

**COBRE IN STROKE RECOVERY
PILOT PROJECT PROGRAM
REQUEST FOR APPLICATIONS (RFA) and SUBMISSION GUIDELINES
2019-2020 FUNDING CYCLE**

KEY DATES

RFA Release Date: Monday, June 3, 2019
Letter of Intent Due Date: Monday, June 17, 2019, 5:00 p.m.
Application Due Date: Monday, July 15, 2019, 5:00 p.m.
Earliest Anticipated Funding Date: December 1, 2019

OVERVIEW

COBRE in Stroke Recovery'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 COBRE in Stroke Recovery Pilot Project Program will include various types of awards, modeled on SCTR's categories, as shown below.

Grant Categories	Brief Description	Award Amount	Award Duration
Fast Forward	Generate critical preliminary data for a planned submission/resubmission of an extramural grant application within 6 months.	Up to \$10,000	Up to 1 year
Mentored Investigator (Choose Early Career on SCTR website)	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.	Up to \$30,000	Up to 1 year
Discovery	Provide strategic support to explore the feasibility of projects that might become collaborative R01s or center grants.	Up to \$30,000	Up to 1 year

TO APPLY

Access the application submission portal at:

https://sctrweb2.musc.edu/appsite/sctr_retreat_pilot_applications/new

STROKE COBRE SCIENTIFIC SCOPE AND CORES

<https://education.musc.edu/colleges/health-professions/research/stroke-recovery>

PROGRAM QUESTIONS:

Dr. Narendra Banik

Email: baniknl@musc.edu

ADMINISTRATIVE QUESTIONS:

LuAnne O'Connor

Email: harleylu@musc.edu

Phone: 843-792-3320

KEY ELEMENTS OF THE COBRE IN STROKE RECOVERY PILOT PROJECT PROGRAM

The main objective of the program is to promote the growth of the COBRE in Stroke Recovery through the development of new extramural funding and the utilization, enhancement and advancement of critical technologies and COBRE in Stroke Recovery 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 COBRE in Stroke Recovery Cores (Fast Forward, Mentored Investigator and Discovery Grants).

PILOT GRANT CATEGORIES

Pilot project grants will support four general categories of pilot projects associated with COBRE in Stroke Recovery: Fast Forward Pilot Grants, Mentored Investigator Pilot Grants and new translationally-based Discovery Pilot Grants. 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. 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 COBRE in Stroke Recovery. 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 COBRE in Stroke Recovery theme. Proposals in this category must include a compelling rationale that clearly establishes direct relevance to the COBRE in Stroke Recovery 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.

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 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 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 could conceivably apply for a future Discovery grant.
- **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 or Discovery).

The Letter of Intent should be submitted by email to the COBRE in Stroke Recovery Pilot Project Program office LuAnne O'Connor (harleylu@musc.edu) by 5:00 p.m. on **June 17, 2019**.

Resubmission of an Application

Applicants will have the opportunity to submit **one revised application** in response to review comments from a previous COBRE in Stroke Recovery Pilot Project Program application. Revised applications should be submitted during the following COBRE in Stroke Recovery RFA cycle. Investigators submitting a revised 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://academicdepartments.musc.edu/sctr/programs/pilot_projects). All applications consist of an online form and four PDF uploads.

Online Form (Entries with an * are required fields)

- PI Name*
- PI eRA Commons User Name*
- PI Biosketch*. Please use the new NIH Biosketch format (PDF upload 1 Biosketch) at <http://grants.nih.gov/grants/funding/424/index.htm>. Adhere to the 5-page limit and follow the instructions based upon the most recent NIH Notice NOT-OD-16-080.
- Degree*
- PI Faculty Rank*
- PI Tenure Track*
- PI Home Institution*, College/School, Department*, Center Affiliation and Division within institution.
- PI Phone Number*
- PI Email Address*
- Business Manager Name*, Phone Number*, Email Address*
- Co-I/MPI/Mentor information (similar to information captured for the PI)
- 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 COBRE in Stroke Recovery Pilot Project Program office (harleylu@musc.edu). **Investigators are strongly encouraged to begin the regulatory approval process prior to submitting the pilot project application.** Investigators needing assistance should submit a request through SCTR SPARC Services Catalog (<https://sparc.musc.edu/>).
- **Funding Entity Code: Please select COBRE - Stroke**
- Project Title*
- Grant Category* Select "Fast Forward", "Early Career" or "Discovery". Please note that "Early Career" should be selected as the category choice for applications in the "Mentored Investigator" category.

PDF Upload 2: Project Description and Relevance

- 1 page for Project Description and Relevance, Arial font size 11, at least 0.5 margins, PDF only.
- The Project Description 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).
- Combine all documents into a single PDF document for uploading under “Upload Proposal”.
- 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>). 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 (<http://academicdepartments.musc.edu/sctr/programs/biostatistics.html>). Investigators wishing to use this service should submit a request through SCTR SPARC Services Catalog (<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 COBRE in Stroke Recovery Cores in this proposal.
 2. State how you plan to secure future extramural funding and how you plan to utilize the COBRE in Stroke Recovery 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 COBRE in Stroke Recovery Core Director describing how the proposed methodology or technology would be incorporated into the existing COBRE in Stroke Recovery 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 O’Connor, harleylu@musc.edu or 843-792-3320, to discuss budget and receive assistance with pilot project budget development.

- For the budget, please use PHS 398 Form Page 4: Detailed Budget for Initial Budget Period (1 page) at <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Use continuation pages as needed for the budget justification. Upload the budget and justification as a single PDF file. The COBRE in Stroke Recovery reserves the right to reduce requested award amounts.
- **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 is not allowed.**
- **Unallowable Costs:** General office supplies, equipment, computers and laptops, tuition, membership dues and fees, publication costs, subscription costs, mailing costs, and rent. No COBRE funds can be committed in a pilot project sub-award to a Non-IDEA state.
- **Facilities and Administrative Costs:** Facilities and administrative costs, also known as indirect costs, are not permitted.
- In-kind budgetary items (i.e. faculty/staff salary) will be considered as cost-share, and the PI's primary department will be required to provide a cost-share commitment in writing as part of the application. If applicable, a letter of commitment should be uploaded as part of the budget justification in the application. If funded, the College of Health Professions will establish a unique cost-share UDAK into which the PI's Home Department will transfer the funds to cover the cost-share amount. At the end of the project, any unused cost-share funds will be returned to the PI's Department.
- The COBRE in Stroke Recovery uses a variety of fund sources to support the Stroke COBRE Pilot Project Program. The fund source (MUCR or MUCU) used to fund the project will dictate whether Affiliate Salary can be supported (i.e. MUCU fund sources do not pay Affiliate Salary). The PI should communicate with their Department Administration and Ms. O'Connor to determine the proposed fund source and whether this will impact reimbursement of any potential Affiliate Salary.
- Post-award management of pilot project funds and any related cost-shares will be managed by the COBRE in Stroke Recovery Grant Administrator and the College of Health Professions Research Administration team. An individual UDAK will be established for funded pilot projects and cost-shares, 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. Statistical reviews will also be conducted on each application as appropriate. 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 COBRE in Stroke Recovery. Funding recommendations will be forwarded to the COBRE in Stroke Recovery External Advisory Committee for final funding decisions. Applications selected for funding by the COBRE in Stroke Recovery 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. Investigators needing assistance should submit a request through SCTR SPARC Services Catalog (<https://sparc.musc.edu/>).

Citations:

Each publication, press release, or other document about research supported by the Stroke COBRE Pilot Project Program must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute Of General Medical Sciences of the National Institutes of Health under Award Number P20GM109040. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

In addition, the PI should also add the SCTR grant acknowledgment information if they receives any form of SCTR support, consults etc. Please see the weblink below.

<https://research.musc.edu/resources/sctr/about/cite-the-grant>

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 COBRE in Stroke Recovery 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 COBRE in Stroke Recovery Cores?
- Does the proposal stimulate collaborations with COBRE in Stroke Recovery 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 COBRE in Stroke Recovery mission and objective in stroke recovery?
- Has the investigator defined a need for funding to support the proposed research?