REQUEST FOR APPLICATIONS (RFA)
Southeast Collaborative
Pilot Project Awards

OVERVIEW

The Southeast Collaborative (P50) (NIH Grant 1P50MD017347-01) was established in 2021 as a regional partnership to enable research to improve chronic disease disparities in African Americans and Hispanics/Latinos in the Southeastern US, led by Vanderbilt University Medical Center (VUMC), Meharry Medical College (MMC), and the University of Miami (UM). The Center Investigator Development Core (IDC) will support career development of post-doctoral fellows, early-career faculty, and other early-stage investigators (ESI) in behavioral, clinical, and translational research focused on chronic diseases health disparities that disproportionately affect African Americans, Latinos and other populations experiencing health disparities. Central to this mission is the pilot project awards program, designed to allow ESI to generate preliminary data for extramural grant proposals focused on disease prevention, treatment, and management to characterize the root causes of health disparities and to address disparities in the incidence, morbidity, and mortality of chronic diseases. The IDC will assure that ESI are linked to outstanding local career development opportunities to increase their participation, advancement, and leadership capabilities.

PURPOSE OF RFA

African Americans and Hispanics/Latinos continue to experience disproportionately higher chronic disease burdens compared to non-Hispanic whites. The primary drivers of these racial/ethnic health disparities include a complex interplay of social, behavioral, environmental, and biological factors. There is an urgent need to identify evidence-based interventions that can reduce and ultimately eliminate chronic disease health disparities. We will apply innovative strategies to provide robust research career development resources, leveraging technology and data science to address disparities in chronic diseases, and mentoring of junior faculty and post-doctoral fellows and create a holistic, individualized, and rigorous track for each Center participant. Each supported Center investigator will commit to a development plan and work with a mentorship committee and collaborators. This core will formalize these mentor-mentee relationships for each ESI, leverage existing infrastructure and expertise to cross-train Center investigators in chronic diseases research, convene cross- disciplinary mini-retreats to foster new collaborations across health disparities in chronic diseases, enhance community engagement for recruitment, and leverage existing Vanderbilt Institute for Clinical and Translational Research (VICTR) Studio infrastructure to provide Center investigators targeted input across the continuum, from initial hypothesis to publication of study results, create scientific working groups in chronic diseases to promote idea exchange and proposal development among investigators. Central to this model and the success of Center ESI will be their ability to effectively compete for extramural research funding. The core will launch creative, collaborative, and innovative research, accelerating discoveries to address determinants of health at two or more levels of influence relevant to chronic diseases in the regions that the three institutions serve to address health disparities in chronic diseases.

This Request for Applications invites pilot projects that will address chronic disease health disparities. Please see the NIH RFA: Centers for Multiple Chronic Diseases Associated with Health Disparities: Prevention, Treatment, and Management (P50 Clinical Trial Required)**.** We encourage applicants to read the RFA entirely to be informed with relevant definitions and requirements for your application, (e.g., chronic disease health disparities, community

engagement, etc.). **https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-21-007.html**

This RFA encourages ESI to apply for pilot projects at each site. One pilot project will be awarded at each site (Vanderbilt, Meharry and Miami). The IDC leadership of each site will help and facilitate the identification of mentors and collaborators for pilot project awardees and will work with them to foster their career development as described in the RFA. The pilot project awardees at each site will become members of the Center.

REQUIREMENTS
In addition to proposing highly significant, innovative, and rigorous science, pilot projects must meet three key requirements that are described below:

1) Relevance to chronic disease
2) Relevance to health disparities
3) Inclusion of community engagement

KEY DATES
RFA Release Date: Tuesday, January 24, 2023
Informational Webinar Date: Wednesday, February 1, 2023 (3 pm EST/ 2 pm Central)
**The link and call information will be sent to all who request pre-application consultation*
Deadline to Request Pre-Application Consultation (for guidance on preparing your application): **Friday, March 3, 2023**
eLOI- Letter of Intent: https://redcap.link/h62xktyx due: Deadline Friday, March 17, 2023
Applications Due: Monday, April 17, 2023 (6PM EST/5PM Central)
Scientific Merit Review Completion Date: Tuesday May 16, 2023
NIMHD Administrative Review: May - June 2023
Project Start Date: July 1, 2023
Project Completion Date: June 30, 2024

AVAILABLE FUNDING: The Center IDC will award at least three pilot awards for up to $50,000 direct costs each for a 12-month period. Each site (VUMC, MMC, UM) will be awarded with one pilot project per year. The proposed project cannot duplicate aims of any currently or previously funded award. Institutional Review Board (IRB) approval of projects **greater than minimal risk** will be required prior to disbursement of funds to selected awardees.
PRE-APPLICATION CONSULTATION: We strongly encourage applicants to request a pre-application consultation with a member of the Center Investigator Development Core, Community Engagement Core, or other cores to receive feedback on:

1) Whether the proposal would be responsive to the RFA, and how to modify the proposal to be more responsive
2) Identifying and connecting with potential trans-disciplinary collaborators who could bring complementary expertise to the project (e.g., adding a collaborator with expertise in chronic disease health disparities, adding a collaborator with clinical, behavioral, or social determinant of health experience)
3) Integrating community engagement
4) Integrating clinical data, social determinants of health, environmental data, behavioral data, big data science or other biologic data
5) Identifying resources and support available through the Center cores or other sources

Submit a consultation request at least one month prior to the submission deadline at this link:

Request Pre-Application Consultation

ELIGIBILITY: Any post-doctoral fellow, early-career faculty, and other early- stage investigators (ESI) member at the Center member organization, including Vanderbilt University Medical Center, Meharry Medical College, and the University of Miami, having the skills and experience to carry out the proposed work may submit an application to conduct behavioral, clinical, and translational research focused on chronic disease health disparities.

APPLICATION REVIEW CONSIDERATIONS: It is expected that these pilot applications will be equivalent in scope to R03 and/or R21 grants submitted to the NIH. The proposals will be reviewed using current NIH review criteria. These include overall impact, significance, investigator, innovation, and approach.

Applications that do not include the following components are unlikely to be deemed meritorious.

- Relevance to chronic diseases
- Relevance to health disparities
- Inclusion of community engagement

Applications meeting compliance with all guidelines will be reviewed by a panel to be established through the Center Investigator Development Core. In addition, all applications that are recommended for potential funding will undergo an additional review by staff at the National Institute of Minority Health and Health Disparities (NIMHD).

APPLICATION INSTRUCTIONS

Submission Format: Submit your application using this link: https://redcap.link/yh2kgobn (***as a single pdf file)***.

Applicants must use PHS 398 continuation page format:

Instructions and Form Files for PHS 398 (nih.gov)

Margins must be no less than 0.5 inches and text must be in Arial 11-point font size.

Applications should include the following components:

1) **Cover page (one page)**
   a) Project Title
   b) Principal Investigator(s)' (Name and Title)
   c) Organization/Institution
   d) Address, Phone and Email
   e) Requested Amount
   f) Names, titles, and institutions of mentor(s), collaborator(s), and/or consultants(s) on the project
   g) Lay/public description: A brief description, not to exceed 200 words, for release to the general public should this application be chosen for funding. This should be written in language that can be understood by non-scientists, or a 5th grade reading level.
2) **Project Scientific Summary: (one page):** Please provide a scientific abstract of no more than 400 words that concisely summarizes the proposed work including aims, research design and methods. Include relevance of the project to chronic disease health disparities.
3) **Budget and Budget Narrative (max 2 pages).** Provide a brief explanation/justification of how you expect to allocate the dollar amounts in different areas, including (as appropriate) support for investigator salary. If awarded, a formal budget using PHS 398 budget pages, will be required. The Center Administrative Core will collaborate with your organizational representatives to develop this budget. (See Appendix B)
4) **Bio-sketch: (Use NIH format, for up to 2 PIs and/or collaborators, up to 5 pages each):** Include bio for the principal investigator and up to one additional key investigator, faculty, or project personnel (as salary or consultants if needed). Their role and brief background should be mentioned in the narrative and/or budget summary but please keep the bios limited to only

the one or two primary investigators on the project. Please use link for new bio-sketch instructions.

Biosketch Format Pages, Instructions and Samples | grants.nih.gov

5) **Specific Aims (1 page):** Concisely state the goals of the proposed research and summarize the expected outcome(s). In this section also briefly summarize plans for subsequent funding of the project based on your project's results and the impact that the results of the proposed research may have on chronic disease health disparities research and/or clinical practice.
6) **Project Description (up to 4 pages, no appendices allowed)**
   a) **Significance**: Include purpose of the project, importance of the problem to be addressed, relevance to chronic disease health disparities and description of the population and/or community to be served by the project.
   b) **Innovation**: Explain how the application challenges and/or seeks to shift current chronic disease health disparities research or clinical practice including any novel concepts, approaches or methodologies or intervention(s) to be developed. Innovative approaches for community/stakeholder engagement should also be highlighted in this section.
   c) **Approach**: Describe the overall strategy, methodology, and analyses to be used. If appropriate, include feasibility, preliminary studies, potential problems, and alternative strategies. If not already discussed, include role of relevant stakeholders and /or community engagement in the design and conduct of the study.
   d) Community Engagement (see Appendix A).
   e) **Bibliography and References** (not included in page limit)

FUNDING ACKNOWLEDGEMENT: All funded applicants must agree *to acknowledge* the granting agency in each publication, press release, or other document related to your project, using this language: *Research reported in this publication was supported by the National Institute on Minority Health and Health Disparities (NIMHD) under Award Number* P50MD017347*. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.*

CONTACT INFORMATION: For any questions, inquiries, or additional information please contact: Program Managers Denise Holland (LHolland@mmc.edu), Dr. Alecia Fair (alecia.fair@vumc.org), and Maria Freeman mxf1084@med.miami.edu

Refer to Appendices A-B

Appendix A. Relevant definitions and requirements.

1. Community Engagement (Appendix A)

All pilot projects must include community engagement as part of the proposed study plan. In the context of the pilot grants, some examples of community engagement that would fulfill this requirement include:

1) Presenting the study design to an existing community advisory board (e.g., those established by a CTSI as an example) or other such community groups for feedback and input
2) Seeking advice from community members on how to recruit/engage patients/participants from different communities
3) Joint planning with community partners on dissemination of culturally and contextually-sensitive study related research findings and/or other study relevant health information
4) Other forms of partnering with community-based groups or coalitions that have experience in collaborating with the communities of interest

Applications should clearly state what the community engagement plan is. Applicants are strongly encouraged to request a pre-application consultation with the Community Engagement Core (Director Dr. Olveen Carrasquillo, OCarrasquillo@med.miami.edu) and other members of the Community Engagement Core for guidance on the level and types of community

engagement that would be appropriate for the specific study and how the Community Engagement Core can provide resources and support if it is funded.

Appendix B: General Budget Guidelines

A. Allowable Expenses:

1. Investigator(s) salary. NOTE: Salary caps apply. Same as all other NIH grants.
2. Salary support for research staff
3. Consultants, including stakeholder/community partners on the project
4. Research supplies
5. Domestic travel when necessary to conduct and disseminate the proposed research
6. Publication costs, including reprints
7. Special fees (pathology, photography, etc.)

B. Non-Allowable Expenses:

1. Indirect costs
2. Administrative/secretarial/ grants management personnel
3. Tuition and stipends
4. Foreign travel
5. Non-research services to patients
6. Construction or building maintenance
7. Major alterations
8. Purchasing and binding of periodicals and books
9. Office and laboratory furniture
10. Office equipment and supplies
11. Rental of office or laboratory space
12. Dues and membership fees in scientific societies

Appendix C: Below are some thematic areas and examples of projects we would consider as responsive to the RFA. Please note that these are provided only as examples and applications are certainly not limited to these areas or examples.

• **Thematic area:** Developing novel methods to integrate individual, contextual, and environmental data (including genomic, social, cultural, environmental, and person-reported data) to accurately identify groups at risk for disparities.
Specific example: Testing methods to integrate air quality data, clinical records, and gene expression to identify individuals at highest risk of asthma exacerbations.

• **Thematic area:** Translating pharmacogenomic discoveries to racial and ethnic minorities experiencing disparate outcomes; specifically, to identify effective person-specific treatments that enhance therapeutic outcomes.
Specific example: Pilot an educational intervention for clinicians to consider genetic testing (instead of presuming non-adherence) in minorities taking warfarin who are not at anticoagulation goal.

• **Thematic area:** Examining differences in drug therapy outcomes among racial and ethnic minorities experiencing disparate health outcomes and correlating these with biological, social, cultural, and environmental factors to better understand variability in drug responses.
Specific example: Evaluate difference in clinical outcomes among minorities treated with metformin and correlate with area deprivation indices

• **Thematic area:** Developing and testing new tools and approaches to address genomic and environmental diversity in analyses.

Specific example: Test a refined method of admixture mapping and correlate with expanded options for self-reported race and ethnicity

• **Thematic area:** Examining genomic variations in disparate conditions with known biological underpinnings (including asthma, obesity, chronic kidney disease and premature births) to develop valid predictive models (person-specific) for preventing, screening, and treating conditions.
Specific example: Develop a predictive model for preventing obesity among African American and Latina women using gut microbiome and food environment data

• **Thematic Area:** Addressing return of genetic tests results or genomic risk profiles to persons, particularly in the context of research with vulnerable populations.
Specific Example: Studies that include an aim of garnering input from participants or community stakeholders regarding how best to communicate risk