01 sub-project or equivalent. Mentored Investigator PIs must designate a primary research mentor for the pilot project, who may be from inside or outside MUSC. The mentor must have recognition as an accomplished scientist in his/her chosen field, a strong history of competitive research support, and a track record of success in training independent investigators.

• Applicants for Discovery Pilot Grants and Pilot Grants for Novel Methods and Technologies may be faculty of any rank at MUSC and should have a record of accomplishment in their chosen field.

• Previous recipients of a Mentored Investigator Pilot Grant would not be eligible to compete again for additional funding in that category. However, a Mentored Investigator grantee or a Discovery grantee who could conceivably apply for a future Discovery grant and recipients in either category might develop a future proposal addressing Novel Methods and Technologies.

• Applicants with current IDeA (e.g., COBRE or CTR) or INBRE funding are not eligible for funding under this opportunity.

THE APPLICATION PROCESS

Letter of Intent

Although a Letter of Intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows us to estimate the potential review workload and plan the review. Prospective applicants are asked to submit a Letter of Intent that includes the following information:

- Descriptive title of proposed research.
- Name, email address, and telephone number of the PI.
- Complete listing of the investigative team with each individual’s academic title, primary department and proposed role on the project.
- Pilot grant category (Fast Forward, Mentored Investigator, Discovery or Novel Methods & Technologies).

The Letter of Intent should be submitted by email to the SCRCRS Pilot Project Program office (harleylu@musc.edu) by June 15, 2015.

Resubmission of an Application

Applicants will have the opportunity to submit one revised application in response to review comments. Revised applications should be submitted during the following SCRCRS RFA cycle. Investigators submitting an amended application will be expected to address the review critiques using the NIH-modeled Introduction to Resubmission Application, limited to 1 page. The Introduction must summarize all substantial additions, deletions and changes to the application. The Introduction also must include a response to the issues and criticism raised in the Summary Statement. Revisions must be highlighted throughout the revised application to
facilitate the re-review process. Substantial scientific changes must be marked in the text of the application by bracketing, indenting or changing typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. Additional guidance can be found in section 2.7 “Resubmission” Applications, of the NIH Application Guide SF424 (http://grants.nih.gov/grants/funding/424/index.htm).

Full Application
Applicants should submit the application materials through the SCTR website by clicking the appropriate “Apply” link (http://sctr.musc.edu/index.php/programs/pilot-projects). All applications consist of an online form and four PDF uploads.

Online Form (Entries with an * are required fields)
  o PI Name*
  o PI eRA Commons User Name*
  o PI Biosketch*. Please use the new NIH Biosketch format (PDF upload 1 Biosketch) at http://grants.nih.gov/grants/funding/424/index.htm#biosketch. Adhere to the 5-page limit and follow the instructions based upon the most recent NIH Notice NOT-OD-15-085.
  o Degree*
  o PI Faculty Rank*
  o PI Tenure Track*
  o PI Home Institution*, College/School, Department*, Center Affiliation and Division within institution.
  o PI NIH Specialty Code*
  o PI Phone Number*
  o PI Email Address*
  o PI Mailing Address*
  o Business Manager Name*, Phone Number*, Email Address*, Mailing Address*
  o Optional Contact Person Name, Phone Number, Email Address
  o Co-I information (similar to information captured for the PI)
  o Project information (e.g. IRB, IACUC). Please note that funding cannot be released until all applicable institutional human, animal, and biosafety protocols (such as IRB, IACUC, IBC), and any other required regulatory documents (such as INDs, IDE, and CITI Training) have been approved and copies sent to the SCRCRS Pilot Project Program office (harleylu@musc.edu). Investigators are strongly encouraged to begin the regulatory approval process prior to submitting the pilot project application.
  o Child Health Component*
  o Intellectual Property Potential*
  o Have you ever applied for funding or published with any of the Co-I(s)?*
  o Project Title*
  o Grant Category* Select “Fast Forward”, “Early Career”, “Discovery”, or “Novel Methods”. Please note that “Early Career” should be selected as the category choice for applications in the “Mentored Investigator” category.

PDF Upload 2: Project Summary and Relevance
  o 30 lines of text for Project Summary, Arial font size 11, at least 0.5 margins, PDF only.
  o The 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 relatedness of the project to stroke recovery. 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. Using no more than two or three sentences, describe the Relevance of this research to public health. The Relevance statement should be succinct and written using plain language that can be understood by a general, lay audience.

**PDF Upload 3: Research Plan**

- 5 page limit: (1 page for Specific Aims, 3 pages for Research Strategy and 1 page for Additional Review Criteria), Arial font size 11, at least 0.5 margins, PDF only. Revised applications must include a 1 page Introduction at the beginning of the Research Plan (see Resubmission of an Application section for further details).
- The **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, 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. The **Specific Aims section must be limited to one page**.
- The **Research Strategy** should follow the standard NIH format which includes Significance, Innovation and Approach. Further information can be found in Section 5.5.3 of the PHS Grant Application Guide ([http://grants.nih.gov/grants/funding/phs398/phs398.html](http://grants.nih.gov/grants/funding/phs398/phs398.html)). The research proposal should be informative enough for reviewers to understand the proposed research without any supporting documents. Applicants should include all the required details based on the grant category and its review criteria within the proposal without referring to additional pages/documents.
- The **Research Strategy section** should describe how the data will be analyzed and used to make inferences regarding the Specific Aims. The **Research Strategy section must be limited to three pages**.
- A Biostatistical Justification of sample size should be included for animal studies and any aims that include human tissue samples, patients, or healthy volunteers. Statistical consultations are available through the SCTR Biostatistics, Epidemiology and Research Design Program ([https://sctr.musc.edu/index.php/programs/biostats](https://sctr.musc.edu/index.php/programs/biostats)). Investigators wishing to use this service should submit a request through SCTR SPARC Services Catalog ([https://sparc.musc.edu/](https://sparc.musc.edu/)). Please plan accordingly when submitting statistical consultation requests to allow for ample time prior to application deadline. The Biostatistical Justification should be placed at the end of the Research Strategy and is not included in the page limit.
- The **Literature Cited section** should be placed at the end of the Research Strategy and is not included in the page limit.
- The **Additional Review Criteria** section should include a response, if applicable, to the four points listed below. The **Additional Review Criteria section must be limited to 1 page and 1 support letter**.
  1. State how you plan to utilize the SCRCRS Cores in this proposal.
  2. State how you plan to secure future extramural funding and how you plan to utilize the SCRCRS Cores in future grant proposals. Please be sure to state funding agency, mechanism and timeline (ALL Grant Categories).
  3. Provide a detailed letter of commitment from the Pilot Project Mentor describing the mentoring arrangement (e.g. frequency of meetings, access to space and/or equipment) and focal areas (knowledge, techniques or skills) critical to the project’s outcome and the pilot investigator’s career development (Mentored Investigator Category ONLY).
4. Provide a detailed letter of support from the respective SCRCRS Core Director describing how the proposed methodology or technology would be incorporated into the existing SCRCRS Core and managed. Include, if appropriate, a pro forma cost analysis and fee schedule (Novel Methods & Technologies Category ONLY).

**PDF Upload 4: Budget and Justification**

- Prior to submission applicants should schedule a **Proposal Development Meeting** with LuAnne Harley, harleylu@musc.edu or 843-792-3320, to discuss and receive assistance with pilot project budget development.
- **Personnel Support**: Salary and fringe benefits are allowed for protected time for the PI to conduct the proposed research and/or technical support, such as: Investigator, Mentor, Postdoctoral Fellows, Research Specialists and Study Coordinators.
- **Non-personnel Research Expenses**: Allowable expenses include research supplies, animal purchase and per diem, institutional core service fees, research subject compensation and transportation, and data analysis/statistical support. All expenses must be directly related to the proposed research. Funds for research equipment may be requested only in the Novel Methods & Technologies Category.
- **Unallowable Costs**: General office supplies, computers and laptops, tuition, membership dues and fees, publication costs, subscription costs, mailing costs, and rent.
- **Facilities and Administrative Costs**: Facilities and administrative costs, also known as indirect costs, are not permitted.
- **In-kind budgetary items** will be considered as cost-share, and the PI’s primary department will be required to provide a cost-share commitment in writing.
- **Post-award management** of pilot project funds will be managed by the SCRCRS Grant Administrator and the College of Health Professions Research Administration team. An individual UDAK will be established for funded pilot projects, and instructions for the process of funding personnel and ordering supplies will be provided upon official notification of award.

**APPLICATION REVIEW CRITERIA AND PROCESS**

**Overview**

Each application will be assigned to at least two reviewers with appropriate expertise and without conflict of interest, who are faculty members at MUSC or outside academic institutions. Reviewers are instructed to evaluate the quality of the research (significance, investigator(s), innovation, approach, environment) using the 9-point NIH rating scale (1= Exceptional to 9= Poor). The reviewers will address the ‘Additional Review Considerations’ listed below for each application as applicable, and will generate an Overall Impact Score based on the quality of the research and the ‘Additional Review Considerations.’ An NIH-style study section meeting will be held to discuss reviews and prioritize the applications based on the overall impact score, Summary Statement, and the programmatic needs of the SCRCRS. Funding recommendations will be forwarded to the SCRCRS External Advisory Committee for final funding decisions. Applications selected for funding by the SCRCRS Executive Committee and External Advisory Committee will then be submitted to NIH for final approval. Applicants are **strongly urged** to begin the process of obtaining required IRB, IBC, and IACUC approvals associated with project as soon as possible, as final approval from NIH to begin the project cannot be provided until all
Approvals are in place.

**Additional Review Considerations for ALL Grant Categories**
- Does the proposal address an important stroke recovery-related problem and, if successful, will the results have a substantial impact on stroke recovery?
- Does the proposal utilize one or more SCRCRS Cores?
- Is the project focused, feasible and achievable, and does it have a high potential to secure future extramural funding that will utilize one or more SCRCRS Cores?
- Does the proposal stimulate collaborations with SCRCRS members that otherwise might not have taken place?
- For clinical and animal studies, do applications include a statistical power analysis? Does the proposal describe statistical methods required for analysis of study data? Although applications will primarily be pilot projects, they must be adequately powered to provide meaningful information about the feasibility and size for planned future extramural grant applications.

**Additional Review Considerations for Mentored Investigator Pilot Grants**
- Does the proposal include a support letter describing a clearly defined mentorship plan with a senior/established investigator?
- Will the investigator receive adequate supervision and mentoring?
- Does the proposal describe a plan for achieving research independence and potential to lead to extramural independent funding?
- Has the investigator defined a need for funding to support the proposed direction of research?

**Additional Review Considerations for Discovery Pilot Grants**
- Does the proposed research incorporate ideas and aims that have direct relevance to the SCRCRS mission and objective in stroke recovery?
- Has the investigator defined a need for funding to support the proposed research?

**Additional Review Considerations for Novel Methods & Technologies Pilot Grants**
- What is the likelihood that the new method or technology will directly enhance, advance or replace one or more functions or services within a designated SCRCRS Core?
- Does the novel method/technology have potential value to multiple investigators in stroke recovery; if so, how many potential users?
- Does the novel method/technology have the potential to support extramurally funded research projects?
- Does the application include a support letter from a SCRCRS Core Director describing how the proposed method/technology would be incorporated into the existing SCRCRS Core and managed?
- Does the application intend to establish a new shared resource and does it include a business, management and governance plan? Does it include an institutional support letter describing the institutional and long-term operating support?
- Does the application include details about total costs of acquisition, installation, maintenance and training, vendor quotes and letters of support to document all sources of support?
- Does the application contain the appropriate internal and external advisory members with knowledge of the proposed method or technology?