Tribal Advisory Committee (TAC) Meeting
September 14-15, 2017
National Institutes of Health (NIH)
Building 60 (The Cloisters), First Floor, Room 144/142 (Chapel/Lecture Hall)
1 Cloister Court
Bethesda, Maryland

Meeting Summary

1. Call to Order, Introduction, Welcome and Meeting Goals

The Tribal Advisory Committee (TAC) in-person meeting began at 9:02 a.m. with a call to order from TAC Chairperson L. Jace Killsback, president of the Northern Cheyenne Tribe. Chester Antone, a councilman for the Tohono O'odham Nation, gave the invocation before President Killsback led introductions around the table and around the room.

James M. Anderson, M.D., Ph.D., welcomed meeting participants to Bethesda, noting the agenda's intense focus on policy issues. NIH experts and decision makers came prepared to listen and engage in productive discussion. Further, NIH Director Francis S. Collins, M.D., Ph.D., planned to hear from TAC members rather than give a structured presentation. Liana Onnen, TAC co-chairperson and chairwoman of the Prairie Band Potawatomi, read the Federal Advisory Committee Act meeting requirements and discussed meeting goals and expectations. TAC members sought these outcomes from the meeting:

- Get more information from the agency about specific NIH research policies that will soon be implemented
- Provide better understanding of tribal concerns and processes around research conducted in Native communities, and
- Discuss how tribes and NIH can work together to develop policies and programs around research that benefit both sides.

The TAC's focus on data sharing and ownership coincides with similar conversations occurring in other national organizations, said Chairwoman Onnen. Growing in partnership with NIH inspires large and small tribes to understand the impact of data and research on tribal sovereignty and ongoing issues in Indian Country.

A. Roll Call

1. Tribal Advisory Committee Members
Chester Antone, Tucson Area Delegate
Debra Danforth, National At-Large Delegate
Denise Dillard, Ph.D., Alaska Area Delegate
Eddie Johnson, Aberdeen/Great Plains Area Proxy
L. Jace Killsback, Billings Area Delegate
Lynn Malerba, D.N.P., National At-Large Delegate
Liana Onnen, National At-Large Delegate
Walter Phelps, Navajo Area Delegate

Bobby Saunkeah, Oklahoma Area Delegate
Joshua Saxon-Whitecrane, California Area Delegate
Jeromy Sullivan, Portland Area Delegate
Malia Villegas, Ed.D., National At-Large Member Delegate

2. **Technical Advisors**
Deana Around Him, Ph.D., National At-Large Member
Breannon E. Babbel, Ph.D., National At-Large Member
Lyle Best, M.D., Aberdeen/Great Plains Area
Karol Dixon, J.D., Portland Area
Christy Duke, Nashville Area
David Foley, Navajo Area
Kori Novak, Ph.D., M.B.A., California Area
Michael Peercy, Oklahoma Area
Teshia Arambula Solomon, Ph.D., Tucson Area
Timothy Thomas, M.D., 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

- Highlights of Tribal Activities at NIH and Discussion
- Strong Heart Study Presentation and Discussion
- Navajo Nation Institutional Review Board Presentation and Discussion
- Working Lunch: NIH Genomic Data Sharing, Clinical Trials and Single IRB Policies
- Chickasaw Nation Institutional Review Board Presentation and Discussion
- Discussion with NIH
- TAC Charter Discussion
- BRAICELET Program Presentation and Discussion
- Alaska Area Specimen Bank Presentation and Discussion (video-cast)
- Lunch with NIH AI/AN Scholars
- ECHO Research Program Update and Discussion
- *All of Us* Research Program Update
- Discussion on Priorities and Next Steps

C. Action Items

- Regarding data sharing exceptions across the Institutes and Centers (ICs), Director Francis S. Collins, M.D., Ph.D., said NIH will continue to address the issue of becoming one organization during regular weekly meetings.

- TAC member Bobby Saunkeah will talk with Juliana Blome, Ph.D., about Oklahoma outreach efforts for the Environmental Influences on Child Health Outcomes (ECHO) program.

2. Highlights of Tribal Activities at NIH and Discussion

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

Dr. Wilson began by introducing THRO staff members Ted Keane and Marissa Rodriguez. Ms. Rodriguez plans to officially come on-board September 25. Mr. Keane, who formerly worked with the Center for American Indian Health, came to the THRO office about four months ago.

Dr. Wilson's comments focused on THRO meetings, student engagement, publication collaborations and the Tribal Health Research Coordinating Committee (THRCC). As Dr. Wilson continues to stand up the THRO, frequent meetings, engagement and collaboration increase the office's exposure and promote its vision. Many of the NIH ICs, for instance, remain unaware of the THRO, said Dr. Wilson. Investigatory conversations with external stakeholders and organizations help the THRO identify community needs and areas of collaboration. Dr. Wilson further uses meetings and conversations to develop the THRO strategic plan.

Meeting highlights from 2017 include the National Indian Health Board (NIHB) Public Health Summit in June and the American Indian Higher Education Consortium Behavioral Health Research Institute June 19-21. Dr. Wilson also noted the historic, transformational August 31-September 1 Tribal Data Sharing and Genetics workshop at the University of New Mexico's Comprehensive Cancer Center.

In April, the THRO held its first meeting with the Trans-NIH THRCC, which includes representatives from all the ICs. This group of hard-working collaborators has focused on drafting the first American Indian/Alaska Native (AI/AN) Portfolio Analysis and a strategic plan for the THRO. Several ICs have stepped up to collaborate with THRO staff, including the National Institute of Mental Health, which attended the first Tribal Leaders Behavioral Health Summit in Tulsa, OK. To increase support for Tribal Epidemiology Centers (TECs), THRO also has worked closely with the National Institute of Minority Health and Health Disparities. Dr. Wilson also highlighted work with the National Human Genome Research Institute (NHGRI) and the National Institute on General Medical Sciences.

Focusing more closely on the THRO strategic plan, Dr. Wilson noted these five priorities:

- Build research capacity;
- Expand research;
- Evaluate progress;
- Enhance communication and coordination between tribal nations and the NIH; and,
- Ensure that cultural competency and community engagement remain central to all these efforts.

These priorities clearly demonstrate the office's holistic approach in engaging tribal communities. NIH will eventually reflect these goals throughout the agency, said Dr. Wilson.

The THRO also has engaged with NIH summer interns as well as policy fellows from NIHB. Last, Dr. Wilson highlighted the THRO website, as well as recent office publications, including Beyond Belmont: Ensuring Respect for AI/AN Communities through Tribal IRBs, Laws and Policies.

Navajo Nation Councilmember Walter Phelps thanked Dr. Wilson and Chief of Staff Juliana Blome, Ph.D., ECHO program, for a recent visit to the Navajo Nation. Input from Navajo leaders and Institutional Review Board (IRB) colleagues on data sharing will further inform NIH efforts, Councilman Phelps added. Several TAC members also noted that the staff growth and success of the THRO has exceeded the committee's expectations. Ongoing collaboration with national organizations will provide further guidance and insight, said Chairwoman Onnen.

3. Strong Heart Study Presentation and Discussion

Lyle Best, M.D., Principal Investigator, Dakotas Center, Great Plains Area Technical Advisor, TAC

Mona Puggal, M.P.H., Scientific Program Specialist, National Heart, Lung, and Blood Institute

Dr. Best highlighted the history and goals of the Strong Heart Study, a pioneer in community-based research. Phase I of the program began in 1988 with participants in Arizona, Oklahoma and the Dakotas. Phase II and III operated between 1993 and 1999. Phase IV and V, a family study, occurred from 2000 to 2010. Phase VI, surveillance, started in 2013 and will run through 2018.

The Strong Heart Study has recruited and retained 7,000 individuals over multiple exams. Further, the program has helped more than 50 young American Indian investigators attain advanced degrees. The study also was among the first to incorporate genetic analysis. Strong Heart's efforts have confirmed the relevance of Framingham risk factors in the American Indian population and helped establish the critical importance of diabetes as a cardiovascular disease "equivalent." In addition, research uncovered a high incidence of stroke in American Indians and a high prevalence of left ventricular hypertrophy in youth.

Strong Heart Study results also have informed tribal leaders and health directors, including the Department of Health and Human Services (HHS). A Data Book, which addresses the epidemiology of cardiovascular disease and diabetes in lay terms, has been useful in lobbying. Further, Strong Heart data has been critical for the Special Diabetes Program for Indians (SDPI). The program also has trained tribal members in research fields and assisted in the development of IRBs. Dr. Best highlighted such new researchers as Dr. Stacey Jolley and the Minority Supplement to the Strong Heart Study (Dakotas Center) for Kaytlin Lawrence.

Taking a closer look at data sharing and privacy, Dr. Best noted that sharing does not happen easily, even among scientists. The goal is to maximize the utility of research collected. The Strong Heart Study, however, has consistently maintained to NIH the need for government-to-government discussion related to data sharing for research.

Dr. Best also noted the inconsistently applied 2008 NIH Genomic Data Sharing (GDS) Policy. The implications for inadequate genetic studies for American Indians include the lack of understanding of the genetic architecture in American Indians and the risk of disease relative to other populations, including Mexican Americans who might share susceptibility alleles. Dr. Best also stressed the inability to fully characterize disease susceptibility in population groups that suffer disproportionately from complex diseases.

Noting Dr. Best's well-articulated concerns on data sharing and privacy, Chief of Mohegan Tribe Lynn Malerba, D.N.P, said tribal elders typically do not want to share anything due to past experiences with social stigmatization or generalizations about tribal people. Current tribal leaders, however, use data to advocate on Capitol Hill, including for the reauthorization of SDPI. Finding the middle ground remains difficult, said Chief Malerba.

Similarly, Malia Villegas, Ed.D., council member for the Native Village of Afognak, focused on the use of data in lobbying with the Environmental Protection Agency for Brownfields clean-up, and how Native corporations, particularly in Alaska, have capacity and capability to do that clean-up. Science and industry capacity should come together to make the best claims about the need for clean-up efforts, said Dr. Villegas.

Returning to the question of finding middle ground between privacy and data for advocacy, Dr. Villegas said the goal should be ethics. What kinds of ethics and guidelines should lead decision-making about the proper use of data? The TAC has a role to play in developing those guidelines in connection with other thinking about ethics, said Dr. Villegas.

Tribal leaders also deal with the political component, said President Killsback. Leaders see how industry, science, local governments, and elections intermingle outside of tribal communities. The only way to build tribal capacity is with true partnerships. As research and science continue to affect basic elements of tribal life including the testing of well water, tribal leaders must gain more relevant education and understanding of data sovereignty, said President Killsback. Ms. Puggal added that the Strong Heart Study would receive funding for another seven years.

Councilman Antone raised questions about informed consent related to the NIH *All of Us* Research Program and asked to address the matter at some point during the two-day meeting. Dr. Wilson said the TAC would touch on that issue during the lunchtime presentation by Sara Chandros Hull, Ph.D., chair of the NHGRI IRB.

Denise Dillard, Ph.D., Director of Research at Southcentral Foundation, said that NIH lacks an agency-wide position on data sharing that involves indigenous groups. The TAC needs clarity on NIH's goal in light of such inconsistent rules across the ICs. As the head of the office of coordination, Dr. Anderson deals with that issue every day. Historically, NIH's 27 ICs did have variations in interpreting policies. The TAC's role is to bring everyone together to agree on trans-NIH approaches.

4. Navajo Nation Institutional Review Board Presentation and Discussion

Beverly Becenti-Pigman, Chair, Navajo Nation Human Research Review Board

David Begay, Ph.D., Navajo Nation Human Research Review Board

The Navajo Nation Human Research Review Board has seen great successes as it works to ensure that the Navajo Nation can take care of its own. The research program supports efforts that promote and enhance the interests and vision of Navajo people; encourage a mutual and beneficial partnership between the Navajo people and researchers; and create an interface where different cultures, lifestyles, disciplines and ideologies can come together in a way that improves, promotes and strengthens the health of Navajo people.

The review board, launched in 1995, meets monthly and seeks to develop relationships with such academic institutions as the University of New Mexico, University of Utah and Arizona State, as well as Diné College and Navajo Technical University. The board requires researchers to select Navajo college students as a co-Principal Investigators (PIs). The board also conducts conferences every two years to share research findings. Most members of the board are non-tribal employees.

The board approves research protocols for one year and ensures that all data are returned back to the Navajo Nation. Ultimately, most of the data goes to the tribe rather than the review board. The tribe, through its TEC, shares data with the state of Arizona and the Indian Health Service (IHS).

Equipment bought with federal grant funds goes back to the community from which the researcher did the study. Researchers also must help the community write grants to fund those services. The board does not approve studies without a consent form, said Ms. Becenti-Pigman. The Navajo Nation also follows the research principles and guidelines of the Belmont Report.

Ms. Becenti-Pigman discussed the 12-step human research review and approval process. This customized process helps the Navajo Nation keep track of studies. Regarding data sharing, Ms. Becenti-Pigman said Native communities must understand which takes precedence: NIH law or tribal law. Is the tribal privacy act more important than the Health Insurance Portability and Accountability Act? Further, Ms. Becenti-Pigman stressed the benefit of NIH providing financial assistance to the Navajo Nation to develop a data ownership facility so the tribe will have ownership of data and can control and secure the information.

The Navajo Nation Privacy Act acknowledges that data belongs to the individual, said Dr. Begay. An individual can share data with the Navajo Nation through a consent form, and the Navajo Nation can in turn share the information with outside entities. Dr. Begay also reported on the Navajo Nation's efforts to lift a moratorium on genetic research after 15 years. The administration seeks to develop a policy that will regulate and monitor all genetic research.

Dr. Villegas appreciated Navajo's 12-step review and approval process and wanted to know what the research board had learned from talking to researchers about study timelines. Territorial jurisdiction also remains an enormous issue, Dr. Villegas added.

Regarding studies conducted off of Navajo Nation, Ms. Becenti-Pigman encourages researchers to get Navajo approval because someone injured during a study will take that researcher's organization or college to tribal court. Dr. Begay suggested launching an inter-tribal organization or confederation to protect urban Indians from these research issues.

5. Working Lunch: NIH Genomic Data Sharing, Clinical Trials and Single IRB Policies

M. Khair ElZarrad, Ph.D., M.P.H., Office of Science Policy (OSP)

Sara Chandros Hull, Ph.D., Chair, NHGRI Institutional Review Board Director

Listening is key to creating relevant, responsive science policies, said Dr. ElZarrad of the Clinical and Healthcare Research Policy Division. Single IRBs and data sharing are part of a larger, long-term NIH effort related to clinical trial and transparency reforms.

Noting the life cycle of a clinical trial, Dr. ElZarrad highlighted the importance of good clinical practice, review, protocol templates and the single IRB policy. Data sharing encompasses this entire process because the value of a clinical trial must be transparent to the public for researchers to use the data. Data sharing reduces unnecessary replication of unsuccessful studies and ensures that successful interventions get to actual practice. Data sharing also builds public trust. As part of its long-standing culture of sharing, NIH expects the results and accomplishments of the activities that it funds to be available to the public. This policy is consistent with informed consent.

Dr. ElZarrad stressed the frequent collaboration between the OSP and the THRO, noting that such partnership remains essential to developing and implementing policies. The Office of Extramural Research also plays a key role in implementation. Ongoing efforts among these offices include the development of a fact sheet and Frequently Asked Questions for studies with tribal populations. The OSP also participates in consultation sessions with THRO.

The NIH Policy on Use of a Single IRB (sIRB) for multi-site research establishes the expectation that domestic sites of NIH-funded multi-site studies will use a single IRB of record to conduct the ethical review of research. This applies to grant applications submitted on/after January 25, 2018. The previous effective date of September 2017 was extended.

The policy received 167 comments, including those from the IHS and Cherokee Nation. The NIH policy does not apply to tribal populations, including tribal colleges and universities (TCUs), to show respect for tribal sovereignty and acknowledge the importance of firsthand knowledge of local tribal customs, cultural values and tribal sensitivities. This effort acknowledges the benefits of tribal and TCU reviews.

The policy has two exceptions: When review by the proposed sIRB would be prohibited by a federal, tribal or state law, regulation or policy or if there is a compelling justification.

Multiples resources remain available for investigators conducting research involving tribes, including the THRO and a toolkit from the Collaborative Research Center for American Indian Health.

Looking more closely at the GDS Policy, Dr. ElZarrad discussed the Points to Consider for Institutions and Institutional Review Boards. This document assists IRBs in their review and certification of investigator applications and proposals involving the submission and access of human genomic data under the GDS policy.

The document indicates that if research involves tribal populations, the Authorized Institutional Official should consider tribal laws and regulations, and whether consultation with tribal communities might be appropriate. The OSP Website offers additional information. Further, a workgroup across NIH continues to examine the scope and applicability, and existing NIH data sharing policies.

Dr. Hull examined this issue further in the next presentation on NIH sIRB and GDS Policies: Honoring the Exceptions, Limitations and Alternatives. The topic highlighted NIH efforts to support tribal sovereignty. Tribal IRB review serves as an important expression of a Native community's ability to govern research.

The examples of unethical, harmful or problematic research that have occurred in tribal communities illustrate the profound disconnect between common academic research practices and legitimate tribal expectations. Tribes have reasonable complaints as well as concerns and interest in promoting the good of their communities, said Dr. Hull. New language in the Common Rule acknowledges tribal sovereignty, the ability of tribes to set policies that offer additional protections.

A key question remains: Are NIH policies flexible enough to permit collaborative research and data sharing to occur in partnership with sovereign tribal nations? NIH must be able to say that the answer to this question is yes, said Dr. Hull. This will occur in targeted case studies as Institutes make different decisions. Extramurals also make different decisions than intramurals. As an IRB chair for the NHGRI, Dr. Hull encourages colleagues to work as partners to get to the correct answer.

Dr. Hull offered additional details on the Single IRB Policy that will take effect in January 2018, and the GDS Policy in effect since 2015. The NIH Policy on Use of a Single IRB for Multi-Site Research includes built-in exceptions for tribal communities. Researchers need more education on honoring those exceptions. Tribes also must know how to exercise sovereignty and operate under this policy to appropriately claim the kinds of review needed to protect Native communities. A September 2016 Webinar inspired conversation between federal policymakers, tribal policy leaders and researchers.

Walking through the NIH GDS Policy, Dr. Hull noted the lack of community involvement. The process does not address return of results or oversight along the way. During the policy's draft comment period, the public commented on these and other issues, said Dr. Hull. The final policy has the potential to address these concerns. Data use limitations and alternative data sharing plans could require additional layers of IRB review, community engagement or other requirements. NIH and Native leaders must continue to discuss how this would work for tribal research.

Following the presentation, Councilman Antone asked whether data under a grant that is tribal would be an exception to the rule. Dr. ElZarrad said the requirement for submission for results of clinical trials is for summary results, not individual level data.

A waiver mechanism can waive the requirement for result submission for clinical trials that requires justifications. Another mechanism exists for appeals. Dr. ElZarrad hoped for more discussion on the benefits of this data and the need for sharing.

Councilman Antone ceded his seat to Technical Advisor Teshia Arambula Solomon, Ph.D., for further discussion. Dr. Solomon noted an active exercise intervention study on the Navajo Nation. The team did the work required on the Navajo Nation to receive permission to move the study forward, but now the effort must be registered as a clinical trial. The agreement with the Navajo Nation was that information would not be shared. The matter is relevant to the topic of waivers or exceptions as well as permissions and requirements early or late in the process.

The goal is to determine how to make everyone comfortable, said Jodi Black, Ph.D., Deputy Director of the Office of Extramural Research. Dr. Solomon added that the process of community engagement required is different for each tribe. Throughout the process, researchers must ask permission ahead of time. If policies are addressed up front specific to the needs of tribal nations in a general scope, that might eliminate the need for an exception. Dr. Black noted the need for clear understanding of the value of the information on both sides within the registration process. Dr. Solomon encouraged greater thoughtfulness in establishing research goals and seeking exceptions. Dr. Solomon then turned the seat back over to Councilman Antone.

Chief Malerba asked about sample sizes and whether tribal research is relevant to a community or a broader population. Tribes must begin with the consent process and study design in determining where and how to share data. Dr. Villegas discussed a process by which a tribe could self-identify its preference. Dr. Villegas also encouraged looking at data sharing and data use. Giving permission to share data in a repository is part of the issue. The other is how to use and get permission to use the data. Last, a closer look at Belmont shows the importance of protecting communities against research violations. Councilman Phelps encouraged giving Dr. Hull additional guidance on alternative data sharing and data use limitations. President Killsback added that the question regarding NIH policies and tribal sovereignty still requires some clarity.

6. Chickasaw Nation Institutional Review Board Presentation and Discussion

Bobby Saunkeah, Manager, Division of Research and Population Health, and IRB Chair, Chickasaw Nation Department of Health and Oklahoma Area Delegate, TAC

Michael Peercy, Epidemiologist and IRB Administrator, Chickasaw Nation Department of Health and Oklahoma Area Technical Advisor, TAC

Mr. Saunkeah began the discussion on Chickasaw Nation's IRB process with a closer look at the Native experience in Oklahoma. The state has the second largest population of American Indians in the United States, second only to California. The Chickasaw Nation comprises 13 counties in rural, south-central Oklahoma. The area has 356,000 residents and 35,065 Native Americans.

Tribal IRBs aim to control new health science research, set research agendas and protect tribal residents through the perpetuation of sovereignty rights. An executive order by Governor Bill Anoatubby established the Chickasaw IRB in 1998. Recent projects have focused on genetics research, health disparities, climate change, substance abuse and pre-eclampsia. The Chickasaw IRB works closely with the four or five other tribal IRBs in Oklahoma.

During the second half of the presentation, Mr. Peercy offered a closer look at excerpts from the Chickasaw Nation's IRB policy and research agreement to show some of the principles and guidelines that tribal leaders enforce. All policies note that the Chickasaw Nation has the inherent sovereign authority to govern itself and provide for the health and general well-being of the Chickasaw people and the American Indian people served according to the highest standard of ethics.

Policies also state that the tribe values research, what research can bring to the tribe and how research can help the Chickasaw Nation serve its people. Regarding participation in research, the Chickasaw Nation can only govern research within the department of health's service area. The IRB will review the merit of all proposed research and determine whether the Chickasaw Nation will participate. The Chickasaw Nation will not participate in any proposed research that includes the denial of medical treatment to patients.

One of the Chickasaw Nation's more controversial policies requires ad hoc review and approval of all publications prior to dissemination, no matter the type of research. The Chickasaw Nation has disapproved only a few over the years, said Mr. Peercy. These publications, which can include written reports, papers, manuscripts or other types of materials, must represent the Chickasaw Nation without unfair stigma or harm to the community.

Investigators must sign agreements prior to conducting research. Any and all data findings generated within the research project belongs to the Chickasaw Nation. Any use of the data and findings, including genomic data, generated from research conducted within the Chickasaw Nation requires prior review and approval by the IRB. This includes secondary use.

Mr. Peercy noted that federal policy provides for exemption from IRB review for certain types of research. However, such exemption does not apply to dissemination of findings. Researchers receive the Chickasaw Nation's policy and agreement up front, and some investigators ultimately decide against conducting research on the Chickasaw Nation, said Mr. Saunkeah. Mr. Saunkeah agreed to share copies of the nation's policy and research agreements with other TAC members.

7. Discussion with NIH

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

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

Seeking a conversation with TAC members, Dr. Collins used this session to listen to and answer questions about opioid addiction, data access and the *All of Us* Research Program that aims to enroll one million people in a prospective long-term study of health and illness. Reflecting on nearly 25 years in research, Dr. Collins noted the value of listening more and presenting less when addressing questions about the effects of research in local communities.

Dr. Dillard began the conversation with a question about the ethics underlying the needed exceptions to data sharing in terms of the potential for stigmatization and the role of tribal sovereignty. Does each NIH Institute have the ability to decide when to make exceptions to data sharing? NIH has a long, complicated history of having been formed Institute by Institute over the years, said Dr. Collins. Until the last 20 years or so, many Institutes operated somewhat autonomously. NIH continues to see a growing trend toward more agreed-upon policies across all of the ICs; however, Congress gives the budget for each IC as a line item, so Institute directors have a fair amount of authority.

Taking the question as an action item, NIH will continue to address the issue of becoming one organization during regular weekly meetings with the ICs, said Dr. Collins. Tribal sovereignty and the importance of waivers for data access issues, particularly in regard to clinical trials, remain critical issues that NIH should honor consistently.

Speaking on behalf of the United South and Eastern Tribes (USET), Chief Malerba thanked Dr. Collins for restoring the funding to the TECs. Tribal set-asides also are vital when involving tribal nations and research. USET hopes for a less cumbersome process in the future. Last, the organization wanted to know Dr. Wilson's role in evaluating tribal research. Would there be expert review when tribal research is being proposed?

The THRO can provide that kind of expert advice across NIH to ensure consistency in the review of research applications, said Dr. Collins. At a minimum, the ICs might seek advice from the office when these issues arise. Dr. Wilson noted initial conversations with the Center for Scientific Review as the THRO continues to determine what such a process looks like and areas for improvement. Dr. Tabak reminded TAC members to submit to Dr. Wilson the names of prospective reviewers.

Dr. Dillard commented on a larger issue of how the review process in general favors certain types of credentials. Conversation should continue on the underlying processes and biases that result in funding the same types of grants to the exclusion of others.

Councilman Antone recommended discussions on the Native specimens for the *All of Us* biobank project. At this point, the biobank seems to be open for any researcher to use the specimens for any research. Tribes have ongoing concerns about this issue as it has the potential to do good as well as harm, said Councilman Antone. Dr. Collins noted that the *All of Us* biobank at the Mayo Clinic will be the repository for blood and urine specimens from those who agree to participate in the million Americans' efforts to understand health and disease. A review process will oversee the biobank to ensure that specimens are used for research that aligns with the consents of the participating individuals.

Because the *All of Us* Research Program remains in the beta testing phase, the review process for the biobank is still incomplete. Many of the plans regarding governance are still in draft form. Dr. Collins expected the TAC to get more insight during the second day of the meeting.

Many of the issues the TAC continues to address come down to responsibility, said Dr. Villegas. With the *All of Us* Research Program, for example, questions remain about how NIH addresses the role of industry, particularly pharmaceutical companies. As Native leaders, TAC members want to know who is responsible, what is the motivation for the initiative and what is the intent.

Dr. Villegas also expressed concerns about investigator-driven exceptions and responsibilities on investigators. Broader systems, including universities and industries, have responsibilities as well in policy conversations. Overall, as communities contribute into large repositories, how should stewards of that data structure its use? Tribal leaders and Native organizations should be part of that conversation.

Data that can lead to exciting cures also relates to people, their personhood, and concerns about privacy and use, said Dr. Collins. The *All of Us* Research Program will likely set up a system where data is shareable but not available without clear explanation of the data's use to a group representing the interests of the participants.

Others also have wondered about industry's participation, said Dr. Collins. NIH does not carry treatments all the way through to the point of having them clinically available. That is industry's role. Industry will move quickly toward treatments when it has a chance, with legitimate reasons and oversight, to see the data.

Councilman Phelps raised three issues: Will there be a time for tribal consultation on the Common Rule? Second, the *All of Us* Research Program will not go through the tribal IRB process but there is still a need for tribal input into that initiative. And last, in areas of dispute resolution, the Navajo Nation wants to settle issues in tribal courts.

Dr. Collins agreed that tribal sovereignty dominates if there is a concern about a particular issue. NIH issued the final rule regarding the Common Rule but it has many areas of potential interpretation in terms of how to apply it in given circumstances. As the Common Rule will not go into effect until early next year, hearing from tribes could be a good idea.

Regarding *All of Us*, Dr. Collins noted a May workshop that brought together the perspectives of several tribes and NIH staff. More work remains, and no one benefits from rushing through the process. Further, NIH wants to respect tribal sovereignty in every way.

Representing California, Joshua Saxon-Whitecrane asked how NIH seeks to prioritize research needs surrounding opioids, and how multiple Institutes might address the issue. Indian Country faces pain management problems as well as mental health and social concerns, said Councilman Saxon-Whitecrane, a councilmember for the Karuk Tribe.

Dr. Collins agreed that the opioid crisis is not a simple matter. Many addicts have other overwhelming mental health issues. NIH remains interested in identifying more effective options for treating about 2 million opioid addicts. Another concern: For programs that show some evidence of working, do those programs work long term or is the relapse rate extremely high? Last, NIH hopes to speed up the development of potent, nonaddictive alternatives to opioids for those who need pain treatment. 26 million people in the United States suffer daily from pain, said Dr. Collins.

The White House is working to get industry to accept its role and responsibility in finding other solutions. NIH also continues to collaborate on this unprecedented health crisis with IHS, the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration and other agencies.

As Dr. Collins prepared to leave, President Killsback stressed the importance of including meaningful tribal consultation in every aspect of the topics raised during the TAC conversation. Dr. Tabak took a question from Mr. Saunkeah, who noted that the current research grant structure is not conducive to developing participatory relationships. These relationships require time to build trust before tribal communities want to participate in research. Will the system make allowances for the grant structure so researchers and tribes have time up front to address tribal health priorities?

Some NIH Institutes might be further along in this type of thinking, said Dr. Tabak. Dr. Tabak further suggested consultation with relevant NIH staff and the committee as a separate exercise or part of a future meeting. A consultation on the opioid crisis also could bring tribes into the conversation. Climate change and environmental health also present critical challenges, said Dr. Villegas. Infectious diseases could be on the increase due to Hurricane Harvey, and these storms will not stop coming. Tribes see a role for research and science in helping to guide solutions. The TAC can assist in this effort as NIH defines its role in environmental health research, said Dr. Villegas.

Dr. Tabak noted that changes in climate influence health. Although NIH does not study the causes of climate change, the agency does address how those changes affect human health. Most of this work occurs through the North Carolina-based National Institute of Environmental Health Sciences (NIEHS). The Institute continues to address such topics as worker safety in areas affected by natural or manmade disasters. Discussions on these issues should take place before tragic events occur, said Dr. Tabak. NIEHS also can quickly receive, review and fund research due to the temporal nature of these events. Further, NIEHS has a diverse portfolio that addresses AI/AN research, said Dr. Wilson.

Councilman Phelps yielded to Dr. Begay, who returned to the subject of tribal sovereignty. If tribes don't participate in federal research, will that mean a cessation of federal funding support to tribes? Further, Navajo Nation law states that the tribe owns the data, but what does that really mean? Perhaps a test case could pave the way and present an option that other tribes could replicate, said Dr. Begay. Such an effort would go beyond rhetoric and work out all the details.

One example of a test case is the Navajo Nation's work with the ECHO program, said Dr. Tabak. NIH used a flexible, communicative approach to encourage the tribe's participation. Overall, NIH hopes to be inclusive, not exclusive, said Dr. Tabak. If participation benefits the tribe and the study, NIH will take the additional time, energy and effort to work through complicated issues to ensure participation. No tribal participation at all is the worst option, added Dr. Tabak. ECHO has served as a good example because Dr. Blome, and Director Matthew Gillman, M.D., have listened to tribal communities and made the program more inclusive and ultimately more effective, added Dr. Wilson.

TAC members ended the day with a brief discussion on a few proposed changes to the TAC charter. The meeting adjourned at 4:37 p.m., to resume at 9:00 a.m. on Friday, September 15.

Tribal Advisory Committee Meeting
September 15, 2017
Day 2

Welcome and Introductions

In the absence of President Killsback, Chairwoman Onnen opened the second day of the TAC meeting with a brief recap before the committee moved into tribal caucus.

8. BRAICELET Program Presentation and Discussion

Marcia O'Leary, Manager, Missouri Breaks Industries Research, Inc.

Joseph M. Yracheta, Senior Researcher, Missouri Breaks Industries Research, Inc.

Understanding requires data, said Ms. O'Leary of Missouri Breaks. Speaking on the topic of sovereignty, equity and data sharing, Ms. O'Leary noted that communities cannot make decisions without reliable information.

The Strong Heart Study recruited Missouri Breaks to conduct morbidity, mortality, and eventually the Sleep Heart health study. Today, Missouri Breaks serves the Rosebud, Pine Ridge, Cheyenne River, and Spirit Lake tribal communities by bringing data and building research capacity. The organization's research serves some of the poorest communities in the United States. Rather than charitable support, Missouri Breaks wants these communities to have a place at the table.

Since 1995, Missouri Breaks has participated in research with the Centers for Disease Control and Prevention (CDC), NIH including the National Institute of Diabetes and Digestive and Kidney Diseases, and private institutions. These efforts have impacted thousands of participants, said Ms. O'Leary. Missouri Breaks encourages communities to grow their own and educate residents. The organization conducts annual research symposiums to recruit students. Further, students have learned to mentor other students. Even with funding stops and starts, Missouri Breaks continues to succeed thanks to partnerships that help sustain and move the program forward.

Ms. O'Leary devoted time to focus on the Biorepository for American Indian Capacity, Education, Law, Economics and Technology (BRAICELET). Teaming up with various entities helps Missouri Breaks ensure that Native communities benefit from research.

Mr. Yracheta spoke on efforts to turn precision medicine into precision health, which accounts for genomics, prevention, lifestyle choices, maternity and fetal care, early childhood and economics. BRAICELET is one of three projects researchers have directed toward minority groups, seeking to take data from previous research back to these communities. These populations will determine their own definition of meaningful research. In addition to BRAICELET, projects include a Mexican American pediatric obesity project and a focus on breast cancer in minority women in the San Francisco Bay area.

BRAICELET came from a 2009 project on autoimmune illnesses. Studies have shown a high prevalence for rheumatoid arthritis, a disease not deeply researched in American Indian communities. This study has led to a comprehensive analysis that includes clinical visits and examination of such lifestyle issues as smoking in addition to epigenomics.

Mr. Yracheta also discussed the differences between parity and equity in relation to research. Tribes would rather be at the table than on the menu, said Mr. Yracheta. The NIH *All of Us* Research Program seems to pursue parity. Tribes hope to bridge the gap between parity and equity.

The BRAICELET grant includes mechanisms that protect data and help tribes see a way forward. Efforts from the United Nations Indigenous Council and other indigenous groups led to principles that help tribes begin from a place of ownership to establish parity. Further, biorepositories ensure long-term data while promoting ethical/moral uses. Samples can be repatriated back to tribes, which helps Native communities feel more comfortable with genomic endeavors.

Mr. Yracheta also hopes to create a biobank for non-human genomes given the interest in microbiome and plant and pharmaceutical research. Banking environmental samples also can help researchers identify, for example, when mercury levels increased in a water supply. All these efforts assist with social determinants of health.

Science can offer a pathway to good health by identifying the changes governments and societies should make. Ultimately data sharing can serve as a good tradeoff that leads to infrastructure and capacity building, more accurate findings and solutions to public health concerns. Programs such as BRAICELET and Strong Heart, along with partnerships with NIH, will enhance tribal research and lead to policies and procedures that will benefit tribal communities.

Ms. O'Leary hopes to continue to grow community researchers, work with university partners, team up with tribal colleges and inform tribal leaders. Community advisory groups can assist by conducting surveys on how people feel about genomic research and biobanks. These advisory groups also may serve as in-community lobbyists and advocates who may help researchers design projects. To fully participate in data sharing, tribes need access, control, legal protections, economic leverage and the ability to grow sovereignty. Most of all, tribal communities must solve their own health disparities.

Dr. Anderson asked how Missouri Breaks plays a role in the pipeline of improving health. Ms. O'Leary noted that a recent screening for Human Papillomavirus (HPV) showed that the HPV strain that doctors vaccinated for was not the strain found in the community. As a result, Missouri Breaks let IHS know that it needed to change its vaccine. Dr. Villegas expressed interest in connections to industry and workforce. Mr. Yracheta responded by highlighting efforts to attract and train interns.

Responding to a question from Dr. Wilson on the biobank's long-term vision, Mr. Yracheta hopes other tribes will participate in a genomic research study. Missouri Breaks continues to work toward a regional, inter-tribally governed biobank while increasing lab capabilities and research curricula on tribal colleges. NIH can help by providing sustainable funding and encouraging researchers to understand tribal sovereignty. Tribal leaders should focus on educating elected officials and decision makers about basic Native issues, added Chairwoman Onnen.

9. Alaska Area Specimen Bank Presentation and Discussion (Videocast)

Karen M. Rudolph, Ph.D., Director, Alaska Area Specimen Bank

Denise Dillard, Ph.D., Director of Research, Southcentral Foundation, Alaska Area Delegate, TAC

Dr. Rudolph spoke via video-cast to highlight the purpose and efforts of the specimen bank. The Arctic Investigations Program (AIP) is the Anchorage-based field station of the CDC. Located on the Alaska Native Health Campus, the program focuses on infectious disease prevention and control research studies through applied epidemiology, laboratory, computer and statistical sciences. AIP seeks to prevent infectious disease morbidity and mortality in Arctic and Subarctic people. The program puts special emphasis on diseases of high incidence and concern among indigenous peoples.

Human health research in Alaska addresses health disparities and improves the health of all Alaskans, said Dr. Rudolph. The agencies involved in conducting research established a policy to save and store biological specimens from human subjects research that were not depleted during the course of a study. The secondary testing of previously collected biologic specimens can allow assessment of disease prevalence, contribute to the understanding of the natural history of disease and benefit the health and well-being of populations.

The policies and procedures document that governs the management and operations of the bank establish purpose, ownership and objectives. The bank ensures that researchers use stored biologic specimens collected as part of human research studies in accordance with:

- the conditions specified in informed consent
- the health priorities of Alaska Native peoples, and
- the principles of good scientific methods.

Consenting individuals retain ownership of their specimens, and they can ask for removal, destruction or testing at any time. The Alaska Area Specimen Bank Work Group provides oversight of the bank. The Specimen Bank Committee manages day-to-day operations.

Providing a closer look at the bank's process of informed consent, Dr. Rudolph noted that study participants must agree to have remaining specimens saved for future testing. The consent process has two parts: consent to be in a research study and then consent to store and test specimen at a later date.

This additional consent allows the study participant to agree or decline to have any remaining specimen stored in the bank for future testing. The bank does not store anonymous specimens.

Future testing or secondary use of specimens in the bank may be related or unrelated to the original study. Any future testing related to the original study goal will require an amendment to the original study protocol, which must be approved by the IRBs and tribal health organizations that approved the original study.

Future testing not related to the original study will require a new research protocol that is subject to appropriate IRB and tribal health organization approval. Any new study that requires access to banked specimens linked to a participant's identifying information requires that individual's consent.
Dr. Rudolph's comments also addressed specimen deposits and withdrawal, specimen bank costs, storage and the materials currently housed in the bank. The bank has more than 340,000 specimens, representing more than 104,000 people. Nearly 80 percent have come from Alaska Native/American Indian persons.

The Southcentral Foundation conducted a survey in 2017 to explore the views of biobanking and future use of samples among Alaska Native leaders and community members. Respondents expressed concerns about

- Previous harmful research
- History of poor care with little explanation provided
- Harm due to stigmatization
- Concerns about future research and technologies such as cloning, and
- The return of specimens upon death

Survey respondents also provided their expectations about research. Respondents wanted to know the motive behind collecting specimens, and they desired an extensive consent process. The community also questioned how the biobank would store, share or destroy specimens. Sharing results presented another concern. People wanted their individual findings returned. Residents also wanted community leaders to see the results before public dissemination, and rather than just a presentation of findings, communities requested answers that can spark real change.

Dr. Dillard answered a few questions about biobank protocols and cost. When Southcentral Foundation has a study that involves depositing specimens in the bank, the cost has been about $30 a specimen. That is a one-time cost, Dr. Rudolph added.

Dr. Dillard noted that in some studies, about 40 percent of the people participate in the research study and agree to have a specimen banked for future use. In other studies across Alaska, as many as 75 percent of people who participate in a study agree to have specimens banked. Most of the data may be in the possession of individual investigators, said Dr. Dillard. Dr. Best proposed that NIH make efforts to either modify legislation for the Clinical Laboratory Improvement Amendments or develop a workaround to share findings with participants.

10. Lunch with American Indian/Alaska Native (AI/AN) Scholars

During the working lunch, TAC members enjoyed remarks from Native scholars Sara Kimmich, Alec Calac and Kimberly Paul, Ph.D. The students discussed their research projects, future goals, unique paths to NIH and ways to give back to Indian Country.

Ms. Kimmich appreciated growing up in a tribal community and receiving encouragement at every level of education. Ms. Kimmich continues to work with the local Native American Research Centers for Health.

Mr. Calac highlighted rewarding experiences in biomedical research and advocacy for the betterment of AI/AN health. Working with NIHB and Tribal Youth Health Policy Fellows, Mr. Calac promoted a program tentatively called the Special Behavioral Health Program for Indians. The program mirrors the successful SDPI program. Other priorities for Mr. Calac include substance abuse prevention in youth and tribal food sovereignty.

Dr. Paul is the first Blackfeet Indian to have a Ph.D. in a science, technology, engineering or math field. With such a pivotal role, Dr. Paul keeps tribal needs in the forefront and hopes to create a larger pipeline of students to come to NIH. Part of that process includes using Native college students as a co-PIs in research on tribal lands, similar to the strategy used by the Navajo Nation Research Board. Ms. Kimmich challenged the TAC to think beyond pipelines to creating platforms for highly qualified students who are well-prepared for challenging roles.

TAC members can support the scholars by providing encouragement, said Rita Devine, Ph.D., of the National Institute of Neurological Disorders and Stroke.

11. Environmental influences on Child Health Outcomes (ECHO) Program Update and Discussion

Juliana Blome, Ph.D., Chief of Staff

The ECHO program continues to focus on walking softly and listening carefully, said Dr. Blome. As a new program, ECHO seeks to build partnerships, understand tribal culture and sovereignty, and develop policies and procedures. Tribes also should benefit from ECHO as the program works to enhance the lives of children for generations to come, said Dr. Blome.

Childhood exposures that go from society to biology, macro to micro, can include air pollution, stress and maltreatment, diabetes and cardiovascular disease. ECHO researches those exposures from conception to age 5. The program also focuses on such high impact health conditions as obesity and neurodevelopment issues that occur during childhood and adolescence.

One area of focus for ECHO includes cohorts. Relying on existing and new data, researchers address solution-oriented questions. ECHO also offers a Pediatric Clinical Trials Network that occurs in Institutional Development Award (IDeA) states where there are children living in rural, medically underserved areas. Information from both focus areas can help answer broad, scientific questions.

ECHO has just begun discussions with the Navajo Nation, added Dr. Blome. To better understand this work, Dr. Blome and Dr. Gillman have traveled to Alaska, Navajo and Albuquerque to gain valuable perspective. These travels revealed the need for deeper communication, outreach and engagement. ECHO staff also gained a better respect for the lack of trust expressed in tribal communities, said Dr. Blome. With new understanding, staff can focus on building trust and allowing for planning flexibility. Researchers must demonstrate respect for tribal sovereignty, IRBs, and laws and policies. Concepts of equity, justice and fairness must also have a seat at the table.

Dr. Blome next highlighted the Navajo Birth Cohort Study, one of 83 cohorts that make up the ECHO program. When the research application came in, the data sharing details were incomplete. However, ECHO thought the work was important enough to take the time to work on those details, engage the community, and think about how to achieve this effort.

The Navajo Nation is already sharing data with the University of New Mexico, with the approval of the Navajo Nation Research and Review Board. ECHO hopes to put all the cohorts together in a data analysis center. This effort can assist tribes by researching birth defects or examining exposures and outcomes. Dr. Blome also shared the working plan for ECHO data sharing, which would include a central repository at Johns Hopkins University.

Dr. Villegas asked about ways to connect research occurring in different domains. Dr. Phelps gave thanks to Dr. Blome for visiting with Navajo and NIH for its research investment. Mr. Saunkeah asked about outreach in Oklahoma, also an IDeA state. Dr. Blome offered to talk to Mr. Saunkeah offline.

12. *All of Us* Research Program Update

Provided by Dara Richardson-Heron, M.D., Director, Community Research

Presented by David Wilson, Ph.D.

Due to a conflict, Dr. Richardson-Heron could not meet with the TAC. Dr. Wilson read Dr. Richardson-Heron's brief update with hopes of following up on the topic during a TAC conference call.

Dr. Richardson-Heron noted that NIH has encouraged the *All of Us* Research Program to take its time rather than rushing through development. The program remains in the early stages of creating features, tools and resources for optimal participation.

Before opening widely, the program seeks to enroll a limited number of people as a beta or initial testers. In this beta phase, interested AI/AN participants can enroll. However, consortium partners will not conduct any targeted enrollment of AI/AN individuals until the program leadership has worked collaboratively with key thought leaders from the AI/AN community to develop a national strategy.

The *All of Us* Research Program plans to officially launch on a national scale either during late 2017 or early 2018. The programs expects that the research portal will be accessible and research studies on the collected data will begin approximately one year following the national launch.

Initial participants are answering questions about their lifestyle, environment and health history. They also are providing blood and urine samples and sharing their electronic health record.

The data collected goes well-beyond genetics, and it is at the intersection of lifestyle, environment and biology. The program hopes to enable thousands of research studies with the collected data so everyone can learn more about what causes health and illness and thus create more precise treatments. The results of the *All of Us* research studies, done as part of the research program, will be made available to all participants. This is an important part of the value proposition that *All of Us* is making to individuals who join the program.

The program seeks to ensure that Native researchers gain access to the data and have the ability to perform science studies that will help answer some of the important preventative and wellness questions that are most relevant and will benefit Native individuals.

The *All of Us* leadership fully recognizes the need to obtain input and recommendations from leaders and experts in tribal nations to help address some of the potential challenges and identify mutually acceptable solutions that will allow and encourage robust AI/AN participation in the program.

The *All of Us* Research Program has thus far been in an information-gathering and learning phase to understand the concerns and potential barriers for tribal participation and the best way to engage with tribal nations. Representatives have either met or had calls with tribal researchers or leaders of tribal organizations, including the National Congress of American Indians, NIHB, and the Association of American Indian Physicians. The IHS, HRSA, colleagues at NIH and leaders serving on TAC also have given input.

All of Us leaders also have attended or plan to attend several AI/AN conferences. Based on research and conversations, the *All of Us* team has mapped out a three-part engagement plan:

- The formation of a Tribal Collaboration Working Group (TCWG). This group will include tribal leaders, researchers, providers and other experts in AI/AN engagement. A few TAC members also will serve on the working group.
- Ensure the TCWG feedback incorporates community perspectives. The working group will seek additional input from listening sessions, Webinars and Requests for Information. The *All of Us* Research Program also will request tribal consultation for additional input.
- The NIH team will ask the working group to prepare an initial report, including recommendations, by January 2018. NIH leaders and consortium members will review the TCWG's input and determine next steps. The *All of Us* Research Program also will explore opportunities to partner with tribal nations, IHS clinics, community health care centers or tribal researchers to further enhance and facilitate AI/AN enrollment.

Councilman Antone asked if the *All of Us* Research Program receives funds through congressional appropriation or the NIH appropriation. Dr. Anderson said Congress has found funds for the program and defines the amount of money each year.

The *All of Us* Research Program must clearly show the differences among the TAC, the working group and consultation, and how all three will inform *All of Us*, said Dr. Villegas. Dr. Villegas also asked about future working groups and TAC subcommittees.

13. Discussion on Priorities and Next Steps

Giving the TAC an opportunity for dialogue, Chairwoman Onnen highlighted two priorities: the *All of Us* committee and working group, and consultation. TAC members previously discussed the Consultation Policy for HHS. The TAC may need to outline a procedure as to how consultation will occur to create understanding between the TAC and the THRO, said Chairwoman Onnen. Dr. Villegas added to the discussion by asking what the process looks like when TAC members receive a request for consultation. The TAC also must determine the process for future NIH consultations. Kendra King Bowes directed the committee to the NIH Guidance on the Implementation of the HHS Tribal Consultation Policy in the meeting binder.

Other discussion points:

- The role of the TAC in assisting NIH, possibly through workgroups, to influence outcomes.
- Possible ways to engage with NIH and its ICs to address inconsistencies.
- Consultation on opioids. Dr. Anderson noted the importance of TAC input as NIH makes a major push in the area of opioids across the Institutes. Karol Dixon, health services director for the Port Gamble S'Klallam Tribe, briefly noted an innovative strategy the tribe implemented to address opioids. Chief Malerba encouraged the TAC to address substance abuse holistically. Councilman Saxon-Whitecrane requested condensed solutions/toolkits that tribes can use immediately.
- Previous TAC priority lists.
- Cultural competency training for reviewers and NIH program officers. Dr. Wilson noted the development of a best practices guide for conducting research among AI/AN people.
- Participation from all NIH ICs at TAC in-person meetings. The TAC also can use the monthly conference calls to hear from the ICs.
- A summary on the Common Rule for tribal council members. The TAC also should determine whether tribes need consultation on the Common Rule, said Councilman Phelps. Dr. Wilson is working on a Common Rule fact sheet with the Office of Science Policy.
- The inclusion of urban Indians and the Native Hawaiian community on the TAC.

As the meeting came to a close, Dr. Wilson acknowledged the participation of TAC delegates Dr. Villegas and Chief Jeromy Sullivan, Port Gamble S'Klallam Tribe, who will rotate off the committee at the end of September. Ms. King Bowes discussed possible dates for future in-person meetings. Councilman Antone proposed a tribal site meeting. Several members noted that the TAC and NIH continue to make strong progress forward. Following a closing prayer by Dr. Begay, the meeting adjourned at 2:46 p.m.