R-CENTER Collaborative Clinical and Translational Pilot Projects Program
Funding Opportunity Announcement (FOA)
May 2019

Letter of Intent Deadline (Required): **May 10, 2019** ***by 5:00 PM (EST)***
Application Deadline: ***June 7, 2019 by 5:00 PM (EST) (No late or incomplete applications will be accepted)***
FOA Overview & SF- 424/ASSIST Training (Mandatory for MSM Investigators): May 14, 2019 ***at 10:00 AM (EST)***

A. Purpose

The purpose of the R-CENTER's Pilot Project Program is to support Morehouse School of Medicine (MSM), , Georgia Clinical & Translational Science Alliance (Georgia CTSA), and Atlanta University Center Consortium (AUCC) faculty investigators in developing and implementing meritorious, short-term research projects which will generate preliminary data and new discoveries and technologies which aims to improve minority health, eliminate health disparities, achieve health equity, and advance clinical and translational sciences. Innovative health disparities investigations in basic, clinical, community and population-based science are solicited in the funding opportunity announcement (FOA) which is consistent with purpose of the pilot project program and the goals and objectives of the R-CENTER in advancing clinical and translational science at MSM. The overall goal of this pilot research is to identify solutions to health disparities through community engagement and to generate findings that will inform evidenced-based health practices.

Under this FOA, the R-CENTER is soliciting applications to support individual and multidisciplinary pilot projects. These projects are expected to generate pilot data, create new multidisciplinary teams of faculty investigators with the greatest potential to transform the MSM research landscape, and enhance the competitiveness of MSM faculty investigators for extramural funding based on pilot project findings. Thus, the pilot projects should have the potential to stimulate additional research, lead to long-term impact, promote research sustainability, and advance faculty members as capable independent researchers and research leaders in clinical and translational science as a career choice.

B. Eligibility Criteria

To receive funding, an investigator as Principal Investigator (PI) must be a full-time faculty member at the rank of instructor or above. The PI, at the instructor level, must obtain a letter from their academic department chairperson confirming that the investigator holds a full-time faculty appointment. **ALL** PIs must obtain a letter indicating that the academic department intends to develop and support the faculty member as a research investigator in clinical and translational science. All faculty investigators must represent distinct scientific disciplines.

The FOA solicits pilot project proposals from faculty members in the following categories:

1) New and current junior faculty investigators (i.e., instructors and assistant professors) without a track record of independent research funding
2) Senior faculty investigators who are transitioning from basic science to clinical research
3) Faculty members (mid-career and senior faculty) with research training, demonstrated research experience and/or accomplishments who are transitioning to new, unique areas of scientific endeavors and those transitioning from major administrative roles to protected time for independent clinical and transitional research

A faculty investigator may submit ONLY ONE application, either as a Principal Investigator (PI) of an individual project or Principal Investigator (PI) of a multidisciplinary project.

Ineligibility:

An applicant who currently has or previously had a R-CENTER Career Development Award, currently has or within the past two years been awarded other pilot or career development award, or has received funding as Principal Investigator (PI) through any MSM pilot funding mechanisms more than twice are **NOT eligible** to submit an application for this funding announcement. *Doctoral students, medical residents, postdoctoral fellows, and other individuals in part-time adjunct or temporary positions are **NOT eligible** to apply to this pilot project program.*

C. Funds Available

The pilot project program anticipates awarding approximately $300,000 in this round of funding: individual faculty investigator-initiated awards (up to $50,000 in total costs) and multidisciplinary faculty investigator-initiated awards with three (3) or more faculty investigators with complementary expertise and research experience (up to $100,000 in total costs). **The multidisciplinary faculty investigator-initiated award team must include an MSM investigator.** The majority of the interdisciplinary team members must meet the eligibility criteria described above for clinical/translational researchers. Each project will be funded for a 10-month period **(July 1, 2019 - April 30, 2020)**. Pilot grants funds may be used for salaries, supplies, research subject incentives, patient care costs and travel costs. A detailed budget and budget justification will be required for each pilot project. In general, up to 25% of the award may be used for salary support. The purchase of any major equipment ($5,000 or greater) must be in line with MSM guidelines (e.g., computer systems, medical technologies, and other necessary equipment) will be subject to approval. **This funding mechanism does not provide an opportunity for carry over. All proposed project activities must be completed in the designated timeframe provided.**

D. Application Requirements Checklist:

Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide**, including Supplemental Grant Application Instructions (if using human subjects) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.**

- ☐ A complete SF 424 application: **R-CENTER PILOT PROJECT APPLICATION 2019**
- ☐ A complete Human Protections and Data Safety Monitoring Plan
- ☐ Collaborative Institutional Training Institute (CITI) Certificates of completion for PI and key personnel for the "Human Subjects Research: https://www.citiprogram.org/
- ☐ Current MSM HIPAA Compliance Certificate (or partnering institution) for PI and all key personnel
- ☐ Letter of support from the Academic Department Chair
- ☐ Certification Statement that this application is not under review or will not be submitted to another MSM/RTRN/RCMI Pilot or Small Grant Pilot Project Program while under review by the R-CENTER Pilot Project Program or any other funding opportunity

E. Proposal Narrative

Please refer to guidelines for the completing the Form SF424, SF424 (R&R) Application Guide. In addition, the pilot project proposal should be organized to address the following components:

1. **Research Plan**
   - **Specific Aims (1-page limit)**
   - **Research Strategy (6-page limit)**

     - **Significance**
       - Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
       - Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
       - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

     -Innovation
       - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
       - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
       - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

     -Approach
       - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
       - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
       - If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
       - Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
       - Refer to NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for further consideration of NIH expectations about sex as a biological variable.
       - If your study(s) involves human subjects, the sections on Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample, but it must also be addressed here in the "Approach" section of the "Research Strategy" attachment.
       - Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment below.
       - If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.

2. **Project Summary/Abstract-** (No longer than 30 lines of text)

3. **Project Narrative-** (Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.)
4. **Bibliography & References Cited**
5. **Facilities and Other Resources**
6. **Equipment**
7. **Resource Sharing Plan**

F. Budget and Budget Justification

Applicant should include a detailed budget and budget justification that clearly outlines all costs associated with the proposed scope of work. A detailed SF 424 Research & Related (R&R) Budget should be provided. **DO NOT** use the PHS modular budget option.

G. Current NIH Biosketches- The new NIH biosketch format must be used. Please select the link for the new biosketch form and sample biosketch (New Biosketch Form and Sample).

Selected Peer-reviewed Publications Mandatory Requirement- When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the **NIH Manuscript Submission reference number** (e.g., NIHMS97531) or the **PubMed Central (PMC)** reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference.

H. Review and Selection Process

Proposals will be evaluated for scientific merit by MSM Scientific Officer, the Office of Research and Development and the multidisciplinary Scientific Advisory Committee (SAC) composed of members from MSM Academic Departments, Centers, Institutes, Research Programs, and the RCMI Translational Research Network (RTRN).

Proposals will be carefully evaluated to determine scientific merit, relevance to the elimination of health disparities and clinical and translational research. After excluding individuals with potential conflicts of interest, expert reviewers will be assigned to review project proposals. The review process will follow the National Institutes of Health (NIH) peer-review format with at least three independent expert peer reviewers (i.e., a primary, secondary, and tertiary reviewer) assigned to each application. Each application will receive an overall impact score based on a 9-point NIH Scoring System. Each application will be scored on the following criteria:

-Significance
-Innovation
-Approach

All applicants will receive decision letters within approximately 30 days of the proposal submission date (June 30, 2019). Decision letters will include reviewer scores and anonymous reviewers' comment.

Note: Each applicant recommended for funding by the SAC must provide documentation for human subjects and animal protection, data security and privacy measures, IRB approval or exemption letters, and all other federal requirements prior to a final funding decision.

All awardees are required to:

1) Participate in the MSM Mentoring Academy
2) Participate in R-CENTER Professional Development Core Activities
3) Present one seminar on the pilot project research
4) Submit one abstract
5) Submit one manuscript for publication by the end of award period
6) Submit quarterly reports to R-CENTER Program Manager
7) Submit one proposal for extramural funding based on pilot project research by or within three months of the end of pilot award period

I. Funding Opportunity Announcement and SF424/ASSIST Training:

To assist new and junior faculty investigators in the grant submission process, the R-CENTER's Pilot Program and Professional Development Core will partner with the Office of Sponsored Research Administration (OSRA) to offer a technical assistant training to provide a general overview of the FOA and instructions on how to successfully complete the SF 424 application in ASSIST. The link to the application in ASSIST will be provided to investigators who submit a letter of intent. Investigators may also request proposal development assistance from the R-CENTER Cores. The training will be open to all MSM, Georgia CTSA and AUCC faculty investigators (**May 14, 2019 at 10:00 AM (EST)**).

All administrative inquiries, applications and letters of intent should be sent by e-mail to:

Rondereo Sidney
R-CENTER Program Manager
Morehouse School of Medicine
Telephone: 404-752-1664
Email: rsidney@msm.edu

Queries related to programmatic or scientific issues should be sent by e-mail to:

Robert M. Mayberry, M.S., M.P.H., Ph.D.
Professor of Epidemiology and Vice Chair
Department of Community Health and Preventive Medicine
Director, R-CENTER Research Design and Biostatistics Core
Morehouse School of Medicine
Email: rmayberry@msm.edu

Letters of intent (2 single-spaced pages or less) in response to this FOA should include:

- **Names of the PI and key collaborators**
- **PI's Academic Department and Center/Institute**
- **Health Disparity the Proposed Project Will Address**
- **Specific Aims of the Proposed Pilot Project**
- **A Brief Summary of the Proposed Research, including Questions and Methods**
- **A Paragraph Describing the Significance of the Research Project Relative to the Stated Purpose and Goals of This FOA**

Letters of intent should be emailed to: Rondereo Sidney, rsidney@msm.edu, on or before May 10, 2019 by 5 PM (EST). Applications must be received by 5 PM (EST) on or before June 7, 2019. No late or incomplete applications will be accepted.