NIH Tribal Consultation Advisory Committee (TCAC) Meeting
September 15-16, 2016
National Institutes of Health (NIH)
John Edward Porter Neuroscience Research Center
Bethesda, Maryland

Meeting Summary

I. Call to Order, Introduction and Meeting Goals

The meeting began at 9:04 a.m. with brief remarks from TCAC Chairperson Aaron Payment, chairperson of the Sault Ste. Marie Tribe of Chippewa Indians. Following the invocation from Beverly Cook, chief of the Saint Regis Mohawk Tribe, Chairperson Payment led introductions around the table and around the room. The introductions served as roll call.

Chairperson Payment also read the Federal Advisory Committee Act (FACA) meeting rules and invited TCAC members to share their meeting goals and expectations. The TCAC's plans for transitioning to the next Administration served as the top goal for Chester Antone of the Tohono O'odham Nation. Jace Killsback of the Northern Cheyenne Tribe requested details on the Tribal Health Research Office director position. Bruce Pratt, president of the Pawnee Nation of Oklahoma, agreed. Chairperson Payment suggested addressing the issue during a recess. Vernon Miller, chairperson of the Omaha Tribe of Nebraska, requested a future education session regarding NIH research issues facing AI/AN communities such as smoking, obesity, diabetes, or heart disease. Several tribal leaders also asked for such follow-up materials as a progress report or letter.

Chairperson Payment ended the opening session with a call for a motion to accept the meeting agenda with the addition of a review of TCAC priorities after the tribal caucus discussion. Councilman Antone made the motion. Walter Phelps, council delegate for the Navajo Nation, seconded.

A. Roll Call

1. **Tribal Consultation Advisory Committee Members**
   Chester Antone, Tucson Area Delegate
   Russell Attebery, California Area Alternate
   Alison Ball, Ph.D., National At-Large Alternate
   Beverly Cook, Nashville Area Delegate
   Denise Dillard, Ph.D., Alaska Area Delegate
   L. Jace Killsback, Billings Area Delegate
   Vernon Miller, Great Plains Area Alternate
   Aaron Payment, Bemidji Area Delegate
   Walter Phelps, Navajo Area Delegate
   Bruce Pratt, National At-Large Member Delegate
   Malia Villegas, Ed.D., National At-Large Member Delegate

2. **Technical Advisors**
   Tom Anderson, National At-Large Member
   Lyle Best, M.D., Great Plains Area
   Christy Duke/Kate Grismala, Nashville Area
   David Foley, Navajo Area

Deana Around Him, Dr.PH., National At-Large Member
Vanessa Hiratsuka, Ph.D., Alaska Area
Larry Jacques, Bemidji Area
Teshia Arambula Solomon, Ph.D., Tucson Area
Lisa Rey Thomas, Ph.D., National At-Large Member

3. **National Institutes of Health**
   James M. Anderson, M.D., Ph.D., NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives
   (See attached attendee list for other federal staff in attendance, but not at the table)

4. **Contractor Support**
   Kendra King Bowes, Native American Management Services
   Laura C. Jackson (note taker), Audio Associates

B. Meeting Agenda

- Highlights of Tribal Activities at NIH and Discussion
- Educational Session for NIH Staff on Tribal Caucuses
- Initial TCAC Charter Discussion
- Working Lunch with National Institute of Mental Health
- Administration on Native American Research Centers for Health (NARCH) Update and Discussion
- Precision Medicine Initiative® Cohort Program Presentation and Discussion
- Final NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research Presentation and Discussion
- Cancer Control in American Indian/Alaska Native (AI/AN) Populations Presentation and Discussion
- TCAC Charter Discussion
- Lunch with NIH AI/AN Scholars
- Discussion with NIH Director Francis Collins, M.D., Ph.D.

Action Items

- Chairperson Payment asked Dr. Anderson to circulate final plans for the October 9 consultation during the National Congress of American Indians (NCAI) Annual Convention to the rest of the TCAC members.
- Chairperson Payment asked for the revised charter to be circulated among the TCAC members for review.
- Dr. Villegas requested as part of the cancer discussion, more engagement with institutions that already have data and research capacity.
- Dr. Croyle requested specific examples on the types of infrastructure and research desired.
- Dr. Collins recommended TCAC members suggest the names of qualified individuals for review panels that reflect diversity.

II. Highlights of Tribal Activities at NIH and Discussion
James M. Anderson, M.D., Ph.D.

Dr. Anderson began by thanking the TCAC members who will rotate off the committee. NIH has received nominations for some but not all of the vacant seats. TCAC members were encouraged to assist with identifying prospective nominees.

The search for the Tribal Health Research Office (THRO) director continues to move ahead. Applications should be sent to the search committee in mid-September with interviews planned for October and November. NIH hopes to make a selection later in 2016. One of the first tasks of the new director is to work with NIH and AI/AN communities to create a strategic plan for the office.

The upcoming consultation will take place in conjunction with the NCAI Annual Convention being held October 9 in Phoenix. The top two TCAC recommended agenda items were:

- Environmental health
- Mental health

Dr. Anderson requested advice from TCAC members on how to organize and structure the consultation session. Councilman Phelps asked about the agenda for the consultation. TCAC tribal leaders recommended a short listening or roundtable session prior to consultation to encourage deeper discussion. Providing examples of how research has led to positive change for tribes or broader communities would also add value.

Dr. Villegas asked about the goals and impact of NIH research on mental and environmental health, and how Native communities can provide input. What are the tribal priorities? What are the key local and cultural insights and interventions regarding these issues? How will tribal ecological knowledge (TEK) play a role in the conversation? Chairman Miller said NIH should consider additional regional, area-wide consultations to reach tribes who will not be attending the NCAI Annual Convention in October. Chairman Miller also recommended co-chairing the consultation with a tribal leader. Chairperson Payment asked Dr. Anderson to circulate plans for the consultation to the rest of the TCAC members.

Dr. Anderson also noted that a member of the TCAC who is also a member of the Secretary's Tribal Advisory Committee (STAC) requested consultation on human subjects protections. This event, planned for fall 2016, may address such topics as:

- NIH's implementation of the Common Rule and relevant subparts
- A brief overview on what is involved with studying human subjects from NIH's perspective, with an emphasis on protecting vulnerable populations
- Research design and IRB approval
- Considerations on how researchers should explore specific areas of tradition and culture appropriately when studying Indian Country
- NIH guidance or points to consider on the involvement of tribes in research design

NIH will consider data sharing as a separate consultation topic. Dr. Anderson ended the presentation with a discussion on new initiatives in training, infrastructure and research such as epigenomics and funding for collaborative hubs to reduce suicide among tribal youth.

Chairperson Payment noted that research on epigenomics might legitimize the concept of historical trauma. Appropriate interventions, however, remain a problem in Native communities, said Dr. Alison Ball, health and human services director for the Confederated Tribes of the Colville Reservation. Rather than conducting studies and jumping to solutions, researchers should take time to identify good interventions for tribal communities.

Mr. Killsback agreed, noting the need for collaboration and partnership building to sustain the research and put valuable data to use when research projects end. Mr. Killsback also hoped to develop Native researchers who will see AI/AN communities through the same cultural lens.

Chief Cook added that science is catching up to what Indian Country has always known about health, diet, and the environment. So-called "experts" rarely listen, however, because decisions come down to money. Councilman Chester Antone designated Dr. Teshia Arambula Solomon to speak on his behalf and she recommended NIH collaborate with the National Library of Medicine or U.S. Department of Education to develop programs for schools. Chief Cook gave up her seat to Christy Duke who encouraged data sharing between researchers and Tribal Epidemiology Centers (TECs). Chairperson Payment hoped that the TCAC could identify which federal agencies conduct research and how that research informs practice.

III. Educational Session for NIH Staff on Tribal Caucuses

The session on tribal caucuses sought to promote transparency and learning between NIH and TCAC members, said Dr. Malia Villegas, TCAC co-chairperson and councilmember of the Native Village of Afognak. Dr. Villegas said tribal leaders seek to respect all participants' time during tribal caucuses while educating each other on the issues and developing a unified response. Caucuses also give TCAC members an opportunity to consider the needs of tribal communities not represented during the meeting.

Councilman Phelps noted that leadership meetings have become more popular for the Navajo Nation Council. During these events, council members identify a subject matter and bring in the key tribal leaders who need help or are involved with a certain issue. Leadership meetings help council members come to consensus before making a final decision.

IV. Initial TCAC Charter Discussion

During this session, TCAC members addressed changes to the charter, taking time to streamline, merge, or move language into more appropriate sections. The charters from the STAC and the AI/AN Health Research Advisory Council (HRAC) provided helpful guidance. As part of the conversation, members present at the meeting agreed to change the name of the group to Tribal Consultation and Advisory Committee.

Chief Cook asked if the incoming President could get rid of the TCAC. Dr. Anderson said NIH can establish advisory groups, so it is unlikely that the TCAC will go away.

Chief Cook also asked whether the charter should require elected leaders given that some tribes appoint leaders. TCAC members agreed that the current language seemed sufficient.

The members tabled the remaining discussion to prepare for the working lunch.

V. Working Lunch with Staff from the National Institute of Mental Health (NIMH)
Pamela Y. Collins, M.D., M.P.H
Associate Director, Special Populations
Director, Office for Research on Disparities and Global Mental Health
and Office of Rural Mental Health Research

Catherine Roca, M.D.
Chief, Women's Programs
Lead, American Indian/Alaska Native Research Programs
Office for Research on Disparities and Global Mental Health
Office of the Director

Dr. Collins began the working lunch with a presentation on an initiative that is under the U.S. chairmanship of the Arctic Council and particularly relevant to Alaska Natives. The RISING Sun effort stands for Reducing the Incidence of Suicide in Indigenous Groups -- Strengths United through Networks. NIMH is the technical lead under the Arctic Council.

The project uses research tools through stakeholder engagement and consensus building to come to agreement about outcome measures for suicide prevention interventions. The goal, said Dr. Collins, is to end up with a toolkit or set of interventions that communities can test or implement. RISING Sun encourages holistic approaches to mental health that address the social, economic, political, and legal resources that ultimately affect people's well-being.

Dr. Roca presented collaborative hubs to reduce suicide among AI/AN youth. These hubs are center grants that would fund collaborative groups of researchers, whether in one or across several Indian Health Service (IHS) areas, that want to investigate culturally appropriate, preventive interventions for youth suicide. Researchers must get input from communities right from the beginning of the project. Further, organizations involved in health care delivery and policy making also should play a role from the start so that communities can sustain successful projects.

Noting that these projects are good examples of community intervention, Dr. Villegas asked about the potential moving away or restructuring of budgets within the National Institute on Minority Health and Health Disparities, particularly around transdisciplinary collaborative centers. Dr. Collins said NIMH is one of the institutes that does have a division of services and intervention research. The office specifically focuses on services and implementation science in low-resource settings. Dr. Roca added that there will be interaction between the researchers for the global hubs and AI/AN researchers.

Councilman Antone appreciated the focus on a holistic perspective, which could aid in the understanding and healing from historical trauma.

Dr. Roca said historical trauma is one of the areas that researchers could address to promote resilience and reduce suicide rates. In the past, NIMH has funded a small number of studies on historical trauma.

Councilman Phelps asked if tribes have access to a program that goes through the state department. Chairperson Payment added that perhaps under the new Administration, tribes could be under the State Department, which would be more appropriate for international relations as tribes are independent sovereigns.

Dr. Collins clarified that the collaborative hubs are part of an NIH initiative. Through RISING Sun, NIMH works with the State Department specifically because of the U.S. chairmanship of the Arctic Council. NIMH provides a RISING Sun website and listserv.

Dr. Ball designated Dr. Thomas to speak and she posed a few questions about the number of proposals received, the regions represented and the participation of AI/AN principal investigators (PIs). Dr. Roca couldn't comment on the number of applications received but noted the involvement of AI/AN PIs.

Mr. Killsback stressed the need for tribal set-asides as Native communities struggle to write capacity building grants or renew Methamphetamine and Suicide Prevention Initiative (MSPI) funding from IHS. Collaborative hub funding has arrived a bit after the fact, said Mr. Killsback. Even so, such funding shows that NIH considers the perspectives of Native communities and researchers.

Dr. Villegas highlighted the value of disaggregating data and focusing on gender trends. A focus on mental health issues and homelessness, particularly among youth and veterans, also would greatly serve tribal communities. Further, researchers should consider the intersection between the environment and mental health. Co-occurring conditions need more attention, and the federal government should promote more cross-agency collaboration.

Discussions about research also should highlight such issues as indirect costs and dispute resolution, said Councilman Phelps. Last, Chairperson Payment reiterated a call for a comprehensive study on historical trauma.

VI. Administration of Native American Research Centers for Health (NARCH)
Update and Discussion
Sheila Caldwell, Ph.D.
Program Director, National Institute of General Medical Sciences (NIGMS)

NARCH supports collaborations between federally recognized AI/AN tribes/tribal organizations and research-intensive academic institutions. NIGMS is the coordinating Institute for the NARCH program and also contributes the largest sum of funds of the ICs. NIH provided $9,521,243 of FY2016 funding for NARCH VII and VIII projects from 13 Institutes. NARCH has established grant submission dates for 2016 and 2017.

Dr. Villegas wondered if NARCH capacity building mechanisms can help Native communities identify supportive interventions as well as the training and infrastructure needed along with research.

Dr. Caldwell said the NARCH program now works alongside the Institutional Development Award (IDeA) program, which has been in existence for quite a few years and is a congressionally mandated program. The IDeA program focuses on capacity and research infrastructure building. That means, for example, not only building a lab but developing institutional review boards (IRBs) and bringing in people who can conduct clinical trials that respect the community.

Chairman Attebery presented these health-related ideas and issues from the Karuk Tribe:

- Recruitment/retention of doctors and dentists in rural areas
- Diabetes prevention and treatment
- Youth and adult alcohol abuse treatment
- Elder care and treatment
- Behavioral health/opioid treatment
- Telehealth
- Accreditation exceptions in rural/frontier health
- Dental prevention and care

Dr. Dillard addressed the small amount of NARCH funding from such well-funded areas as the NCI, wondering if applications didn't receive funding or if NARCH didn't receive a large number of applications. Dr. Caldwell said NCI didn't receive many cancer applications. The Institutes would like to see the submission of more diverse research projects in different areas.

Dr. Dillard also asked if the NARCH funding is set-aside dollars. Dr. Caldwell said each Institute knows ahead of time how much money it can put toward NARCH. As tribal leaders commented on the success of NARCH in Native communities, Dr. Caldwell asked for ideas on better promoting the program. Dr. Ball encouraged Dr. Caldwell to promote NARCH during an NCAI conference. Dr. Caldwell was also encouraged to get staff members to work the phones.

VII. Precision Medicine Initiative® Cohort Program Presentation and Discussion
William T. Riley, Ph.D., Associate Director for Behavioral and Social Sciences Research, and Director, Office of Behavioral and Social Sciences Research, and Acting Deputy Director, PMI Cohort Program

The Precision Medicine Initiative (PMI), announced by President Barack Obama in 2015, will enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward the development of tailored, individual care.

Using PMI for cancer is a little further along, said Dr. Riley. In this arena, the process uses NCI clinical trial for models, identifies cancer subtypes and tests precision therapies with private sector partners. A national meeting on precision medicine and cancer in AI/AN communities will occur November 10 in Oklahoma.

The cohort program is a longer-term, more epidemiologic effort that will look at the full range of health and disease. This will include donated data from self-reporting, physicals, biospecimens, and medical records as well as technological and geographic sources. The cohort aims to include 1 million U.S. volunteers in addition to health care provider organizations and direct volunteers.

The PMI will involve its participants throughout the process and provide immediate feedback about their data. NIH hopes the cohort will reflect the rich diversity of America to produce meaningful health outcomes for populations traditionally underrepresented in health research. The effort will include participation across race/ethnicities, socioeconomic status, and geographic areas. Data collection will start small and grow over time. Privacy and security remain top concerns.

The University of Arizona has worked with the Inter Tribal Council of Arizona and the Navajo Nation to begin discussions on involving AI/ANs in the cohort study. Dr. Riley requested feedback from TCAC members on such issues as tribal nation consent, culturally appropriate content and materials, distribution of volunteer information, and pertinent research questions. TCAC members also could weigh in on the value of a pilot project specifically in AI/AN communities.

Chairperson Payment encouraged Dr. Riley to consider conducting virtual consultations via a webinar as well as consultations held in conjunction with such national tribal organizations as NCAI or the National Indian Health Board. Chairperson Payment also discussed research red flags for tribal communities such as handling human specimens and collecting, disaggregating, and using the data afterward.

Dr. Villegas asked about the value of the cohort project to tribes. Tribal research should both protect and benefit Native communities. NIH must identify the value of the project to help TCAC leaders and others spread the word. The project will generate numerous questions about collecting and reporting on the data as well as the involvement of any community stakeholder groups other than the participating colleges and universities, said Dr. Villegas.

Chairperson Payment asked how the cohort study will verify Native heritage or tribal enrollment. Tribal membership cards serve as one possibility in this complex issue. Councilman Antone added that if tribal members participate through a state health care center, tribal health care facilities should still have a connection to that data to render assistance as well. He then designated Dr. Solomon to speak on his behalf. Dr. Solomon followed up with numerous questions, including the purpose of the study, the method for gathering consent, and the sampling framework. Further, how will others use, interpret, and protect the data? Dr. Solomon also noted that some tribal members are also Mexican. How will the cohort study classify those members -- and who will make that decision? Will the data represent accurate information?

Last, Dr. Solomon asked how cohort participants have been fully involved in the study's sampling design. Although the study doesn't have a single participant as of yet, participants involved in the pilot process have assisted with survey approaches, said Dr. Riley. Those participants came from existing registries and internet-based panels.

Regarding the issue of identifying tribes, at this point the cohort study relies on standard national health interview survey types of models for determining race and ethnicity as a self-report measure. Cohorts are still in development, so the study hasn't finalized anything or collected any data. Councilman Antone said the identification of tribes will be important for follow-up care.

Chief Cook noted that her tribe has its own IRB, so the cohort study and purpose will need to be clear. Data use remains a major question as well -- and researchers will have to come back and request permission again to use the tribe's information in the future. Data and specimens usually come back to the tribe, said Chief Cook.

Chairperson Payment agreed that individual AI/AN participation in the cohort study presents jurisdictional issues as some tribal leaders may believe they have dominion over tribal members. Native Americans who live off or near a reservation might feel differently. Dr. Riley appreciated the TCAC's assistance in recognizing these and other complications as appropriate trust issues due to the history of Indian Country. At the same time, the study doesn't want an inadequate representation of AI/ANs.

Chairman Attebery sought ways for the cohort study to collaborate with NCAI's tribal data exchange. Noting the financial investment in the cohort study as well as other federal projects, Councilman Phelps asked about duplicative efforts. Councilman Phelps further questioned whether the study would address individual genetics or environmental factors as those from Navajo Nation remain concerned about water contamination, uranium exposure, and downwinders.

Councilman Phelps then designated his seat to Dr. Joslynn Lee who asked how researchers would interpret the data in the cohort study. Reviewers or Native researchers can keep others from skewing the data.

Dr. Riley said that at the point where data access is available, researchers must come in and ask to analyze the data. The PMI also will provide tiers of access. Returning to Councilman Phelps' question, Dr. Riley said the various projects under the U.S. Department of Health and Human Services are separate but coordinated.

Although tribal nations are complex, they have been on the North American continent the longest and can bring great value to the cohort study, said Chairperson Payment. NIH should seek to work with tribes as true partners.

A focus on genetics as well as poverty, environmental issues, and access to quality health care would certainly benefit communities such as the Colville Tribe, which suffers from high rates of cancer, diabetes and heart and lung deaths, said Dr. Ball. NIH should consider replicating the cohort study in Native communities in partnership with IHS because AI/AN communities suffer the most from health disparities, Dr. Ball added.

Dr. Dillard said researchers should follow tribal approval processes given the risk of stigmatization and harm. Tribal leader review and approval remain essential for study recruitment, data collection and publication. In his closing remarks, Chairperson Payment recommended organizing a large listening session to address these issues. Once that occurs, a framework can go to tribal consultation.

VIII. Final NIH Policy on the Use of a Single IRB for Multi-Site Research
Presentation and Discussion
Valery Gordon, Ph.D.
Director for Clinical Research Policy
Office of Science Policy

Dr. Gordon's presentation focused on the NIH Single IRB Policy and how AI/AN communities will not be affected by that policy. The policy, published in June 2016, will not take effect until September 2017 (the date was announced as May, but was extended after the TCAC meeting). Implementation plans are still under way. The draft policy proposed exceptions, and most commenters agreed that there was a need to allow for exceptions to the uses of a single IRB. A number of comments called for additional exceptions to those proposed in the policy. Dr. Gordon indicated that TCAC input will play an invaluable role in helping NIH to implement the policy.

Dr. Gordon reported that tribal nation commenters pointed to the importance of firsthand knowledge of local tribal customs, cultural values, and tribal sensitivities and supported exceptions to address those needs and respect tribal sovereignty. In its comments, the Cherokee Nation said a single IRB cannot adequately represent the unique needs and interests of the Cherokee Nation and other Native peoples. Further, tribal IRB reviews preserve tribal sovereignty and the rights of citizens and prevent irresponsible interpretation or publication of research data. The tribe supports the exemption in the draft policy.

The NIH policy applies to domestic sites of NIH-funded multi-site nonexempt human subjects research where all sites are conducting the same protocol.

There are exclusions to the policy: foreign sites; certain types of NIH awards (career development (K), institutional training (T), and fellowships (F)); and where review by the proposed single IRB would be prohibited by a federal, tribal, or state law, regulation, or policy. The policy also allows consideration of other exceptions if a compelling justification is provided.

NIH continues to work on implementation guidance, language for funding opportunity announcements and notices of award. NIH also is developing training for investigators and staff.

Dr. Gordon wants to reassure tribal nations that NIH understands the importance of tribal nation local review. Study sites that involve these populations will not be expected to use a single IRB, while the other domestic sites participating in a particular study will be expected to use a single IRB. Dr. Gordon asked for the TCAC's assistance in crafting language that reflects these expectations.

Regarding the exemptions process, Dr. Villegas asked who would initiate the exemptions and how would investigators and institutions learn of the exemptions? How would tribal communities find out about prospective research that might affect their interests? How will NIH track the policy's implementation? Dr. Gordon noted these and other questions to bring them to the policy implementation committees. As the exceptions committee's work gets under way, NIH should ensure tribal participation, said Chairman Miller.

TCAC members adjourned the meeting at 4:16 p.m. to go into tribal caucus. The meeting resumed at 9:00 a.m. on September 16, 2016. Chairman Miller did not attend the meeting on September 16.

IX. Cancer Control in AI/AN Populations
Presentation and Discussion
Robert Croyle, Ph.D.
Director, Division of Cancer Control and Population Sciences
National Cancer Institute (NCI)

Dr. Croyle compared cancer between various groups, particularly AI/AN communities. Variations between regions and between different areas of Indian Country have created the urgency for research. Dr. Croyle, for example, noted the differences between the northern plains and the southwest in terms of lung cancer incidence rates – reports strongly related to tobacco use. Alaska, on the other hand, reported high rates of colorectal cancer incidence. High rates of liver cancer show a connection to alcohol use and obesity, Dr. Croyle added. Kidney cancer also is of interest to researchers in the southwest.

Dr. Croyle noted the benefits of reducing tobacco use, even though there are economic benefits from tobacco sales. Colorectal screenings also present a great opportunity for reducing cancer mortality. Obesity rates are relevant as obesity is a risk factor for some types of cancers. Physical inactivity is a risk factor as well.

The cancer registry linkage depends on collaboration with IHS, said Dr. Croyle. The effort has involved a constant process of data linkage, verification of cancer cases and improving data quality. The trans-NIH collaboration involves working with other NIH Institutes on testing interventions to modify risky behavior and reduce risk with health promotion interventions. NIH has funded a number of grants to reduce tobacco use, obesity and alcohol use, Dr. Croyle added.

As the initiative continues to focus on developing interventions, adapting to community needs and working with other stakeholders, Dr. Croyle encouraged TCAC members to respond to the funding announcements or share the information with others.

Dr. Croyle also noted that NCI has a large clinical trial infrastructure, which assists with testing new drugs, therapies and technologies as well as imaging and screening strategies. Increased clinical trial participation from AI/AN communities would increase sample sizes and provide the statistical power to test questions. NCI continues to look at rural populations and the role that geography plays in cancer. A recent national conference on geospatial measures and approaches in cancer attracted nearly 500 people and included some AI/AN presentations. This issue has implications for Native communities, said Dr. Croyle.

The initiative also will continue to focus on data quality issues to improve the accuracy of cancer incidence estimates in AI/AN populations. A New Mexico registry, in collaboration with IHS and the

Centers for Disease Control and Prevention (CDC) has spearheaded the collection of AI/AN cancer incidence and mortality data and works on misclassification of AI/AN research information. Researchers also continue to focus on studies in small communities or within small populations.

Dr. Dillard asked if NIH has considered special calls for proposals that specifically address AI/AN populations – funding for cross-site studies or efforts that put resources behind the issue of small sample sizes. Further, the rates of colorectal screenings connect to the underfunding of the IHS budget. As a result, sufficient funding for screenings might not be available, said Dr. Dillard.

Dr. Croyle noted that as many people die from cancer due to poverty as from getting the wrong drugs. This remains a challenge as NIH is primarily a research funder. Quality-of-cancer-care issues and the lack of infrastructure for care delivery and dissemination of evidence-based care have come up during interim discussions of Vice President Joe Biden's Cancer Moonshot task force. NIH's role is to generate evidence to inform discussions with congressional staff, the CDC or IHS. Evidence already in hand regarding the scale of disparities, the types of cancers affected or evidence-based action steps to reduce cancer rates can assist in informing funding or policy strategies. State and local governments also play a role in interacting with tribes.

Regarding the call for proposals, Dr. Villegas requested more research in co-occurring conditions. In developing a talk on a Diabetes Moonshot to end diabetes in Native communities, Dr. Villegas noted the connection between cancer and diabetes. TECs remain established institutes of data and research. Dr. Villegas requested more engagement with institutions that already have data and research capacity. Further, coordinating centers would help data go forward so researchers can continue to learn from collected information.

Although data isn't a strength for IHS, it has partnered with the NIH Manuscript Submission system, demonstrating that partnerships can improve data. Last, cancer and diabetes awareness and prevention also raise concerns about pain management, said Dr. Villegas.

In response, Dr. Croyle requested specific examples on the types of infrastructure and research desired. Putting the consortium of cancer centers to work in Native communities also would help.

Referrals out for preventive procedures is the reason why tribal members receive late terminal diagnoses, said Mr. Killsback. The health care system keeps tribal members from seeking screenings.

In looking for creating solutions, tribes might have to link up with a biomedical company that could do a clinical trial on a reservation so the AI/AN community can receive early detection. These and other borderline ethical/unethical projects might be necessary to prevent more deaths in Indian Country. Even at the IRB level, tribes have been approached by drug companies that have circumvented or bypassed IHS to do drug trials, said Mr. Killsback.

Councilman Phelps asked how Dr. Croyle got the data shown in the presentation charts. How was the data aggregated in different regions and how were samples collected? For cancer treatment in the Navajo area, referrals go through contract health services, going off the reservation. IHS does not capture that data. Further, the Resource and Patient Management System (RPMS) that IHS uses can't gather data efficiently.

Dr. Kathy Cronin, who works with the NCI surveillance program, said incidence rates come from state registries. Cancer health care providers must report cases to these registries. For rates on Native

Americans, researchers used counties linked to IHS and tapped into the contract health services delivery area (CHSDA). Data outside of these resources likely will underestimate the rates.

Chief Cook agreed that data numbers are a mess, noting that doctors doing outside cancer referrals often will identify Native patients as white or other. Further, census numbers are inaccurate. The best data would come from tribal leaders or governments, said Chief Cook.

Chairperson Payment said one-third of the Sault Ste. Marie Tribe lives outside a CHSDA area. Further, Chairperson Payment's tribe needed two years to share data with the cancer registry due to trust issues. Tribes need a Cancer Moonshot for Indian Country as cancer might be a top killer in Native communities due to environmental issues and climate change. Chairperson Payment also wants HRAC to come up with guidelines on how to oversample.

Chairman Attebery wondered about research on polluted rivers. Fish in the Klamath River in California have long been a food source for the Karuk and other area tribes. However, studies have shown that 4,000 times the allowable toxic release is going into the river.

Dr. Croyle said NCI would have a small role as the National Institute of Environmental Health Sciences would serve in the lead role along with the Environmental Protection Agency (EPA).

In a cancer cluster investigation, NCI would consult with the state health department while the EPA would serve as the regulator. NCI must determine how to do more to answer those types of questions from Indian Country. That involves an interagency process to identify toxins. Doing the actual study to assess local impact and exposure would be outside of NCI's purview. NCI would focus on what to do from a health perspective once the data is available, said Dr. Croyle.

As NCI focuses on prevention, researchers must understand that smoking or alcohol use might be the result of childhood abuse, said Chief Cook. Researchers must look at a patient as a whole person who is part of a community. Tribes don't have the capacity or infrastructure to take a longer view on research. And perhaps the solution isn't more research but more funding to address the problems.

Councilman Antone agreed that tobacco, alcohol, and drug use connect to emotional issues. In areas where smoking or alcohol use is the highest, what has happened to those populations environmentally? Is there a change that researchers can attribute to tobacco misuse? The Tribal Behavioral Health Agenda can address these issues, added Councilman Antone.

NCI has created a health care delivery research program to measure and assess the systems level context of individual behavior in a cancer controlled context, said Dr. Croyle. TCAC members can teach investigators how to measure the contextual factors that researchers often overlook in traditional studies.

X. TCAC Charter Discussion

In the final charter discussion, TCAC members proposed language that encourages prospective members to have experience or interest relevant to research in general or NIH activities. TCAC chairs or co-chairs should be elected or appointed tribal leaders. TCAC members will select the chair and co-chair, who will serve for a term of one calendar year. There is no limit on the number of terms.

Further, during vacancies in the delegate position, the alternate will perform the duties of the delegate.

A replacement delegate or alternate will serve the remainder of the unexpired term of the original member and, if nominated again, may serve successive consecutive terms. Other changes to the charter addressed consecutive absences, technical advisors, and the desire to convene two face-to-face meetings each year depending on the availability of funds.

In another change, TCAC members or their respective tribes will submit the name and curriculum vitae of a proposed technical advisor to the NIH. Tribal leaders chose to remove "for consideration" from that sentence.

Chairperson Payment asked for the revised charter to circulate again among the TCAC members for review. The group recessed for tribal caucus prior to the lunch with the AI/AN scholars.

XI. Lunch with the NIH AI/AN Scholars

During this event, four NIH scholars shared their background, research and experiences with the TCAC members. **Sarah Kimmich** just finished a postbaccalaureate at NIH and will participate in a graduate program at NIH for two more years before going off to the University College London. **Alec Calac's** research at the National Institute of Neurological Disorders and Stroke (NINDS) focuses on using stem cells to regrow brain tissue. **Geanna Capitan**, who also works in NINDS, conducts research on functional movement disorders. Last, **Loretta Grey Cloud**, a dental assistant by training, works at the Institute for Dental and Cranial Facial Research.

Chairperson Payment reminded the students that Indian Country stands behind them and supports their efforts. These modern day warriors go out and advocate for information that will benefit Native communities, Chairperson Payment added.

XII. Discussion with NIH
Francis S. Collins, M.D., Ph.D.

Dr. Collins shared personal details and career milestones to shed light on important issues in research and ethics, particularly in the area of genetics. After a high school chemistry teacher sparked an interest in science, Dr. Collins studied at Yale University as well as the University of North Carolina's medical school before working at the University of Michigan.

The search for the genes responsible for diseases led Dr. Collins to work on the NIH Human Genome Project during the early 1990s. That project raised questions about applying research in a benevolent way, which led to the Ethical, Legal and Social Implications Project (ELSI), said Dr. Collins. ELSI took a deep dive into philosophy, theology and social science as well as the various ways cultures and groups see these issues. ELSI also gave Dr. Collins an opportunity to interact with Indian Country. Visits to tribal communities in Arizona and New Mexico taught the importance of listening before proposing solutions.

Dr. Collins left NIH in 2008 and returned to lead the agency in 2009. As director, Dr. Collins continues to look for ways to use basic science in a benevolent way to extend healthy life and reduce illness and disability. This work addresses environment, hereditary issues, disease prevention, science, law, public policy, and ethics.

Chairperson Payment noted the importance of NARCH in the success of the AI/AN scholars. Some of the Institutes with the largest budgets, however, make the smallest contributions to NARCH. Chairperson Payment wondered how those Institutes could contribute more. Dr. Collins said that the amount of

incoming applications drives the contributions. Even so, NARCH is a great program, said Dr. Collins, who wants to see more contributions as well.

Dr. Villegas thanked Dr. Collins for meeting with the TCAC and remaining committed to establishing the Tribal Health Research Office. In the area of research, Dr. Villegas noted the ongoing need to generate funding specifically related to AI/AN health.

TCAC members also want to continue examining co-occurring conditions and co-morbidities such as cancer and diabetes, diabetes and trauma, or the connection between physical and mental health. NIH should continue to look at cross-institute funding and invest in transdisciplinary approaches, dissemination and implementation. Further, NIH should work more closely with CDC and the Substance Abuse and Mental Health Services Administration.

As the nation embarks on the Cancer Moonshot and Precision Medicine initiatives, TCAC members seek a greater focus on how cancer and other health concerns present in Native communities due to historical trauma, said Dr. Villegas. NIH should consider a special focus on AI/ANs within these two efforts that is part of the funding. A pilot Precision Medicine program within Indian Country would address disparities and highlight the unique aspects of health in tribal communities.

Investments in research must also focus on infrastructure. How can NIH leverage the support of NARCH and TECs? Some organizations already have capacity around data and research as well as connections to IHS. Conversations about data also raise questions about collection, management, and oversampling, said Dr. Villegas. Adding to the discussion on infrastructure, Chairperson Payment reminded Dr. Collins that tribes have better data than census or CHSDA information.

Responding to the comments, Dr. Collins expressed an unawareness of the TECs. A tribal pilot project would require a thoughtful approach in terms of data access and the role of the private sector. However, the PMI must include everyone to achieve the desired vision, said Dr. Collins.

Dr. Dillard addressed the lack of experience and stereotyping that some researchers bring to their work in Indian Country. TCAC members have collected reviews that reflect biases. Further, western medicine may not fit within Indian Country. Dr. Dillard recommended diverse review committees, noting that poorly scored projects will not receive funding. Indian Country needs that kind of infrastructure investment even during this time of intense competition and limited funding. Dr. Collins agreed that review panels must reflect diversity. To further help this process, TCAC members could suggest the names of qualified individuals.

In addressing cancer prevention in tribal communities, NIH should examine why people drink, smoke, or engage in risky behavior, said Councilman Antone. Native Americans might not realize that traumatic events from the 1900s to the 1950s trigger unhealthy responses to stress today. Addressing those contributing factors might improve prevention.

Chief Cook's husband died two years ago from liver cancer due to the early use of alcohol and drugs in an attempt to self-medicate from childhood physical and sexual abuse. The pattern of alcohol abuse in the family extended back to the boarding school experience and historical trauma, said Chief Cook. The trauma continues today as tribes continue to fight for resources and a listening ear. What are the correct interventions to turn the tide?

Dr. Collins thanked Chief Cook for those personal remarks, noting that researchers often focus on big

ideas and principles rather than the individual. Such a story should remind everyone that research is more than just an academic exercise.

Dr. Ball added that tribes need a mechanism similar to an R21 to help Native communities build family interventions and address incidents such as the one Chief Cook shared. Those stories are typical in Indian communities, said Dr. Ball.

After decades of uranium mining contamination and most recently the Gold King Mine Spill, the Navajo Nation seeks research in the environmental influences and contributing factors of cancers, said Councilman Phelps. The Navajo Nation also needs access to cancer treatment centers so tribal members won't need referrals off the nation to other locations.

In addition to investments in PMI and the Moonshot projects, the Navajo Nation wants funding for tribal needs. Further, NIH must address data management issues in ways that benefit tribes. Dr. Collins said NIH continues to focus on knocking down barriers to information access. That means, for example, making the results of clinical trials immediately available to everyone. In fact, clinical trial information must go on clinicaltrials.gov, a widely used database, within a year after the last data point collection.

Turning to the topic of the elections, Chairperson Payment said that, if needed, TCAC members as well as NCAI can assist NIH in developing or strengthening its transition plan for the next Administration. Dr. Collins said that NIH is not a particularly political organization. Medical research tends to be a bipartisan effort as everyone cares about good health for themselves and their loved ones. Dr. Collins and the head of the NCI are the only two political appointees. NIH will develop a transition plan for the next President so the Institution will not lose momentum on critical projects. As that process begins, NIH staff may follow up for tribal input.

Following the closing prayer, the meeting adjourned at 2:31 p.m.

NIH Tribal Consultation Advisory Committee Meeting
September 15-16, 2016

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