

NIH Tribal Consultation Advisory Committee (TCAC) Meeting February 25-26, 2016

**National Institutes of Health (NIH)
Bethesda, MD 20892**

Executive Summary

The NIH Tribal Consultation Advisory Committee (TCAC) held a two-day meeting February 25-26, 2016 on the National Institutes of Health (NIH) campus in Bethesda, MD.

Chairperson Aaron Payment led and moderated the meeting, which was co-led by TCAC Co-Chairperson Malia Villegas, EdD. Senior Advisor for Tribal Affairs to the Principal Deputy Director Kathy Etz, PhD provided staff support to the committee. TCAC members listened to presentations and participated in discussions around a number of subject areas. Alternates, technical advisors, and staff were also in attendance. The meeting was audiorecorded and videocast; the archived videocast can be found here: <https://videocast.nih.gov>.

Councilwoman Villegas shared the four ways in which the TCAC had begun to define its role:

1. Inform the process of tribal consultation with NIH
2. Assist NIH with developing research policy with significance to Tribal Nations and Native communities by informing the substance and process of policy development
3. Develop a list of priority topics for funding proposals
4. Develop protocols for communication with NIH and meeting processes

NIH American Indian and Alaska Native Activities

Navajo Nation Visit

NIH Principal Deputy Director Lawrence Tabak, DDS, PhD summarized his experience from the NIH visit to the Navajo Nation in January. The visit included representatives from the U.S. Department of Health and Human Services (HHS) operating divisions (OpDivs) of Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

HHS representatives met with Navajo Nation Council leaders and delegates, receiving a broad range of feedback around numerous issues affecting the tribe. The group toured and met with staff at the Fort Defiance Outpatient Center's Department of Behavioral Health Services and Medical Center, witnessing the effective integration of Navajo practice into approaches to treatment and surveillance. Other issues discussed included data systems, data integration, services, and service provision.

Selected Secretary's Tribal Advisory Committee (STAC) Priority Areas

Dr. Tabak shared updates and information on the selected STAC priority areas of suicide prevention research and historical trauma research, sharing examples of work being done in the field. He described the Environmental Influences on Child Health Outcomes (ECHO) program, which seeks to investigate the longitudinal effects of pre-, peri-, and postnatal environmental exposures on pediatric development and health outcomes with high public health impact. Research questions that may be addressed through ECHO include the contributions of genetic and environmental influences on child health, disease resiliency and susceptibility, the molecular and behavioral mechanisms involved in maintaining a healthy weight, factors in chronic disease, and predictors of risk for the key focus areas of childhood outcomes. An open discussion followed, focusing on historical trauma and its effects, and on ECHO.

NIH and Tribal Health Research

NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives (DPCPSI) James Anderson, MD, PhD, will be working directly with the TCAC. DPCPSI's cross-division position at NIH will be critical for tribal health efforts.

Dr. Anderson looks forward to exchanging ideas about how to include cultural context and make research for the Tribal Nations more valid, and he shared ways in which NIH has organized itself to work more productively with the TCAC and federally recognized tribes. He also provided highlights of the NIH implementation of the HHS Tribal Consultation Policy; this includes the establishment of the Tribal Health Research Office (THRO) in fall 2015. Some of the many goals of the office include coordinating tribal health research-related activities across NIH (this includes a trans-NIH coordinating committee that will meet regularly to determine and examine priorities and ways to work together), serving as a liaison to and NIH representative on tribal health-related committees and working groups, coordinating and supporting the NIH TCAC, and collaborating with NIH Institutes and Centers (ICs) to leverage resources or develop initiatives to support tribal health research.

The three main TCP-related activities being started at this time are: 1) Establishing the internal research coordinating committee, as discussed above; 2) Conducting a highly detailed portfolio analysis of AI/AN research and research training portfolio; and 3) Initiating a strategic planning process.

An open discussion followed, focusing on portfolio analysis, organization and assessment, reasons for funding denials, the THRO director, the *NIH Guidance on Implementation of the HHS Tribal Consultation Policy (2013)*, and the coordination of efforts.

Ethical Review of Research with Tribal Communities: NIH Training Opportunities

National Human Genome Research Institute (NHGRI) Institutional Review Board (IRB) Chair Sara Chandros Hull, PhD highlighted five NIH training opportunities. Formal training modules and on-

campus activities exist that are chiefly limited to NIH staff and members; Dr. Hull pinpointed the following specific opportunities that are available to those outside of NIH:

- NIH Ethical and Regulatory Aspects of Clinical Research Course
- Collaborative Research Center for American Indian Health (CRCAIH) IRB Toolkit
- NIH IRB Internship Program
- Native Research Network (NRN) Pre-Conference Workshop
- Potential Public Responsibility in Medicine and Research (PRIM&R) Partnership

Dr. Hull then presented questions for consideration by the TCAC focusing on the use of resources and on identification of participants, topics, content, and ongoing collaboration and partnership.

An open discussion followed that focused on the similarities, differences, and challenges of tribal councils and IRBs; capacity building and technical support; efficiency and resource-leveraging in research; effects of drug research; and shared focus on individuals and communities.

Conversation with NIH American Indian/Alaska Native (AI/AN) Scholars

NIH Native scholars provided brief overviews of themselves, after which an open dialogue took place with TCAC members around supporting the scholars' work and around connecting tribal communities to the resources of NIH. Issues discussed included data ownership, identification and community, postdoc training needs, and the value and struggle of being a native scholar at NIH.

Indigenous Ways of Knowing and the Traditional Ecological Knowledge (TEK) Workshop

Indigenous Ways of Knowing (IWK)

Dr. Etz provided definitions of Indigenous knowledge and examined the ways in which IWK informs NIH-funded AI/AN research. She described Indigenous research strategies and methods, and she shared examples of funding opportunity announcements (FOAs) that incorporate Indigenous knowledge.

Traditional Ecological Knowledge (TEK) Workshop Review and Recommendations

Review

NIH National Institute of Environmental Health Sciences (NIEHS) Health Scientist Administrator Symma Finn, PhD provided an overview of the presentation on the recent TEK workshop: "The Value of Tribal Ecological Knowledge", including recommendations being submitted to the TCAC for its consideration. She described the workshop's development, and she illustrated the context and definition of TEK, the workshop's coordination with other federal and tribal efforts, mutual respect and knowledge sharing at the workshop, and the event's outcomes.

Recommendations

Indian Health Service (IHS) Office of Public Health Support Division of Planning, Evaluation, and Research Director Mose Herne shared the workshop recommendations in three groupings: Research Strategies and Collaboration; Building Research and Health Literacy Capacity; and Policy Considerations.

Saint Regis Mohawk Tribal Council Chief Beverly Cook's TEK Workshop Report

TCAC National At-Large Member Delegate Lynn Malerba, Chief, Mohegan Tribe, shared Chief Cook's report on the TEK Workshop.

Overview of the Center for Scientific Review and NIH Peer Review

NIH Center for Scientific Review (CSR) Director Richard Nakamura, PhD provided an overview of the CSR, and he explained the extensive and multi-layered NIH peer review process for grant applications. In the open discussion about the review process that ensued, the following issues were raised: Decreasing grant success rates; funding of new research ideas; limitations on describing nuances of specific behavioral research; the breakdown of Early Career Review Program invitees by race/ethnicity and background; how AI/AN research projects truly compete in the biased review environment; in-depth analysis of recent applications to NIH that involve AI/AN populations and/or investigators; the need to increase the number of AI/AN reviewers; potential conflicts of interest; Common Rule changes; challenges around research of small populations; the TCAC's engagement around the peer review dialogue; and tribal set-asides.

Office of Science Policy Update and Discussion: Use of a Single IRB for Multi-Site Research

NIH Office of Science Policy (OSP) Director Carrie Wolinetz, PhD introduced the "Use of a Single IRB (sIRB) for Multi-Site Research" policy, explaining the reasoning and process leading to its creation, specifics of the sIRB policy, and its exemptions. The final policy is currently undergoing a bureaucratic review process, is expected to be released in May 2016, and will likely go into effect in January 2017. The policy will only affect new and competing awards and will not be applied retroactively to existing research projects. OSP will develop implementation plans and guidance internally for NIH and for the extramural community.

An open discussion followed, focusing on the bolstering of support for the sIRB policy, ethics, exemptions, concerns around minimization of tribal IRBs, reach and impact, and protection of specimens.

Tribal Caucus

A tribal caucus was held but was not open to the public; it was not audiorecorded or videocast.

Updates from the NIH Director

NIH Director Francis Collins, MD, PhD expressed his goal of meeting with the TCAC as often as possible, and he indicated his desire to share information and his greater interest in listening. He shared a few points that he felt could inform the conversation:

Exceptional Opportunities in Biomedical Research

Dr. Collins provided a brief overview of three broad areas of focus: Unraveling Life's Mysteries through Basic Research; Translating Discovery into Health; and New Initiatives, which include the Precision Medicine Initiative® (PMI) and the National Cancer "Moonshot".

An open discussion followed. Issues raised included oversampling of the AI/AN community in PMI, the definition of "Indian", access of genetic data, building trust to encourage research participation, provision of research resources, application of the NIH model of working with sovereign nations, researching tribal authorities' reach, and the need to educate tribal leaders around technology and interventions.

Panel Presentations and Discussion: Training Opportunities within NIH

Office of Intramural Training and Education (OITE)

NIH OITE Director Sharon Milgram, PhD shared all of OITE's training programs, from the summer internship program for high school students through postdoc programs for senior scholars.

An open discussion followed, focusing on the role in creating opportunities for students closer to home and the students' postbacc and postdoc experiences.

Office of Science Education: Science Education Partnership Award (SEPA) Program

NIH Office of Science Education Director Tony Beck, PhD introduced the Science Education Partnership Award (SEPA) Program, a research science education program in which all tribal communities are eligible to participate. He shared the program's impacts, career support, reach, and access.

NIH's Training and Career Development Programs

NIH Office of Extramural Research (OER) Training Program Policy Officer Henry Khachaturian, PhD provided the TCAC with a brief overview of NIH's formal training programs, sharing advice for navigating them and for determining the best training options. He discussed specific awards, including the Ruth L. Kirschstein National Research Service Award (NRSA) and research career development awards.

Extramural Training Opportunities

NIH National Institute of General Medical Sciences (NIGMS) Program Director Sheila Caldwell, PhD highlighted three of the numerous training opportunities that have been used by those in Indian Country: Bridges to the Baccalaureate (R25); IDeA Networks of Biomedical Research Excellence (INBRE); and Native American Research Centers for Health (NARCH).

Additional Opportunities

Dr. Etz noted additional training vehicles, including the Native Investigator Development Program, the Johns Hopkins Center for American Indian Health (CAIH) Bloomberg School of Public Health's Summer and Winter Institutes, and the Northwest Portland Area Indian Health

Board (NPAIHB) Summer Research Training Institute for American Indian and Alaska Native Health Professionals.

TCAC members then provided guidance on how NIH can improve its outreach efforts to the AI/AN community.

FOA Development: Plants/Natural Products Discovery Program

Dr. Caldwell presented a potential FOA for discovery of bioactive natural products by AI/AN researchers, with the goal of receiving input and feedback from the TCAC as to whether to proceed with the idea. TCAC members expressed interest in and excitement about the project, and they raised concerns around long-term impacts, ethics protections, environmental health, cultural resource protection, community benefits for participating, intellectual property, and credit and compensation for indigenous investigators. Members were pleased to see the federal government recognizing traditional medicine and holistic healing as a part of native peoples' well-being. Ideas related to rollout were discussed.

Discussion with NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives

Dr. Anderson and TCAC members discussed issues relating to the development of the consultation process, parameters, and goals, and about the continuing dialogue between NIH and the tribes. Prioritization of TCAC themes and activities were the source of conversation as well. Thus far, two topics identified as necessitating consultation are the sIRB policy and genomic data sharing.

Committee Planning

Follow-up from this meeting and planning of the next in-person meeting—including scheduling and content—were discussed, along with the timeframe and terms for delegates. Concerns were shared about NIH NARCH grant administration.

Wrap-Up

Meeting notes will be provided after the March 8 teleconference.

This was the final full meeting with Dr. Etz, who will return to the National Institute on Drug Abuse. Appreciation was expressed by both her and by the TCAC.

Dr. Anderson expressed his gratitude to all for their thoughtful input, explaining that it is critical that the research NIH does is valid and useful to the communities that it serves.