Questions:
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MUSC Core Centers for Clinical Research (CCCR)
Request for Applications (RFA) for Pilot Project Program Grants
2019 Funding Cycle

RFA Release Date: Thursday, July 11, 2019- Two to four pilots will be funded from the following sources

- ***COM Deans Office- Any faculty or postdoc in the College of Medicine eligible to apply***
- ***Provost- Any MUSC faculty or postdoc eligible to apply***
- ***CCCR grant- Any MUSC faculty eligible to apply***

OVERVIEW

MUSC's Core Center for Clinical Research is seeking pilot project applications for the 2019 cycle. The CCCR's title is "Improving Minority Health in Rheumatic Diseases." We are requesting applications that address research questions relevant to this topic. The proposal can address directly Minority Health in rheumatic diseases or address questions relevant to improving health in rheumatic diseases regardless of race/ethnicity.

There are two proposal types:

A. Faculty pilot projects: The PI must be on faculty at MUSC at the Instructor level or higher. These grants are for one year and budgets of $25,000 to $35,000 will be accepted. The area of research must be relevant to rheumatic diseases and with direct human relevance.

B. Postdoctoral projects: This is the first offering of pilot project funding for postdoctoral fellows mentored by a tenure track MUSC faculty member. These are one-year awards ranging from $5-$10,000. The area of research must be relevant to rheumatic diseases and with direct human relevance.

The numbers of grants awarded in each category will depend on the budgets of the proposed projects and the relative quality of the projects. We do not have a preconceived number of grants in a given category to be awarded. The one exception is the grant that is part of the CCCR proposal itself which will be awarded to a faculty applicant. Faculty salary can be placed on the faculty grants if necessary. Postdoctoral awards cannot support the salary of either the postdoc or the mentor.

We request a mandatory one page preproposal outlining the project for review by the CCCR Executive Committee. This will allow review of the proposal to assess its relevance to the RFA, to allow for assignment of a CCCR Methodology Core member to work with the applicant and for a CCCR faculty member to also work with the PI to help with relevance and grantsmanship. The PI of the accepted pre-proposals will then be asked to provide a full application.

Recipients of the awards will have access to the cores of the CCCR which include the Methodology Core for statistical and sample size assistance and the Patient Resource Core to determine need for patient samples and aid in recruitment of subjects.

Since this is a "Clinical Center," we require that proposals be directly relevant to human disease. In vitro studies and animal studies are not excluded, but will have to provide convincing arguments that the proposed studies are directly relevant to human disease.

All applicants should contact Dr. Paul Nietert in the Methodology Core at least one week prior to final submission for mandatory prereview. Applications will not be reviewed if preconsultation with Dr. Nietert's group has not been done. For applications that require the Patient Resource Core, please contact either Dr. Ed Smith or Dr. Jim Oates if you have questions regarding availability and feasibility of human samples.

KEY DATES

Applications Due For Mandatory PreReview:
July 29, 2019, 5pm

Anticipated Funding Date:
October 1, 2019

Final Application Due Date:
August 29, 2019, 5pm

TO APPLY:

Submit application to in either word or pdf format to: Gary Gilkeson, MD at gilkeson@musc.edu

SCTR INSTITUTIONS

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

Key Elements of the CCCR Pilot Project Program Grants

The main objective of PPP grants is to support new research studies that will lead to innovative and sustainable projects to impact patients with lupus, scleroderma and other rheumatic diseases. Priority factors that will be considered for funding include the following:

- Does the proposal address an important question in clinical and/or translational research that impacts lupus, scleroderma or another rheumatic disease?
- Collaborative and synergistic teams of researchers from different departments, and/or multidisciplinary investigators within a department will be given strong consideration.
- Does the proposal involve research that is new to the team members (Please note that the CCCR pilot project grants do not support ongoing projects)?
- Is the project designed to generate critical preliminary data that will help to obtain future extramural funding to continue the project?
- Does the proposal address ethnic disparities and mechanisms underlying these disparities in rheumatic diseases?

a. Fields of Research

- Translational experiments that propose a hypothesis that will eventually require a human experiment to validate

- Clinical experiments that involve human subjects or samples
- Observational studies or intervention studies in human populations. Here, the hypotheses address the multitude of approaches that have the potential to impact the health of an individual or a population
- If there are no human subjects involved in your project proposal, please address one of the following:
    - proposed research that creates an infrastructure that will facilitate clinical and translational research within the next 3-5 years
    - provide a persuasive argument that the proposed research will lead to work with human subjects within the next 3-5 years (If the time frame is more than 5 years, a time table clearly indicating targeted end points for the proposed period should be included in the application).

b. Anticipated Outcomes of CCCR Pilot Project Program 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
- development of new collaborations between established investigators and junior investigators as well as between basic scientists and other health-related researchers
- development of potential Intellectual Property and commercialization of technologies

PILOT CATEGORY DESCRIPTIONS

All proposals will fall into the Discovery grant category that includes any proposed projects of the 'discovery' nature and must address an unmet medical need such as identification of new therapeutic targets and agents, and may utilize the expertise and capabilities of translational technologies; a novel fundamental discovery that needs further development to bring it rapidly to a Phase I, II or III trial; a novel fundamental discovery leading to large-scale dissemination/translation; a novel clinical or biomarker discovery that requires rigorous assessment to determine its potential value for large-scale clinical research; a novel device that needs prototype development.

Discovery applications that describe 'Novel Methodologies and Technologies' must include information on the novelty of the target methodology or technology, and its potential to clinical and translational research with consideration of potential value to multiple investigators.

Health Disparities Pilot Projects are encouraged. These proposals can be laboratory, clinical, and/or population based studies that should address critical needs related to health disparities in lupus, scleroderma or other rheumatic diseases and must contribute either to elimination or at least to significantly lower health disparities while availing research teams of the special populations unique to South Carolina and the southeastern United States.

PROGRAM ELIGIBILITY

Principal Investigator (PI):

- Professors, Associate Professors, Assistant Professors and Instructors are eligible to apply as PIs. Can be on the tenure track or the modified track.
- Investigators may serve as the PI of only one proposal per grant for a 12-month period.
- Post-doctoral and clinical fellows appointments can serve as the PI of a "post doc" application, but they must have an identified MUSC faculty member as mentor.

- Since one of the goals of the pilot projects is to help train the next generation of clinical and translational investigators, we encourage junior investigators to submit applications.
- Support of underrepresented minorities in research is also a key goal of the MCRC.

Co-Principal Investigator (Co-PI):

- **One Co-PI is allowed.** However, a Co-PI should have a significant role in the proposed project to be named as the Co-PI. The Co-PI should be clearly identified in the application narrative, on the budget and in the budget justification.
- **On the online application, list the Co-PI as the first Co-I and should be indicated as a Co-PI by their last name by entering (Co-PI) within parentheses.**

Co-Investigator (Co-I):

- Substantial contributors 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).
- **Co-Is that are community members without an eRACommons user name should enter "N/A" in the appropriate box on the online application.**

Consultants:

- If you plan to use consultants for the proposed project, please include their names and the roles in the research proposal.

BUDGET and ALLOWABLE COSTS

For the budget, please use PHS 398 Form Page 4: Detailed Budget for Initial Budget Period in MS Word Version (1 page) at http://grants.nih.gov/grants/funding/phs398/phs398.html and use continuation pages as needed for the budget justification. Each budget item listed in the Form Page 4 must be clearly justified. **On the online application, upload the budget and justification as on single PDF file.**

- Faculty Salary Support: Faculty salary support is allowed as appropriate and the efforts requested are subjected to the NIH salary cap. However you must be able to demonstrate that you can successfully accomplish your proposed scope of work within the budget parameters 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. If an application proposes graduate student support (stipend, undergrad/graduate student research assistant and lab costs etc.), you must provide a justification as to how work on this pilot project related to the students' dissertation or Master's project/thesis. 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- please contact the CCCR Pilot Program office or Dr. Gilkeson for approval prior to the application), travel to one research meeting for one investigator in the team, 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, and rent.
- Facilities and Administrative Costs: Facilities and administrative costs, also known as indirect costs, are not permitted.

- Subawards: No signed documents are needed at the time of submission from subaward institutions. The Finance Office will work with respective PIs to establish subawards once an application is chosen for funding.

AWARD DETAILS

- The correspondence related to the award will be sent to respective PIs via emails. It is PI's responsibility to respond and communicate with the CCCR Pilot Project Program office as appropriate.
- Each award is non-renewable and non-transferable from one PI to another.
- The funds can be used to cover direct costs only. Indirect costs are not allowed.
- Please be advised that upon funding, additional administrative documents may be required.
- The maximum period of award is 12 months for all the grant categories. However, the award period depends on the satisfactory progress of the project as determined by the CCCR Executive Committee.
- The progress will be assessed at a presentation by the PI to the CCCR group meeting approximately 5 months after initiation of funds.
- About a month before the progress presentation will occur, the Pilot Project Program will send the PI a reminder via email. The CCCR has the right to terminate a project if progress report is not submitted or not satisfactory. More details for Progress Reports are listed below.
- Note that the 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 CCCR Pilot Project Program office.
- The CCCR Pilot Project Program office will send the JIT Notice to appropriate PIs via email with a web link to submit JIT information. All the regulatory documents must be received by the Pilot Project Program Office by the appropriate JIT due dates for each cycle and grant category. We understand that some regulatory documents may need longer time to get approval after the JIT Notice is sent to PIs. If for some reason, these documents cannot be submitted by the appropriate due as indicated in the JIT letter, the PI should forward a written letter via email explaining the reasons for the delay. **The project may not be funded if the PPP office does not receive the required documents or reasonable explanation within 8 weeks of the JIT Notice.**
- Upon award, each Pilot Project will be assigned a specific Methodology Core Support Committee member that will work with the PI to guide and assist in providing all the needed resources to ensure the success of each project. Each pilot project PI will also be assigned a mentor from the Executive Committee of the MCRC. The PI is expected to meet with his/her project's Methodology Mentor and Executive Committee Mentor upon request or at least three times a year to review progress and prepare for the presentations to the CCCR biweekly meetings.
- Please note that the CCCR grant is a cooperative agreement with the National Institutes of Arthritis, Musculoskeletal and Skin Diseases (NIAMS), and the Pilot Project Program office will continue to follow the progress of each project post-funding, at least for 5 years after the project close out date to determine the CCCR pilot project funding success in terms of extramural funding applications, publications, IND/IDE, SBIR/STTR, patents, etc. The Pilot Project Program Office will send PIs the progress report forms as a web link when each due date approaches.
- It is PI's responsibility to inform the Pilot Project Program office of any changes to the project, including departure from the PIs institution. This will help to determine how both parties should proceed such as to transfer PIs responsibility to another team member or to close out the project.

THE APPLICATION PROCESS

Submit application to in either word or pdf format to: Gary Gilkeson, MD at gilkeson@musc.edu

FOR ALL GRANT CATEGORIES

- Refer to the APPLICATION REVIEW CRITERIA AND PROCESS section below for category-specific review criteria

  - The **Project Description** following PHS 398 instructions: New NIH Format (1 page limit, Arial font size 11, at least 0.5 margins, PDF only). 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. Using no more than two or three sentences, describe the Relevance of this research to public health. More details can be accessed at http://grants.nih.gov/grants/funding/phs398/phs398.pdf

  - The **Budget and Justification** (discussed above in BUDGET and ALLOWABLE COSTS)
    - The Budget and Justification Upload include two separate budget forms and a justification clearly identifying the expenses to be paid for by the pilot project

  - The **Proposal**: (5 page limit for all grant applications (excluding the specific aim page), Arial font size 11, at least 0.5 margins, PDF only). The research proposal should be submitted using the new NIH format of Specific Aims and Research Strategy, which includes Significance, Innovation, and Approach. Specific aims can be one page as in the NIH format or less (i.e. rest of the proposal sections can be included in the same page). The NIH format can be accessed at http://grants.nih.gov/grants/funding/phs398/phs398.pdf
    - See the APPLICATION REVIEW CRITERIA AND PROCESS section below for **category-specific** review criteria that must be addressed in the proposal section
    - In addition to above, translational potential of the proposed research, whether the CCCR funding would stimulate new and multidisciplinary collaborations that otherwise might not have taken place, plans/potential to secure future extramural funding including funding agency and mechanism (R, P, U, other must be included in the proposal). These additional criteria will be used to evaluate appropriateness and need for CCCR support and extent to which the proposed research is consistent with the CCCR mission of promoting clinical and translational research.
    - **It is mandatory that each proposal PI meet with a member of the Methodology Core for consultation prior to submission for help/advice regarding statistical analysis, samples size calculations etc. Applications will not be reviewed that have not met this criterion. Contact Dr. Paul Nietert at nieterpj@musc.edu for assistance with arranging a consultation at least a week prior to submission/uploading**.
    - 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.
    - Additional 1-2 pages are allowed for literature citations.

APPLICATION REVIEW CRITERIA AND PROCESS

Overview

The applications will be reviewed by at least two reviewers without conflicts of interest, who are either faculty members at MUSC or members of the CCCR external advisory board , according to the new

NIH Peer Review guidelines as indicated at http://grants.nih.gov/grants/funding/phs398/phs398.pdf. If needed, ad-hoc reviewers who have expertise in relevant scientific disciplines and current research areas will be identified to review specific applications. The review committee will prioritize the applications based on final overall impact scores (see below) and will make funding recommendations to the CCCR Executive Committee for final funding decisions.

Review Criteria for ALL Grant Categories

The reviewers are asked to look for the following primary considerations for all the applications regardless of the grant category.

- Is the project scientifically meritorious?
- Is the proposal new and innovative?
- 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 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?

Additional Review Criteria for Health Disparities Applications (desired but not required)

- Does the proposal address critical needs related to health disparities and contribute either to elimination or at least to significantly lower health disparities in unique populations in SC and/or beyond?

Scoring

CCCR and EAB members are instructed to evaluate applications by addressing the six core review criteria and additional review criteria (listed below) as applicable based on the grant category. Each CCCR member's impact score will reflect evaluation of the overall impact of the proposed project in its entirety rather than the reviewer's scores given to each review criterion. For each application that is discussed in the CCCR meetings, a final overall impact score will be given by each review member following the CCCR panel discussion. The CCCR reviewers will address 'Additional Review Considerations' listed below for each application as applicable but these additional review considerations will not be scored and should not be considered in providing an overall impact/priority score.

- **Six Core Review Criteria for Overall Impact/Priority Score for ALL Grant Categories:**

  i. Significance including Scientific Merit of Proposed Project:
  - Does the project address an important health problem or a critical barrier to progress in the field?
  - If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? i.e. translational potential of the proposed research
  - How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

  ii. Potential to Secure Future Extramural Funding:
  - Does the project have high potential to secure future extramural funding?

  iii. Investigator(s):
  - Are the PIs, collaborators, and other researchers well suited to the project? Do they have established roles, skills and experience to carry out the project?

- Is there clearly established new trans-disciplinary collaboration? i.e. collaboration between basic and clinicians, clinicians and community, and vice versa
- If Early Stage Investigators, New Investigators or postdocs, do they have appropriate experience and training?
- If Early Stage Investigators/postdocs, is there a defined mentorship plan with a senior/established investigator (PI is required to submit the plan) and timetable for becoming independent and a plan for achieving research independence and potential to lead to independent funding (with a plan to submit K or R applications).
- If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- If the project is collaborative, do the investigators have complementary and integrated expertise; is their organizational structure appropriate for the project?

iv. Innovation:

- Is the project new, innovative, and translational?
- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- If the proposed project is related to Novel Methodology and Technology, is there a potential value to multiple investigators facilitating clinical & translational research and supporting extramurally-funded research projects? Are there an adequate business plan and cost effectiveness of allowing multiple investigators to use core facilities?

v. Approach:

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- **Is there appropriate statistical underpinning to insure that the proposed outcomes can be reached?**
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
- Is there appropriate justification provided for the number of subjects (e.g. humans, animals) involved?
- If the proposed research is related to the Health Disparities, does the proposal address critical needs related to health disparities and contribute either to elimination or at least to significantly lower health disparities in unique populations in SC and beyond?

vi. Environment:

- Will the scientific environment in which the research will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

vii. Additional Review Considerations:

As applicable for the proposed project, the CCCR reviewers will address each of the following items but will not give scores and should not consider them in providing an overall impact/priority score.

- Budget & Period Support: CCCR members will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.
- Applications with some parts of proposed research conducting in other countries:

  CCCR reviewers will assess whether the proposed project presents special opportunities for furthering research through the use of unusual talent, resources, populations or environments that exists in other countries that are not readily available in the US.