A Partnership to Examine Health Affects – A Collaboration to Manage Health Effects

PILOT PROJECT PROGRAM 2015-2016

Request for Applications

Background

Hampton University has been awarded a cooperative agreement grant from the National Institute on Minority Health and Health Disparities (NIMHD) to establish the Hampton University Regional Transdisciplinary Collaborative Center (HU-TCC), a coordinated transdisciplinary approach to addressing health disparities among male populations, especially in racial/ethnic, low income and rural subgroups. The HU-TCC operates under the umbrella of the Hampton University Minority Men's Health Initiative (MMHI) and takes a comprehensive, integrative approach (research, education, training and outreach) to narrowing and/or eliminating health disparities in racial and ethnic minority male populations. Our focus is primarily on health disparities in African-American and Hispanic populations, but health disparities affecting other racial/ethnic male populations are supported as dictated by research activities of faculty at Minority Serving Institutions (MSIs) in the US Department of Health and Human Services designated regions 3 and 4.

The MMHI places its highest priority on the elimination of health disparities in African-American and Latino male populations; thus, the major component of our funding resources will be allocated towards research, education, training and outreach in these vulnerable male populations. The MMHI hopes to harness the health disparity research resources and expertise of MSIs in HHS Regions 3 and 4, which consist of 85 Historically Black Colleges and Universities (HBCUs) and 13 Hispanic Serving Institutions (HSIs). The MMHI's Pilot Project Program allows the involvement of early career faculty from any of the 98 MSIs in our target area to pursue transdisciplinary collaborative health disparity research aimed at reducing the burden of cancer, diabetes, obesity, cardiovascular disease and violence in male populations.

The Pilot Project Program awards further cultivate transdisciplinary health disparity research collaborations by strengthening the research foci of the initial four Research Sub-Projects and further diversifying the disciplines/processes/approaches being employed by MMHI researchers. "For example, transdisciplinary cancer research may address the biological, environmental, behavioral, and social determinants of cancer risk or outcome and use novel methods drawn from molecular biology, genetic epidemiology, sociology, economics, psychology, biomedical informatics, and health policy. Ideally, transdisciplinary research will have implications for clinical and public health practice, with potential to catalyze critical improvements in the prevention and treatment of cancer." (Excerpt from: Rebbeck, TR, Paskett, E & Sellers, TA "Fostering Transdisciplinary Science." Cancer Epidemiol Biomarkers Prev 2010;19:1149-1150).

Applicants are strongly encouraged to propose health disparity research strategies that employ transdisciplinary collaborations, wherein the Principal Investigator leads a team of scientists (team science) from multiple scientific disciplines (behavioral, social, computational, policy and/or biological) to leverage their expertise in order to develop unified methods, models, or processes aimed at reducing or eliminating health disparities in male populations. Moreover, applicants are encouraged to build inter-institutional
collaborations among health disparities researchers employed at multiple Regions 3 and 4 MSIs. The MMHI's overarching goal is to develop health disparity researchers who implement sustainable and transferable transdisciplinary collaborative research models in its six research areas to positively influence the healthy outcomes of minority male populations.


**Important Dates**
- **Release Date:** Friday, December 5, 2014
- **Pilot Project Program Webinar:** Monday, December 15, 2014 at 12:30PM EST
- **Letter of Intent to Submit Application Due Date (REQUIRED):**
  - Friday, January 23, 2015 at 6:00 P.M. Eastern Standard Time (EST)
- **Full Application Due Date:** Friday, February 20, 2015 at 6:00 P.M. EST
- **Earliest Notification of Funding:** Monday, June 1, 2015
- **Earliest Project Start Date:** Wednesday, July 1, 2015

**Application Characteristics**

**Pilot Project Award:**
- Pilot Project Awards support transdisciplinary health disparity research projects that require substantial amount of time, resources, and/or personnel integrating multiple scientific disciplines to establish transformative minority male health disparity research products that will strengthen the Principal Investigators' application to SC1, R21/R33, R01, or equivalent funding mechanism.
- Pilot Project Awards may request a project period of up to two years.
- The combined budget for total costs for the two year project period may not exceed $250,000. No more than $125,000 in total costs may be requested in any single year.
- The Pilot Project Award cannot be renewed.
- One resubmission is allowed for failed Pilot Project Award applications.
- No preliminary data are required, but may be included if available.
- The Research Strategy may not exceed six pages.
- Principal Investigator (PI) must commit 25% minimum effort towards the proposed project. If multiple PIs, then total combined effort of the PIs must total a minimum of 25% effort.
- A maximum of 1 month summer salary is annually allowed per project.

**Seed Project Award:**
- Seed Project Awards support transdisciplinary health disparity research projects that require small amount of time, resources, and/or personnel to establish initial baseline data to support the development of a minority male health disparity research project that will strengthen the Principal Investigators' application to SC3, R15, MMHI Pilot Project Award, or equivalent funding mechanism. Seed Project Awards should also lay the foundation for the progressive integration of multiple scientific disciplines as the project matures.
- Seed Project Awards are limited to a project period of one year.
- The budget may not exceed $40,000 in total costs.
- The Seed Project Award cannot be renewed.
- The Seed Project Award may be developed into a future Pilot Project Award application.
- One resubmission is allowed for failed Seed Project Award applications.
- No preliminary data are required, but may be included if available.
- The Research Strategy may not exceed four pages.
- Principal Investigator is not required to commit a specific minimum effort.
- A maximum of 1 month summer salary is annually allowed per project.
Note: All Pilot Project and Seed Project applications will be evaluated on the scientific quality of the proposal and the focus of the proposal on transdisciplinary health disparity research among minority men. Applications will also be evaluated based on the applicant’s biomedical and/or behavioral health disparity research career plan; the potential for publications related to the proposal; and the potential for future extramural funding.

Scope
- Exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications that focus on MMHI research areas of cancer (prostate and melanoma in Hispanics), cardiovascular disease, violence prevention, diabetes, and obesity.
- High risk, high reward studies that may lead to a breakthrough in reducing health disparities in minority men.
- Studies projected to result in novel techniques, agents, methodologies, models or applications that will impact research, education, training, and outreach programs in minority men's health disparities.
- Projects should be distinct from those supported through other funding mechanisms.
- It is expected that pilot research projects supported by the MMHI Pilot Project Program will lead to publications and ultimately to a NIH R21/R01 application or to other extramural funding sources.

Research Topics of Interest
- All projects must relate to the core research areas of the MMHI: prostate cancer, melanoma in Hispanics, cardiovascular disease, violence prevention, diabetes and obesity.
- Projects addressing research gaps in the determinants of premature morbidity and/or mortality among minority males across the life course in one or more health disparity minority populations.
- Projects examining the dynamics of minority male-specific health issues and challenges faced across the life course and the influences of early events on health outcomes later in life.
- Studies aimed at the development of collaborative strategies and interventions to better coordinate fragmented minority men's health awareness, disease prevention and/or research efforts at regional, state and/or local levels.
- Studies of sex specific biomarkers for disease risk, prognosis, or benefit of treatment.
- Studies of sex specific biomarkers in response to preventive or therapeutic interventions.
- Assessment of racial and ethnic disparities in prevention and early detection, diagnosis and care management, morbidity, mortality among men and its linkage to social and environmental determinants.

Principal Investigator Eligibility Characteristics
- Research and/or teaching faculty members at MSIs within HHS Regions 3 and 4 may serve as Principal Investigators of Pilot Project and Seed Project Award applications.
- Principal Investigators must meet the NIH New Investigator status criteria (http://grants.nih.gov/grants/new_investigators/), but not the NIH Early Stage Investigator status.
- Principal Investigators must have a MMHI Faculty Sponsor who must provide a Letter of Support, which must be submitted with the Full Application.
- Principal Investigators must include a 1-2 page Career Development Plan (including timeline and description of the specific role played by mentor and/or collaborators in the proposed project).
Previous MMHI Pilot Project Awardees are not eligible to apply for another MMHI Pilot Project Award as the Principal Investigator (PI). They are eligible to serve as a co-investigator for a new Pilot Project Award application. In addition, they are encouraged to recruit other eligible junior faculty members to apply to the MMHI Pilot Project Program.

Previous MMHI Seed Project Awardees are eligible to apply for a MMHI Pilot Project Award.

Previous MMHI Seed Project Awardees are not eligible to apply for another MMHI Seed Project Award as the Principal Investigator (PI). They are eligible to serve as a co-investigator for a new Seed Project Award application. They are encouraged to recruit other eligible junior faculty members to apply to the MMHI Pilot Project Program.

2014 Pilot Project Program Awards

Seed Project Awards (12 months)
Title: Hampton University Ministers’ Conference multimedia men's health project.
PI(s): Debra L. Haggins (contact), Maria Elena Villar, Wayne J. Dawkins and Deidre Gibson
Institution: Hampton University and Florida International University
MMHI Faculty Sponsor: Raymond E. Samuel
Funding: $40,000

Title: Masculinity and racism as predictors of obesity risk among Black young adult men.
PI(s): Anna K. Lee
Institution: North Carolina Agricultural and Technical State University
MMHI Faculty Sponsor: Elimelda M. Ongeri
Funding: $39,581

Title: Geospatial analysis of violence hotspots in Hampton Roads.
PI(s): Shari Wiley
Institution: Hampton University
MMHI Faculty Sponsor: Zina T. McGee
Funding: $40,000

Pilot Project Awards (24 months)
Title: Development of biomarkers of diabetic nephropathy in African-American men.
PI(s): Robert H. Newman (contact) and Elimelda M. Ongeri
Institution: North Carolina Agricultural and Technical State University
MMHI Faculty Sponsor: Elimelda M. Ongeri
Funding: $247,500

Title: Targeting AhR signaling in advanced prostate cancer.
PI(s): Joann B. Powell
Institution: Clark Atlanta University
MMHI Faculty Sponsor: Shafiq Khan
Funding: $248,118

Title: DNA specific sensor for prostate cancer biomarkers.
PI(s): Amir H. Saheb
Institution: Albany State University
MMHI Faculty Sponsor: Raymond E. Samuel
Funding: $199,539

MMHI Faculty Sponsors
Hampton University
Joanne Chan, PhD (joanne.chan@hamptonu.edu; 757-728-6057) - Cancer
Bertha Davis, PhD (bertha.davis@hamptonu.edu; 757-727-5672) - Cardiovascular Disease
Nicholas Kenney, PhD (nicholas.kenney@hamptonu.edu; 757-728-6952) - Cancer
John Mably, PhD (john.mably@hamptonu.edu; 757-728-6058) - Cardiovascular Disease
Linda Malone-Colon, PhD (linda.malone-colon@hamptonu.edu; 757-727-5301) - Violence
Zina McGee, PhD (zina.mcgee@hamptonu.edu; 757-728-6913) - Violence
Michelle Penn-Marshall, PhD (michelle.pennmarshall@hamptonu.edu; 757-727-5267) - Obesity
Candice Wallace, PhD (candice.wallace@hamptonu.edu; 757-727-5041) - Violence
Van Dora Williams, MA (vandora.williams@hamptonu.edu; 757-728-6926) - Violence

Clark-Atlanta University
Kimberly Davis, PhD (kedavis@cau.edu; 404-880-6750) - Cancer
Shaﬁq Kahn, PhD (skhan@cau.edu; 404-880-6795) - Cancer

Howard University
A. Wade Boykin, PhD (aboykin@howard.edu; 202-806-6805) - Violence

Jackson State University
Clifton Addison, PhD (c.addison@jsums.edu; 601-979-2931) - Cardiovascular Disease
M. Edwina Barnett, MD, PhD, MBA (m.e.barnett@rtrn.net; 601-979-0332) - Cardiovascular Disease
David Bandi, PhD (bandi56occupy@gmail.com; 662-648-9115) - Cardiovascular Disease

North Carolina A & T State University
Goldie Smith-Byrd, PhD (gsbyrd@ncat.edu; 336-334-7907) - Diabetes and Obesity
Scott Harrison, PhD (scotth@ncat.edu; 336-285-2179) - Diabetes and Obesity
Elimelda Ongeri, PhD (ongeri@ncat.edu; 336-285-2182) - Diabetes and Obesity

Non-Participating MSIs and Non-MSI Institutions
Faculty at MSIs located outside of HHS Regions 3 and 4 and other non-MSI institutions may collaborate on Pilot Project and Seed Project Awards led by MMHI Participating MSI Early Career Faculty members. Note that the primary goal of this Pilot Project Program is to further enhance and advance minority men's health disparities research capacity of MSIs in HHS Regions 3 and 4.

U.S. Department of Health & Human Services Regions

Region 3
Delaware; District of Columbia; Maryland; Pennsylvania; Virginia; West Virginia

Region 4
Alabama; Florida; Georgia; Kentucky; Mississippi; North Carolina; South Carolina; Tennessee

NIH New Investigator Criteria
http://grants.nih.gov/grants/new_investigators/

In general, a Program Director/Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial NIH independent research award. Specifically, a PD/PI is identified as a New Investigator if he/she has not previously competed successfully for an NIH-supported research project other than the following early stage or small research grants or for the indicated training, infrastructure, and career awards:
- Pathway to Independence Award-Research Phase (R00)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Research Education Grants (R25, R90, RL9, RL5)
- Clinical Trial Planning Grant (R34)
- Dissertation Award (R36)
- Small Business Technology Transfer Grant-Phase I (R41)
- Small Business Innovation Research Grant-Phase I (R43)
- Shannon Award (R55)
- NIH High Priority, Short-Term Project Award (R56)
- Competitive Research Pilot Projects (SC2, SC3)
- Resource Access Award (X01)
Additionally, the PD/PI is not excluded from consideration as a “New Investigator” if he/she has been the PD/PI or received an award from any of the following classes of awards:

**Training-Related and Mentored Career Awards**
- All Fellowships (F awards)
- All individual and institutional career awards (K awards)
- Loan repayment contracts (L30, L32, L40, L50, L60)
- All training grants (T32, T34, T35, T90, D43)

**Instrumentation, Construction, Education, Health Disparity Endowment Grants, or Meeting Awards**
- G07, G08, G11, G13, G20
- R13
- S10, S15, S21, S22

**Note regarding grants with Multiple PD/PIs:** In the case of a grant application that involves more than one PI, all PD/PIs must meet the definition of New Investigator in order for the application to have the New Investigator designation.

**Note regarding transitional grants:** Research grants that combine a smaller initial award that transitions without further competition to a second phase supported by a substantial, independent research grant will discontinue the New Investigator status for the PD/PI(s) at the point of transition to the larger award. This includes combined, transitional awards like the R21/R33, R41/R42, R43/R44, U43/U44, UH2/UH3, and the UT1/UT2.

**HU-TCC: MMHI Pilot Project Program Letter of Intent to Submit an Application (Required)**

Please note that all applicants to both the Pilot Project Award and the Seed Project Award MUST submit a Letter of Intent (LOI) in order to qualify for the submission of a Full Application. The Letter of Intent (LOI) package should include:
- PI's Name, Faculty Rank, and Institution
- Co-Investigator(s) and Faculty Rank(s)
- Senior mentor(s) and Faculty Rank(s)
- MMHI Faculty Sponsor
- Description of how your transdisciplinary collaborative research project will address a research question relevant to the MMHI: prostate cancer, melanoma in Hispanics, cardiovascular disease, violence prevention, diabetes, and obesity.

Letters of Intent and applications may not be submitted in paper format. Only electronically submitted LOI (in a SINGLE PDF file) will be reviewed. Email your LOI (in a SINGLE PDF file) on or before Friday, January 23, 2015, at 6:00 P.M. EST to: mmhi-info@hamptonu.edu.

**Technical assistance** on the development of the LOI may be offered if requested. If you have questions concerning the submission of the LOIs, please contact the MMHI administrative office: **Office: 757-728-6030; Email: mmhi-info@hamptonu.edu**.
**MMHI Pilot Project Program Full Application Guidelines**

**Application Format and Content**

Investigators should submit an NIH-format application on **combined PHS 398 forms** as ONE PDF file ([http://grants.nih.gov/grants/funding/phs398/phs398.html](http://grants.nih.gov/grants/funding/phs398/phs398.html)). Investigators should use Arial 11 point font, with one-half-inch margins on the top and bottom of the pages. Investigators should include the following:

- A paragraph in lay language describing how this project will be translated to help improve health disparities in the minority male population.
- Describe plans for preparing papers for peer-reviewed publication and how the proposed Pilot Project or Seed Project will lead to a competitive proposal for submission to the NIMHD.

**The format of the grant application is as follows:**

- **Face Page**
- **Project Summary/Abstract Relevance (1 page)**
  
  *Describe how the project will be translated to help improve health disparities in minority male populations.*

- **Project/Performance Sites**
- **Scientific/Key Personnel**
- **Other Significant Contributors**
- **Table of Contents**
- **Detailed Budget for Each Year and Total Years**
- **Budget Justification**
- **NIH Biographical Sketches (4-page format, including research experience)**
  
  Resources (List those currently available for the applicant’s use in the proposed project)

- **Research Plan**
  
  - **Specific Aims (1 page)**
  
  - **Research Strategy (Pilot Project: 6 pages; Seed Project: 4 pages)**

- **Principal Investigator’s Health Disparity Research Career Plan (1-2 Pages).**
- **Health Disparity Faculty Mentor - letter of support and mentorship plan (1-2 pages)**
- **MMHI Faculty Sponsor’s Letter of Support (1 page)**
- **Human Subjects Certification (if applicable)**
- **Literature Cited**
- **Other Letters of Support**

**HU-TCC:MMHI Pilot Project Program Funding Restrictions**

**The following types of expenditures are allowable:**

- Research supplies and animal maintenance
- Technical assistance
- Domestic travel when necessary to carry out the proposed research
- Publication costs, including reprints
- Cost of computer time
- Special fees (pathology, photography, etc.)
- Compensation for services rendered by graduate students and postdoctoral assistants.
- Equipment costing less than $5,000
- Computers and software for use by research personnel engaged in research project
- Registration fees and routine travel expenses for scientific meetings

**Must include travel expenses for all funded research personnel to attend two (Fall and Spring) mandatory MMHI Research Retreats at Hampton University during each annual funding period.**
Principal Investigator Salary: Pilot Project Award requires a minimum of 25% effort during academic year. Seed Project Award does not require a minimum level of effort. A maximum of 1-month summer salary is annually allowed in project budget.

Institutional Indirect Costs (IDC) are not to exceed 10% on all Pilot Project Program awards, consistent with the early-career faculty development goals of the MMHI Pilot Project Program.

Full Federal negotiated Institutional rates are not applicable to the MMHI Pilot Project Program awards.

The following types of expenditures are NOT allowed:
- Secretarial/administrative personnel
- Student tuition/Stipends
- Foreign travel
- Honoraria and travel expenses for visiting lecturers
- Per Diem charges for hospital beds
- Non-medical services to patients
- Construction or building maintenance
- Major alterations
- Purchasing and binding of periodicals and books
- Office and laboratory furniture
- Office equipment and supplies
- Rental of office or laboratory space
- Recruiting and relocation expenses
- Dues and membership fees in scientific societies

The Full Application may not be submitted in paper format. Only electronically submitted applications (in a SINGLE PDF file) will be reviewed.

Your Full Application must be emailed by your Institutional Sponsored Program Official (one PDF file), including all components requested above, on or before Friday, February 20, 2015, at 6:00 P.M. EST to: mmhi-info@hamptonu.edu.

Technical assistance regarding the development of the full application may be offered, if requested. If you have questions concerning the submission of the Pilot Project or Seed Project proposals, please contact the MMHI administrative office:
Office: 757-728-6030; Email: mmhi-info@hamptonu.edu.

Application Review Criteria and Considerations
The following NIH Standard Review Criteria and Considerations will be used to review the projects:

Review Criteria for Research Grants and Cooperative Agreements
The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact. Reviewers will provide an overall impact/priority 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 following review criteria in the determination of scientific and technical 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? 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/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or 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? 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? 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?

**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/priority score, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Revision

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

- Select Agent
- Resource Sharing Plans
- Budget and Period Support