

**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)**

Building 31, Sixth Floor Conference Room 6  
Bethesda, MD

**September 9, 2014**  
8:30 a.m. – 4:30 p.m.

**Meeting Minutes**

**Council Members Present**

Yvonne T. Maddox, Ph.D., Chair, Acting Director, NIMHD  
Linda T. Adams, Ph.D., R.N., FAAN  
Eddie Greene, M.D.  
Lisa A. Newman, M.D., MPH, FACS, FASCO

***Ad Hoc* Members**

Margarita Alegria, MA, Ph.D.  
Judith Bradford, Ph.D.  
Linda Burhansstipanov, MSPH, DrPH  
Sandro Galea, M.D., MPH, DrPH  
Linda S. Greene, BA, JD  
Hilton H. Hudson, M.D., FACS, FCCP  
Jose A. Luchsinger, M.D., MPH  
Brian Rivers, Ph.D., MPH  
Michelle A. Williams, Sc.D.

***Ex Officio* Members**

Michael J. Fine, M.D., MSc  
Gary Martin, D.D.S.  
William Riley, Ph.D.

**Executive Secretary**

Donna A. Brooks

**Also Present**

Ayodola Anise, MHS  
Phil Bourne, Ph.D.  
Jonca Bull, M.D.  
Joyce A. Hunter, Ph.D.  
Nathan Stinson, M.D., Ph.D.  
Hannah Valantine, M.D.

## **CALL TO ORDER AND INTRODUCTORY REMARKS**

Yvonne T. Maddox, Ph.D., Acting Director of the National Institute on Minority Health and Health Disparities (NIMHD) called to order the Open Session of the 37th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) at 8:30 a.m. Dr. Maddox welcomed all Council members and other participants to the meeting. Council members, NIMHD senior staff, and visitors introduced themselves.

### Meeting Minutes – June 9, 2014

The Council unanimously approved the minutes of the June 10, 2014, meeting.

### Future Meeting Dates

The next NACMHD meeting is scheduled for February 24, 2015. Subsequent meeting dates are: June 9, 2015; September 15, 2015; February 23, 2016; June 7, 2016; and September 13, 2016.

## **NIMHD DIRECTOR'S REPORT**

### **In Memoriam: William T. Coleman, Jr., Ph.D.**

Dr. Maddox announced that Bill Coleman, Ph.D., NIMHD Scientific Director, passed away on August 18, 2014 after a heroic battle with cancer. Dr. Coleman, who began his NIH career in 1974, was the first African American scientific director at NIH. Dr. Coleman leaves a legacy as a well-respected scientist and teacher, through his research on *Helicobacter*, ulcers, and gastric cancer. His colleagues and those he mentored in NIMHD and throughout NIH, remember him as a dedicated researcher and mentor with an irrepressible sense of humor and optimism. A moment of silence was held in honor of Dr. Coleman.

### **NIH Updates:**

- NIH to Launch Human Safety Study of Ebola Vaccine Candidate  
With the entry of four people for treatment of the Ebola virus, the NIH is prepared for the possibility of admitting an Ebola patient to the NIH Clinical Center (CC). NIH has begun initial testing of an investigational vaccine to prevent Ebola virus disease. The early-stage trial of the vaccine, co-developed by NIAID and GlaxoSmithKline (GSK), will evaluate the safety and ability to generate an immune system response in health adults. If the trial is successful, GlaxoSmithKline will provide 10,000 doses to NIH.
- Enhancing Biosafety and Biosecurity in the United States  
September is National Biosafety Stewardship Month. This past summer, old samples of smallpox and other agents, including ricin and botulism, were discovered in NIH laboratories. All agents were found in sealed containers and were transferred to the Centers for Disease Control and Prevention (CDC). On August 27<sup>th</sup>, NIH released a notice<sup>1</sup> to all institutions, colleges, and universities regarding good stewardship as it relates to biosafety. Amy Patterson, M.D., has been appointed as the first NIH Associate Director for Biosecurity and Biosafety Policy.
- NIH Announces Genomic Data Sharing  
Recently, Dr. Maddox spoke at the Health Disparities and Genomic Medicine Conference in Washington, D.C. On August 28, 2014 NIH announced a new policy<sup>2</sup> for genomic data sharing. The policy will promote sharing of human and non-human genomic data and provides appropriate protections for research involving human data. NIH wants to ensure that genomics data is shared in

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<sup>1</sup> <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-127.html>

<sup>2</sup> [http://grants.nih.gov/grants/guide/notice-files/NOT-OD\[14-124\].HTML](http://grants.nih.gov/grants/guide/notice-files/NOT-OD[14-124].HTML)

a way that protects the data and all trial subjects. Supplemental information to the policy is available at [http://gds.nih.gov/pdf/supplemental info GDS Policy.pdf](http://gds.nih.gov/pdf/supplemental_info_GDS_Policy.pdf).

- **Intramural Research Program (IRP) Review**

At the June meeting of the Advisory Committee to the Director, Dr. Francis Collins charged one of the working groups to review the IRP and recommend how the IRP should ensure its distinctive role in biomedical research and how it should differ from extramural research institutions. The report titled, *The Future of the Intramural Research Program, Synthesis of Issues, Challenges, and Opportunities*, includes the goals and expectations for each intramural research program over the next decade.

- **Establishment of the LGBT-RCC**

The NIH has established a trans-NIH Lesbian, Gay, Bisexual, Transsexual, and Intersex Research Coordinating Committee (LGBT-RCC) to address findings from an IOM report on the health of the LGBTI community. One of the goals of the NIH LGBTI-RCC is to develop a NIH wide strategic plan. In addition to responding to areas of concern from the report, the LGBTI-RCC is developing a health research strategic plan. NIMHD has created a community-based participatory research program that focuses on the needs of the LGBTI community and the HIV/AIDS community.

**Council and NIMHD Staff Updates:**

- NACMHD member Valerie Montgomery-Rice, M.D. will be officially installed as the first woman to serve as President of Morehouse School of Medicine on September 11, 2014.

- **New NIMHD staff:**

Dr. Rina Das joined NIMHD in July 2014 as a new program officer for the Common Fund Diversity Program. Prior to joining NIMHD, Dr. Das was the Acting Chief of the Disparities Research Branch in the NCI Center to Reduce Cancer Health Disparities.

Mr. Sy Shackelford joined NIMHD in July 2014 as a grants management specialist in the Grants Management Branch, OERA. Prior to joining NIMHD, Mr. Shackelford was a senior grants management specialist with NCI.

Dr. Fatima Karzai joined NIMHD in July 2014 as a Clinical Fellow working in the Division of Intramural Research. Prior to joining NIMHD, Dr. Karzai was a Clinical Fellow at NCI.

Dr. Sherine El-Toukhy joined the Division of Intramural Research in August 2014 as a postdoctoral visiting fellow. Prior to joining NIMHD, Dr. El-Toukhy was a postdoctoral research associate at the University of North Carolina at Chapel Hill, Gillings School of Global Public Health.

Ms. Angela Bates joined NIMHD, on detail from Office of Research on Women's Health in August 2014 as a Special Assistant to the Director. Ms. Bates duties include Advisory Council Coordination.

Dr. Anna Bellatorre joined the Division of Intramural Research in September 2014 as a postdoctoral fellow. Prior to joining NIMHD, Dr. Bellatorre completed her Ph.D. in sociology from the University of Nebraska-Lincoln in sociology.

Ms. Kina Hendrick joined NIMHD in September 2014 as a senior ethics specialist. Prior to joining NIMHD, Ms. Hendrick was an ethics specialist with NCI for eight years.

Ms. Karen M. Hendricks, J.D. will be a consultant working in legislation assisting with the establishment of the Friends of NIMHD.

Dr. Kevin Gardner is serving as acting deputy scientific director, NIMHD. Dr. Gardner is a tenured senior investigator in the Genetics Branch, NCI and head, Transcription Regulation Section. Dr. Gardner also holds the position of senior investigator in the NIMHD IRP. Dr. Gardner received his B.S. from Yale University and earned his M.D. and Ph.D. from the Johns Hopkins University School of Medicine. He was a recipient of NIH Director's awards in 2007 and 2011. A major research focus in Dr. Gardner's laboratory is the role of epigenetic modifications in the control of gene expression and cellular phenotypic change.

#### **NIMHD Updates:**

- Notice of NIMHD Participation in PA-13-302 "Research Project Grant (Parent R01)"  
On July 10, 2014, NIMHD released a program announcement to inform potential applicants that the NIMHD is participating, effective immediately, in the Research Program Grant (Parent RO1) investigator-initiated program. Dr. Michael Sayre is the primary NIMHD contact for these applications.
- Operational Planning Meeting - July 2014  
NIMHD held a staff retreat to present and discuss the current NIMHD portfolio, to pave the way to further define the science of health disparities, and to inform future fiscal decisions. Dr. Collins, who participated in the retreat, expressed his support for the Institute and its work. More than 40 potential initiatives for fiscal years (FY) 2015 and 2016 were discussed by the staff. In addition to three concepts that the Council will review, an initiative for research on health disparities and pain will be released as a program announcement in collaboration with two other Institutions. Other areas of focus are systems level service and policy research on health disparities; health disparities across the lifespan among various populations; and closing the gap in HIV/AIDS-related disparities.

#### **NIMHD Staff Presentations and Outreach:**

- Dr. Maddox participated in the Healthy, High Achieving School Program with GENYouth and the National Dairy Council. This program looked at healthy living as it relates to physical activity and good nutrition in youngsters, including health disparities in schools and school breakfasts, as well as the impact of breakfast on students' learning capacity and cognitive development. Dr. Maddox presented at the Conference to Eliminate Health Disparities in Genomic Medicine on September 4<sup>th</sup> and held in Washington, DC.
- Nathan Stinson, M.D., Ph.D., spoke to the United Health Foundation at the Diverse Scholars Forum on July 24, 2014 in Washington, DC.
- Joyce Hunter, Ph.D., spoke at the National Dental Association's 101st Annual Convention on strategic directions for health disparities research at NIH and NIMHD at the National Dental Association's 101<sup>st</sup> Annual Convention on July 25, 2014 in New Orleans, LA.
- Derrick Tabor, Ph.D., gave a presentation on research as it relates to the minority scientist and developing short-term education programs for undergraduates. The research symposium was sponsored by NIDDK and held August 4<sup>th</sup> in the Natcher Conference Center.
- The annual NIMHD Translational Health Disparities Course was held August 11-22 under the leadership of course director Irene Dankwa-Mullan, M.D., MPH. Of 304 applicants, 94 scholars were accepted for the course, which was taught by 40 health disparities faculty members from across the country. Topics included social determinants of health, ethics of human research subject protection, research integrity, and health disparities and public policy, among others. Video interviews with

course participants will be posted on the NIMHD website. NIMHD is exploring ways to translate this course to universities and colleges across the country.

#### **NIMHD-Relevant Legislation:**

- HR 4631: On August 8, 2014, President Obama signed the Autism CARES Act (P.L. 113-157), which requires the Secretary of Health and Human Services (HHS) to designate an official to oversee national autism spectrum disorder research, services, and support activities and directs the official to implement such activities according to the strategic plan developed by the International Autism Coordinating Committee (IACC) to ensure cross-agency duplication is minimized.
- HR 3548: On August 8, 2014, The President also signed the Improving Trauma Care Act of 2014 (P.L. 113-152), which amends the Public Health Service Act, with respect to trauma care and research programs, to include the definition of “trauma” as an injury resulting from extrinsic agents other than mechanical force, including those that are thermal, electrical, chemical, or radioactive.
- HR 5294: On July 30, 2014, Representative Lucille Roybal-Allard (D-CA) introduced the Health Equity and Accountability Act of 2014, which has been referred to the Subcommittee on Health. The bill has 70 co-sponsors and contains ten titles, many of which include provisions for NIH. The titles include: Data Collection and Reporting; Culturally and Linguistically Appropriate Health Care; Health Workforce Diversity; Improvement of Health Care Services; Improving Health Outcomes for Women, Children, and Families; Mental Health; Addressing High Impact Minority Diseases (including cancer, viral hepatitis and liver cancer control and prevention, acquired bone marrow failure disease, cardiovascular disease, and chronic disease, HIV/AIDS, diabetes, lung disease, osteoarthritis and musculoskeletal diseases, and sleep and circadian rhythm disorders); Health Information Technology; Accountability and Evaluation; and Addressing Social Determinants and Improving Environmental Justice.

#### **NIMHD Program Funding:**

- The NIMHD budget for FY2014 is \$268 million, of which 85 percent is expended on extramural research. Since June, \$53,000 was transferred to HHS for department-wide cybersecurity needs, and \$800,000 was transferred for the Indian Health Service Tribal Epidemiology Center Program. NIMHD received \$881,858 in unspent funds from the National Children’s Study, which is on hold pending protocol revisions.
- Since June, NIMHD has spent approximately \$4 million on 10 awards for basic and applied biomedical research; \$7.6 million on R01 awards for social and behavioral health research; and \$200,000 on conference and scientific meetings support. One award was supported with funds provided by the NIH Office of Behavioral and Social Sciences Research (OBSSR). Six Small Business Innovation Research (SBIR) awards were made for a total of \$1.1 million. Finally, \$15 million was used to fund five centers through the limited competition for centers in minority institutions for clinical and translational research.

#### **Upcoming NIMHD Activities:**

- NIMHD Seminar Series: The Health Disparities Seminar Series will host seminars on September 18 and November 20.
- NIMHD/NIH American Indian and Alaska Native Research Forum: On October 3, 2014, NIMHD and NIH will host its first research forum to showcase NIH-funded American Indian/Alaska Native researchers and their contributions to biomedical research. A goal of the forum is to expand the pool of scientists, researchers and health professionals with the American Indian and Alaska Native community.

- The Common Fund Diversity Program kickoff is scheduled for October 27, 2014 and will be held on the NIH campus in the Natcher Conference Center. The purpose of the event is to bring together the principal investigators of the Building Infrastructure Leading to Diversity (BUILD) sites, the National Research Mentoring Network (NRMN), and the Coordination and Evaluation Center (CEC), NIH Program and Grants Management staff and NIH Common Fund leadership for discussions on procedures, plans and processes for establishing the diversity consortium.
- 2014 Minority Health & Health Disparities Grantee's Conference: NIMHD will hold a grantee workshop at National Harbor to showcase excellence and innovation in basic, translational and clinical research from the programs supported by NIMHD, focus on early career investigators through training and professional development workshops, mentoring, and meet the experts sessions, and offer opportunities for sharing research information related to minority health and health disparities in various diseases and conditions.

### **The Science of Health Disparities Research**

Currently, NIH provides \$2.8 billion to support 1,877 projects related to health disparities. Some projects might be relevant to health disparities and/or involve minority health populations, but they are not health disparities research. A challenge in understanding the NIH health disparities portfolio is that the field is not well defined. Multiple groups, including NIH, have composed definitions of health disparities, health inequities, and minority health and health disparities populations. NIMHD needs to be a leader in the field of health disparities for NIH and the community at large. Research is needed to identify differences among populations and to understand the reasons for those differences, including behaviors that mitigate risk, biologic differences, knowledge, education, and socioeconomic factors, housing availability, and other issues, in order to develop effective interventions. NIMHD considered what it could do in the field of health disparities that other NIH Institutes are not likely to address and identified 57 health determinants, including behavioral risks. The Institute is developing a framework for identifying differences among populations, understanding how and when those differences lead to health disparities, and designing interventions to reduce health disparities. NIMHD has received \$250,000 to establish a science of health disparities research initiative. A taskforce is being assembled with the input of NIH leadership to plan the initiative.

#### *Discussion:*

- Presentations on infant mortality should include data from American Indian, Alaska Native, Native Hawaiian, Pacific Islander, and Asian communities, which experience infant mortality rates three to four times as high as the general population.
- NIMHD can take a leadership role for research on population determinants of health rather than biological determinants, as well as on issues of institutional, community and systems support.
- Efforts to make the Translational Health Disparities Course more accessible and available, possibly through a Web-based approach, were encouraged.
- Defining the LGBTI community as a "population" has been a step forward for this diverse group.
- The science of health disparities research initiative should include a focused approach to measure the outcomes and effects of interventions that are developed to reduce health disparities.

### **PRESENTATION: NIH DIVERSITY ACTIVITIES AND UPDATES – Dr. Hannah Valantine**

Hannah Valantine, M.D., NIH Chief Officer for Scientific Workforce Diversity updated the Council on recent NIH activities related to diversity. Scientific workforce diversity fuels innovation and creativity in research and is key to narrowing the health gap among various populations and ensuring fairness in all NIH activities and policies. By 2050, groups that have traditionally been named as minority or

underrepresented will constitute the majority. It is critical the intellectual capital of these groups be included in the scientific enterprise.

Several areas that would be harmed by not diversifying the workforce, including: scientific innovation, global competitiveness, quality of training and quality of researchers, prioritization of research, the recruitment and retention of clinical study subjects, and public trust. The lack of diversity can be attributed to two issues: underrepresentation of some groups in the career pipeline and attrition as the career path progresses from student to independent investigator to leadership. Analyses of the NIH scientific workforce have revealed gaps in research funding among Ph.D. and M.D. researchers by race. Another study found that the major determinants of receiving an R01 grant are related to having appropriate networks, getting mentoring, and coauthoring papers, rather than training.

At Stanford University, Dr. Valantine focused on diversifying the applicant pool for new recruits, as well as retention and advancement of faculty. Over 8 years, the number of faculty from underrepresented groups increased from 34 to nearly 100, while the overall faculty increased by 40 percent. The proportion of female faculty members increased from 25 to 36 percent. While the increase was important, analysis suggested that it would take 28 years for Stanford to reach 50 percent representation of women on the faculty, and even longer for peer institutions or the national cohort to reach that marker. These data underscore the need to address institutional culture, including implicit bias, stereotype threats (fear of succumbing to a negative stereotype that affects one's identity, creating anxiety that undermines performance), faculty career flexibility, and intensive mentoring/sponsorship.

The ACD issued 13 recommendations related to pipeline, mentoring, peer review, and infrastructure, which have led to several initiatives. The Building Infrastructure Program will focus on the transition from undergraduate to graduate training and provides infrastructure for less research-intensive institutions to partner with more research-intensive institutions. The National Research Mentoring Network will provide the type of mentoring that is essential for persistence, progression, and success as a scientist. The Center for Coordination and Evaluation will coordinate these efforts. Grant applications have been reviewed for these initiatives, and a funding plan is in place. Other activities include an effort to ensure fairness in peer review and a review of 84 extramural programs focused on diversity and the transition from undergraduate to graduate degrees. Dr. Valantine is also looking at the demographics of the NIH IRP, which comprises 36% women, 1.3% African Americans, 4% Hispanics, and 0.4% Native Americans on the tenure track. The NIH IRP can be used to test interventions for diversifying the workforce that may be translatable to other institutions. In the extramural program, NIH is incorporating diversity into funding announcements and developing evaluation metrics for diversity plans.

Dr. Valantine's vision is to develop a bold, national, comprehensive plan for innovation in scientific workforce diversity to enable sustainable transformation that creates seamless transitions across the medical/research career path. The overarching goal of eliminating transition barriers will be achieved with strong networks and infrastructure that rely on an evidence-based approach, implementation and scaling science, tracking and evaluation, and strategic partnerships. The interdisciplinary plan will focus on scientific careers, translation, and moving diversity innovation findings into interventions.

**PRESENTATION: FOOD AND DRUG ADMINISTRATION (FDA) ACTION PLAN TO ENHANCE THE COLLECTION AND AVAILABILITY OF DEMOGRAPHIC SUBGROUP DATA – Dr. Jonca Bull**

Jonca Bull, M.D., Director of the FDA Office of Minority Health spoke about the 2012 FDA Safety and Innovation Act. The Act required FDA to develop a report on the extent to which clinical trial participation and safety and effectiveness data by demographic subgroups (sex, age, race/ethnicity) are

included in applications submitted to FDA. The Act also required development of an action plan to enhance the collection and availability of demographic subgroup data.

For the report<sup>3</sup> on the inclusion of demographic subgroups, FDA looked at a 1-year cohort of approved applications (72 in 2011). The report found that most applications described the demographic profiles of trial participants and included some degree of subset analysis. However, inclusion of participants from different subgroups in clinical trials did not mean that sufficient data were collected to analyze by subgroup. This information is shared through consumer updates, product labeling, and publicly posted reviews. In a public comment period, multiple stakeholders expressed concerns: the proportions of women, minorities, and elderly patients in industry-sponsored trials are not consistent with the prevalence of diseases in those populations; health care providers and patients do not have sufficient demographic data to make well-informed diagnostic and treatment decisions; the use of foreign data can be problematic for achieving racial/ethnic participation with relevance to U.S. subgroups; and a lack of awareness and limited physical access to clinical trials may impede inclusion of some subgroups.

The FDA action plan<sup>4</sup> identified three priorities: improve the completeness and quality of demographic subgroup data collection, reporting, and analysis; identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation; and make demographic subgroup data more available and transparent. The report articulated 27 discrete actions. For example, FDA will assess how well the agency executes against its regulations and guidance documents. Staff training will be revised to include the importance of demographic subgroup inclusion, analysis, and communication. FDA will work with sponsors to revise medical product applications in ways that enhance information on demographic subgroups. FDA will enhance its systems for data standardization and electronic submissions to include categories for age and race/ethnicity. MedWatch will be updated to include data fields for race/ethnicity. FDA will expand its research on demographic subgroups as they relate to specific regulatory research questions. In coordination with the Institute of Medicine, FDA will examine contemporary barriers to participation of minorities and other subgroups in clinical trials. FDA will partner with NIH and others to exchange best practices related to inclusion policies, practices, and challenges. FDA will explore ways to better communicate information to the public in plain language and implement communication strategies with an emphasis on language access and health literacy.

Dr. Bull emphasized that the action plan is forward-looking in terms of responding to scientific advances. Collecting and analyzing data from demographic subgroups are keys for realizing the promise of personalized medicine—getting the right drug to the right patient at the right time.

**PRESENTATION: PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI) – Ms. Ayodola Anise**

Ayodola Anise, MHS, Program Officer for the Addressing Disparities Program, provided background on PCORI, describing the national priorities and focusing specifically on PCORI's focus on addressing health disparities. PCORI was authorized by the 2010 Patient Protection and Affordable Care Act. The mission is to help people make informed health care decisions and improve health care delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research that is guided by patients, caregivers and the broader health care community.

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<sup>3</sup><http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/UCM365544.pdf>

<sup>4</sup><http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/UCM410474.pdf>



PCORI strategic goals are: to increase the quantity, quality, and timeliness of research information; to speed implementation and use of evidence; and to influence the research that is funded by others. To accomplish these goals PCORI does the following:

- Engages patients and stakeholders in all aspects of its work (e.g., topic selection, research prioritization, and the merit review process)
- Emphasizes a focus on patient-centered comparative clinical effectiveness research, where research questions and outcomes of projects are driving by patients, caregivers, and other stakeholders
- Provides minimal methodology standards developed by the PCORI Methodology Committee to guide the conduct of patient-centered outcomes research.

National priority areas and corresponding program areas that fund research are: Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; Addressing Disparities; and Accelerating Patient-Centered Outcomes Research (PCOR) and Methodological Research. Through these program areas, PCORI funds investigator-initiated studies, targeted studies where PCORI determines the study components (e.g., study design, patient population, outcomes), and pragmatic clinical studies in real-world settings. Since 2012, PCORI has supported 280 research projects at \$464 million.

The mission of the Addressing Disparities program at PCORI is to reduce disparities in health care outcomes and advance equity in health and health care. The program funds research to identify best options for reducing and eliminating disparities, rather than simply to identify disparities. Since 2012, the program has supported 45 projects at \$88 million, including targeted research on treatment options for uncontrolled asthma in African Americans and Hispanics/Latinos. Upcoming initiatives include a targeted funding announcement for obesity treatment options in primary care settings in minority populations. Other topics in development include hypertension disparities, disparities in perinatal care, and reducing lower extremity amputations in minority populations. The Addressing Disparities program focuses on racial/ethnic minorities, low income groups, rural populations, populations with low health literacy and limited English proficiency, individuals with special health care needs, including disabilities, and the LGBTI population. Of the studies funded by the program, research areas include chronic conditions (37% of the portfolio), mental health (21%), oncology (6%), infectious diseases (6%), and other topics (e.g., sexual health, substance abuse, health care delivery systems, trauma, neurologic disorders, smoking cessation).

To help access impact, the program uses a framework and driver model to guide its efforts and to help access efforts to reach the goal of reducing/eliminating disparities in health care outcomes. In addition, "PCORI Evidence to Action Networks" (E2ANs) have been created to facilitate dissemination. The goals of the E2ANs are to engage awardees and facilitate learning across PCORI-funded projects and to link awardees with end-users to increase the likelihood of uptake of findings. These E2ANs will be organized around health topics or conditions, interventions, and methodologies. The first one, the Asthma Evidence to Action Network, will comprise all of PCORI's asthma related projects.

#### **PRESENTATION: HEALTH DISPARITIES AND MINORITY HEALTH RESEARCH IN NORTHERN MANHATTAN – Dr. Jose Luchsinger**

Jose A. Luchsinger, M.D., MPH, Director of the Northern Manhattan Center of Excellence on Minority Health and Health Disparities, described the Center's research on health disparities in the Northern

Manhattan community. The Center comprises faculty from the medical, public health, and nursing schools at Columbia University, as well as from New York University and other institutions.

The Northern Manhattan Diabetes Community Health Worker Outreach Project (NOCHOP) was a trial of 360 Hispanic persons with poorly controlled diabetes randomized to community health worker intervention or usual care for 12 months. The treatment arm showed a 0.35% improvement in hemoglobin A1c versus 0.05% improvement in the control arm (non-significant). A difference between this trial and others that have shown statistically significant effects of health care worker interventions was that the NOCHOP workers were not directly supervised by a nurse or physician and were not integrated in a larger health care team. The Diabetes and Memory in Minority Elderly (DIAMEM) study enrolled 613 minority elderly persons with type 2 diabetes to study the longitudinal association of glycemic control with cognitive impairment. Results to date have shown that better diabetes control was related to better cognition, higher adiponectin was related to higher mortality, and neither mild cognitive dysfunction nor depression was related to worse diabetes control. A randomized trial of a behavioral intervention to improve hypertension control evaluated the effect of a senior center-based comprehensive therapeutic intervention versus a control condition on blood pressure reduction at 12 months in 260 minority elderly persons. No difference was found between the arms. Finally, a cohort study of 600 Hispanic persons, age 55-64 years, is examining the relation of pre-diabetes, diabetes, and obesity to mental health outcomes.

Several programs have been supported by supplements to the Center of Excellence. The Lang Youth Program provides after-school, weekend, and summer programs in the health sciences for high school students in Washington Heights. The Northern Manhattan Center of Excellence in Comparative Effectiveness Research to Eliminate Disparities conducts and disseminates comparative effectiveness research. The first project of this center was the Northern Manhattan Caregiver Intervention Project (NOCIP). NOCIP randomized 139 Hispanic caregivers to intervention (NYU caregiver intervention) with a community health worker doing case management versus community health worker alone. Most caregivers were daughters, had low income, and had high levels of depressive symptoms. After 6 months, both arms showed improvements in depressive symptoms with no difference between them. A bioethics initiative found that community members from underrepresented minorities were supportive of research, but the main barrier to participation was a perceived lack of dissemination. Also, research participants preferred initial contact by physicians or principal investigators rather than research staff. The Environmental Protection Agency Center of Excellence examines social determinants of health in conjunction with several Center projects. One finding is that discrimination in health care moderated treatment response in the diabetes trial: a history of experiencing discrimination in healthcare settings was associated with more improvement in A1c in the intervention versus control group. This suggests that someone who distrusts the health care system and had more adverse experiences may benefit more from community health worker intervention.

NOCEMHD also collaborates with projects funded by other institutes. Columbia is a trial site for the Multiethnic Study of Atherosclerosis (MESA), and investigators are studying the socio-demographic correlates of cognition. The Washington Heights and Inwood Community Aging Project is a multiethnic cohort study of people age  $\geq 65$  years looking at aging outcomes. A 2012 report showed that a significant proportion of disparities in cognitive impairment in African Americans and Hispanics in Northern Manhattan may be accounted for by diabetes disparities. Columbia has a number of training, mentoring, and underrepresented minority pipeline programs. Community partnerships and a community advisory board help the Center establish priorities for and conduct comparative effectiveness research.

## **PRESENTATION: NIH BIG DATA INITIATIVES – Dr. Philip Bourne**

Phil Bourne, Ph.D., NIH Associate Director for Data Science, discussed initiatives being developed by NIH related to Big Data. Dr. Bourne sees opportunities to use data and analytics as catalysts to break down boundaries across the 27 NIH Institutes and Centers by forming a collective digital enterprise. In 2012, the NIH Advisory Committee to the Director issued the Data and Informatics Working Group Report, which led to the Big Data to Knowledge Initiative. That report focused on applications and methods for digital data sharing, informatics science, training, and development of a campus-wide information technology strategy, all of which affect the research lifecycle from concept development and data collection to analysis and publication. This effort is aligned with the call for greater data-sharing across all federal agencies issued by the Office of Science and Technology Policy and will also enhance data science at the NIH by deepening the engagement of the private sector (e.g., PhRMA, cloud providers).

Dr. Bourne envisions creating a supportive ecosystem for biomedical research which includes people, technologies, and policies driven by the science that NIH supports. The goals for big data initiatives include sustainability, reproducibility of research, and standard development for common data elements of clinical and research data across NIH and other agencies. The office awarded \$32 million in extramural grants in FY 2014 and expects to award around \$80 million next year to stimulate the ecosystem. NIH proposes to develop a digital common space with two rules: anything put into the Commons (e.g., data, software) must have a unique identifier and it must include certain metadata, such as the name of the creator and versioning. Many institutions could deposit data into the Commons, creating opportunities to identify commonalities, analyze across multiple datasets, and make new connections among researchers.

Plans for training include a proposal to support collaborations between minority institutions and those with more established data science programs. The initiative is also examining ethical, legal, and social issues related to the use of clinical data for research, private sector engagement in the use of clinical data, and the use of electronic health records for outcomes research. Other efforts are ongoing to address clinical data harmonization, data citation and publication, review of data-oriented grants, and international collaboration on funding and use of data sets.

## **PROGRAM CONCEPT REVIEW AND CLEARANCE**

The Council reviewed concepts for new NIMHD initiatives and cleared all for further development:

- **SBIR, technologies for healthy living:** The objective of the initiative is to increase the number of small businesses that the Institute engages in improving minority health and health disparities through technologies that engage, empower, and motivate individuals, communities, and health care providers and institutions. The RFA is expected to improve the quality and relevance of SBIR applications submitted to the Institute. NIMHD will make up to four awards of up to \$150,000 for 1 year. Only phase 1 applications for testing feasibility of a technology would be eligible for funding.
- **Academic Research Enhancement Award (AREA) program:** The NIH has supported the AREA program since 1985, although NIMHD has not participated to date. AREA grants are limited to institutions that receive no more than \$6 million total NIH funding in each of 4 of the last 7 years. NIMHD would support health disparities research in institutions that train a significant number of scientists but are not major recipients of NIH support. This initiative is intended to stimulate interest in the science of health disparities among students from diverse backgrounds, especially undergraduate students, by providing opportunities for hands-on participation in original research. The initiative would leverage NIMHD's investments in infrastructure and capacity-building at AREA-eligible institutions. While some council members suggested that the initiative should encourage partnerships with RIUs,

others believe that such partnerships may result in RIUs drawing most of the money, contrary to AREA program goals. Applications may request up to \$300,000 in direct costs for the life of the project, up to 3 years.

- Behavioral interventions for HIV prevention: This FY 2016 initiative would support multisite trials of behavioral HIV prevention interventions that have broad applicability to young men who have sex with men (MSM), age 13-24 years, from diverse populations. Trials would include representation from all NIH-designated health disparities populations in sufficient numbers that valid subgroup analyses could be performed. A cooperative agreement mechanism would be used to enable active participation of NIH staff in the trial design. NIMHD will seek collaboration with other NIH institutes and centers, as well as the CDC. Prior to release of a funding opportunity announcement, NIMHD will publish a request for information to solicit best practices, as well as research and intervention gaps. Council members suggested allowing trials that include ancillary therapy with promising pharmacologic treatment alone or in combination with behavioral therapy and advised that staff review experiences with previous trials in this area to ensure that new trials are well designed.

### **CLOSED SESSION**

*A portion of the meeting was 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.*

### **REVIEW OF GRANT APPLICATIONS**

Dr. Maddox called the Closed Session to order at 2:28 p.m. Dr. Hunter led the second level review of grant applications submitted to NIMHD programs. The Council considered more than 85 applications requesting an estimated \$93,046,940 in total costs. Applications from five Requests for Applications (RFAs) were considered: Development and Translation of Medical Technologies to Reduce Health Disparities (SBIR); Limited Competition: NIMHD Exploratory Centers of Excellence Pilot Research Projects; and three RFAs in collaboration with the NIH Common Fund: NIH Building Infrastructure Leading to Diversity Initiative, NIH National Research Mentoring Network, and Diversity Coordination and Evaluation Center. For review of applications submitted in response to each initiative, Council members with conflicts of interest left the meeting room and did not participate in the discussion or vote. All funding recommendations for each initiative were made by a vote of eligible Council members. Funding recommendations for all remaining applications submitted in response to program announcements and special program review announcements were made by the Council through *en bloc* voting.

### **CLOSING REMARKS**

After reopening the meeting, Dr. Maddox discussed the possibility of creating a subcommittee of the Advisory Council that will assist NIMHD in developing the agenda for Council meetings and organizing a retreat for portfolio planning. Council members expressed appreciation for the larger conference room space on the main NIH campus that allowed more staff to participate in person. Members also commented on the usefulness of the information provided throughout the day and the professional organization of the meeting. Dr. Maddox thanked Council members for their participation.

**ADJOURNMENT**

Dr. Maddox adjourned the 37th NACMHD meeting at 4:07 p.m.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

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/Yvonne T. Maddox/  
Yvonne T. Maddox, Ph.D.  
Acting Director  
National Institute on Minority Health and Health Disparities, NIH

\_\_\_\_\_  
4/29/15  
Date

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/Donna A. Brooks/  
Donna A. Brooks  
Executive Secretary  
National Institute on Minority Health and Health Disparities, NIH

\_\_\_\_\_  
4/29/15  
Date