

Tribal Advisory Committee (TAC) Meeting**March 13-14, 2018****National Institutes of Health (NIH)****Building 31C, Sixth Floor, Room 10****31 Center Drive****Bethesda, Maryland****Meeting Summary****I. Call to Order, Introduction, Welcome and Meeting Goals**

The Tribal Advisory Committee (TAC) in-person meeting began at 9:00 a.m. with a call to order from Chairperson and National At-Large Delegate Liana Onnen. Walter Phelps, a councilman for the Navajo Nation, gave the invocation before Chairperson Onnen led introductions around the table and the room. Chairperson Onnen, who is also chairwoman of the Prairie Band Potawatomi, read the Federal Advisory Committee Act (FACA) meeting requirements and discussed meeting goals and expectations.

James M. Anderson, M.D., Ph.D., welcomed meeting participants to NIH. Now in its third year, the TAC has picked up momentum, especially with the development of the Tribal Health Research Office (THRO) and the arrival of THRO Director David Wilson, Ph.D. The release of THRO's strategic plan later in 2018 will serve as a real milestone for the office, said Dr. Anderson.

Dr. Wilson challenged TAC members to use the two-day working meeting to identify ways to collaborate more effectively as the committee moves forward and identifies priorities. Further, as engagement opportunities increase, TAC members should think about representing the committee in different venues, said Dr. Wilson. Dr. Wilson suggested postponing additional discussions on the committee charter until TAC members identify roles and ways to work together. During the fall 2018 in-person meeting, Dr. Wilson will present a list of changes/modifications to the TAC for discussion. The charter would then go to the Office of General Counsel for approval.

Dr. Wilson also asked TAC members to submit via e-mail chair and co-chair nominations for the next year. Dr. Wilson planned to present a list of nominations to the TAC for a final vote at the beginning of the Wednesday, March 13, meeting session.

A. Roll Call**1. Tribal Advisory Committee Members**

Co-Chairperson Chester Antone, Tucson Area Delegate (*via telephone*)

Alison Ball, Ph.D., National At-Large Delegate

Denise Dillard, Ph.D., National At-Large Delegate

Eddie Johnson, Aberdeen/Great Plains Area Delegate

Lynn Malerba, D.N.P., National At-Large Delegate

Chairperson Liana Onnen, National At-Large Delegate

Walter Phelps, Navajo Area Delegate

Daniel L.A. Preston III, Tucson Area Alternate

Bobby Saunkeah and David Wharton, Oklahoma Area Delegate and Alternate

Andrew Shogren, J.D., Portland Area (*proxy for Delegate Robin Little Wing Sigo*)

Tina Woods, Ph.D., Alaska Area (*proxy for Delegate Donna Galbreath*)

2. Technical Advisors

Breannon E. Babbel, Ph.D., National At-Large

Lyle Best, M.D., Great Plains Area

Christy Duke, Nashville Area

David Foley, Navajo Area

A. Jay Mooney, National At-Large

Michael Peercy, Oklahoma Area

Yvette Roubideaux, M.D., National At-Large

Jennifer Shaw, Ph.D., National At-Large

Teshia G. Arambula Solomon, Ph.D., Tucson Area (*via telephone*)

Abbie Wolfe, Alaska Area

3. National Institutes of Health

Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, National Institutes of Health

James M. Anderson, M.D., Ph.D., NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives

David R. Wilson, Ph.D., Director, Tribal Health Research Office

(See attached attendee list for other federal staff in attendance, but not at the table)

B. Meeting Agenda

- Conversation with NIH Director Francis Collins, M.D., Ph.D.
- Highlights of Tribal Activities at NIH
- Presentation from the National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- A review of Points to Consider, a document designed to assist those conducting research in Indian Country
- Focus on 2018 TAC priorities
- Discussion on the 2018 Tribal Consultation
- ECHO Research Program Update
- Thoughts on the Roles of TAC Technical Advisors
- *All of UsSM* Research Program Highlights

C. Action Items

- During the fall 2018 in-person meeting, Dr. Wilson will present a list of changes/modifications to the TAC charter for discussion.
- Lawrence Tabak, Ph.D., recommended planning a conversation with the Center for Scientific Review (CSR) during the next TAC in-person meeting.
- Dr. Wilson will talk to Tucson Area Delegate Chester Antone about planning a traditional medicine conference.
- The Tribal Health Research Office will send out a Dear Tribal Leader letter announcing TAC vacancies.

2. Highlights of Tribal Activities at NIH and Discussion

David R. Wilson, Ph.D., Director, Tribal Health Research Office (THRO)

Dr. Wilson opened the first TAC meeting presentation by recognizing THRO Health Science Policy Analyst, Marissa Rodriguez, who assisted in developing the office's new logo. THRO began working on the logo in November 2017 to prepare for 2018 Native American Heritage Recognition Month. The logo clearly depicts how THRO seeks to coordinate all the NIH activities that impact tribal nations. The logo also highlights five key areas: Research Careers, Programs, Policies, Health Research and Community Engagement.

Dr. Wilson discussed the following priority topics for the TAC:

2018 Tribal Consultation

The opioid consultation / listening session, scheduled to take place in Prior Lake, Minnesota, continues to generate great interest. The consultation will take place May 21-22, followed by the National Indian Health Board (NIHB) Ninth Annual National Tribal Public Health Summit May 22-24. Collaborating with the NIHB helps the THRO educate Native American leaders on the important research occurring at NIH to address the opioid issue.

The national tribal consultation / listening session on the effects of opioids in Indian Country will present extensive information from three agencies: NIH, the Indian Health Service (IHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA). Several of the NIH Institutes and Centers (ICs) also plan to participate, including the National Institute on Drug Abuse, the National Institute on Mental Health, and the National Institute on Minority Health and Health Disparities (NIMHD).

Dr. Wilson provided a draft consultation agenda. THRO continues to seek input from the TAC on a uniform structure for future NIH tribal consultations.

THRO Engagement with NIH Programs

Dr. Wilson briefly discussed ongoing efforts with such NIH programs as the Environmental influences on Child Health Outcomes (ECHO) and the longstanding Strong Heart Study with the National Heart, Lung, and Blood Institute. Each engagement activity helps the THRO staff create a strategy that can show others how to work effectively with tribal communities.

FY15 AI/AN Portfolio Analysis Update

THRO continues to format and prepare a completed American Indian/Alaska Native (AI/AN) Health Research Portfolio Analysis for FY2015. The THRO will use this initial analysis to assess NIH's investment in tribal health research. TAC members will receive a review copy soon. Because the analysis serves as a starting point, members should think of ways to better present the data and make note of any missing information in this initial analysis.

Strategic Plan Update

Completing the strategic plan is a paramount goal as THRO staff and TAC members seek direction for addressing health research needs in Indian Country. Dr. Wilson has consolidated lists of TAC priorities into a short list of goals. The 2017 NIH Consultation in Alaska provided further input and refinement.

Members of the NIH Tribal Health Research Coordinating Committee (THRCC), including some who have worked on tribal issues for decades, offered extensive knowledge about IC priorities that would affect tribal communities. Those recommendations also shaped initial draft priorities for the strategic plan. Further, the THRO's Request for Information (RFI) ended in February.

Responding to a question from National At-Large Delegate Lynn Malerba, D.N.P., Dr. Wilson noted that the RFI requested additional comments electronically from the NIH community. The RFI also went to such stakeholders as NIHB, the American Indian Science and Engineering Society (AISES), and the Society for Advancement of Chicanos/Hispanics and Native Americans in Science. Comments received focused largely on professional/workforce development. Other comments touched on environmental factors that the THRO did not initially include. THRO continues to incorporate RFI input into the strategic plan.

TAC members have received an extensive list of the proposed strategic priorities. Each priority includes strategic objectives. Committee goals for 2018 should fall within these five areas:

- Enhance Communication and Coordination
- Build Research Capacity
- Expand Research
- Evaluate Progress
- Cultural Competency and Community Engagement

Next steps for the strategic plan include incorporating the RFI data and sending another draft to the THRCC. The strategic plan will then come back to the TAC for review and comment. NIH Director Dr. Francis Collins also will read and approve the document before THRO publishes the strategic plan.

2017 NIH Native American Heritage Month

Erik J. Sorensen, Ph.D., of Princeton University's Department of Chemistry, lectured at NIH in November to highlight research in organic chemistry synthesis and discuss the challenges of increasing Native American participation in chemistry.

This event honored Native American Heritage Month and met a top TAC priority: to build a strong, coordinated community of AI/AN researchers. THRO will continue to expand this pool of scientific community members. Dr. Sorensen's talk also addressed another goal: addressing cross-cutting areas of cultural competency and community engagement. Dr. Sorensen's ideas and best practices can help NIH increase its recruitment/retention rates for AI/AN students and researchers. Dr. Wilson challenged the TAC to begin thinking of ideas for the November 2018 event.

Focus on Strategic Priority 2 in 2018: Build Research Capacity

This year the THRO aims to build a strong, coordinated community of AI/AN researchers and expand scientific knowledge to improve the health of Native communities. Activities to support Priority 2 include these points:

- Coordinate summer internship activities across NIH so that Native students have support while working in a unique environment
- Collaborate with the largest AI/AN scientific society

Dr. Wilson presented a summer internship information flier developed in coordination with the Office of Intramural Training and Education (OITE). The flier highlights available programs that might interest AI/AN students. Tribal communities can use this document to help young adults prepare for 2019.

THRO also plans to conduct the fall 2018 TAC in-person meeting during the AISES National Conference October 4-6 in Oklahoma City. During this event, which is expected to attract 2,500 participants, TAC members can talk to undergraduates about careers in biomedical research and explain how such work can benefit tribal communities. TAC members also will learn how to address student challenges. OITE will attend the conference as well to help students navigate the NIH student internship process. NIH hopes to increase its AI/AN recruitment numbers after this event, said Dr. Wilson.

Dr. Wilson also highlighted the Navajo Nation Genetics Workshop summary and a Joint Tribal Advisory Committee meeting scheduled for July 24, 2018, at the Omni Hotel in Washington, DC. A summit on AI/AN Behavioral Health will follow July 25-27, 2018, in the same location.

NALM Delegate Denise Dillard, Ph.D., asked for more details on the NIH THRCC. The committee typically meets every month, said Dr. Wilson. The group has not yet discussed how it will address Strategic Priority 2; however, this large committee remains engaged and represents various NIH offices and ICs. The committee helped push through the portfolio analysis and the strategic plan. The next big task: how to work together to unify the summer internship process.

3. National Institute on Alcohol Abuse and Alcoholism (NIAAA) Presentation and Discussion

Judith A. Arroyo, Ph.D.

Minority Health and Health Disparities Coordinator

Office of the Director

NIAAA has launched the Native Communities Alcohol Intervention Review (Native AIR) to collect, evaluate and summarize peer reviewed published research on prevention or treatment interventions that include data on alcohol misuse. NIAAA will develop a Website to disseminate this information to help tribal leaders, health professionals and program staff (end-users) review and implement scientifically tested interventions in their communities.

NIAAA started the project with Fetal Alcohol Spectrum Disorder because it has a manageable literature of seven interventions. At the request of end users, NIAAA added information on the costs, staff's needs and level of cultural engagement associated with the interventions.

Dr. Arroyo shared the project methodology before walking TAC members through the website demonstration. From the opening page, end-users can click active links to receive intervention details, references and articles. Most of the information on the NIAAA Web tool focuses on prevention. The field has only begun to address how to care for a child born with Fetal Alcohol Syndrome.

Turning to next steps, Dr. Arroyo requested suggestions from TAC members. The project also will go through the tribal consultation process. Further, NIAAA will continue the literature review process for prevention and treatment literature and therefore seeks more reviewers and editors. Other ICs also can use this format to disseminate research literature in tribal communities.

The searchable site will include contact information for the article authors. Training also will be available on the site. The site, however, needs more Native images, said Dr. Arroyo, and hard copies might be necessary. Chief Malerba, chief of the Mohegan Tribe, agreed, noting that many rural Native communities do not have access to broadband. Councilman Phelps added that parents on the front lines of caring for children with Fetal Alcohol Syndrome need ways to access this information. TAC members must find a way to bring this high-level information home to Indian Country.

NIAAA can help perhaps by mailing hard copies of the site to tribal leaders and colleges as well as the IHS. TAC leaders also can share links to other organizations. Other promotional options include targeting area behavioral health consultants and contacting existing grant projects. Christy Duke, technical advisor for the Nashville Area, added that the IHS Meth and Suicide Prevention Initiative and the Domestic Violence Prevention Initiative have tribal awardees that participate in regular conference calls.

Despite the limited amount of information on the site, NIAAA should make the tool available as soon as possible, said Portland Area Technical Advisor Andrew Shogren, J.D. Resources on the small site could save someone's life. NIAAA also should visit the Northwest Portland Area Indian Health Board, said Mr. Shogren, Health Director for the Suquamish Tribe.

Bobby Saunkeah, delegate for the Oklahoma Area, requested more information on how researchers disseminated results back to tribes. Discussing the issue of cultural engagement, Mr. Saunkeah also noted that Tribal or Community-Based Participatory Research might be a stronger measurement than level of cultural inclusion. High participation with a tribe should result in high cultural inclusion, said Mr. Saunkeah, who represents the Chickasaw Nation Department of Health. Dr. Arroyo said the research spans a timeframe from the '70s to current day. Today's standard is likely full cultural engagement and community-based or tribally based participatory research.

Chief Malerba asked whether traditional healing or historical trauma factors into the research. Dr. Arroyo said project coders could include that information in the comments. Chief Malerba also suggested making the information relevant for tribal leaders, policy makers and care providers. The site could include an overview in layman's terms for non-researchers.

4. Discussion with NIH

Francis S. Collins, M.D., Ph.D.
Director, NIH

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director, NIH

With its agenda as the largest supporter of biomedical research in the world, NIH wants to remain in touch with the issues affecting Native communities. TAC input has influenced such large efforts as the *All of Us* Research Program and the development of the THRO. TAC also has played a role in shaping the THRO strategic plan, which should be ready by the end of the year. The plan should chart a course forward toward open, fruitful exchanges and effective programs and plans that reflect TAC priorities and concerns, said Dr. Collins.

To provide the most information possible on the effects of opioids in tribal communities, NIH has teamed up with IHS and SAMHSA for the May 2018 consultation, said Dr. Collins. This joint event will provide new insight from various perspectives as well as guidance for the ICs. Science can contribute something significant to drug prevention/treatment and the rapid development of nonaddictive, nonpharmacological pain treatments. NIH will listen closely to tribal concerns and determine appropriate solutions, said Dr. Collins.

Chairperson Onnen began the tribal discussion by recognizing Dr. Wilson's work in THRO. Chief Malerba next asked about creating a formal tribal consultation policy for NIH. Although the agency falls under the Department of Health and Human Services (HHS), a policy specific to NIH might be helpful.

Dr. Collins agreed and asked Dr. Wilson whether incorporating a consultation policy could be part of the strategic planning process. Dr. Wilson supported the recommendation, noting that the TAC will continue to discuss how to create a formal, uniform consultation process.

Yet another goal for the TAC is "Indian 101," said Chairperson Onnen. This effort would help researchers and staff understand tribes as government entities. A primer of some sort would offer guidance on the government-to-government relationship, sovereign nations and ways to work with tribes. Dr. Collins welcomed that idea as well. Helping the ICs understand the relationship between tribal nations and the U.S. government remains a THRO priority.

Dr. Dillard asked how the TAC could address barriers in NIH requirements or procedures such as the scientific review process. How can the TAC work best within the NIH structure? The agency remains concerned about potential bias in the review process, said Dr. Collins. Dr. Tabak also noted numerous efforts to address unconscious bias. Dr. Tabak recommended addressing the issue offline with Dr. Wilson and Richard Nakamura, Ph.D., who heads the Center for Scientific Review (CSR). Someone from CSR could then come back and have a conversation with the TAC.

Councilman Phelps requested guidance to help tribes develop policies for conducting research. Although researchers might want to present findings on a national level, tribes want to know the impact on Native communities as well. Tribes want to rely on basic principles when dealing with researchers, said Councilman Phelps.

At a minimum, researchers should never conduct a program involving tribes and Indian Country without a full understanding and an ability to listen to community concerns, said Dr. Collins. Accessible data can advance medical breakthroughs; however, tribes have the right to decide how to use data coming from individuals and the tribe. NIH seeks to slow down, learn from past mistakes and develop a more

thoughtful approach. Further, although each tribe might have a different set of standards, a general framework could help research and assist tribes that still wrestle with this issue, said Dr. Collins.

Participating via teleconference, Tucson Area Delegate Chester Antone elaborated on a request for a traditional medicine conference. Such an event could show Native youth how to combine traditional methods with science. Dr. Tabak recommended further discussion with Dr. Wilson. Dr. Wilson further proposed including the THRCC in developing such a conference. Alison Ball, Ph.D., said efforts such as the NIAAA Native AIR project can identify literature others have already completed as well as research gaps. Other ICs can make similar presentations, which would provide vital information to Indian Country, said Dr. Ball, a national at-large delegate from the Colville Confederated Tribes.

Chief Malerba discussed the capacity issues that hinder tribal research. Perhaps NIH would consider consolidated grant applications. Dr. Tabak encouraged the TAC to think about potential areas where that strategy might work. Another possible model is the Special Diabetes Program for Indians (SDPI), said Mr. Saunkeah. Mr. Shogren noted that a lack of funding in tribal communities results in less-effective care. The outsized effect of opioids in Indian Country likely comes from doctors sending tribal members home with opioids rather than providing better care. Direct funding would help tribes serve their communities effectively.

5. 2018 TAC Priorities Discussion

Chairperson Onnen led the TAC priorities discussion, which began during Tribal Caucus. One of the top goals for the committee is a consultation document or policy. Although NIH comes under the HHS Tribal Consultation Policy, can the committee frame that policy to be more specific to NIH? The TAC will consider creating a subcommittee to focus on a policy.

Other priorities include:

- A short video to help NIH staff understand tribes as government entities. THRO can use as a model available from SAMHSA.
- Building capacity within peer review committees to appropriately review AI/AN focused research projects. In light of comments noted in some reviews, Dr. Wilson recommended having a conversation with Dr. Nakamura, the head of the CSR. That conversation should address the review process, what CSR controls internally and other parameters. CSR could begin the process by participating in a monthly call.
- Participating via conference call, Teshia G. Arambula Solomon, Ph.D., suggested a more focused conversation on improving the process. The conversation might be specific to Native populations but could be relative to other larger groups or issues, added Dr. Solomon, technical advisor for the Tucson Area.
- National At-Large Technical Advisor Yvette Roubideaux, M.D., noted the tribes that propose to study only one population should not receive lower scores during a review because AI/ANs have a special relationship with the federal government. Dr. Roubideaux ceded the seat back to Chief Malerba.

- Dr. Anderson noted that NIH does not actually do the reviews but oversees the process. Dr. Anderson requested TAC input on training reviewers. Chairperson Onnen sought further education on the review process before the TAC begins identifying solutions.
- Data Sharing/Data Sovereignty: Mr. Saunkeah requested further information on NIH processes regarding data sharing, tribal exemptions and single institutional review board (IRB) issues. A TAC workgroup might hammer out these concerns most effectively, added Mr. Saunkeah.
- Direct funding to tribes for opioid interventions. This priority could be part of funding culturally effective practices versus evidence-based practices.

Councilman Phelps also requested a report on TAC accomplishments. This could be a sharable document that could go coast to coast, Chairperson Onnen added. The report also could help recruit new TAC members, said Dr. Ball.

Dr. Wilson will compile these goals and send them back out so the TAC can rank them in priority order. Chairperson Onnen asked Dr. Wilson to note the TAC participation needed to accomplish each goal. TAC members also can leverage technical advisors to assist in this work.

6. 2018 Tribal Consultation Discussion

Returning to the topic of the 2018 consultation, Dr. Wilson focused the discussion on ways to create a standard, uniform tribal consultation. Some events have been two or three hours. For the 2018 event, three HHS operating divisions will devote four hours to addressing opioids in Indian Country.

Tribes, however, have requested that the consultation focus on more than just opioids. Because other forms of substance use and abuse continue to impact Native communities, planners have sought to determine other co-morbidities associated with the opioid epidemic that may not show a direct link. That research has produced an extensive amount of data, said Dr. Wilson. Staff continue to search for the most effective way to present the information.

NIH also hopes to provide additional sessions during the consultation so participants can get more detailed information about specific initiatives available within the agency. Those may include:

- A Trans-NIH initiative on opioids: This presentation will highlight research efforts sponsored by ICS.
- Medication-Assisted Treatment (MAT) and other approaches to address opioid use: Presenters will address treatment strategies and other methods to reduce Opioid Use Disorders in AI/AN communities. MAT raises concerns in Indian Country as some communities do not support using one drug in place of another. The session will present research on the efficacy of these treatments.
- The National Drug Early Warning System: This presentation will focus on public health surveillance efforts that help local experts and collaborators generate critical information about drugs and the public health consequences in specific geographic areas.

- Behavioral and Social Aspects of the Opioid Crisis: This roundtable will convene researchers to discuss the other conditions (alcoholism, anxiety and depression) associated with opioid addiction.
- Tribal Perspectives on the NIH Grant Process: This session will show tribes how to build capacity to acquire research funding.

In creating a standard NIH consultation, tribes across the country may come to understand the agency's process, said Dr. Wilson. Chief Malerba noted that consultation typically involves tribal leaders in a government-to-government dialogue. Consultation also can include a list of objectives a government agency seeks to achieve. Chief Malerba also recommended regional consultations in addition to one large meeting. Further, tribal leaders would want guidance from the latest research to protect and improve Native communities.

Dr. Wilson said NIH plans to send out "prompts" ahead of the meeting to spark discussion and encourage tribal testimony. NIH also plans to videocast the consultation. The agency hopes to gather the specific needs for each community to identify gaps and create research opportunities in specific areas. Gathering that information will require actively engaged tribal leaders, said Dr. Wilson.

Chief Malerba encouraged NIH to consider holding events in conjunction with such organizations as the National Congress of American Indians (NCAI) or the United South and Eastern Tribes (USET) to reach a broader audience and gain further insight. Chairperson Onnen recommended quarterly consultations in different regions or with a different organization. The 2018 opioid consultation also could include the Department of Justice and the Bureau of Indian Affairs. Due to limited planning time, NIH was unable to include those two agencies, said Dr. Wilson. TAC input can help guide those decisions during future consultations.

Mr. Saunkeah noted that in compiling a laundry list of research concerns in Oklahoma, opioids did not reach the top 15. The TAC must play a stronger role in advising NIH on consultation topics. TAC also can help NIH execute a consultation or get details on local event opportunities, such as a recent USET meeting in Washington, DC. Further, Dear Tribal Leader letters can help NIH get additional tribal input, said Chief Malerba.

Chief Malerba ceded time to Dr. Roubideaux, who noted that, according to HHS and IHS policy, critical events typically trigger consultation. In this case, the critical event is available funding dollars for opioid research, from which tribes should benefit. The next step requires developing a question that encourages a response from tribes to influence a decision.

Consultation is not random input on a topic, added Dr. Roubideaux, director of NCAI's Policy Research Center. In light of the HHS Tribal Consultation Policy, the May 2018 meeting should not be the only opportunity to give input. Dr. Roubideaux ceded the seat back to Chief Malerba.

For the opioid consultation, the question/decision point centers on the NIH research focus and research gaps, said Dr. Wilson. Following closing comments, the meeting adjourned at 4:02 p.m., to resume at 9:00 a.m. on Wednesday, March 14.

7. Environmental influences on Child Health Outcomes (ECHO)

Research Program Update and Discussion

Matthew W. Gillman, M.D.

Director, ECHO Program

Chairperson Onnen welcomed committee members to the second day of the TAC in-person meeting before turning to Dr. Gillman, director of the ECHO program. Dr. Gillman, who met with the TAC a year ago, appreciated the opportunity to come back and listen to advice from tribal leaders. Juliana Blome, Ph.D., program chief of staff, met with the TAC in September 2017.

ECHO seeks to enhance the health of children for generations to come. This nationwide program focuses on research that, among other things, serves AI/AN communities directly and enhances consortia-wide research that improves knowledge and influences practices and policies. ECHO remains committed to consultation with tribal nations and collaboration with AI/AN partners.

During the presentation, Dr. Gillman updated the TAC on work with the Navajo Nation Birth Cohort Study and data sharing efforts. The birth cohort study follows families from the prenatal period through early to mid-childhood. The program operates as a collaboration between Navajo and the University of New Mexico, where Dr. Johnhnye Lewis, the principal investigator resides. The study recognizes that uranium and other metals, often from abandoned mines, remain widespread across the reservation. The study examines how exposure to these metals during pregnancy affects brain development/neurodevelopment and excess weight gain. The program also studies how the development of the immune system explains these relationships.

The study, which has about 1,000 participants, can help Navajo address mitigation activities under way through the Environmental Protection Agency and other areas of the federal government.

Conducting analysis across multiples cohorts with tens of thousands of kids could contribute to a broader understanding of metals and other exposures, said Dr. Gillman. A larger sample would help ECHO understand how effects vary by gender, race, geography and socioeconomic condition. This ECHO-wide cohort will have 50,000 children and their families.

Sharing data for this ECHO-wide cohort comes with some risks. Dr. Gillman discussed the protections developed for an ECHO-wide data platform and a program-specific agreement with the Navajo Nation. This effort will begin with non-biospecimen, non-genetic data. The program includes special protections for individuals as well as the nation that occur at many steps along the process.

Dr. Gillman provided further details of the ECHO-wide Cohort data sharing protocol. Existing and new data would go to a data analysis center at Johns Hopkins University. Investigators can access relevant data only after a Steering Committee approves a detailed analysis proposal. Dr. Gillman also shared details on the ECHO-wide Cohort data-sharing draft agreement with the Navajo Nation.

Dr. Ball asked about safeguarding the data after the study ends. Dr. Gillman said ECHO is in the second year of a seven-year process. Although discussions continue, Navajo would have the right to take back the data so it would not get stored long-term.

Chief Malerba said the ECHO work meets a vital need as 24 percent of the Superfund sites are on tribal lands. Chief Malerba also wondered if the Navajo Nation has the ability to disagree with a research proposal. Further, does Navajo Nation have to agree to publication? Dr. Gillman said Navajo members or reviewers have the option of stopping at the analysis proposal stage and the publication review stage. ECHO, however, hopes a conversation would occur at both junctures.

A Publication Committee reviews and approves analysis proposals before those proposals go to a Steering Committee for final approval. Any individual cohort analysis in the Navajo Birth Cohort Study would have Navajo co-investigators. ECHO-wide cohort studies are open to all co-investigators, including those from AI/AN backgrounds.

Dr. Dillard asked about tribal oversight for urban Indians. ECHO remains aware of those issues and will continue to seek advice from the TAC as the project goes forward, said Dr. Gillman. ECHO has primarily dealt with tribal members within the geographic confines of tribal lands.

Councilman Phelps noted that ECHO project research is being done by the University of New Mexico, with Dr. Lewis serving as the chief investigator. Dr. David Begay, the assistant principal investigator, is Navajo and serves on the nation's IRB. The Health Committee of the Navajo Nation Council addresses issues that come to the Navajo IRB. The Division of Health also plays a role. Learning more about the Navajo Nation process can assist other tribes, TAC members said. Mr. Saunkeah recommended regular TAC presentations on various tribal IRB processes. Dr. Wilson said that would be a good idea for a TAC subcommittee.

Prior to the next session, Dr. Wilson presented the list of 2018 TAC chair/co-chair nominees. Committee members were to e-mail their selections to Dr. Wilson by the end of lunch.

8. NIH Research Training Programs

Sharon Milgram, Ph.D.

**Director, Office of Intramural Training and Education
Office of Intramural Research**

Dr. Milgram shared details on training emerging scientists and informing Native communities about NIH internship programs. Working in a research environment at NIH is only one part of the training experience, said Dr. Milgram, who encourages a holistic approach that develops healthy adults.

Every NIH IC that has an intramural program can have a training program. OITE supports those students while also operating its own programs. OITE places its students, in collaboration with the ICs, into research groups. Dr. Milgram discussed these OITE-sponsored programs during the TAC presentation.

OITE programs give students a clear understanding of the culture of science and health care careers as well as NIH expectations. These programs develop resilient learners who know how to explore careers, overcome setbacks and thrive under pressure. Further, a process of 360-degree mentoring allows college students to inform community college students and so on.

Dr. Milgram highlighted the appropriate summer program for students in tribal or community colleges or those who transferred from such institutions to a four-year campus. This program also benefits first-generation college students or any student facing barriers to success. Other OITE programs include:

- The Amgen Fellows Program, a public/private partnership that focuses on leadership and health disparities training.
- G-SOAR, a program that offers graduate student opportunities for advancing research.
- The Undergraduate Scholarship Program for students with an interest in biomedical research.
- The NIH Postbac program, which annually attracts about 1,000 students who want to explore next steps following college graduation.
- The NIH Academy Enrichment program, which funds a cadre of NIH Academy postbacs. This program focuses on students from broad backgrounds who have an interest in leadership, mentorship and career development.

As the TAC reflected on vital student services, Dr. Ball said tribes often need help supporting students who go away to school. One of the biggest barriers to success is loneliness, Dr. Ball added.

Dr. Milgram noted community requests for NIH to share material on resilience and develop a toolkit. Although OITE has not yet developed a toolkit, it does offer a two-day train-the-trainer event in July, so others can review and learn the information.

Tina Woods, Ph.D., a proxy for the Alaska Area, spoke of the value of resilience and determination in overcoming childhood abandonment and abuse. The OITE internships encourage students and help them overcome obstacles, said Dr. Woods. Dr. Milgram hopes to understand the effects of trauma on student learning and would welcome more discussion with TAC members. Dr. Woods suggested using videoconferencing to train students in how to conduct culturally responsive research in rural communities. Mentors also could benefit from such a videoconference, said Chief Malerba.

Dr. Milgram will work more closely with Dr. Wilson this year to promote programs and the internships in tribal communities. TAC members can also give Dr. Milgram's contact information to prospective interns. Dr. Milgram will also come into local communities to discuss careers and internships.

Responding to a question from Councilman Phelps on remedial education needs, Dr. Milgram said an academic coach can assist interns with basic science skills, and postbacs can get funding for evening classes.

9. All of Us Research Program Update and Discussion

Dara Richardson-Heron, M.D.

Chief Engagement Officer and Scientific Executive

All of Us Research Program

Lynn Malerba, D.N.P.
Chief, Mohegan Tribe

The *All of Us* Research Program is a bold effort to accelerate health research and medical breakthroughs, enabling individual prevention, treatment and care. The program aims to enroll 1 million or more diverse U.S. volunteers. The data will inform a variety of research studies. The basis for the program is precision medicine, an emerging approach for disease treatment and prevention that takes into account lifestyle, environment and biological makeup. Familiar examples of precision medicine include allergy treatments, hearing aids and eyeglasses.

As the process gets under way, NIH has developed a Tribal Collaboration Working Group to provide input on developing meaningful, culturally sensitive collaborations with AI/AN populations. The working group also will address unique considerations (such as tribal sovereignty, cultural beliefs/traditions and historical distrust) and solutions for consideration. Input will inform future tribal consultations.

Chief Malerba, who serves as a co-chair for the 16-member working group, provided an update on the group's topic areas and strategies for gathering input on such critical issues as governance, sovereignty and consent, and partnership and engagement opportunities. The working group also continues to address questions about ethics, IRBs, biospecimen storage and access, and community protection and benefit.

Overarching considerations include

- Start from the position of respecting tribal authority
- Acknowledge the history
- Engage urban Indian leaders
- Remain responsive

Chairperson Onnen, who serves on the working group, said the *All of Us* program can establish protocols and processes applicable to other types of future research. Working group member Dr. Dillard noted the debate surrounding the enrollment of urban Indians. Group members have attempted to find a balance between an individual person's freedom to participate in the study and the potential for family or group harm.

Dr. Richardson-Heron said *All of Us* senior leadership would prefer input rather consensus because the effort remains bound by FACA regulations. Chief Malerba ceded to Dr. Roubideaux, who reminded committee members that the TAC is advising a decision maker and can make consensus recommendations. The TAC also can make a formal list of specific recommendations. *All of Us* leadership, however, does not need consensus from the working group before a recommendation can go forward, said Dr. Richardson-Heron.

Dr. Roubideaux also asked the date of a tribal consultation and sought to clarify the decision maker who determines which recommendations are selected. Another question: Regarding the issue of tribe versus individual, will a tribe be a data point, and will researchers have access to that data point? The working group and *All of Us* leadership should determine the answer to that contentious question as soon as

possible. *All of Us* decision makers include senior leadership and the Steering and Executive Committees of the research program, said Dr. Richardson-Heron.

Dr. Roubideaux also asked who would become members of oversight boards. Tribes need representatives on those boards right away so that Indian Country has a voice in any decision-making. Dr. Richardson-Heron said consultation will occur after the working group's final report. Suggestions about board/governing committee membership will go to leadership as an input recommendation.

Dr. Roubideaux also reminded the TAC that AI/ANs are a political group. Leaders should make decisions on the basis of political status, not race. Under its current structure, the *All of Us* Program does not have information about race, ethnicity or political group until after a person submits that information, said Dr. Richardson-Heron. Although the working group has not developed a final strategy for collaborating with Indian Country, the program does not want to restrict anyone from participating. Chief Malerba noted that NCAI will develop a webinar about the project. That will be the beginning of the working group's efforts to spread the word. Dr. Roubideaux ceded the seat back to Chief Malerba.

Following a brief recess, the TAC heard farewell remarks from Tribal Scholar Alec Calac, who has worked for nearly two years in a lab at the National Institute of Neurological Disorder and Stroke (NINDS). Mr. Calac, who graduated from the University of Arizona in 2016, will enter a Medical Scientist Training Program at the University of California, San Diego. Mr. Calac is a member of the Pauma Band of Luiseño Indians, also in San Diego.

10. Working Lunch

National Institute on Aging

Carl V. Hill, Ph.D., N.P.H

Director, Office of Special Populations

National Center for Complementary and Integrative Research

Lanay M. Mudd, Ph.D., Training Officer

Program Officer, Clinical Research Branch

Two members of the THRCC led informal discussions to further educate the TAC about programs serving Indian Country.

The National Institute on Aging (NIA) looks at aging processes, aging-related diseases and special problems and needs of the aged. As part of its health disparities research, NIA focuses on racial/ethnic populations, AI/ANs and other groups as defined by public law and guided by NIMHD.

Carl V. Hill, Ph.D., has led the development of a framework to spark more extramural research in health disparities and minority aging. The framework has launched several funding opportunity announcements, including support for the Native Elders Research Center at the University of Colorado. The center provides training for Native researchers and links Native postdocs and assistant professors with mentors for career development. This program has been a flagship grantee for the last 20 years, said Dr. Hill. NIA also has created opportunities for programs that address Alzheimer's disease.

Dr. Ball requested access to more data and research, noting that rural health professionals often cannot find the most recent information needed to assist tribal members. NIA continues to work toward solutions, said Dr. Hill.

The National Center for Complementary and Integrative Research (NCCIR) examines the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care. An intramural program on campus focuses on mechanisms of pain/pain processing. This effort is relevant due to the need for nonpharmacological approaches to pain management, especially now in light of the opioid crisis.

Native American research includes a study on adapting mindfulness-based stress reduction into tribal communities to improve adherence to behaviors that might prevent diabetes. The study uses a community-based participatory research approach with tribal communities. Great Plains Delegate, Eddie Johnson, asked if the researcher collaborates with the SDPI. Other TAC questions included a discussion on cannabis research and a request to engage NCCIR in traditional foods, healing and/or medicine.

11. Points to Consider Update and Discussion

Kathy Etz, Ph.D.

Director of Native Programs

Program Director

Division of Epidemiology, Services and Prevention Research

National Institute on Drug Abuse

The Points to Consider project aims to develop a document on AI/AN research that will:

- Assist investigators and communities engaged in AI/AN health research as they develop competitive applications for support from NIH
- Assist reviewers and staff for review panels at the NIH who evaluate AI/AN focused applications, and
- Provide applicants, staff and reviewers “best practices” to use as they consider AI/AN health research, select reviewers, plan new initiatives and set priority areas

Similar documents are available out of Australia and New Zealand as well as NCAI and the Canadian Institutes of Research. NIH should have a voice as well, said Dr. Etz. The NIH document should broadly and specifically recognize the varied implications of tribal sovereignty in conducting health research. This effort would be the first step in developing a living document that might need ongoing updates.

The document set out to address such topics as context and history of AI/AN research, data sharing and ownership and unique review considerations. NIH contracted with four external AI/AN scientists to write the document, including TAC member Dr. Dillard. The NIH team working on the project serve as editors. Feedback from an external working group meeting in December 2017 led to turning the effort into documents for four different audiences: reviewers, NIH staff, researchers/new grantees and the

community. The draft of the first document has gone to NIH staff. Dr. Etz shared next steps with the TAC, noting the NIH team and the authors still need a plan for the next three documents.

Chairperson Onnen and Dr. Ball acknowledge the difficult behind-the-scenes work of the writers and Dr. Etz. Mr. Saunkeah highlighted the need for the documents, noting that others have judged Chickasaw Nation science on the basis of preconceived ideas of what tribal research capacity looks like. Dr. Etz asked TAC members to submit positive and negative examples of research reviews, including those with inappropriate comments. Each section of the document will include samples of good comments and remarks that leave room for improvement, said Dr. Etz. Councilman Phelps asked if the document would end up in the Federal Register. Dr. Etz clarified that this is not a policy document; instead, the document would likely be on a website and serve as a link when CSR assigns reviews that include tribal populations. Hard copies might also be available.

As committee members prepared to move on the next meeting session, Dr. Wilson announced the creation of a listserv for the TAC. Dr. Wilson also acknowledged Liana Onnen and Walter Phelps as the newly elected TAC chair and co-chair for 2018.

12. Discussion on the Role of Technical Advisors

The announcement of the TAC's 2018 leadership sparked conversation on ways to involve TAC delegates, alternates and technical advisors in monthly conference calls as well as subcommittees and other tasks. Dr. Wilson noted that technical advisors will not make decisions for delegates and alternates during the monthly calls; instead, the technical advisors will support committee members, answer questions and ensure area representation. Further, there is no need to cede a seat during a conference call.

Chairperson Onnen discussed the help and support received from technical advisor A. Jay Mooney. Chairperson Onnen further challenged TAC delegates and alternates to recommit to serving the committee as it enhances and improves tribal research. Good communication will enable technical advisors to present an informed viewpoint when delegates or alternates cannot participate in a call. Technical advisors also can suggest items for the agenda or construct letters back to the NIH director on behalf of the TAC. The letter would serve as a formal notice of meeting outcomes.

Dr. Dillard asked about the high number of alternate vacancies on the TAC. THRO will send out a Dear Tribal Leader letter announcing TAC vacancies and provide a long lead time to encourage a response. TAC members can help by informing other tribal leaders and organizations of the committee's important work, said Dr. Wilson. The Joint Tribal Advisory Committee meeting in July might also create more awareness. Chief Malerba said other national tribal organizations also struggle with attracting representation. Chairperson Onnen said the TAC has made great strides, and building awareness will take time. Chairperson Onnen continues to share with other leaders the importance of research and data in tribal decision-making.

Chief Malerba requested a list of common NIH acronyms as well as more time built into the meeting schedule for TAC member discussion. Dr. Solomon, participating via conference call, requested a TAC member recruitment brochure or packet. Dr. Solomon also expressed interest in a document on Fed-speak. Winding down the discussion, Dr. Wilson suggested editing the TAC charter to allow one

elected tribal leader and one appointed representative to serve as chair or co-chair. TAC members, noted however, that tribal leadership represents the government-to-government relationship. Appointed members perhaps could head subcommittees to ensure tribal leaders maintain a voice on the TAC.

Making closing remarks, Dr. Anderson said the TAC strategic plan will identify goals and help the committee designate assignments and move forward. The TAC also has a cast of supportive NIH program officers on the THRCC who will assist with the strategic plan, said Dr. Wilson. The TAC continues to move forward and has plenty of time to implement the goals within the five-year plan. Following a closing blessing from Chief Malerba, the meeting adjourned at 2:30 p.m.

NIH Tribal Advisory Committee Meeting

March 13-14, 2018

List of Attendees

NIH Tribal Advisory Committee Members and Technical Advisors

Breannon Babbel

Technical Advisor
National At-Large Member
National Indian Health Board
bbabbel@nihb.org

Alison Ball

Delegate
National At-Large Member
Confederated Tribes of the Colville Reservation
alison.ball@colvilletribes.com

Lyle Best

Technical Advisor
Aberdeen/Great Plains Area
lbest@restel.com

Denise Dillard

Delegate
National At-Large Member
King Island Native Corporation
dadillard@SouthcentralFoundation.com

Christy Duke

Technical Advisor
Nashville Area
United South and Eastern Tribes
cduke@usetinc.org

David Foley

Technical Advisor
Navajo Area
Navajo Department of Health
david.foley@nndoh.org

Eddie Johnson

Delegate
Aberdeen/Great Plains Area
Sisseton-Wahpeton Sioux Tribe
ejohnsonj77@gmail.com

Lynn Malerba

Delegate
National At-Large Member
Mohegan Tribe
lmalerba@moheganmail.com

A. Jay Mooney

Technical Advisor
National At-Large Member
Prairie Band Potawatomi Nation
JayMooney@pbnation.org

Liana Onnen

Delegate
National At-Large Member
Prairie Band Potawatomi Nation
LianaOnnen@pbnation.org

Michael Peercy

Technical Advisor
Oklahoma Area
Chickasaw Nation Department of Health
Michael.Peercy@chickasaw.net

Walter Phelps

Delegate
Navajo Area
Navajo Nation
nakaidinee@yahoo.com

Daniel L.A. Preston, III

Alternate
Tucson Area
Tohono O'odham Nation
daniel.preston@tonation-nsn.gov

Yvette Roubideaux

Technical Advisor
National At-Large Member
National Congress of American Indians
yroubideaux@ncai.org

Bobby Saunkeah

Delegate
Oklahoma Area
Chickasaw Nation Department of Health
Bobby.Saunkeah@chickasaw.net

Jennifer Shaw

Technical Advisor
National At-Large Member
Southcentral Foundation
JShaw@SouthcentralFoundation.com

Andrew Shogren

Proxy
Portland Area
Suquamish Tribe
ashogren@suquamish.nsn.us

David Wharton

Alternate
Oklahoma Area
Choctaw Nation Health Services Authority
dfwharton@cnhsa.com

Abbie Wolfe

Technical Advisor
Alaska Area
Alaska Native Tribal Health Consortium
awolfe@anthc.org

Tina Woods

Proxy
Alaska Area
Alaska Native Tribal Health Consortium
tmwoods@anthc.org

National Institutes of Health Attendees

Lynn Adams

NIH/National Institute of Nursing Research
adamsls@nih.gov

Rashada Alexander

NIH/National Institute of General Medical
Sciences
rashada.alexander@nih.gov

James Anderson

NIH/Office of the Director/Division of Program
Coordination, Planning, and Strategic Initiatives
james.anderson2@nih.gov

Judith Arroyo

NIH/National Institute on Alcohol Abuse and
Alcoholism
jarroyo@mail.nih.gov

Laura Bartlett

NIH/National Library of Medicine
bartlett@mail.nih.gov

Aamna Bhatti

NIH/National Institute on Alcohol Abuse and
Alcoholism
aamna.bhatti@nih.gov

Juliana Blome

NIH/Office of the Director/*All of Us* Research
Program
blomeju@od.nih.gov

Vence Bonham

NIH/National Human Genome Research
Institute
bonhamv@mail.nih.gov

Sheila Caldwell

NIH/National Institute of General Medical
Sciences
caldwells@mail.nih.gov

Dorothy Castille

NIH/National Institute on Minority Health and Health Disparities
dorothy.castille@nih.gov

Francis Collins

NIH/Office of the Director

Roberto Delgado

NIH/National Institute of Mental Health
roberto.delgado@nih.gov

Rita Devine

NIH/National Institute of Neurological Disorders and Stroke
rita.devine@nih.gov

Kathy Etz

NIH/National Institute on Drug Abuse
ketz@nih.gov

Matthew Gillman

NIH/Office of the Director/ECHO Program
matthew.gillman@nih.gov

Jonathan Horsford

NIH/National Institute of Dental and Craniofacial Research
jonathan.horsford@nih.gov

Daozhong Jin

NIH/OD/*All of Us* Research Program
daozhong.jin@nih.gov

Edmund Keane

NIH/Office of the Director/Tribal Health Research Office
Edmund.keane@nih.gov

Charlene Le Fauve

NIH/Office of the Director
charlene.lefauve@nih.gov

Sharon Milgram

NIH/Office of Intramural Research
milgrams@od.nih.gov

Lanay Mudd

NIH/National Center for Complementary and Integrative Health
lanay.mudd@nih.gov

Dara Richardson-Heron

NIH/Office of the Director/*All of Us* Research Program
dara.richardson-heron@nih.gov

Marissa Rodriguez

NIH/Office of the Director/Tribal Health Research Office
marissa.rodriguez@nih.gov

Lawrence A. Tabak

NIH/Office of the Director

David Wilson

NIH/Office of the Director/Tribal Health Research Office
dave.wilson2@nih.gov

Troy Zarcone

NIH/National Institute on Alcohol Abuse and Alcoholism
troy.zarcone@nih.gov

Guests

Susan Karol

HHS/Centers for Medicare and Medicaid
susan.karol@cms.hhs.gov

Rachael Tracy

HHS/Indian Health Service
rachael.tracy@ihs.gov

Wilbur Woodis

HHS/Indian Health Service
wilbur.woodis@ihs.gov