

**U.S. Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
National Institute on Minority Health and Health Disparities (NIMHD)
National Advisory Council on Minority Health and Health Disparities
(NACMHD)**

9000 Rockville Pike, Bethesda, MD
Building 31, 6th Floor Conference Room 6
September 10, 2015
8:30 a.m. – 5:00 p.m.

Meeting Summary

Council Members Present

Eliseo J. Pérez Stable, Ph.D. Chair
Linda T Adams, Ph.D., RN, FAAN
Margarita Alegría, BA, MA, Ph.D.
Maria R. Araneta, Ph.D.
Judith B. Bradford, Ph.D.
Linda Burhansstipanov, MSPH, Dr.PH
Sandro Galea, M.D., MPH, Dr.PH
Eddie L. Greene, M.D.
Linda S. Greene, B.A., J.D.
Valerie Montgomery Rice, M.D.
Lisa A. Newman, M.D., MPH, FACS, FASCO
Brian Rivers, Ph.D., MPH

***Ex Officio* Members Present**

Michael J. Fine, M.D., M.Sc.
Cara Krulewitch, CNM, Ph.D., FACNM

Executive Secretary

Joyce A. Hunter, Ph.D.

Presenters

Gregory Farber, Ph.D.
Christopher Austin, M.D.
Lawrence A. Tabak, D.D.S., Ph.D.

NACMHD Meeting Summary

September 9, 2015

CALL TO ORDER AND INTRODUCTORY REMARKS

The 40th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) was called to order at 8:31 AM by Dr. Eliseo J. Pérez- Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD). Dr. Pérez Stable asked Council members to introduce themselves, followed by NIMHD staff and invited guests. He then asked Dr. Joyce Hunter, Deputy Director, and NACMHD Executive Secretary, to review the confidentiality and conflict of interest information with Council members. Dr. Perez-Stable requested that Council members inform us if there is a schedule conflict.

NACMHD Meeting Minutes – February 24, 2015

The Council unanimously approved the minutes of the June 29, 2015 meeting.

Future Meeting Dates

The next NACMHD meeting is scheduled for February 8th and 9th 2016. Future meeting dates are listed below:

| 2016 | 2017 |
|--------------------------------|---------------------------------|
| Tuesday, February 8-9, 2016 | Tuesday, February 13-14, 2017 |
| Tuesday, June 6-7, 2016 | Tuesday, June 5-6, 2017 |
| Tuesday, September 21-22, 2016 | Thursday, September 19-20, 2017 |

Dr. Hunter emphasized the importance of attending Council meetings to achieve a quorum, and reminded members that they are allowed to miss one meeting per calendar year. Members cannot serve on NIH scientific review panels during their tenure on the Council.

NIMHD DIRECTOR'S REPORT AND DISCUSSION

Dr. Pérez-Stable provided the report on recent activities at NIMHD and across the NIH. He started by commemorating the passing of Dr. Louis Stokes, a member of Congress, a political leader in the African-American community, one of the first elected representatives in the House of Representatives, and a long-standing supporter of research on healthcare disparities. Dr. Stokes was instrumental in the creation of the Center on Minority Health and Health Disparities in 2000 which was a fundamental shift in emphasis at NIH.

Institute changes across NIH

Dr. Pérez-Stable announced that Dr. Walter Koroshetz is the new Director of the National Institute of Neurological Disorders and Stroke (NINDS) and Dr. William Riley has been appointed as the new Director for the NIH Office of Behavioral and Social Sciences (OBSSR). Dr. Sally Rockey will be leaving NIH to become the Director of the Foundation for Food and Agriculture Research. Dr. Alan Guttmacher, the Director of NICHD is retiring in October. Dr. Catherine Spong, the NICHD Deputy Director, will serve as the Acting Director while NIH conducts a national search for a new NICHD Director.

Precision Medicine Initiative (PMI)

This initiative will forge a new model for scientific research that emphasizes engaged participants and open, responsible data sharing with privacy protections. The NIH Precision Medicine National Research Cohort includes more than 1 million participants. Researchers are able to collect and share participant genomic data, lifestyle information, electronic health records and biological samples. Dr. Pérez-Stable thanked Dr. Regina James who has represented NIMHD at the PMI meetings. He emphasized that monitoring of physiological parameters that can help move towards standardized measures of social determinants of health. NIH has allocated \$130 million to create the PMI National Research Cohort.

Besides the national cohort, there is a second piece of the PMI which relates to cancer, PMI Oncology. PMI-Oncology has a separate budget allocation for NCI. It will apply tenets of precision medicine to cancer research. To reach this goal, PMI-Oncology will enable research to use NCI clinical trials as models, identify new cancer subtypes and therapeutic targets, test combination therapies, partner with the private sector to test precision medicine and understand and combat drug resistance.

Dr. Pérez-Stable discussed the possible uses for information from the PMI National Research Cohort such as evaluating a wide array of mHealth applications and improving the utility of eHRs in population health. The PMI National Research Cohort can facilitate research therapeutic safety efficacy and/or metabolism, provide unbiased determinants of risk and standardized measures of social determinants. He mentioned that one of the goals for NIMHD is to make sure that the cohort is diverse and represents the America population in terms of lifestyle, race, ethnicity and age. Below is a list of PMI workshops held in 2015.

- **February 11 & 12:** Building a precision medicine research cohort (NIH)
- **April 28 & 29:** Unique scientific opportunities for the national research cohort (NIH)
- **May 28 & 29:** On cohorts and electronic health records (Vanderbilt University, Nashville, TN)
- **July 1 & 2:** On participants and community engagement (NIH)
- **July 27 & 28:** On mHealth (Intel Corp., Santa Clara, CA)

NIMHD Updates

2015 Translational Health Disparities Course

The NIMHD Translational Health Disparities Course, *Integrating Principles of Science, Practice and Policy*, was held August 3-14, 2015 on the NIH campus in Lister Hill Auditorium. Ninety-six scholars were selected from a competitive pool that included PhDs, MDs, DDS, PharmDs and MPHs. Four Advisory Council members, Dr. Margarite Alegría, Dr. Happy Araneta, Dr. Judith Bradford, and Dr. Ross Hammond, served as faculty members.

Science Visioning for Health Disparities Research

Dr. Pérez-Stable stated the NIMHD Science Visioning Process builds upon the current observations and new opportunities to advance the field of health disparities research. A Request for Information (RFI) was released on April 17th (NOT-MD-15-006) and closed on July 31st. The RFI solicited information into the NIH Science Vision to Advance Health Disparities Research. Ninety-two submissions representing more than 400 individuals and organizations were received.

Initiatives and Activities

NIMHD partnered with Omega Psi Phi Fraternity, Inc. Educational Outreach Initiative

The NIMHD and Omega Psi Phi Fraternity, Inc. launched, “Brother, You’re on My Mind: Changing the National Dialogue Regarding Mental Health among African American Men” that focuses on raising awareness about mental health challenges associated with stress and depression affecting African American men and their families.

HIV/AIDS ADELANTE Program: Assisted Development of Early-Career Researchers Focusing on Latino/Hispanic-Community AIDS Investigations of Prevention, Care, and Treatment.

The goals of the ADELANTE Program are to decrease HIV-related health disparities in the Hispanic/Latino community and to promote the mentored development of new investigators who will focus on HIV/AIDS in the Hispanic/Latino populations.

ENCODE – Encyclopedia of DNA elements: The Encyclopedia of DNA Elements

The National Human Genome Research Institute (NHGRI) launched a public research consortium called ENCODE, the Encyclopedia Of DNA Elements. The ENCODE Consortium was launched in September

2013. It is an international collaboration of NIH-funded research groups building a comprehensive “parts list” of functional elements in the human genome, including regulatory sequences that control gene expression.

Population Architecture: Using Genomics and Epidemiology (PAGE 2)

Dr. Pérez Stable announced the collaboration with NHGRI on PAGE 2. This initiative study will focus analysis and genotyping entirely on 50,000 non-European ancestry individuals to better characterize how genetic factors influence susceptibility to disease.

NIMHD Program Funding

Funding Opportunity Announcements

| Title | Application Due Date |
|---|-----------------------------|
| Advancing Health Disparities Interventions Through Community-Based Participatory Research (U01) | 8-3-2015 |
| NIMHD Transdisciplinary Collaborative Centers for Health Disparities Research Focused on Precision Medicine (U54) | 9-17-2015 |
| Building Population Health Research Capacity in the U.S. Affiliated Pacific Islands (U24) | 12-9-2015 |
| Data Coordinating Center for Sickle Cell Disease Implementation Consortium (SCDIC): Using Implementation Science to Optimize Care of Adolescents and Adults with Sickle Cell Disease (U24) | 11-13-2015 |
| NIMHD Transdisciplinary Collaborative Centers for Health Disparities Research on Chronic Disease Prevention (U54) | 12-17-2015 |
| Behavioral Interventions to Prevent HIV in Diverse Adolescent MSM (U01) | 1-15-2016 |

Legislative Updates

- On July 10, 2015, the House passed H.R. 6, the 21st Century Cures Act, as amended, by a recorded vote of 344-77. The 21st Century Cures Bill: establishes the Innovation Fund, raises the cap on loan repayment programs, seeks to reduce the administrative burden for researchers and requires a strategic plan.
- Other bills of interest:
 - S.1903 – On July 30, 2015, Senator Corey A. Booker (D-NJ) introduced S. 1903 to provide for a study by the National Academy of Medicine on health disparities, to direct the Secretary of Health and Human Services to develop guidelines on reducing health disparities.
 - H.R. 2730 – On June 11, 2015, Representative G.K. Butterfield (D-NC) introduced the National Prostate Cancer Plan Act. The bill would establish the National Prostate Cancer Council on Screening, Early Detection, Assessment, and Monitoring of Prostate Cancer within the HHS Office of the Secretary.
 - H.R. 2651 – On June 4, 2015, Representative Diana DeGette (D-CO) introduced the Eliminating Disparities in Diabetes Prevention, Access, and Care Act of 2015. The bill would amend subpart 3 of part C of title IV of the PHS Act to prevent and treat diabetes, and to promote and improve the care of individuals with diabetes, and to reduce health disparities, relating to diabetes, within racial and ethnic minority groups.

Budget Update

Dr. Pérez-Stable stated that NIH has been proposed for a modest increase in the FY2016 budget. Over the last decade a steady decrease in dollars allocated to the NIH has occurred as a result of inflation and a flat budget. The NIMHD's budget of \$271 million is allocated as follows: A significant investment is made in the Centers of Excellence (19%), The Research Centers in Minority Institutions Programs (20%), and the Transdisciplinary Collaborative Centers for Health Disparities Research (8%). Other investments include: Research Project grants (15%), Endowment (7%), Community-Based Participatory Research Program (6%), Operations (5%), Loan Repayment Program (3%), Intramural Research Program (2%), Taps (3%), and other Programs (12%).

NIMHD Outreach Updates

On June 17, 2015, NIMHD hosted a virtual meeting with Dr. Richard H. Carmona, the 17th U.S. Surgeon General and the President of the Canyon Ranch Institute (CRI) Board of Directors, to discuss possible areas of collaboration with CRI.

On June 24, 2015, at the request of Coalition for the Advancement of Health through Behavioral and Social Sciences Research, NIMHD, along with staff from OBSSR, NIAAA, NIDDK, NCI, NHGRI, NIAMS, NEI, NICHD, and NHLBI, participated in a congressional poster session about Healthier Lives through NIH-Supported Behavioral & Social Sciences Research.

NIMHD Grants Submitted and Awarded

The funding of R01s at NIMHD was the following: In 2013, 3.9% of applications were awarded. In 2014, 12.1% of applications were awarded in line with other NIH ICs funding of R01s. By June Council of 2015, 8.2% of applications were awarded, however, more grants will be funded by the end of the fiscal year.

| Mechanism | Year/Council Cycle | Applications Submitted | Applications Awarded |
|-----------|--------------------|------------------------|----------------------|
| R01 | February-June 2015 | 158 | 13 (8.2%) |
| R01 | 2014 | 280 | 34 (12.1%) |
| R01 | 2013 | 283 | 11 (3.9%) |

The success rate for new or early stage investigators was 5.1% in 2013, 10.9% in 2014 and 9.5% by the June Council of 2015. For established investigators, the success rates are 2.7% in 2013, 13% in 2014 and 7.1% in 2015. The low success rate for both types of investigators in 2013 reflects sequestration reductions.

| Year/ Council | NI/ESI Applications | | | | Established Investigator Applications | | | |
|--------------------|---------------------|----|-----------------------------------|--------------|---------------------------------------|----|-----------------------------------|--------------|
| | S | A | Pay line | Success Rate | S | A | Pay line | Success Rate |
| February-June 2015 | 74 | 7 | RFA: 23 PA: 23 rd % | 9.5% | 84 | 6 | RFA: 23 PA: 18 th % | 7.1% |
| 2014 | 119 | 13 | 25 | 10.9% | 161 | 21 | 23 | 13.0% |
| 2013 | 136 | 7 | 27 | 5.1% | 147 | 4 | 20 | 2.7% |

Note: S = Submitted A = Awarded

NIMHD Funded Science Advances

Over the last year, several prominent papers were published based on studies from the NIMHD grant portfolio.

New, Early Stage Targets to Reduce Childhood Obesity

Taveras EM, Gillman MW, et al., Reducing racial/ethnic disparities in childhood obesity: The role of early life risk factors. *JAMA Pediatrics*. 2013 Aug 1; 167(8):731-8.

Tailored Online Messaging Shows Promise for Weight Loss

Manuvinakurike R, Velicer WF, et al. Automated indexing of Internet stories for health behavior change: weight loss attitude pilot study. *J Med Internet Res* (2014): 16(12), e285.

Culturally Based Eldercare Services Show Benefit

Angel JL, Rote SM, et al. Nativity status and sources of care assistance among elderly Mexican-origin adults. *J Cross Cult Gerontology* (2014):29(3), 243-58.

Vitamin D Deficiency Links to Prostate Cancer Risk

Murphy AB, Nyame Y, et al. Vitamin D deficiency predicts prostate biopsy outcomes. *Clin Cancer Res*. 2014 May 1; 20 (9):2289-99.

Role of Genes in Asthma Risk and Lung Function

Pino-Yanes M, Thakur N, et al. Genetic ancestry influences asthma susceptibility and lung function among Latinos. *J Allergy Clin Immunol*. 2015 Jan; 135(1):228-35.

NIMHD Staff Updates

Departing NIMHD

Deborah Henken, Ph.D., has returned to NICHD full-time in her role as a Health Science Administrator. She served NIMHD on detail as the Acting Director of the Office of Extramural Research Administration.

Cherie Duvall Jones has moved to the FDA's Office of Regulatory Affairs as a health communications specialist.

Gail Taylor, Laboratory Operations Coordinator, retired from federal service on June 30th.

Candace Tingen, Ph.D., has moved to NICHD to serve as program official in the Gynecologic Health and Disease Branch.

New Appointments

Angela Bates joined NIMHD as the NIMHD Advisory Council Coordinator. Angela has been on detail with NIMHD since August 2014. Prior to joining NIMHD, she was a program analyst in the NIH Office of Research on Women's Health.

Thomas Vollberg, Ph.D., has joined NIMHD as the chief of the Scientific Review Branch. Prior to joining NIMHD, he served as chief, Research Technology and Contract Review Branch, Division of Extramural Activities, NCI.

Dr. Richard Palmer, AAAS Fellow, has join NIMHD this fall to support Dr. Dankwa-Mullan with the NIMHD Science Visioning process.

Staff Accomplishments

Dr. Rick Berzon was selected to join a HHS-CDC 3 month detail in support of Ebola Field Emergency Response Deployment. He served as the Associate Director for Science and CDC-USAID DART (Disaster Assistance Response Team), Liaison for West Guinea.

Council Discussion

Advisory Committee members thanked the NIMHD staff for keeping them informed and engaged through the change in NIMHD leadership. Members inquired about the role of Council in the Science Visioning Process. Dr. Pérez-Stable affirmed their participation in the process. Currently, he is working with Dr. Dankwa-Mullan and several staff members to establish a working group of the NACMHD. The topic of diversifying the scientific workforce and how NIMHD can contribute to NIH Strategic planning process was discussed. NIMHD can contribute by emphasizing the training of a diverse group of researchers. Council members also inquired about NIMHD funding; whether the IC has sufficient funds to conduct research in a diverse population as well as the recruitment and retention of participants.

STATEMENT OF UNDERSTANDING – Dr. Priscilla Grant

Chief Grants Management Officer, Ms. Priscilla Grant summarized the Council operating procedures contained in the Statement of Understanding (SOU) between the NIMHD and the Advisory Council. A copy of the SOU was included in the Council member folders.

BRAIN Initiative – Dr. Gregory Farber, Director, OTDC, NIMH

Dr. Gregory Farber provided a history and overview of the BRAIN program initiated by President Obama. He stated that it is critical to address brain disorders because they account for the highest burden of disease in the US, and the social and financial costs are growing. We currently do not know enough about how the brain works to address this challenge. Innovation in this area has been driven by new tools (neural mapping, brain imaging, optogenetics, and the human connectome) rather than new concepts. Two years ago, President Obama gathered experts to develop the BRAIN Initiative to understand the brain in action—how we think, learn, and remember—and to address brain disease.

The BRAIN Initiative is a private and public effort, involving NIH, DARPA, NSF, FDA, as well as private foundations such as HHMI, Kavli Foundation, Simons Foundations, and Allen Institute. There are also a number of academic institutions that have devoted resources to contribute to the BRAIN initiative. The 2015 BRAIN Working Group Final Report was the culmination of public meetings around the country and synthesis of information from a variety of sources. There are 7 primary priority areas identified in the report: (1) Discovering diversity of cells in the brain, (2) Maps at multiple scales from synapses to the whole brain, (3) The brain in action (dynamic picture of functioning brain), (4) Demonstrating causality (linking brain activity to behavior), (5) Identifying fundamental principles of biological bases of mental processes, (6) Advancing human neuroscience (understanding the human brain to treat its disorders), and (7) integrating everything and putting it all together.

In FY2014, 58 awards were made across 6 RFAs focused on cell classification, novel tools, human imagining, and understanding circuit function. They are large awards that involve collaborations between neuroscientists and many other types of scientists, including engineers, computer scientists, statisticians, etc. They are already published in several high impact journals. There is also a new R03 PA that was just released on technology transfer, where the labs that developed these technologies work with universities. There are also international partnerships with Canada and Australia to allow for cross funding of initiatives, and work is also planned with Japan and China.

Questions from Council members included what steps were being taken to ensure awards go to minority investigators and how these tools can address health disparities. Dr. Farber indicated that so far there had been very few applications from minorities or women, and asked the Council for recommendations to address this problem. The IC's will decide how to best use these tools going forward to address health disparities, since future initiatives will be funded by the ICs, not BRAIN. Council members suggested using diversity supplements to increase the diversity of investigators in this area, to present the initiative at professional society meetings to inform young investigators, to facilitate collaborations between small businesses and universities, and to reach out to HBCUs with engineering programs. Dr. Farber indicated that this was the purpose of the R03 initiative to help institutions build collaborations and acquire the necessary equipment. It was also emphasized that institutions needed capacity building so there would be an infrastructure in which to conduct this research.

Catalyzing Translational Innovation – Dr. Christopher Austin, Director, NCATS

Dr. Christopher Austin, Director of NCATS, presented an overview of NCATS. The Center was established to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. Key to this work is operationally defining translation as the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral change. The center focuses on understanding the underlying general scientific translational principles, such as predictive toxicology, predictive efficacy and de-risking of un-druggable targets. Additionally, other areas of focus include organizational principles, including how to give credit for health improvements, data transparency and release, IP (intellectual property) management, and the integration of project management. One issue that was highlighted is the development of organizational principles, for example, academic valuation of credit for developing health improvement that may influence the way scientific contributions are valued in both NIH review and academic advancement settings. Scientific initiatives support clinical, pre-clinical, and re-engineering translational science. Basic science is out of scope for NCATS support.

Dr. Austin highlighted some of the programs supported by the CTSA (Clinical and Translational Science Awards) program that established approximately 60 sites across the U.S. by NIH Director Zerhouni. These sites create an academic home for translational research to build internal local capacity to support research. NCATS is working to develop a national network that will address some of the national scientific and organizational problems. Among the focal activities with respect to developing a national network is a series of administrative supplements called Trial Innovation Centers (TICs), to provide central IRB review, common contracting, and consolidation of GCP training to address issues of duplicative IRBs, subcontracting, and site qualification. To address issues around participant recruitment into NIH-funded clinical trials, half of which fail to meet their recruitment goals, NCATS is building a national recruitment capacity across the CTSA network using electronic health record data, referred to as Recruitment Innovation Centers (RICs).

Dr. Austin discussed several CTSA-RCMI-CoE partnerships targeting the scientific and organizational principles spotlighting the collaborations on projects funded by NCATS and/or NIMHD and these are potential future IC partnerships. He described a highly innovative approach to addressing issues of efficacy or safety of drugs prior to the first human studies. This is accomplished by creating 3-dimensional human organoids in microfluidic platforms that would represent critical structural and functional elements of all human organs that are affected by xenobiotic toxicity. He gave an example of a kidney chip that had been developed to address processes around kidney failure that disproportionately affects African American men and women.

NIH-Wide Strategic Plan- Dr. Lawrence Tabak, Principal Deputy Director, NIH

Dr. Tabak gave a presentation on the NIH-wide Strategic Plan including detailed information regarding the relevant public law, the content and the timetable for completing and submitting the Strategic Plan, and a status report on the progress made so far. CR Omnibus H.R. 83 - 346 (enacted December 16, 2014) states that NIH will submit a five-year strategic plan to Congress no later than one year after enactment. The Strategic Plan will be completed by December 16, 2015 and this plan will be the strategic document over the next 5yrs. Dr. Tabak is visiting each council through October. To date, nearly a thousand people/organizations have provided feedback on the plan.

Issues that will be addressed in the plan and congressional priorities are 1) rare and pediatric diseases; and 2) maintaining the biomedical workforce. The Strategic Plan is a living document to articulate the approaches and opportunities that are forward-looking and inspirational, and identify major trans-NIH efforts to advance biomedical science. The Strategic Plan does not describe what NIH does or will do in the future nor address priorities of individual ICs. The NIH Strategic Plan is meant to complement but not replace an IC's strategic plan.

The Advisory Committee to the Director (ACD) has provided input on the draft of the overall plan and framework. The ACD advocated for additional emphasis on the interconnectivity of science, the importance of data sciences and workforce retention, and cutting edge clinical methodologies. Areas of opportunity to apply across the biomedicine fundamental science space include:

1. Health promotion/disease prevention
2. Early diagnoses and detection
3. Evidence-based reduction/elimination of health disparities – a responsibility for all NIH ICO's
4. Treatment/Cures
5. Unifying principles (setting priorities, enhancing stewardship, recruiting and retaining an outstanding research workforce, diversifying the workforce, encouraging innovation, optimizing approaches to inform funding decisions, and supporting partnerships within and across the government, private and public.
6. Alignment with the HHS Strategic Plan

Big Data to Knowledge (BD2K) Initiative - Xinzhi Zhang, MD

Dr. Zhang provided an overview on the Big Data to Knowledge (BD2K) Initiative, which covered the initiative's mission, goals, budget, review process, management, and award process. Dr. Zhang emphasized the importance to enhance diversity in the biomedical data science workforce. NIMHD has a supportive role and issued an R25 (RFA-MD-15-005) Enhancing Diversity RFA. "Big data" is not only having a lot of data, but the capacity to utilize it. Changes in technology, more cost effective storage, and increasingly powerful analysis capacities have generated enormous amounts over the last 10 years. In the private sector, it is contributing to increased competitiveness and targeted advertisements. In the public sector, it is providing evidence based decision making and offering opportunities in the healthcare sectors to reduce cost and better inform prevention efforts in minority and health disparity populations. The BD2K Initiative, proposed by President Obama in 2012, also relates to 1) the Precision Medicine Initiative by facilitating predictive models, 2) the National Strategic Computing Initiative which invests in high-performance computing to accommodate the use of big data for smaller institutions, and 3) data systems.

CLOSED SESSION

A portion of the meeting is closed to the public in accordance with provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended, U.S.C. Appendix 2.

