CBMHR

CENTER FOR BIOMEDICAL & MINORITY HEALTH RESEARCH

2024-25

Pilot Project Program

Funding Opportunity Announcement

Investigator Development Core
Center for Biomedical and Health
Disparity Research
Texas Southern University

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Part 1. Overview Information

Funding Opportunity Title:	**TSU Center of Biomedical and Minority Health Research (CBMHR) Pilot Project Program**
Funding source:	NIH/NIMHD Research Centers in Minority Institution Program (RCMI) U54MD007605
Number of Awards:	3 (2024-25)
Award amount:	$50,000 (direct cost)
Eligibility criteria:	TSU Early-Stage Investigators (ESIs) (assistant professors, postdocs and research scientists) from College of Pharmacy and Health Sciences (COPHS), College of Science, Engineering and Technology (COSET), College of Liberal Arts & Behavioral Sciences (COLAB), and School of Public Affairs (SOPA)
Funding Opportunity Purpose:	The primary goal of the pilot project program is to support ESIs in basic biomedical, behavioral, and/or clinical science research
Key Dates:	Letter of Intent & Specific Aims Due Date: December 15, 2023 before 5:00pm Full Application Due Date: Jan 26, 2024 before 5:00pm Submit to CBMHRpilotprojects@tsu.edu
Scientific Merit Review	Feb-March
NIH Review	April-May
Earliest start date:	June 1, 2024

Overview of Center for Biomedical and Minority Health Research (CBMHR)

The Texas Southern University (TSU) Center for Biomedical and Minority Health Research (CBMHR) is supported by the National Institute of Health's (NIH) National Institute on Minority Health and Health Disparities (NIMHD). The goals of the CBMHR are to: (1) enhance TSU's biomedical research capability through continuous infrastructure building and development; (2) equip all investigators to secure competitive extramural support for biomedical research, particularly on diseases that disproportionately impact underrepresented minority populations; (3) promote professional development for new and early career investigators; (4) foster an environment conducive to scientific inquiry that promotes new basic science research focused on diseases that affect minority populations; and (5) provide enhanced mechanisms for the development of collaborations and partnerships with community-based organizations. The CBMHR is organized into four cores: Administrative Core (ADC), Research Infrastructure Core (RIC), Investigator Development Core (IDC), Community Engagement Core (CEC), and one independent research project. The CBMHR supports basic biomedical research for diseases that disproportionately impact underrepresented minority populations (e.g. cancer, infectious diseases). Through the CEC, the CBMHR promotes community engagement activities in bridging the health disparity gaps for underrepresented minority populations in the Greater Houston Community.

With the purpose of supporting basic biomedical research for diseases that disproportionately impact underrepresented minority (URM) populations (e.g. cancer, infectious diseases), the CBMHR will focus on enhancing research infrastructure and fostering scientific advances for early stage investigators. The unique and collective strengths of CBMHR cores, innovative research projects, excellent resources and structured career enhancement program will make it a novel synergistic and first-of-its-kind resource (at

TSU and in the Texas Medical Center (TMC)) that will provide comprehensive, integrated and centralized infrastructure and high quality capabilities for advanced biomedical research innovation. With over 709 ethnically diverse faculty members, TSU has gained tremendous momentum under new leadership, and recruited and retained a large talented and diverse pool of faculty, including URMs focused on addressing health disparity concerns within its geographical location. Through this award, TSU will continue to play a key role in using a multi-prong approach in addressing diseases that disproportionately impact racial/ethnic minorities and other health disparity populations.

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The primary goal of the CBMHR Investigator Development Core (IDC) is to implement a pilot project program to support preliminary studies of ESIs in basic biomedical, behavioral, and/or clinical science research. TSU ESIs (assistant professors, postdocs and research scientists) from College of Pharmacy and Health Sciences (COPHS), College of Science, Engineering and Technology (COSET), College of Liberal Arts & Behavioral Sciences (COLAB), and School of Public Affairs (SOPA) will be eligible to apply to the pilot grant program.

Background

Increasing the number of URM researchers in the sciences remains a major problem. TSU is committed to train and aid URM junior faculty members to be involved in innovative scientific research studies so they can obtain external funding, be promoted to higher faculty rank, and develop innovative solutions that impact minority health and reduce health disparities. An issue of tremendous importance to TSU is health disparities among African Americans and other URMs. The mortality for African Americans is higher than Whites in heart diseases, stroke, cancer, asthma, influenza, pneumonia, diabetes, HIV/AIDS. In the recent COVID-NET study of 580 hospitalized COVID-19 patients, 33% of those who were hospitalized were black, although blacks only make up 18% of the study population, suggesting that black populations are disproportionately affected by COVID-19. African Americans have the highest mortality rate of any racial and ethnic group for all cancers combined and for most major cancers (lung, prostate, stomach, breast, pancreatic cancers).

TSU currently has biomedical research programs that have been funded by extramural federal agencies (NIH, NSF), industry, and most recently the state of Texas (CPRIT; Cancer Prevention Research Institute of Texas). TSU has received RCMI support since 1986. The pilot project program also helped to establish strong mentorship relationships (internal and externally with TMC institutions) that were crucial to ensure the ESIs' career pathways to success.

Funding priorities

The Greater Houston Community (GHC) contains nine Texas counties: Austin, Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery and Waller. Chronic conditions including diabetes, hypertension, cancer, obesity, and dyslipidemia have been consistently reported as the top 5 health concerns by URMs in the GHC. Disparities in behavioral risk factors and access to preventive care services are persistent among URMs. Heart disease, cancer, and cerebrovascular disease (CVD)/stroke are the top 3 causes of mortality in the GHC, and most recently coronavirus disease 2019 (COVID-19) infection. Unfortunately, all these diseases disproportionately affect GHC URMs. While all biomedical, behavioral, and/or clinical research projects submitted by TSU ESIs are eligible for funding, those that were submitted by URMs and focus on health disparities affecting GHC URMs and collaboratively linked to community engagement are strongly desired and may be given preference. Additional health concerns that may be experienced by URMs can be found at the Houston Department of Health, Houston State of Health, and Community Health Needs Assessments.

Scope

To increase the rigor of the pilot project program, each pilot project recipient is required to participate in all the Administrative Core (ADC) career development and TEAM^{RCMI} program activities and additionally the following activities specific to the individual needs of the pilot project recipient.

- Pilot project applicants must identify two mentors with previous extramural grant awards (NIH/NSF), one from TSU and one from external institutions, matched to their research interests with shared values/cultural background. Applicants from the ESIs pool in the ADC TEAM^{RCMI} program may already have mentors identified, but for those who were not in the TEAM^{RCMI} program and need mentors, IDC will coordinate with ADC and external collaborators (Baylor College of Medicine, Gulf Coast Consortium-GCC) to identify appropriate mentors.
- Mentors for pilot projects are required to receive mentoring training through our existing collaborator the GCC. For experienced mentors, this requirement can be waived. GCC, located in Houston, Texas, is a dynamic, multi-institution collaboration of basic and translational scientists, researchers, clinicians and students in the quantitative biomedical sciences, who benefit from joint training programs, topic-focused research consortia, shared facilities and equipment, and exchange of scientific knowledge. Working together, GCC member institutions provide a cutting-edge collaborative training environment and research infrastructure beyond the capability of any single institution. The GCC hosts mentor trainings for postdocs/research staff, for faculty, and a Train The Trainer workshop each at least twice per year. Master trainers certified by the National Research Mentoring Network with established research experience from TMC affiliated institution facilitates each mentor training session. After the mentoring training, mentors will meet with mentees at least once per month and will help with all aspects of mentee's pilot projects, review mentee's IDP (Individual Development Plan), and provide assistance and enhance competitiveness of future grant proposals.
- Pilot project recipients and their mentors are required to follow ADC TEAM^{RCMI} program procedures and reporting requirements as discussed in the ADC core. To strengthen the sustainability of the IDC, each pilot project recipient will also be required to complete the GCC Mentor training and/or the Train the Trainer workshop to learn how to facilitate a mentoring training. We envision that each pilot project recipient will become a well-trained mentor and possibly even become a future facilitator for mentorship training. Participation in this mentor training will tremendously benefit both ESIs and mentors in the RCMI program. It will allow ESIs to meet and receive training with their peers from multiple (> 10) institutions in the Gulf Coast area.
- Each pilot project recipient will be required to complete an IDP using the *myIDP* online tool, and reviewed with respective mentor. The GCC provides training for ESIs using the *myIDP* online tool developed by the American Association for the Advancement of Science (AAAS). The IDP tool will help each ESI examine his/her skills, interests, and values and set strategic goals for the coming year with reminders to keep ESIs on track. Each ESI's mentor will review the mentee's IDP and provide constructive feedback on action items to overcome potential obstacles and achieve annual goals.
- To promote personal growth, each pilot project recipient and mentors will enroll in Unconscious Bias training offered by National Research Mentoring Network (NRMN) to develop self-awareness and equip with a tool kit to overcome microagression and racial prejudice. Pilot project recipients are required to attend the monthly RCMI seminar, biannual grant writing workshop, and annual collaborative RCMI symposium organized by the Administrative Core. Pilot project recipients will present their pilot project findings to the new ESIs in the ADC TEAM^{RCMI} program. These presentations will teach pilot project recipients leadership skills in serving as mentors to new ESIs in the RCMI program and will help inspire new ESIs in applying for pilot project awards. Each pilot project recipient will be required to submit abstracts and present research findings at the RCMI Symposium and National Conferences. They will also attend the Rigor & Reproducibility workshop organized by GCC. These are great opportunities for ESIs to improve presentation skills and build local and nationwide research collaborations.

Section II. Award Information

Funds Available and Anticipated Number of Awards

Each year, three one-year pilot projects will be selected based on reviewers' scores and comments. Each pilot project will be awarded up to $50,000. Successful projects that meet proposed objectives and projected milestones may receive additional funds from the institutional funds up to 15K for their project. Pilot project recipients will be required to carry out the project and participate in ADC TEAM^{RCMI} program. Importantly, all ESIs who receive pilot funding will have access to CBMHR equipment and resources within the Research Infrastructure Core (RIC).

Award Project Duration

12 months

Section III. Eligibility Information

Eligible Applicants

ESIs (assistant professors, postdocs and research scientists) from COPHS, COSET, COLAB, and SOPA will be eligible to apply to the pilot grant program.

Section IV Application and Submission information

Submission information

The **over-arching goal** of the IDC, in collaboration with other RCMI core facilities, is to provide a mechanism and support for TSU ESIs to acquire preliminary data necessary for obtaining future competitive extramural funding (e.g. NIH K- or R-series awards). Therefore, the Pilot Project Program requires applicants to prepare a NIH PHS 398 application to provide a simulated experience in grant application.

Instructions for Application Submission

It is critical that applicants follow the instruction described in this RFA. Applications that do not comply with these instructions may be delayed or not accepted for review.

To submit your application, save all files into one PDF file and email your application to Dr. Ivy Poon at CBMHRpilotprojects@tsu.edu before the deadline listed above.

The following section should be prepared according to the instruction and included in the application. The fillable files can be found here. Combine all the documents into one PDF file in your application submission.

1. Form Page 1: Face Page
2. Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
3. Project/Performance Site Format Page
4. Form Page 3: Research Grant Table of Contents
5. Form Page 4: Detailed Budget for Budget Period (one year)
6. Project summary*
7. Project narrative*
8. Specific aims*
9. Research strategies*

10. References*
11. PHS Human Subjects and Clinical Trials Information (if human subjects are involved)*
12. Vertebrate animal section (if applicable) *
13. Personal statement*
14. Community engagement plan*
15. Expectation and future plan*
16. Biosketches of applicants and mentors
17. Other support form
18. Budget justification
19. Letters of support

*use NIH continuation format page

Additional Requirement

- Applicants are required to submit a personal statement to the pilot project application to provide reviewers a more comprehensive review of each applicant's interests, perspective, and goals for health disparities research. Pilot project recipients will revise and discuss their personal statement annually to evaluate their personal and professional goals towards community engagement and health disparities research.
- Each applicant is required to develop a community engagement plan through CEC in the pilot project proposal. CEC will train IDC pilot project recipients and mentors on community engagement activities through TEAM^{RCMI}
- Applicant should provide an expectation and future plan page to describe what preliminary data will be produced as a result of the pilot project funding and the impact on chances to achieve NIH funding in the future.

Page Limitations

Section of Application	Page Limits
Project Summary/Abstract	30 lines of text
Project Narrative	three sentences
Specific Aims	1
Research Strategies	6
Personal statement	1
Community engagement plan	1

Section of Application	Page Limits
Expectation and future plan	1

Funding Restriction

Pilot project funds can be utilized to cover awardee's time and effort to carry out the project, purchase supplies for the project, and travel to attend and present at the RCMI National Conference. Pilot project recipients will have access to equipment, instrumentation, and programs in all of the CBMHR cores.

Section V. Application Review Information

Criteria

Project Review

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit,and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

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?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable?

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested?

Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

Will the scientific environment in which the work 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?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Applicant Review

Personal statements, community engagement plan, and mentorship plan will be reviewed.

Review and Selection Process

Proposals will be reviewed by the RCMI Executive Leadership Team (ELT) [and/or Advisory Committee (AC) member] and senior researchers with NIH/NSF grant experience in the applicant's topic area.

Anticipated Announcement and Award Dates:

Earliest award date: June 1, 2024

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