

**National Institutes of Health
Tribal Consultation
Monday, September 21, 2015, 1:30 p.m.
Washington Hilton, Washington, DC
Meeting Summary**

Moderators:

Lisa Elgin—Tribal Administrator, Manchester Band, Pomo Indians; National Indian Health Board (NIHB), California Area Board Member

Kathy Etz, PhD—Senior Advisor for Tribal Affairs, NIH, HHS

Presenters:

Sheila Caldwell, PhD—Program Director, Center for Research Capacity Building (CRCB), National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), US Department of Health and Human Services (HHS)

Gwynne Jenkins—Office of the Director, NIH, HHS

Jon Lorsch, PhD—Director, NIGMS, NIH, HHS

Shobha Srinivasan, PhD—Health Disparities Research Coordinator, Office of the Director, National Cancer Institute (NCI), NIH, HHS

Meeting Attendees

See Addendum 1

Meeting Summary

Tribal Opening

Ms. Elgin offered a prayer for the meeting and its participants. She welcomed and thanked all representatives of NIH and all tribal leaders for joining today's session.

Welcome and Opening Remarks from NIH

Jon Lorsch, PhD—Director, NIGMS

An Overview of NIH

Dr. Lorsch explained that NIH is one of 11 operating divisions of the US Department of Health and Human Services (HHS). Other HHS operating divisions include Centers for Disease Control (CDC), Indian Health Service (IHS), and the Food and Drug Administration (FDA). NIH is comprised of 27 Institutes and Centers, most focusing on specific diseases or issues. NIGMS supports research in basic biomedical sciences—i.e. understanding how living systems work and how system breakdown leads to disease.

Office of the Director

Francis S. Collins, PhD, MD has served as director of NIH since August 2009, after being appointed by President Obama and approved by Congress. He is known as the “Singing Scientist”, and videos of him singing his original songs can be found on YouTube by searching “Francis Collins singing”. He is the former director of NIH’s National Human Genome Research Institute and was the leader of the Human Genome Project (HGP), an international scientific research project with the goal of identifying and mapping all of the genes of the human genome from both a physical and functional standpoint.

Locations

The large, central NIH campus is located in Bethesda, MD, and most administrative operations are housed there. Other NIH sites exist in the region and throughout the United States, including in North Carolina and Montana.

Mission

NIH's mission is twofold:

1. As the nation's medical research agency, to seek fundamental knowledge about the nature and behavior of living systems
2. To apply that knowledge to enhance health, lengthen life, and reduce illness and disability

The Institutes and Centers of NIH unite to advance the mission of improving human health and reducing suffering. They work to understand human biology and to use that knowledge to create better ways of diagnosing diseases and to develop new cures and better treatment therapies. However, NIH is a research agency and does not administer health care.

Impact

NIH's work has had a major impact on human health. Some significant advances include:

- The mean life expectancy in the US rose from age 74 in 1979 to almost age 79 in 2013.
- Cardiovascular disease death rates have fallen more than 70% in the last 60 years.
- Cancer death rates are now falling about 1% each year; each 1% saves about \$500 billion.
- Therapies enable people infected by HIV in their 20s to live to age 70 and beyond.

NIH Research Priorities and the Grantmaking Process

Dr. Lorsch explained that NIH has a dual research track:

- *Intramural research* takes place on the NIH campus and at its satellite sites. This research comprises about 11% of the overall budget and involves approximately 6,000 scientists.
- *Extramural research*: NIH funds research and training that supports more than 400,000 scientists and research personnel located in more than 2,500 universities, medical schools, hospitals, and other research institutions throughout the US and overseas. Out of the approximately 70,000 applications it receives each year, NIH awards about 40,000 grants. Extramural research makes up around 80% of the agency's budget.

NIH funds high-caliber research projects focusing on specific diseases or processes in living systems. NIH does not support the delivery of services except in a research context. The President presents, and Congress passes, a budget that allocates money to each of NIH's Institutes and Centers to award grants.

Over 60% of extramural funding provided by the NIH is used to support investigator-initiated research—that is, ideas developed by researchers in the field. NIH develops its own major initiatives to foster the acceleration of knowledge and to solve critical problems as identified by the agency or by Congress. One example of this is the development of a universal Ebola vaccine.

A Range of Applicants and Grant Opportunities

NIH encourages diversity of the biomedical research workforce, with the awareness that diversity of ideas, approaches, and questions—all fed by a multiplicity of backgrounds and experiences—is critical to the strength of the biomedical investigation process. This core tenet informs funding decisions and leads the agency to solicit broad input from a wide variety of stakeholder groups when setting research priorities.

Scientists from federally recognized institutions that include public and private, for-profit and not-for-profit organizations—including federally recognized tribal organizations—may apply for NIH grants.

Grants are awarded to graduate and medical students; postdoctoral fellows; and early, middle, and senior career scientists. NIGMS in particular also provides support to some undergraduate students with the goal of increasing the diversity of its biomedical research enterprise through encouraging students from underrepresented groups to enter the field.

NIH supports a variety of grants, the most ubiquitous being the R01, or Research Project Grant. Those considering applying are encouraged to contact the relevant Institute program director. Also, investigators can find a wealth of information about the grant application process at grants.nih.gov.

NIH makes information on funded research both public and searchable by location and area of study through Research Portfolio Online Reporting Tools (RePORT), found at report.nih.gov.

Funding decisions involve a multi-tiered process:

1. An investigator submits an application based on her/his research interests.
2. Applications are assigned to panels of scientific experts, known as “study sections” for peer review.
 - a. Study sections review 40-100 applications three times a year.
 - b. Panel experts review how pressing the need is and how well the applicant lays out the research plan. Review criteria include investigator, significance, approach, institution, and innovation.
 - c. The study section scores the applications.
3. Program officers (NIH staff) assist investigators to prepare applications and help them to interpret the results of the peer review.
4. The reviewed applications are presented to the related Institute’s national advisory council, which is made up of experts from around the country along with public, non-scientist representatives.
 - a. The council assesses the peer review process and advises the Institute or Center on funding priorities.
5. The Institute or Center director makes the final funding decisions and determines how the funds are allocated.
 - a. Scientific merit, public health needs, scientific opportunity, and the diversity of the funding portfolio are considered as factors in funding decisions.

NIH Targeted Initiatives

Precision Medicine Initiative (PMI)

Dr. Lorsch introduced PMI, announced by President Obama in his State of the Union address this year. The initiative builds off of the human genome project and focuses on individualizing medical care to advance human health by using genomic and genetic information to allow better-targeted medical interventions. Harnessing and utilizing that knowledge can lead to a positive effect on the efficiency and effectiveness of the health care system.

Big Data to Knowledge (BD2K) Initiative

BD2K focuses on the information gathered from human research participants, as housing that data carries potential advances as well as potential risks. BD2K seeks better, computational ways to mine the vast amount of data—including but not limited to genetic sequencing and movement patterns—and use

the data to advance health care and improve human health. It also seeks to safeguard personal information and to use it only in ways approved by the individuals involved.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

BRAIN seeks to map the connections between neurons and to understand the complex wiring of the brain.

NIH Programs of Interest to Native Communities

Diversity of the NIH-Funded Workforce

Despite efforts, NIH has not had the hoped-for impact on the diversity of the agency-funded scientific workforce over the last 30-plus years. To overcome this ongoing challenge, the agency has established numerous programs that work to ensure researchers reflect the makeup of the larger population and thereby bring a diversity of ideas and backgrounds to the work.

Dr. Lorsch shared the rates at which American Indians and Alaska Natives (AI/AN) die as compared to other Americans from the following diseases and behaviors:

- Chronic liver disease and cirrhosis (368% higher)
- Diabetes mellitus (177% higher)
- Unintentional injuries (138% higher)
- Assault/homicide (82% higher)
- Intentional self-harm/suicide (65% higher)
- Chronic lower respiratory diseases (59% higher)

He noted that such information exemplifies the need for a diversity of researchers, including those from AI/AN communities.

NIGMS Programs Supporting Research in and by AI/AN Communities

Native American Research Centers for Health (NARCH)

NARCH, started in 2000 jointly by IHS and NIGMS with participation across NIH, bolsters partnerships between federally recognized tribes or tribal organizations and institutions that conduct intensive, academic-level biomedical, behavioral, and health services research. NIGMS funds a wide variety of projects, all driven by the communities' agendas. One of the main goals of NARCH is to build the research capacity of the tribes and tribal organizations by training investigators and build infrastructure in the communities so they can continue to conduct research.

Institutional Development Award (IDeA)

IDeA was authorized by Congress as part of the 1993 NIH Revitalization Act. Its intent is to enhance the geographic distribution of biomedical research in the US in order to positively affect diversity and build strength. The program targets states that historically have received less than the average amount of NIH funding for research. Currently, 23 states and Puerto Rico are eligible for funding. The following two programs are funded through IDeA:

Centers for Biomedical Research Excellence (COBRE)

COBRE supports the expansion and development of biomedical faculty research capability and the enhancement of research infrastructure, including the establishment of core facilities needed to carry out the objectives of a multidisciplinary, collaborative program. The centers target specific research

questions and promote interactive efforts among researchers with complementary backgrounds, skills, and expertise.

IDeA Networks of Biomedical Research Excellence (INBRE)

The goal of INBRE is to build research infrastructure through statewide multidisciplinary research networks of doctoral degree-granting and undergraduate institutions and community colleges, including minority-serving institutions (MSIs) such as Hispanic-serving institutions, historically black colleges and universities (HBCUs), tribally controlled colleges and universities (TCUs), and Alaska Native and Native Hawaiian (NH)-serving institutions.

Research Opportunities at NIH

Numerous research opportunities are available at NIH, and members of tribal communities have participated in them.

- *The Summer Internship Program (SIP)* welcomes eligible high school, college, graduate, and professional students to spend 8 to 10 weeks conducting biomedical research with NIH investigators. Approximately 15 tribal students participated this past summer.
- *The Undergraduate Scholarship Program (UGSP)* provides up to \$20,000 in scholarship support per year to eligible undergraduates, including from underrepresented groups, who are pursuing degrees in fields related to biomedical research.
- *The Postbaccalaureate Intramural Research Training Award (IRTA) Program* is a biomedical research program that enables eligible recent college graduates planning to apply to graduate or professional school to spend one or two years gaining intensive research experience working with investigators at the NIH.
- *The Graduate Partnerships Program (GPP)* is an opportunity to conduct all or part of one's dissertation research at NIH.

Dr. Lorsch appealed to tribal representatives to share information about these programs within their communities, explaining that the only thing limiting more AI/AN students from attending them is a lack of applications from qualified students. More information about the programs can be found here: www.training.nih.gov/programs.

NIH Program and Policies

Sheila Caldwell, PhD—Program Director, CRCB, NIGMS

Dr. Caldwell serves as a Center for Research Capacity Building (CRCB) program officer, overseeing extramural researchers supported by NIGMS throughout the US. She expounded upon the programs introduced by Dr. Lorsch.

NARCH

Dr. Caldwell explained that NARCH was developed almost 15 years ago by three people: Leo Nolan, assistant to the Indian Health Service director; Clifton Poodry, PhD, director of the NIGMS Division of Minority Opportunities in Research; and William Freeman, MD, also from the Indian Health Service. These three stressed the urgency for a program that allows communities to specify their research needs. Originally operated in conjunction with IHS, NARCH remains a trans-NIH program with participation and funds contributed by many NIH institutes.

NARCH supports collaborations between federally recognized tribes and research-intensive academic institutions. Grants support health research projects prioritized by the communities and are awarded to tribal organizations that, in turn, maintain control over the research.

NARCH supports training of AI/AN scientists and health professionals engaged in biomedical, clinical, and behavioral research. Dr. Caldwell highlighted the benefit of trained tribal researchers working in their communities. This builds the capacity of AI/AN organizations and communities, enabling them to seek other grant opportunities within NIH and to continue research.

Components of a NARCH project may include any of these:

- Administrative core
- Student development project
- Faculty development project
- Capacity building project
- Research projects (including pilot projects)

No overarching scientific theme is required for NARCH applications; instead, the overarching goal of the application should be focused on the health research needs and requests of the AI/AN community.

IDeA

Dr. Caldwell briefly mentioned IDeA, noting that Dr. Lorsch had described the program earlier. She described INBRE's role in supporting research-intensive institutions in a state to work in a network with undergraduate institutions, rural community colleges, and tribal community colleges (known as TCUs) to develop and enhance research capacity and infrastructure. More than 20 TCUs currently work with INBREs. Some schools develop coursework that helps expose students to science, while other, more advanced programs have developed their own research projects and laboratories. TCUs are connected with INBREs and with each other in collaborative and mentoring relationships.

Research Supplements to Promote Diversity in Health-Related Research

This trans-institutional grant supplement program aims to improve the diversity of the research workforce by providing supplements to ongoing NIH-supported grants. This facilitates recruitment and training of students and postdoctoral fellows from diverse backgrounds—including underrepresented racial and ethnic groups, individuals with disabilities, and individuals from economically or educationally disadvantaged backgrounds—to pursue careers in biomedical research. Eligible grants must have at least two years remaining. The supplement program facilitates recruitment and training.

NIH Visit Week

This three-year-old program, which involves a week-long experience for high school and undergraduate students, exposes American Indian/Alaska Native and other young people to research opportunities at NIH, biomedical research and career opportunities and realities, and networking and career development support.

CRCB and the NIH Office of Intramural Training and Education (OITE) collaborate to expose students to science career workshops, hands-on laboratory and clinical research experiences, a science journal club, and networking opportunities with professionals and fellow students, including those associated with the Society for Advancing Chicanos/Hispanics and Native Americans in Science (SACNAS).

Some Visit Week attendees come back to NIH, while others are assisted in finding research opportunities in their local communities. Dr. Caldwell shared the story of an AI woman who participated in Visit Week, returned to perform an internship the following summer, and subsequently encouraged both her high school son and her sister to take part in the program. A male student returned after Visit Week for a summer internship, and a female student returned for a post-baccalaureate position and has just completed her first year of nursing graduate school.

More information about the training programs can be found here: www.training.nih.gov/programs. OITE Director Sharon Milgram, PhD has produced YouTube videos teaching students how to apply for research opportunities.

NARCH Scientific Highlight

Dr. Caldwell highlighted three NIH-supported projects in the AI/AN community:

- An Oklahoma NARCH project studied differences in diagnosing rheumatic diseases in the AI and Caucasian communities, with significant morbidity in AI populations. It appears that a more specific biomarker may exist in AI patients. The results were published in scientific journals, and the team translated the information into layman's terms and clinically implemented the diagnosis protocol.
- The Southwest Tribal American Research Center for Health/Albuquerque Area Indian Health Board created a program to support research internships in AI higher education to help students develop social and career skills in conducting behavioral and health science research. It provided tuition scholarships to 33 AI/AN graduate-level students and supported 18 AI/AN students through graduation with health science degrees.
- The North Dakota INBRE and Turtle Mountain Community College studied preeclampsia, a pregnancy complication characterized by high blood pressure that can cause organ damage. The purpose of the study, run by University of North Dakota professor Lyle Best, was to determine who may be at higher risk for severe preeclampsia in order to take preventive measures during pregnancy. The published results indicate that two variants of the c-reactive protein are associated with a risk of the disease in an AI population.

Interventions for Health Promotion and Disease Prevention in Native American Populations (R01) Funding Opportunity Announcement (FOA)

Shobha Srinivasan, PhD—Health Disparities Research Coordinator, Office of the Director, NCI

Dr. Srinivasan introduced the Intervention Research to Improve Native American Health (IRINAH) collaborative program within NIH. Nine Institutes participate in IRINAH, which is now in its fourth funding cycle. The Institutes are:

- National Institute on Alcohol Abuse and Addiction (NIAAA)
- National Cancer Institute (NCI)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Mental Health (NIMH)
- National Institute on Minority Health and Health Disparities (NIMHHD)
- National Institute on Nursing Research (NINR)
- Office of Behavioral and Social Sciences Research (OBSSR)

IRINAH FOA Goals

The goal of the R01 IRINAH FOA focuses on health promotion and disease prevention. It does not focus on a specific disease, and it is not directed toward treatment. It was largely developed with input from the tribes, the community, and researchers in order to identify the issues faced by the tribes and communities as well as methods for addressing them. Therefore, most of the issues incorporated within the FOA are relevant to the community, and the group hopes that it will address them.

Twenty-two projects are currently being funded by IRINAH, and proposals will next be reviewed on September 30. Applications are accepted once yearly. Information about funded projects and applying for grant monies can be found at www.cancercontrol.cancer.gov/nativeamericanintervention.

IRINAH research is expected to adapt, develop, and test interventions in the AI/AN populations in order to improve risk profiles at the individual, familial, and community levels. A combination of qualitative and quantitative methods can be used, and it requires researchers to partner with tribes or communities to:

- Identify concerns and issues of the community;
- Adopt or adapt methodologies that are relevant to and appropriate for AI/AN populations; and
- Implement appropriate study designs to address the complex and multi-layered causes of health inequities.

When needed, IRINAH encourages the development of tribe-researcher agreements that recognize tribal governance. An agreement may include a timeline for approval of manuscripts and abstracts. Dr. Srinivasan noted that such agreements may not be necessary when working in urban communities.

IRINAH FOA Requirements and Modifications

IRINAH is R01 research, which means it is investigator initiated and generally builds evidence based on existing data. Due to the specific needs of the AI/AN community—most specifically the exceedingly small sizes of many tribes and communities—some R01 requirements have been waived for this population. Consequently, generalization (i.e. how the study is applicable to other populations) is not required for IRINAH research funding, and previous pilot studies and/or data from the current community or tribe need not be provided. Instead, investigators can use similar appropriate studies in another community to provide justification for the proposed full-scale intervention and/or prevention study. The research plan must be consistent with community attitudes and account for community readiness for the intervention.

Research should incorporate a Community-Based Participatory Research (CBPR) approach, a collaborative approach that equitably involves all partners in the research process and recognizes unique community and cultural strengths and resiliencies. Applications should demonstrate a partnership between researchers and tribes or communities. If the application does not come from the community, then the research organization is encouraged to partner with the community; alternatively, tribes and communities that apply are encouraged to collaborate with researchers.

Recruitment of Individuals and Communities

Applicants must demonstrate evidence of a community's support and capacity to recruit participants, including its ability to:

- Implement measurement and intervention protocols in the target population
- Provide appropriate oversight
- Maintain appropriate levels of recruitment and retention throughout the intervention and follow-up period

Data Management

Issues of ownership, control, and storage of data and biological samples should be addressed in any application. Tribes and communities may wish to retain ownership or control of data and biological samples; this needs to be addressed in the application. Investigators need to address a Data Safety Monitoring Plan/or establish of a Data Safety Monitoring Board.

Innovation and Dissemination

R01 studies are expected to be innovative. IRINAH regards administering studies in small populations, replete with the challenges of implementing and adapting interventions, innovative in and of itself; applicants should be sure to affirm this in their grant applications. As well, the potential of the intervention to be incorporated into the medical care system, public-health system, and/or community structure of Native communities should be addressed in the application. Dr. Srinivasan noted the importance of demonstrating how the intervention may be disseminated and the scale of the study expanded for implementation in the communities in which the study was conducted.

Questions and Answers

Question 1

Tom Anderson (Cherokee) and with the Oklahoma City Area Indian Health Board, which is made up of 43 federally recognized tribes in Oklahoma, Kansas, and Texas, asked about the necessity of developing evidence-based projects in order to receive funding.

Answer: Judy Arroyo

Dr. Arroyo of NIAAA shared an example of a sobriety intervention that illustrated a tribe's ability to procure funding for a project that uses appropriate methodologies and builds the intervention beginning at the community level, rather than adapting a current intervention.

Answer: Dr. Srinivasan

Dr. Srinivasan validated Dr. Arroyo's point, adding that methodologies need not be limited to randomized control trials. IRINAH is flexible on study design, but applicants must justify the proposed methodologies. Dr. Srinivasan explained that she, Kathy Etz, PhD; and Dr. Caldwell have presented trainings across the US, including for the Native Research Network and at Spirit of the EAGLES meetings, focused on how to apply to this FOA. She encouraged communities and researchers to come together to apply. Currently, two more funding cycles are planned.

Question 2

IHB Vice Chair Laura Borden of the Yurok Tribe stated her concern about high cancer rates in Northern California tribes and asked about the potential of funding of research in that community.

Answer: Dr. Srinivasan

Dr. Srinivasan encouraged applying for funding to study a potential cancer cluster.

Answer: Dr. Etz

Dr. Etz distinguished the roles of NIH and CDC, noting that CDC would track disease rates to determine the existence of cancer clusters while NIH would research the disease indicators.

President's Precision Medicine Initiative (PMI)

Gwynne Jenkins, PhD—Executive Secretary, PMI Working Group of the Advisory Committee to the Director, Office of the Director, NIH

Dr. Jenkins provided background information regarding the evolution of PMI, starting with challenges to health care needs:

- Many diseases, such as diabetes, lupus, cancer, and chronic conditions including fibromyalgia, lack effective prevention strategies, diagnostics, or treatments.
 - Options fail to consider key differences among individuals, such as genes, lifestyle, and environment that affect quality of life.
- Research can be slow, costly, under-enrolled, and narrow in scope, and may not reflect “real world” situations in communities.
- Participants in biomedical research are often treated as subjects and not partners.
- Research findings take too long to be implemented into clinical practice.

Dr. Jenkins shared a clip of President Obama's State of the Union Address during which he discusses PMI, in response to which both parties stood and applauded.

Defining Precision Medicine

Precision medicine is defined as:

“An approach to disease treatment and prevention that seeks to maximize effectiveness by taking into account individual variability in genes, environment, and lifestyle. Precision medicine seeks to redefine our understanding of disease onset and progression, treatment response, and health outcomes through the more precise measurement of molecular, environmental, and behavioral factors that contribute to health and disease.”

Dr. Jenkins translated the definition above to “getting the right treatment to the right person at the right time.” PMI involves having the tools to make more accurate and precise diagnoses and to develop more rational disease prevention strategies grounded in the experiences that inform our individual health needs. It includes better treatment selection and the development of novel therapies.

PMI History

Since Dr. Collins proposed a similar initiative approximately 10 years ago, technology has greatly improved and costs have gone down significantly, making this moment ripe for PMI. Sequencing the humane genome went from \$22 million and two weeks in 2005 to about \$2,000 and less than one day in 2014. Sixty-six percent of people currently own smartphones, and electronic health records (EHR) are now used in 90% of hospitals (vs. 20-30% 10 years ago). Computing power is needed to handle this wealth of genetic and behavioral data, and it is now 16 times greater than it was a decade ago. Electronic data can add to our knowledge of what creates resilience and can illustrate disease onset and evolution.

The President proposed a budget of approximately \$215 million to support PMI. About \$5 million is earmarked for the Office of the National Coordinator for Health Information Technology, which assists with data standards in order to ensure communication between information systems, such as those in doctors' office and in hospitals. The Food and Drug Administration received funds for regulatory improvements, and \$70 million went to NCI for work on precision medicine oncology. Most of the PMI budget—\$130 million—funds the PMI Cohort Program.

In March of this year, Dr. Collins established the Working Group of PMI Advisory Committee to the NIH Director, charging it with developing a design for a PMI national research cohort. Members of the working group represent participants, industry, multiple research disciplines, academia, and other federal agencies.

The group organized four PMI Workshops over a five-month period. They were:

- Unique Scientific Opportunities for the PMI Cohort (NIH)
- Digital Health Data in a Million-Person PMI Cohort (Vanderbilt University)
- Participant Engagement and Health Equity (NIH)
- Mobile and Personal Technologies in Precision Medicine (Intel)

Other inputs included two requests for information (RFIs), which received feedback from 69 domestic and international responders, and the Foundation for the National Institutes of Health (FNIH) *Survey of Public Attitudes about Participation in PMI Cohort*.

Working Group Recommendations

The working group completed its report and presented it to Dr. Collins. The report was accepted on September 17 and included the following recommendations:

- The cohort should include at least 1 million US volunteers of all ages, health statuses, and geographic and economic diversity.
- Participants must be integrally involved in the design and implementation of the research and must be able to choose when to participate.
- Participants need to be able to choose when their data is used in research.
 - Dr. Jenkins noted that NIH is working with the Office of the National Coordinator of Health IT and the US Digital Service to address data security issues.
 - There is a need for balance between protecting personal information and providing access to the data.
- Technologies need to be innovative and interoperable.
 - EHRs need to be able to communicate with each other.
- Results must be returned to the individuals in the cohort at their request.

Possible Uses of a National Research Cohort

Dr. Jenkins shared potential uses of data collected through the PM cohort. They include:

- Sub-classification of diseases (i.e. identifying which groups do and do not develop certain diseases and then analyzing determinants)
- Testing of pharmacogenomics and the correlation of individual genetic variation with drug responses (i.e. delivering the right drug, including over-the-counter medication, to the right person at the right dose)
- Unbiased quantitative determination of disease risk (behavioral and genetic)
- Identification of resistance to disease as well as resilience
- Provision of new targeted therapies for disease
- Incorporation of participant-reported outcomes and engagement of participants in the shaping of research studies based on their preferences and needs
- Assessment of consequences of environmental exposures on health and disease
- Improvement of the utility of EHRs and other digital health data

NIH is able to plan implementation of the working group's recommendations. Dr. Etz noted the high level of prioritization for the project by NIH, expressed her hope that tribes would participate in it, and solicited suggestions for addressing communities' concerns and ways to better engage them.

Questions and Answers

Question 1

Mr. Anderson asked whether NIH has a policy or plan to do direct outreach to the tribes for conducting research and funding tribes directly.

Answer: Dr. Etz

Dr. Etz clarified that some NIH programs are solely directed to tribes or tribal organizations, such as NARCH. Also, because of its connection with tribal colleges, INBRE is a counterpart to direct outreach. She explained that, because of its mission relative to other operating divisions of HHS, NIH has most commonly awarded grants to the research institution where the lead investigator is employed (vs. to states or tribes). However, tribes are eligible to apply for NIH funding opportunities. She added that NIH does not currently have a plan to set aside funds for tribal communities; however, it is open to discussion about how to better engage and partner with them, and it hopes to receive input on this through tribal consultation as well as from the newly formed Tribal Consultation Advisory Committee (TCAC), which will hold its first in-person meeting soon. She then received the following ideas from the meeting participants:

1. Jerry Folsom of the Lummi Nation emphasized the need to begin the outreach process with tribal councils and governments, as they are the decision-makers and providers of funds and access to contacts outside the community.
2. Ms. Borden recommended working with IHS clinics to gain better access to tribal data as well as to engage participants.
3. Based on Mr. Folsom's and Ms. Borden's comments, Dr. Arroyo asked about whether e-mail lists for tribes exist for use in disseminating information and funding opportunity announcements (FOAs). Dr. Etz mentioned that the NIH Office of the Director is in the process of developing a website that will include all NIH FOAs relevant to tribal communities. It is also hoping to partner with the National Congress of American Indians by having links on its website. A new product is an NIH newsletter that will be disseminated four times annually to all tribal community health representatives (CHRs); the bulletin will highlight various research findings from NIH Institutes, with the goal of creating awareness and allowing tribes to clinically implement the findings.
4. Councilman Chester Antone of the Tohono O'odham Nation and TCAC Tucson Area delegate shared that Dr. Collins had indicated in an earlier meeting that there are no PMI study participant quotas in either direction and that all study participants will be self-referrals. Councilman Antone agreed with Mr. Folsom that the conversation of engaging in Native communities and soliciting study participants needs to take the form of a government-to-government consultation. Tribes will choose how much they will assert responsibility over their members; in those tribes where it is left to the individuals, self-referral would still be a viable option.

Tribal Comments, Issues, Testimony, Priorities

Dr. Etz entreated tribal leaders to mention anything or ask any questions that they had not shared to that point. Three leaders provided comments:

David Jesosee (sp) of the Navajo Nation in Arizona

Mr. Jesosee (sp) is a board member of the Fort Defiance Indian Hospital (FDIH). He raised concerns regarding the hospital's relationship with IHS. He noted that FDIH operates under the Indian Self-Determination and Education Assistance Act of 1975 (Public Law 93-638). The board has run the hospital under contract for almost 10 years and receives positive feedback. A nearby hospital recently began experiencing difficulties, and patients who would normally access it are coming instead to FDIH, whose service unit covers 16 local government chapters, each with a population of over 1000. This influx from other service units does not guarantee that payment follows those patients, and it is keeping many people who are in the service unit from being served.

Mr. Jesosee (sp) pointed to three areas in need of ongoing study:

- In 2008, a five-year plan was developed, and several federal agencies and the Navajo Nation began to work to clean up uranium. Remains of close to 500 uranium mines exist across the Navajo Nation; 10 of these have been designated as the highest priority as they pose the greatest danger to the communities.
- A birth cohort study is ongoing.
- This year, 3 million gallons of toxic wastewater from the Gold King mine were accidentally released into the Animas River and then the San Juan River. The environmental effects, which have been downplayed by the Environmental Protection Agency (EPA), are as yet unknown. Mr. Jesosee (sp) mentioned that effects in the community from an earlier spill into the Little Colorado River and eventually into the Colorado River have since been uncovered.

Ms. Borden

Ms. Borden explained that copious amounts of marijuana are grown in northern California. The growers are diverting water from creeks and streams, and the chemical runoff is damaging rivers and killing the fish that feed the Yurok tribe. This has plagued the tribe, affecting groundwater, land, a major food source, the Klamath River, Lake Klamath, and the community. Ms. Borden suggested that research is warranted and could affect policy and programs.

Dr. Etz will forward Ms. Borden's and others' comments to NIEHS for its consideration, as the environmental concerns raised today fit within that Institute's purview. She added that NIEHS is highly committed to hearing from the AI/AN community and to improving programs related to it. It will host a meeting in December focusing on traditional ecological knowledge and its ability to inform all research, particularly environmental health studies such as those introduced here.

Councilman Antone

Councilman Antone is looking forward to NIH supporting the tribal behavioral health agenda.

Closing Comments

Dr. Etz noted that this meeting was the first of its kind and that NIH is committed to engaging with the AI/AN community. She expressed the importance of tribal leaders' ongoing input and clarified that NIH is keenly aware that research is not always embraced by tribal communities. It is fiercely dedicated to conducting research with integrity and respect, and to ensuring participants' safety.

Dr. Etz reminded the tribal leaders that NIH does not deliver health services but wants to learn what it can do in its area to better serve communities. One way is by using research to identify the most effective interventions, thereby helping communities with few resources to use them most efficiently and powerfully. Another way is by providing information on unique disease markers for certain ethnic

groups in order to improve and more quickly employ interventions for certain diseases. The goal is to ensure that tribal communities have access to the tools NIH can bring to bear on positively affecting public health.

Dr. Etz thanked all presenters, particularly Dr. Lorsch, and recognized NIH staff members in attendance.

Ms. Elgin thanked everyone for providing valuable information to the attendees.

Closing Prayer

Councilman Antone offered the closing prayer.

Meeting adjourned at 3:37 p.m. ET.

Addendum 1: NIH Consultation Meeting Attendees

Tribal

Joe Aguilar, Santo Domingo Pueblo
Amber Anderson, Oklahoma City Area Indian Health Board
Tom Anderson, Oklahoma City Area Indian Health Board
Chester Antone, Tohono O'odham Nation
Wynette Arviso, Gallup Indian Medical Center Health Board
Fern Bates, United Indian Health Services
Laura Borden, Yurok
Kathy Castillo, Fort Mojave
Andrea Cazares-Diego, Greenville Rancheria
Adrian Dominguez, Urban Indian Health Institute
Nancy Ehlers, MACT Health Board
Jerald Folsom, Lummi
Kimberly Fowler, National Council of Urban Indian Health
Lila Garcia, ROCHE
Audre Gifford, Kenaitze
Laura Gon, Tuba City Regional Health Care Corporation
Vera Heubel, Stockbridge Munsee
Karla Iron, Oklahoma City Area Indian Tribal Health Board
Carol Larsen, United Indian Health Services/Paiute
Moriah O'Brien, Hobbs Strauss
Kris Rhodes, American Indian Cancer Foundation
Mary Tenorio, Santo Domingo Health Corporation
Julie Thorstenson, Cheyenne River Sioux Tribe
Matt Vogel, Cheyenne River Sioux Tribe
David, TMC
Stan, Gallup Indian Medical Center
Esther, BOD Tribal Regional
Laverne, SSU
Wanda

Federal

Paul Allis, FDA/Oneida
Robin Johnson, FDA
Sharece Tyer, SAMHSA
Jean Plaschke, SAMHSA/Lumbee

NIH

Dorothy Castille, NIH
Carl Hill, NIH/NIA
Joyce Hunter, NIH/NIMHD
Elizabeth McNeil, NIH/NINDS
Mona Puggal, NIH
Marc Smolonsky, NIH