

U.S. Department of Health and Human Services (HHS)
National Institutes of Health
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, Maryland

February 24, 2015
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., RN, FAAN
Eddie L. Greene, M.D.
Lisa Newman, M.D., MPH, FACS, FASCO
Michael Rashid, MBA

Ad Hoc Members

Margarita Alegría, BA, MA, Ph.D.
Maria R. Araneta, Ph.D.
Judith B. Bradford, Ph.D.
Linda Burhansstipanov, MPH, Dr.PH, CHES
Sandro Galea, M.D., MPH, DrPH.
Linda S. Greene, B.A., J.D.
Ross Hammond, Ph.D.
Brian Rivers, Ph.D., MPH

Ex Officio Members

Michael Fine, M.D., M.Sc.
William Riley, Ph.D.

Executive Secretary

Donna A. Brooks

Also Present

Joyce A. Hunter, Ph.D.
Nathan Stinson, M.D., Ph.D.
Deborah Henken, Ph.D.

CALL TO ORDER AND INTRODUCTORY REMARKS

The 38th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) was called to order on Tuesday, February 24, 2015 at 8:30AM by Dr. Yvonne T. Maddox, Acting Director of the National Institute on Minority Health and Health Disparities (NIMHD). Dr. Maddox welcomed Council and ad hoc members and attendees. Council introduced themselves along with the invited guests.

Dr. Joyce Hunter, Deputy Director, NIMHD reviewed the confidentiality and conflict of interest information with Council members.

Meeting Minutes – September 9, 2014

The Council unanimously approved the minutes of the September 9, 2014 meeting

Future Meeting Dates

The next NACMHD meeting is scheduled for June 9, 2015. Future meeting dates are listed below:

2015	2016
Thursday, September 10, 2015	Tuesday, February 23, 2016
	Tuesday, June 7, 2016
	Tuesday, September 13, 2016

NIMHD DIRECTOR’S REPORT - Yvonne T. Maddox, Ph.D., Acting Director of the National Institute on Minority Health and Health Disparities (NIMHD)

NIH Updates

National Library of Medicine Director Retires

Dr. Donald Lindberg, who served as the Director of the National Library of Medicine for 37 years will retire at the end of March 2015. Dr. Collins established an Advisory Committee to the Director Working Group (ACDWG) to formulate a new vision of NLM over the next decade. The ACDWG will be co-chaired by Dr. Harlan Krumholz from Yale University and Dr. Eric Green, the Director of NHGRI.

New Name for the National Center for Complementary and Alternative Medicine

The National Center for Complementary and Alternative Medicine (NCCAM) has a new Congressionally-mandated name, The National Center for Complementary and Integrative Health (NCCIH).

President Obama Visits the NIH Campus

In December 2014, President Barak Obama visited the NIH campus to congratulate the scientists for delivering a potential Ebola vaccine. During his visit, the President visited the research scientists who worked in the intramural labs developing the first candidate vaccines when the first Ebola patient was admitted to the NIH Clinical Center. He emphasized the importance of scientific research to help fight global threats such as the Ebola virus.

Use of a Single IRB for Multi-Site Research

NIH solicited comment on a draft policy to promote the use of a single Institutional Review Board (IRB) for domestic sites of NIH-funded multi-site studies. The goal of the single IRB is to enhance and streamline the IRB review process and to reduce inefficiencies so that research can proceed without compromising ethical principles and protections. If the policy goes into effect, protocol review meetings should run more efficiently, and there could be significant financial savings. Currently input from the solicitation is being reviewed.

Precision Medicine Initiative

In the 2015 State of the Union address, President Barak Obama unveiled the Precision Medicine Initiative. The Precision Medicine Initiative is a new enterprise to revolutionize medicine and generate the scientific evidence needed to move the concept of precision medicine into every day clinical practice. Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. Significant advances in precision medicine have focused on select

cancers. Many efforts are underway to help make precision medicine the norm rather than the exception for other diseases.

The BRAIN Initiative

Last September, NIH made its first investment in the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative with the opening of the new Porter Building. 58 awards were made in fiscal year 2015 and \$135 million is requested for fiscal year 2016 – an increase of \$70 million. Current funding will be used to:

- Develop innovative technologies to advance basic neuroscience;
- Generate methods for classifying the brain's diverse cells/circuits;
- Create/optimize technologies for recording and modulating groups of cells that act together in circuits;
- Develop new and non-invasive tools for human brain imaging.

NIH Common Fund: *Enhancing Diversity in the NIH Biomedical Research Workforce*

NIMHD developed a program to enhance diversity in the biomedical research workforce. Supported by the Common Fund and NHLBI, NIMHD developed RFAs for three inter-related initiatives:

- BUILD: learning about effective ways to attract students from diverse backgrounds into the biomedical research workforce and encourage their persistence.
- NRMN: Addresses the critical need for increased access to high quality research mentorship and networking opportunities
- CEC: Work with Consortium to determine hallmarks of success (academic and psychosocial), metrics for measuring goals

There are a total of 12 awards within this program, with many institutions joining in as partners. All awards within the program work as an integrated consortium, with award-specific objectives contributing to the broader goals. In addition, the Diversity Program Consortium will work in partnership with the NIH IC's. The program is expected to be supported for 10 years (pending availability of funds). The estimated yearly support for all three initiatives is approximately \$50 million.

News and Notes from NIMHD

Expanding Communications

In December 2014, NIMHD launched a staff newsletter *The Health Disparities Courier*, to highlight news about operational, administrative, legislative and budget matters and recognize prominent staff accomplishments. The newsletter also features research that focuses on moving health disparities science forward. On February 23rd, NIMHD established a social media presence with a Facebook page and Twitter account.

Council and Staff Update

Dr. Maddox announced several staff changes:

- Dr. Hui Chen has moved to the Center for Scientific Review after 2.5 years as a Scientific Review Officer at NIMHD.
- Dr. Courtney Ferrell Aklin joined NIMHD in January 2015 as the acting chief of staff. She is on a detail from NINDS where she served as a program director in the Office of Special Programs and Diversity.
- Dr. Nancy Breen will join NIMHD as a detailee to assist NIMHD in enhancing measurement of health disparities and guide programs to include economic strategies. Prior to joining NIMHD, she was a grants management specialist at NIAID.
- Dr. Tilda Farhat joined NIMHD as a health scientist administrator working in the Office of Strategic Planning, Legislation, and Scientific Policy. Prior to joining NIMHD, she was a health scientist administrator at NCI.
- Dr. Kevin Gardener is serving as the acting scientific director, NIMHD. Dr. Gardner is also a senior investigator in the NIMHD intramural program. He is a tenured senior investigator in the Genetics Branch, NCI and is the head of the Transcription Regulation Section.
- Dr. Xinli Nan, a scientific review officer in the NIMHD Office of Strategic Planning, Legislation, and Scientific Policy, is assisting the review branch and is on a detail until June.

- Mildred J. Qualls joined NIMHD as a grants management specialist in September 2014. Prior to joining NIMHD, she was as a grants management specialist at NIAID.
- Kenneth Sonnenberg joined NIMHD in November 2014 while he was on detail from NINDS where he served as a budget analyst. As of February 2015, he permanently joined the NIMHD budget office permanently.
- Terry Williams, a contractor with NIMHD, joined the budget office in November 2014. He previously spent nearly three years working in NIMHD's Grants Management Office before transitioning to the budget office.

Inaugural Staff Recognition Ceremony

Dr. Maddox announced the launch of the inaugural staff recognition ceremony that was held on December 8, 2014 in Building 1, Wilson Hall. The ceremony recognized the extraordinary accomplishments and achievements of institute staff in 2014 that supported the NIMHD mission. Merit and service awards (individuals and groups) were presented. Additionally for those staff members who have been in federal service for more than 10 years were presented with length of service awards.

NIMHD Trans-NIH Collaborations

NIMHD has partnered with several NIH Institutes/Centers/Offices as well as other federal agencies: on a variety of projects

- NICHD/OAR – Adolescent Medicine Trials Network, for which NIMHD provides expertise, and the Office of AIDS Research (OAR) provides the funding support. It is the only national, multicenter research network devoted to the health and well-being of HIV-infected and at-risk adolescents and young adults.
- NIAID/OAR – Center for AIDS Research (CFAR), which has a longstanding history of investigating AIDS across populations and supporting treatment research.
- NIDA – Adolescent Brain Cognitive Development (ABCD) Initiative, a meeting agenda item discussed in detail by Dr. Nora Volkow, NIDA Director.
- NHGRI – A partnership with NIMHD that focuses on inclusion of diverse populations in the genomic database clinical trials and in some of the big data programs, such as registries and bio banks.
- OBSSR – A collaboration with the Office of Behavioral and Social Sciences Research (OBSSR) and the New York Academy of Sciences to co-sponsor a workshop in June on training in population health sciences. The workshop will be held at the Institute of Medicine.
- NIMHD/NICHD/NIEHS/EPA - With other institutes and EPA's National Center for Environmental Research, NIMHD will partner to develop innovative approaches to understand environmentally-driven health disparities and improve access to health environments.
- DIR/OD – NIH Medical Research Scholars Program, a year-long residential program on the NIH campus for medical, dental and veterinary students. NIMHD looked at prior classes and discovered a lack of minority participation and in response, launched a full court press to contact medical schools and colleges to publicize the program. With the help of Drs. Stinson and Hunter, the result has been gratifying. Although initiated late for this year, the results should show in the MRSP cohort for next year.

Inclusion of Diverse Populations in Clinical Trials: Dr. Maddox emphasized the importance of including minorities in clinical trials, which is a challenging mandate. Estaban Burchard has published papers in Nature and Science explaining the difficulties involved, including the fact that therapies prescribed in minority populations for one problem may be contraindicated for another.

NIMHD - Community Outreach

GENYOUth Foundation and Omega Psi Phi Fraternity

Dr. Maddox commented that NIMHD is aligning with public organizations to promote collaborative approaches to health disparities issues. One such group is the GENYOUth Foundation, which teamed with the National Football League (NFL) and the National Dairy Council to encourage young people to live healthier lifestyles. NIMHD is collaborating with GENYOUth by, among other things, providing Spanish translations for the Foundation's publications. NIMHD is also partnering with Omega Psi Phi, a national fraternity, to support the fraternity's Men's Mental Health Initiative whose mission is to help young African-American males to cope with depression and stress.

NIH Medical Research Scholars Program

NIMHD plays an active role in the NIH Medical Research Scholars Program (MSRP) a comprehensive, year-long residential research enrichment program for medical, dental, and veterinary students. This intramural research

program is held on the NIH campus and is co-sponsored by the NIH and private partners via contributions to the NIH Foundation. Scholars are in mentored and engaged basic, translational, or clinical research projects in an area that matches their personal interests and career/research goals.

Staff Presentations, Workshops and Conferences

NIMHD staff have presented, participated and attended several meetings, workshops and conferences nationally and internationally. Below are examples of staff presentations and activities.

Name	Presentation Information	Date
Irene Dankwa-Mullan, Ph.D.	“Research Perspective – Social Determinants of Global Immigrant/Migrant Health,” Rockefeller Bellagio Conference on Place, Migration and Health: Social Determinants of Global Immigrant/Migrant Health, Rockefeller Foundation, Bellagio, Italy	October 2014
Pamela Thornton, Ph.D.	“The Story Behind the Story: Successful Authors Share Lessons from Highly-Cited Maternal and Child Health Journal Articles,” American Public Health Association’s Annual Meeting and Exposition New Orleans, LA	November 17 th
Yvonne T. Maddox, Ph.D.	Grand Rounds - Conquering Health Disparities: Engaging Communities; Florida State University College of Medicine, Tallahassee, FL	January 15 th
Yvonne T. Maddox, Ph.D.	Inaugural UMB-UMBC Research & Innovation Partnership Symposium; University of Maryland, Baltimore County, Baltimore, MD	January 30 th
Yvonne T. Maddox, Ph.D.	2015 Curtis L. Parker Student Research Symposium, Morehouse School of Medicine Atlanta, GA	February 11 th

National Hispanic Medical Association Consensus Summit on Workforce Diversity

On January 30, 2015, NIMHD supported a consensus summit sponsored by the National Hispanic Medical Association (NHMA) was held. Attendees shared lessons learned, discussed best practices, and established innovative strategies and recommendations for future steps toward enhancing workforce diversity in medicine and biomedical and behavioral research. At the summit, participants discussed NIH’s new integrated approach to expanding diversity in biomedical research careers, including a renewed commitment to ensuring fairness in peer review.

Research Forum on HIV/AIDS Behavioral Intervention to Prevent HIV Among Diverse Young Men Sleeping with Men (MSM)

On February 13, 2015, NIMHD held a research forum addressing the current research and challenges regarding behavioral interventions to prevent HIV infection in young men, from diverse backgrounds who have sex with men (MSM). The 15 participants identified effective strategies to facilitate and increase collaboration among researchers and affected communities in developing and disseminating materials on behavioral interventions.

NIMHD American Indian/Alaska Native Activities

In November 2014 two lectures were held: The first lecture *Brain Resilience Training for Huntington’s Disease*, featured Dr. Melanie Cheung, a full bright scholar who spoke about working as a Fulbright New Zealand scholar developing a brain resilience training program for Huntington’s disease. The second lecture, *The American Indian/Alaska Native Research Forum*, was held November 20, 2014 and showcased NIH-funded American Indian/Alaska Native researchers and their contributions to biomedical research.

Budget Update

Dr. Maddox announced that the budget proposal received on December 16, 2014 was \$30.1 billion, NIMHD received \$270.97 million – the budget would be authorized under a full year continuing resolution. The President’s FY 2016 budget was submitted at \$31.3 billion for NIH, and \$281.55 million for NIMHD. The Precision Medicine

Initiative, a multi-IC initiative, will receive \$200 million (\$70 million for cancer and \$130 million for other diseases). NIMHD was allocated \$5.94 million of that funding. NIAID will receive \$100 million for antimicrobial resistance and \$20 million for flu vaccines. Several ICs will participate in the \$70 million allocated for the BRAIN Initiative, and NIA will receive \$50 million for Alzheimer's disease.

In 2014, the majority of NIMHD funds (\$268 million) were spent on the centers program (about \$126 million), and lesser amounts on intramural research (\$6.8 million), MRSP (\$1.5 million), and the endowment fund (\$21 million). An "Other Programs" expenditure of \$32 million went to various projects that were funded at less than \$10 million each.

Looking at the 2015 funding, Dr. Maddox was pleased to announce a budget of over \$41 million for research project grants, mainly RO1s, and NIMHD researchers can now apply for grants at several intervals during the year, rather than having to wait until a grant solicitation is announced. The centers will receive about \$127 million, and "other research" about \$55 million. Training is only \$150,000 for 2015, but in 2016 the institute will participate in a trans-NIH T32 training program, for which NIMHD hopes to allocate \$2 million.

Legislative Update

On the Hill, the Senate Finance Committee heard testimony from Secretary Burwell on February 4. Senator Cardin (D-MD) had asked her to mention her commitment to the NIH funding and in particular funding for NIMHD.

Several bills were discussed in the House and Senate:

- H.R. 45, the Triple-Negative Research and Education Act of 2015, which would require NIH to expand research for that type of cancer, which is resistant to conventional chemotherapies.
- H.R. 258, Half in Ten Act of 2015, a poverty-reduction law that would establish an interagency working group to address the issue of halving poverty in ten years.
- S. 216, National Prostate Cancer Council Act, that would establish a council to enhance screening, early detection, assessment and monitoring of prostate cancer.
- S.Res. a resolution that passed the Senate without amendment, to designate the week, beginning February 8, 2015, as National Tribal Colleges and Universities Week. Dr. Maddox announced that NIMHD has been charged to lead a new NIH Tribal Consultation Initiative, which would be similar to initiatives in other federal agencies.

On December 10, the first meeting of the NIMHD Outreach Coalition as held, its mission to share information about NIMHD's history, mission and research. Shortly thereafter, with support from Dr. Lisa Simpson, AcademyHealth, the Friends of NIMHD was formed. The Friends will be a coalition of stakeholders and supporters who will provide an opportunity for NIMHD to interact with outside groups in support of the institute's mission.

On January 15, Dr. Maddox briefed the Congressional Black Caucus Braintrust about the institute's mission. Finally, On March 2, Dr. Richard Carmona, former U.S. Surgeon General, now head of Canyon Research Institute, will visit NIH to discuss potential collaborations.

Grants and Programs

Dr. Maddox explained that the NIMHD Endowment Program, unique to NIMHD among the ICs, was mandated by P.L 106-525, Minority Health and Health Disparities Research and Education Act of 2000, to fund academic institutions to build research infrastructure, including training and nurturing of students and faculty. An assessment of the program's 15-years was recently completed and the results will be analyzed to determine if it should be continued and, if so, whether it should be changed in any way. During the 15 years the endowment has made 156 awards in the amount of \$410 million. The Council will be invited to consider the final analysis and recommendations at the June Council meeting.

Dr. Maddox briefly mentioned several RFA's that were awarded since the last Council meeting involving system-level health services and policy research; an award to enhance health disparities research at undergraduate institutions; technologies for improving minority health and eliminating health disparities; and a grant entitled "Innovations for Healthy Living."

Dr. Maddox mentioned that, during the visioning session, the Council will hear about the importance of making health disparities a science with a valid research agenda. With help from consultants Drs. Paula Braveman and Peter

MacLeish, a presentation was made to the NIH institute directors in December, who responded with support. The vision statement should be ready for release in November 2015, and it will be addressed broadly to the research community.

Discussion

During discussion, Dr. Maddox clarified the proposal to develop a single IRB is limited to multi-site projects that come under a single protocol. The first step may be to look at some of the existing cooperative agreements developed by other ICs that provide for such an arrangement. Since a request for comment is outstanding, when those comments are received and analyzed a specific proposal will be developed.

Concerning the review of the endowment program, there was a suggestion that the review be conducted by an outside group rather than an internal one to enhance transparency. Dr. Maddox responded that the committee involved in the review has been a fact-finding group, looking at award sites, eligibility requirements, use of funds and results. The review by the Council at the June meeting will be, in effect, an outside review. Dr. Stinson noted that the review was based mainly on the objectives of the original RFA, adding that the funds are placed in the receiving institution's endowment corpus and expended based on the policies of the institution. Dr. Maddox observed that one aspect of the review should be whether the eligibility criteria are broad enough.

PRESENTATION: PRECISION MEDICINE INITIATIVE

Dr. Eric Green, Director, National Human Genome Research Institute

Dr. Green provided the background to what has become the Precision Medicine Initiative. Even as a senator, President Obama was interested in genomics. He introduced a bill, the Genomics and Personalized Medicine Act of 2006 which, although it was not enacted, laid the foundation for the president's future advocacy of precision medicine. He consulted with proponents of personalized medicine, like NIH Director Francis Collins and Eric Lander, an expert in genomics and the current co-chair of the President's Council of Advisors on Science and Technology. Understanding that genomics could significantly affect human health, the president asked for a plan that eventually included the elements of genomics that would define the term "precision medicine." The development of the plan also relied on an Institute of Medicine study published in 2011, entitled *Toward Precision Medicine*, that proposed building a knowledge network for biomedical research and creating a new taxonomy of disease.

Dr. Green commented that most medical care today is based on the expected response to treatment of the average patient. In the future the focus will shift to medical care based on an individual's genetics (genomics), the environment in which he or she lives, and lifestyle. To reach that state rigorous research is needed to establish evidence-based science as a rationale, which will require research contributions from a wide range of disciplines, at an unprecedented scale.

HHS Secretary Sylvia Burwell, speaking at NIH on January 28, confirmed that precision medicine was a White House priority, and on January 30 the president formally announced the Initiative, with an assurance that appropriate funding would be available. The announcement was widely covered in the popular press and in scientific journals. The Initiative would have three components: a short-term focus on cancer research that would provide a model for the longer-term component, research on other priority diseases; and a process to update federal policies to remove barriers to clinical implementation that would involve changing federal regulations related to research study participants, and advancing FDA oversight of precision medicine products.

Dr. Green stated that the last step is creating a specific plan, which is in progress. The National Cancer Institute will be responsible for fleshing out the near-term phase, involving cancer research, and the institute has set up an advisory process that is fully engaged in looking at initial steps. The New England Journal of Medicine published a paper by Dr. Lander suggesting that accelerated oversight of genomic testing would help establish the era of precision medicine. Dr. Green also stated that research now should include the goal of identifying new approaches for detecting, measuring and analyzing a wide, integrated range of biomedical variables – molecular, genomic, cellular, clinical, behavioral, physiological and environmental. The approach will be to develop a significant national research cohort, perhaps greater than a million participants/partners. These volunteers would be valued as more than just subjects in a research project. That goal is made more attainable by the fact that there are many research cohorts, actually hundreds, already in existence, many funded by NIH. The challenge will be to determine

what cohorts can be repurposed for this larger focus. The participants will share a broad range of personal history, largely through electronic health records, that includes genomic information, biological specimens, and lifestyles, with privacy properly protected.

Dr. Green observed that the basic ideas are not new. Dr. Collins proposed a similar idea a decade ago, then deemed too costly. Sequencing a genome at that time cost millions; now a human genome can be created for less than \$5,000. Ten years ago sequencing could take months; now it can be done in a day or so. And ten years ago only about 30% of Americans were covered under an electronic health record; now that number is over 90%, making retrieval of data much faster and cheaper. Gathering data using smartphones is much easier today when over 160 million adults own one. Finally, a significant advance in manipulating “big data” has occurred. With more than a million participants, big data will be an important part of precision medicine.

Dr. Green discussed the need to develop a strategy to recruit the large number of participants, which will include identification of the cohort, developing collaborative partnerships with multiple groups, explaining risks and benefits, and protecting privacy. Recently the first of a number of workshops was held to address these issues, with over a hundred participants, and more than 1,700 remote viewers. Public-private partnerships will be created to support the recruitment effort. Early results will come from testing pharmacogenomics (right drug, right time, right person), identification of therapeutic targets, understanding individual resilience when people don’t become ill when they should (a rare event that requires very large cohorts), and development of mHealth technologies.

Concerning immediate challenges, Dr. Green mentioned several – insuring that new “subjects” are actually true partners in the effort; blending existing cohorts to create a large cohort that can be compatible for a variety of research programs; insuring that health disparities and minority participation is adequately addressed; creating research agreements with international partners; designing cohorts to support a spectrum of studies; taking full advantage of electronic health records; and developing data exchange and data sharing models.

Dr. Green outlined the next steps, beginning with a working group in the Director’s Office to develop a specific vision of what the research cohort will look like. Kathy Hudson, and NIH deputy director, and Rick Lifton, a prominent geneticist from Yale, will co-chair that trans-NIH effort. The product should be delivered in this fiscal year to facilitate funding in 2016, and an interim report is expected by September. Although the report will be needed to enable developing funding proposals by the fall, there will be coordination with other federal agencies, including the Department of Defense, FDA and VA.

Before inviting questions, Dr. Green noted the coincidence of the launch of the Human Genome Project in 1990, almost exactly 25 years earlier, and the anticipated launch of the Precision Medicine Initiative this year. During discussion, Dr. Green commented that there would certainly be involvement of entities beyond the Federal Establishment, including state and local agencies, and private sector participants, especially those who have established stable health care programs supported by extensive and efficient electronic health records systems. There was also assurance that environmental and behavioral input would be included. One clear need will be the development of priorities in the collection and management of data.

PRESENTATION: Adolescent Behavior and Cognitive Development (ABCD) and the BRAIN Initiative
Dr. Nora Volkow, Director, National Institute on Drug Abuse

Dr. Volkow commented on two significant initiatives, The BRAIN Initiative and the Adolescent Behavior and Cognitive Development (ABCD) Initiative. The first was launched in 2013 and called “The Next Great American Project” by President Obama. It would address the significant challenge of sorting out how the most complex human organ system, the brain, functions. It involves several NIH ICs as well as institutions in the private sector, among them the Allen Institute for Brain Science, the Howard Hughes Medical Institute and the Kavli Foundation. Brain disorders are a leading source of disease and cost in the U.S., but recent technological advances have made possible more fruitful investigations of brain disorders. A decision was made to involve NIH in the BRAIN Initiative. The Initiative is a ten-year project. The first five years will be focused on developing technologies. Several institutes and the Office of the Director jointly allocated \$46 million for the program in 2014, and RFAs were published for 58 projects. There was a focus on developing tools and new technologies to look at cells and brain circuitry, some funding for next generation imaging techniques, and money for large-scale recording and

modulation (new technologies), and a look at circuits.. There was an allocation of \$25 million in FY 2015, and since the first RFAs had progressed satisfactorily, they were basically re-published for 2015.

Turning to adolescent addiction, Dr. Volkow explained that studies have shown that the greatest vulnerability to substance abuse disorders occurs in the transition years from childhood to young adult (12-25), peaking at about 16-18). However, that is also a time in life when strong environmental and social support can reduce that vulnerability. Many of those risks are related to the biological characteristics of the brain and the increased neuroplasticity of the brain during the late teen/early adult period in life. Subjecting the brain to stress in this period, including stress related to substance abuse, can lead to long-lasting plasticity changes that support vulnerability to addiction.

Dr. Volkow noted that the brain develops more slowly than any other organ system in the body, which is particularly important in the development of the frontal cortex, the area of the brain related to self-control. Since the frontal cortex does not fully mature until the mid-twenties, teens and young adults are more likely to make poor risk decisions. Therefore, barring positive influences such as the environmental and social support systems available to some, those teens that are risk takers and whose behavior includes abuse of drugs and alcohol, may become addicted faster and the addiction may be more severe and last longer.

Research has shown that about 10% of the population will become addicted, but if exposed to addictive substances in adolescence that rate is more than doubled. Research has also shown that an individual's genetics affects the potential to become addicted, and that potential is in turn affected by environment. The genetic propensity for addiction can be dampened significantly by a strong social support system, which is part of an individual's environment. Scientific approaches, such as epigenetics, provide new tools that will support research to quantify how environment affects brain biology. Tools, such as the MRI, can visualize activity in brain circuitry to compare the brain of an individual who has positive environmental support versus the brain of an individual who is stressed or deprived of that positive support.

Dr. Volkow discussed the changing landscape in the United States with regard to the increased legalization of marijuana. The concomitant risk perception is also changing. About half the states have opted for one of the following: legalization for all purposes, legalization for medical use, or decriminalization. That has made marijuana more accessible. One consideration has to be the impact of regular (i.e., almost daily) use, which has been shown to have increased risk of poor outcomes. Since about 2007, heavy use of marijuana has increased dramatically, nearly doubling, while the perception of risk has decreased. Many studies have shown that high school students who use marijuana on an almost daily basis are half as likely to graduate as those who rarely (less than monthly) use the drug. Other poor outcomes of heavy use include a greater likelihood of becoming addicted to other drugs, an increased incidence of suicide attempts, and a negative impact on IQ.

Dr. Volkow addressed the importance of the ABCD Initiative, as a tool for policymakers, parents, teachers and adolescents, to help them make decisions with regard to the effect of drugs on brain development trajectories. This National Longitudinal Study of 10,000 children beginning at age 10 (presumably prior to drug use), through age 20, would assess brain development with a focus on a standard or metric similar to the one used by physicians to measure and track physical growth.

The study was launched in May 2014, with an expert panel of scientists in the fields of imaging, study design, and phenotype characterization, which produced a request for information (RFI) in July 2014, to solicit suggestions from outside sources. An FOA was released on February 4, 2015, with applications due by April 14. This will be the largest prospective study of adolescents ever undertaken. Dr. Volkow suggested that the greatest challenge will be the valid construction of a phenotype of the children as they transition into adulthood, including an accurate and consistent environmental characterization that includes social stressors and supports. Another challenge will be to insure that the study cohort is representative of the adolescent population, and that they stay with the study to ensure continuity.

During discussion, asked about the effect of population density (e.g., urban versus rural), Dr. Volkow commented that urban density can have a positive effect if the social support system is present, or negative effects if population density makes access to drugs easier. She added that rural areas often have alcohol misuse problems, but that recently the appearance of injectable heroin has shown up in rural areas, with the highest risk group being African Americans.

Asked about prevention versus treatment, Dr. Volkow noted that there have been prevention programs designed that have proven effective is reducing drug use, but that their uptake in the school systems has been slow. The tools are available; the challenge is in the implementation. The same is true for proven effective treatment programs. They work but implementation is spotty.

Finally there was a comment that, in addition to environmental support, effective institutional support could be relevant – for example programs in the school systems that address food insufficiency, an important factor in brain development. Dr. Volkow agreed that nutrition has an important influence on brain development, and it is a factor in developing the environmental phenotypic characterizations that will be important in the study.

Addressing a comment about the ABCD cohort being representative of the adolescent population, Dr. Volkow conceded that, because the study will be conducted in academic centers that have the sophisticated imaging technology required, it is likely that recruitment will be in urban areas. She added that there would be a focused effort to recruit minority participants, including Native Americans.

PRESENTATION: The Environmental Affordances Model for Understanding Population Disparities in Physical and Mental Health

James S. Jackson, Director, Institute for Social Research, University of Michigan

Dr. Jackson's presentation focused on the Environmental Affordances Model. This model is a way to understand the disparities that are observed among racial and ethnic groups in the United States. There is no conceptual or theoretical model that describes how such disparities emerge. One issue is that individual and group motivations have not been integrated into how we think about health disparities. An aspect of the issue is that behavior flies in the face of rational thought. People consume highly salted, fat-laden foods in spite of a rational awareness that such behavior is not good for health. The epidemics of obesity and diabetes are nearly out of control, and both are a significant factor in health disparities. The reason for much of the related poor health practices is chronic stress, which is closely linked to the disparities seen among racial and ethnic groups. The typical result of chronic stress is a depressive disorder.

There are disparities that affect the wellbeing, physical and mental health that typically works to the disadvantage of minority populations, but not always. For example, the lifetime prevalence rate of major depression is higher in non-Hispanic Caucasians than in African Americans. Alcohol abuse is lower in African Americans until age 40, but then becomes higher than in Caucasians over the age of 40. In terms of physical health, African American men and women are usually at a disadvantage. For the past 30 years, the 5-year survival rate in African American melanoma patients is considerably lower than in Caucasians.

Dr. Jackson cited Michael Marmot's thesis that personal power, social participation, environment, behavior and early life experiences are linked to disparities over the lifespan, although that model is not helpful in terms of predicting how those disparities play out. He posited that no one factor can be tied to physical and mental disparities, but that an accumulation of small effects over the life course produce differences in adulthood and older ages among different race and ethnic groups. Those differences are driven by gene-gene and gene-environment interactions, perceived discriminations (that exacerbates the stress process), culture, behavior, socioeconomic status, institutional arrangements, and social and psychological factors. Finally, an individual's allostatic load and the cumulative effects of stress are factors in chronic stress.

Dr. Jackson submitted that chronic stress is a possible pathway for physical and mental health disparities seen in racial and ethnic populations. According to the American Psychological Association and a report in USA Today published in June 2012, stress is increasing, 18% for women and 24% for men during the period 1983 to 2009. There have also been published reports that there are disparities in the living arrangements that favor Caucasian men. Dr. Jackson clarified the definition of "affordances" in the context of the availability of acceptable living arrangements, including neighborhood characteristics. Some neighborhoods afford certain amenities that are not readily available in others – easy access to food and other services, more job opportunities closer to home, and the availability of coping resources.

A health disparities paradox can be seen in the fact that engaging in physical health favors Caucasians, but mental health favors African Americans, which is complicated by the generally accepted proposition that physical and mental health are interrelated. It is also interesting that the timeline for the development of disparities is enigmatic – diabetes in both Caucasian and African American women is relative low, and the incidence is similar until about age 44, when the number of African American women with diabetes dramatically increases by age 65. The difference between Caucasians and African American women will more than double and remain the same until the age of 85. Hypertension in males is similar, but less dramatic. The incidence of hypertension in both African American and Caucasian males is comparable until age 44, when African American males begin to experience the disorder in greater numbers than Caucasians.

Statistically African Americans live the fewest years of any racial or ethnic group. Until after the prenatal stage of life, infants born to African American mothers are up to three times more likely to experience premature death than infants born to Caucasian mothers, but at four years of age the premature death rate in Caucasian infants is higher than in African Americans, and remains that way, if only slightly, until middle age, when the rate of mortality in African Americans begins to exceed that of Caucasians. Looking at specific morbidity/mortality risks, it is interesting that young African American males defer smoking and typically take up smoking at a much lower rate than Caucasians until their mid-twenties when they begin to catch up with Caucasians, and finally exceed then at about age 44. The same is true of African American females, except at a lower rate. The same pattern exists with regard to alcohol and drug use.

Obesity is a different picture, where disparities appear early in the African American child's life between the ages of 2 and 5 years of age, and remain disparate throughout life. It is noteworthy that the proportion of obese females accelerates dramatically in the mid-twenties. However, the age group (40 to 59 years of age), almost 60% of African American women would meet the criteria for obesity. The National Health and Nutrition Examination Survey (NHANES) revealed that the education level has no impact on obesity in African American females throughout their lifetimes. Higher education in Caucasian females seems to reduce the probability of obesity. Finally, a CDC study showed that, throughout life, rigorous physical activity is greater in Caucasian women than in African American women.

Dr. Jackson reiterated that negative disparities related to physical condition are greater in African Americans, but are less than those for mental conditions. He suggested that one reason might be that the coping mechanisms that address non-race and race-specific stressors might be harmful, in and of themselves. Stress-related precursors of mental health problems are easier to recognize (upset stomach or headache after a hard day), versus stressors related to health, which are often invisible (hypertension, a developing carcinoma). Individuals may respond to the former by eating, drinking alcohol or taking drugs – all potentially harmful to physical health.

Dr. Jackson explained the relationship between chronic stress, the actions people take to alleviate stress, and the hypothalamic-pituitary-adrenal (HPA) axis, that is affected by both. Poor health behaviors (eating fatty foods, drinking) interact with the HPA in a way that tends to reduce mental health disorders. That is inconsistent with the fact that the same poor health behaviors that affect the HPA and other brain hormones actually interfere with the neural and hormonal events that, over time, would ordinarily lead to mental disorders.

An effect of chronic stress is depression. Dr. Jackson cited studies (including the Baltimore Epidemiologic Catchment Area Study) that demonstrated that severe distress was reduced with unhealthy behavior. That is, the coping mechanisms of eating, drinking and drugs reduces the anxiety that results in serious depression, but paradoxically negatively affects physical health. He posited that African Americans learn these coping strategies early in life. For example, African American women have the lowest rate of alcohol/drug use, but the highest rate of obesity, perhaps because they grew up in a culture that accepted the consequence of eating – overweight – which continued to be acceptable as they grew older. African American men are very active physically as young men, and when physical aging deters such activity, they turn to alcohol and drugs.

Dr. Jackson concluded his remarks with a discussion of race and ethnicity, noting that in today's research environment race is a self-reported description, which can lead to differences and inconsistencies in study results. Skin tone is a powerful marker of race that leads to discrimination and consequential development of disparities. But race is a more complex construct than skin tone. It is the sum of one's living experience over a lifetime. Therefore, a person's race is best understood as a set of propensities, rather than a fixed and defined category, and

those propensities change over time. If those propensities can be defined, then racialization of an individual might not be limited by skin tone.

Biennial Report: Inclusion of Women and Minorities in Clinical Studies – Dr. Derrick Tabor

Dr. Maddox prefaced the discussion of the biennial report by stating that the report is mandated by NIH to be presented to each institute advisory council as an update to the policy related to the inclusion of women and minorities in clinical trials that include human subjects.

Dr. Tabor reviewed Public Law 103-43, the National Institutes of Health Revitalization Act of 1993, Subtitle B, Clinical Research Equity Regarding Women and Minorities. The requirement is to include women and members of minority groups in clinical research studies unless there is a valid rationale to exclude them (cost is not considered a valid reason for exclusion). They must also be included in Phase III clinical trials, which must be designed to permit valid analysis. Finally, NIH must support outreach efforts to recruit and retain women and minorities in clinical studies.

Dr. Tabor defined clinical research as patient-oriented research involving human subjects (or their tissue specimens or results of cognitive tests), in which the investigators directly interact with the human subjects. The studies may look at mechanisms of human disease, therapies, clinical trials, development of new technologies. It may also include epidemiological and behavioral assessments, and outcomes research and health services research. Patient-oriented research does not include studies that use in vitro tissue samples or de-identified human tissue specimens that cannot be linked to a living individual; or existing data (or human specimens) that are publicly available. Dr. Tabor mentioned that, in addition to complying with the outreach requirement, the NIH Office of Extramural Research also provides regional training in the proper recruitment of human subjects, including the inclusion of women and minorities.

Funded investigators are required to report information related to recruitment of women and minorities at the outset of their studies and annually thereafter. The reporting is facilitated by an NIH-wide electronic reporting system, called the Inclusion Management System. Nonetheless, there are challenges to conforming to the reporting requirement – an investigator may fail to submit complete information or fail to submit any information, information may be submitted late (requiring follow-up action), and there may be a significant number of “unknowns” reported for either gender or race/ethnicity, or both. Investigators who choose not to enroll either women or minorities or both must submit a valid justification. Failure to comply with any of the requirements triggers a “bar” that prevents funding the study.

Dr. Tabor showed data for 2013 and 2014 to illustrate the reporting system as it applied to NIMHD funded studies. The report contains the number of applications reviewed, the number of human subjects involved in the study, and the number of applications approved by the IRG. The report must include specific numbers indicating failure to comply with policy: minority only inclusion, sex/gender only inclusion, minority and sex/gender inclusion, total minority inclusion and total sex/gender inclusion. Those that fail to comply are categorized as “Total Number of Unacceptable App’s.” Final funding depends on resolution of the issue that triggered the bar. If the application is rejected for funding, the issue of the bar is moot. If the application is approved for funding, the bar issue must be resolved and the bar removed.

During discussion, asked about the process of removing a bar, Dr. Tabor explained that it can be simple and quick if it is just a matter of failure to address a particular item, or labor intensive if the investigator left out the entire human subjects section. Final removal of a bar requires approval by a program official, then the division director and finally OER. Asked about the definition of “minority,” Dr. Tabor commented that the report lists the specific minority groups, and an individual subject may be included in more than one racial/ethnic group. Dr. Stinson recalled a GAO inquiry in 2012 that revealed there was confusion about the difference between a clinical trial and a clinical study. Dr. Tabor suggested that epidemiological and behavioral studies, outcomes research and health services research are considered clinical studies/research rather than clinical trials. Finally, there was a comment that relying on electronic health records may not best serve the interests of minority inclusion since the records often fail to include racial/ethnic identity, or a significant amount of the data may be imputed, which leaves accuracy open to question. Also, race and ethnicity is often self-reported. There was also a question raised about the integrity of the information provided by some investigators.

Closing the discussion, Dr. Maddox invited the Council to accept the biennial report as presented by Dr. Tabor. On motion duly made and seconded, the Biennial Report on the Inclusion of Women and Minorities was unanimously approved.

Program Concept Review and Clearances

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

- **Building Public Health Research Capacity in the U.S.-Affiliated Pacific Islands (USAPI)**

The islands included in the proposal are territories of the U.S. located about 3,000 miles northeast of Australia – Guam, Commonwealth of the Northern Mariana Islands, and American Samoa. The U.S. provides funding support to the CDC and SAMHSA mainly for health care, but there is very little NIH support for research. Other limited data sources are available but not well utilized (Medicare/Medicaid, BRFSS). What little research data there is on the USAPI populations is derived from groups of islanders living in the U.S. The proposal would fund institutions located within the USAPI, although 15% could be funded to institutions outside USAPI.

The proposal would rely on existing models of similar programs, such as the U24 projects in the Caribbean. It would fund infrastructure first in order to build capacity. Capacity building would include enhancing health care facilities (including equipment), training personnel, developing research networks, providing distance learning opportunities and mentoring programs, and foundational population research to develop baseline data that could support various studies. The latter would include epidemiological studies of infectious and non-communicable diseases, assessment of healthcare provided, access and barriers to formal healthcare, identification of alternative and indigenous medicine, and a survey of healthcare needs not adequately addressed by the existing by community-based interventions and services. Potential local institutional partners in the USAPI are not research-intensive and would require NIMDH staff support to provide technical assistance and programmatic guidance. Research institutions in Hawaii and California might be appropriate collaborators. Since NIMDH will not specify research projects, the programmatic guidance would help investigators design and execute a program that would support their proposed research. Taking advantage of data derived from the U.S. islander populations would be encouraged. Dr. Maddox invited action on the proposal, and on motion duly made and seconded, the Council unanimously approved developing concept as proposed.

- **Research to Understand Institutional Factors that Promote the Research Careers of Students in Biomedical and Behavioral Research**

NIH has supported training, mentoring, and research education programs to help researchers underrepresented in the biomedical workforce. However, those programs have not increased the diversity of that workforce, and more systematic efforts are needed to resolve that inequity. The National Institute of General Medical Sciences issued an RFA entitled, “Research to Understand and Inform Interventions that Promote Research Careers of Students in Biomedical and Behavioral Sciences,” an RO1 that has been issued several times. Valuable research results have been generated through the awards regarding the recruitment and retention of underrepresented individuals in the field. There are no RFAs available now that solicit research on systemic, institutional-level factors that promote diversity.

The proposed initiative would support research projects that broadly examine the role of institutional characteristics, policies and practices that promote diversity in biomedical research from undergraduate to independent researcher career stages. It is expected that the project will rely on aggregate data and identify interventions that focus on key institutional factors that influence workforce diversity. Most of the existing workforce diversity programs are focused on training, not research. And the NIGMS RFA solicited projects that emphasized individual-level factors rather than overarching ideas and policies that would promote workforce diversity. Regarding the question of involving multiple institutions in the research or relying on one institution to be a model is an appropriate question that has yet to be addressed.

Dr. Maddox announced that the vote on this concept would be deferred until the June meeting, to allow staff to consider additional comments and recommendations.

Visioning: The Science of Health Disparities

Dr. Dankwa-Mullan introduced the session on visioning, noting that the process is about appreciating the values of science and the application of scientific principles to the total environment – including health, safety, well-being,

communities and social networks. This version of visioning relates to an earlier approach to a vision of improving racial and ethnic minority health that was articulated in a report that was published 30 years ago. That report, the Heckler Report, discussed the results of a study launched by then Secretary of Health and Human Services, Margaret Heckler, one that assessed disparities in the health care of minority populations. It was the first such study the federal government had ever undertaken.

The current vision is to build on scientific developments that advance the field of disparities research, an ambitious challenge for NIMHD, NIH as a whole, and the entire research community. The effort, which will require broad buy-in by the scientific community, will seek to improve communications and multidisciplinary collaboration to develop new science and to encourage new technologies. The NIMHD held a visioning retreat on January 26-27 to launch the program. Representatives of other ICs participated. Reflecting on the basic science visioning goal – relying on multidisciplinary systems approaches and team science; using rigorous scientific methods and tools; identifying research gaps and setting priorities; and making some basic assumptions about what would benefit health disparities research – the retreat discussion resulted in five areas of inquiry:

- Modeling systems
- Life course science/ perspectives
- Science of behavioral change
- Population health (scientific measures and methods)
- Translation, dissemination and implementation science

Specifically, the modeling discussions included consideration of conceptual, theoretical and operational models, and emerging theories that might improve on the current knowledge related to modeling. Life course science suggests looking at changes over an individual's lifespan, and includes new sciences such as epigenetics, the physiology of chronic stress, allostatic load, and telomere biology. Behavior is clearly a determinant of health, and there is doubtless a greater negative impact on health when an individual is living a disadvantaged life that exacerbates stress. The prior discussion on brain silence indicated that there is an interaction between a part of the brain that controls abstract (rational) reasoning, and another that is related to impulse reactions, short-term rewards, and greater acceptance of risk. The highly stressed brain tends to respond more to the latter.

Dr. Maddox invited discussion. Dr. Galea saw two steps, the first of which was accomplished by the preparatory work of the retreat, a comprehensive catalog of promising areas for disparities research. The second step would be to identify which areas matter most in light of the NIMHD's mission, and how best the available resources could be deployed. Dr. Bradford pointed out that the life course is not the same for everyone. There are special populations that will need consideration, such as the LGBT community, and particularly those who are aging who might not have a solid social support structure. Dr. Linda Greene posed three questions: What is known about the causes of minority health disparities; what are the most critical health care needs for that population; and at the institutional level what is critical to sustain health disparities research?

Dr. Alegría commented that partnerships and collaborations would be important for efficient use of resources and to avoid duplication of effort. She also believed that some important tools needed for research have not been developed and that a focus on innovation will be required to resolve that issue. She suggested that the RFA route might not be broad enough, and that special innovation awards could produce more transformative results than traditional approaches to population health research. Finally she felt that the present players might have a more narrow science focus than would be available if the participants were selected from a broader range of backgrounds. Referring to the idea of collaborations, Dr. Hammond observed that, in looking at the "to do" list, items that are being addressed currently in other parts of NIH should be identified, perhaps for collaborative effort, or to avoid replication of effort. He also mentioned the possibilities of identifying targets of action that perhaps are overlooked at other ICs, such as special populations, issues that are outside the boundaries of conventional public health (like education and housing), or projects that may be isolated in traditional silos of science that need a more diversified participation.

Recalling the comments about collaborations and building on work in progress, Dr. Adams mention an example, low birth weight babies, which would provide an opportunity to expand the knowledge base with some focus on the gap between Caucasian mothers and, for example, African American mothers. Dr. Araneta emphasized the importance of effective dissemination, describing an example of the minority population of non-obese Asians who have a

diabetes incidence that exceeds the disease burden in any other minority group, including African Americans. When Kaiser Permanent published a report announcing that fact it was a shock to the medical community, which was unaware of the problem in that population. As long as the lay public does not read medical journals, dissemination in other media is very important.

Dr. Burhansstipanov noted that, for independent, nonprofit groups that conduct health research, the typical provisions that are included in proposals to aimed at traditional research institutions can be crippling – indirect charges such as “overhead” for a university can make such research prohibitive for the nonprofit, or requirements in an RFA that restrict researcher or institution eligibility, can both prevent qualified researchers from contributing. With regard to clinical trial recruitment, since that is sometimes a sticking point, she recommended looking to how the most successful studies recruit participants. Finally, Dr. Rivers suggested that the agenda as presented, or in its final form, should be framed so that it leverages the research investment NIMHD has made over the past several years. He also recommended considering priorities based on individual state needs, since demographics, governance and policies are different in the various states. Constructing a national framework for research basically ignores the reality of the diversity among the states.

Dr. Maddox expressed appreciation for the valuable comments, and noted that the next step would be to hold a number of workshops that will produce a number of white papers that will serve as a basis for discussion at a summit in September 2015.

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.

Review of Grant Applications

Dr. Maddox called the closed session to order. Dr. Hunter led the second level review of grant applications submitted to NIMHD programs. The Council considered more than 208 applications requesting an estimated \$59,852,975 in total costs. Applications from the following Request for Applications (RFAs) were considered: Development and Translation of Medical Technologies to Reduce Health Disparities (SBIR) (R43/44); Small Business Technology Transfer Research (STTR); Centers for AIDS Research (CFAR); and Adolescent Medicine Trials for HIV/AIDS Interventions (ATN) (UMI). 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 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 reconvening the meeting in open session, Dr. Maddox announced that the work to create a subcommittee of Council members, called the Subcommittee on Planning and Agenda Setting, to help in developing the Council meeting agenda, was well under way. Dr. Maddox expressed appreciation to the Council members for their participation, and adjourned the meeting.

The meeting was adjourned at 4:30PM.

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/Lawrence A. Tabak/	09/01/15
Lawrence A. Tabak, D.D.S., Ph.D.	Date
Acting Director	
National Institute on Minority Health and Health Disparities, NIH	

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/Donna A. Brooks/	09/01/15
Donna A. Brooks	Date
Executive Secretary	
National Institute on Minority Health and Health Disparities, NIH	