



**RFA Precision Medicine and Health Disparities
Y5 Pilot Project Awards**

OVERVIEW

Precision Medicine (PM) is an approach to disease detection, prevention and treatment based on people's individual differences. The Precision Medicine and Health Disparities Collaborative (PMHDC, NIH Grant #MD010722) was established in 2016 as a regional partnership to enable research using PM approaches to improve health 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 PMHDC is guided by Advisory and Ethics Boards, comprised of representatives from community-based organization members and minority-serving academic institutions who provide overall and project-specific guidance. PMHDC Cores provide support and resources to researchers: <http://pmforallpeople.com/cores/>

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 health disparities. By taking into account individual variation in preventing, detecting, and treating disease, precision medicine holds considerable promise as an emerging, yet understudied, strategy for addressing health disparities.

This Request for Applications invites pilot projects that will address **both** the precision medicine and health disparities foci of the PMHDC. **Appendix B** provides thematic areas and examples of projects we would consider as responsive to the RFA.

REQUIREMENTS

In addition to proposing highly significant, innovative, and rigorous science, pilot projects must meet three key requirements that are described in detail in **Appendix A** of this document:

- 1) Relevance to precision medicine
- 2) Relevance to health disparities
- 3) Inclusion of community engagement

KEY DATES

RFA Release Date: Monday, July 1st, 2019

Informational Webinar Date: Tuesday August 13th, 2019 (3 pm EST/ 2 pm Central) *The link and call information will be posted on the PMHDC website <http://pmforallpeople.com> and also sent to all who request pre-application consultation.

Deadline to [Request Pre-Application Consultation](#) (for guidance on preparing your application): **Monday September 30th 2019**

Applications Due: Friday, November 1st, 2019 (6PM EST/5PM Central)

Scientific Merit Review Completion Date: Friday December 13, 2019

NIMHD Administrative Review: January-March 2020

Project Start Date: April 1, 2020

Project Completion Date: March 31, 2021

AVAILABLE FUNDING: The PMHDC will award up to three pilot awards for up to \$50,000



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direct costs each for a 12-month period. The proposed project cannot duplicate aims of any currently or previously funded award. Institutional Review Board (IRB) approval of projects 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 PMHDC Training and Mentoring Core, Consortium 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 genomic analyses to a behavioral research project, or adding a collaborator with behavioral or population health expertise to a genetic or basic science research project)
- 3) Integrating community engagement
- 4) Integrating clinical, genetic, or other biologic data
- 5) Integrating social, environmental, or behavioral data
- 6) Identifying resources and support available through PMHDC cores or other sources

[Submit a consultation request](https://redcap.vanderbilt.edu/surveys/?s=L3FTWTX7DC) at least one month prior to the submission deadline at this link: (<https://redcap.vanderbilt.edu/surveys/?s=L3FTWTX7DC>)

ELIGIBILITY: Any faculty member or full-time employee at a PMHDC member organization, including Vanderbilt University/Vanderbilt University Medical Center, Meharry Medical College, University of Miami, University of Florida, Morehouse College and University of Mississippi, having the skills and experience to conduct the proposed work may submit an application. Faculty or employees of the organizations in the PMHDC Advisory Board or Ethics Advisory Board are also eligible to submit applications. If you are uncertain about your institution's eligibility, please contact us.

APPLICATION REVIEW CONSIDERATIONS: It is expected that these pilot proposals 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.

Additional review criteria will include meeting these three requirements as described in Appendix A. Applications that do not include the following components are unlikely to be deemed meritorious.

- Relevance to precision medicine
- 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 PMHDC Consortium 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 [to Brendaly Rodriguez at](#)



Brodriguez@med.miami.edu as a single pdf file.

Applicants must use PHS 398 continuation page format:

https://grants.nih.gov/grants/funding/phs398/398_labels.docx

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

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 short 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 health disparities and precision medicine.

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 PMHDC will work with your organizational representatives to develop this (see **Appendix C** for general budget guidelines).

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.

<http://grants.nih.gov/grants/forms/biosketch.htm>

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 project's results and the impact that the results of the proposed research may have on health disparities and precision medicine 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 health disparities and precision medicine, 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 health disparities/precision medicine research or clinical practice including any novel concepts, approaches or methodologies or intervention(s) to be developed. Innovative approaches



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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) and the National Human Genome Research Institute (NHGRI) of the National Institutes of Health under Award Number U54MD010722. 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, inquires, or additional information please contact: Ms. Brendaly Rodríguez, MA at brodriguez@med.miami.edu or 305-243-8433.

Refer to Appendices A-C in the following pages.



Appendix A. Relevant definitions and requirements.

1. Precision Medicine

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, social determinants, and lifestyle. This approach will allow doctors and researchers to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people. It is in contrast to a one-size-fits-all approach, in which disease detection, prevention, and treatment strategies are developed for the average person, with less consideration for the differences between individuals.

The concept of precision medicine is not new, but the possibilities for applying this concept broadly has been dramatically improved by the recent development of large-scale biologic databases (such as the human genome sequence), powerful methods for characterizing patients (such as proteomics, metabolomics, genomics, diverse cellular assays, and even mobile health technology), and computational tools for analyzing large sets of data. Complementing biologic information are new and emerging tools to more collect and precisely measure social and environmental information both of which are particularly important in precision medicine aimed at addressing health disparities.

Requirements for RFA

For purposes of this RFA, in order to be considered responsive to the **precision medicine** focus of the RFA, applications **must** include at least one or more variables involving genetic/biologic information **and** at least one variable having social, environmental, and/or behavioral information. Applications should clearly state how the research meets these criteria for being considered precision medicine. Examples of each type of data to be combined include:

- a) **Clinical or genetic and other biologic data**, such as genomics, proteomics, metabolomics, cellular assays, laboratory test results, or other clinical data (e.g., blood pressure, body mass index)
- b) **Social, environmental, or behavioral data**, such as socioeconomic status (income and education), discrimination, housing quality, access to resources, stress, health behaviors (e.g., smoking, diet, physical activity), emotional trauma, or psychological factors

Applicants proposing pilot studies, particularly those that are primarily basic science in focus, are strongly encouraged to request a pre-application consultation prior to submitting a proposal to help ensure that the proposal is responsive to this requirement.

2. Health Disparities

Health disparities are differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups. These groups or health disparity populations include racial/ethnic and sexual/gender minorities, disabled individuals, those of low socioeconomic status, and those living in rural areas.



For the purposes of this RFA, the Significance section must include the following:

- 1) description of the health disparity population
- 2) documentation of the health disparity, including comparisons to other groups
- 3) description of how the proposed research has the potential to either improve the health of the impacted group or reduce the documented disparity

Relative to the proposed health disparity, the research must focus on one or more of the following: 1) identification; 2) etiology; 3) prevention; 4) diagnosis; or 5) treatment. As noted above, pre-application consultation is strongly suggested, particularly for studies that are primarily basic science in focus, to help ensure that the proposal is responsive to this requirement

3. Community Engagement

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 boards (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 working 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 PMHDC Consortium Core for guidance on the level and types of community engagement that would be appropriate for the specific study and how the Consortium Core can provide resources and support if it is funded.



Appendix B: 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

In addition, please refer to the following list of the projects funded in the 2017-2018 cycle:
<https://www.vumc.org/meharry-vanderbilt/all-news-research-news/pmhd-announces-pilot-project-awards>



Appendix C: 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 carry out 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