

Tribal Advisory Committee (TAC) In-Person Meeting

August 22, 2019

University of Alaska, Fairbanks

Butrovich Building, Room 109

2025 Yukon Drive

Fairbanks, Alaska

Meeting Summary

TAC Participants

Delegates

Breannon Babbel, Ph.D., National At-Large (*proxy*)

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

Yvette Roubideaux, M.D., National-At-Large (*proxy, via phone*)

Andrew Shogren, J.D., Portland Area (*proxy*)

Lisa Sundberg, California Area Delegate

Tim Thomas, M.D., Alaska Area (*proxy*)

Technical Advisors

Lyle Best, M.D., Great Plains Area

Suzanne Sisley, M.D., California Area

NIH

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

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

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

Contractor Support

Kendra King Bowes, Miami Environmental and Energy Solutions

Laura C. Jackson, notetaker, Audio Associates

Summary

- **Call to Order and Welcome**

The second 2019 NIH TAC in-person meeting was called to order at 9:00 a.m. by David R. Wilson, Ph.D., Director of the Tribal Health Research Office (THRO). Following the invocation by Denise Dillard, Ph.D., National At-Large Delegate, the committee went into Tribal caucus.

- **Discussion with NIH: *All of Us* Research Program**
Lawrence A. Tabak, D.D.S., Ph.D.

Following Tribal caucus, the full meeting resumed at 10:46 a.m. with a discussion on the *All of Us* Research Program led by Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director for NIH. Dr. Tabak reminded the TAC of the goals of the research program: to bring together one million or more volunteers from across the United States to donate health information for research. This program will likely be the largest and certainly the most diverse cohort in the nation. Any data collected will remain in a protected enclave. The data can never be sold, and any study that is going to be proposed must be made public as NIH seeks an unprecedented level of transparency.

Of particular interest to the TAC, there is no current active recruitment of American Indian/Alaska Native (AI/AN) members. NIH has conducted listening sessions and met with Tribal leaders during regional consultations throughout the year. NIH has scheduled one or two more sessions in Indian Country during the fall.

NIH reconvened the Tribal Collaboration Working Group (TCWG) to help summarize and give guidance on *All of Us* implementation. Leaders have invited AI/AN individuals to serve on the *All of Us* Resource Access Board. And NIH has removed sorting by AI/AN from the *All of Us* public data browser, said Dr. Tabak.

NIH plans to develop a Summary, Response and Implementation paper that will assess feedback and identify next steps. The TAC will review the document in draft form. Dr. Tabak asked TAC members for advice on the length and style of the paper and guidance on the best ways to frame AI/AN engagement.

Recalling the meetings and discussions that occurred throughout spring and summer 2019, Dr. Tabak shared an overview of Tribal members' key issues and concerns. Tribal leaders gave feedback on the importance of cultural respect, understanding and trust. Conversations also addressed data and biological samples as well as scientific issues. Many have asked for clarification of the research program's use of broad consent. Dr. Tabak asked for the TAC's advice on the approach and cadence of ongoing Tribal engagement after the summary paper's release. Other key questions for the TAC:

- How should the NIH share and disseminate the summary paper for maximum reach and readability?
- Once any kind of AI/AN recruitment collaboration begins, how should NIH approach recruiting urban AI/AN individuals?

- How should NIH split responsibilities between the research program, the Tribal Collaboration Working Group and the TAC?

During the discussion that followed Dr. Tabak's presentation, TAC members requested longer listening sessions to truly absorb the information. Those who attended previous meetings noted that the information presented raised more questions. The 'devil is in the details,' said California Area Delegate Lisa Sundberg, who serves as the TAC co-chairperson. Ms. Sundberg also recommended bringing in experts who understand the legal and scientific implications. These deep-dive sessions can occur during upcoming national Tribal meetings.

Dr. Dillard said members of the Alaska Native Health Board also requested more time to review the *All of Us* materials. Health board members also want to form a workgroup and bring in state experts before making recommendations. Because this project involves complicated issues, *All of Us* should slow the process down to give Tribes enough time for careful consideration, said Dr. Dillard.

Yvette Roubideaux, M.D., proxy for National At-Large Delegate Lynn Malerba, said the TAC appreciated that NIH has escalated attention and resources to understand Tribal needs. Dr. Roubideaux noted that the first round of consultations earlier in the year seemed to either raise more questions or provide conflicting answers. One suggestion: *All of Us* should plan a national meeting that provides a day or two of in-depth detail and understanding. The final day could include a consultation session during which advisors can assist Tribes about the issues.

Broad consent remains an issue, added Dr. Roubideaux. Further, people do not agree that *All of Us* is just a platform. The program recruits people for research and creates data sets with identifiable data. Genetic data and Tribal affiliation are potentially identifiable. *All of Us* must explain why the gathering of data is not research. Because of NIH's government-to-government responsibility, Tribes would consider that a part of the research project, said Dr. Roubideaux. Tribes need more information on the whole process and clear answers before making a recommendation.

Mr. Shogren recalled a successful NIH consultation in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA). The two-day meeting occurred prior to a National Indian Health Board (NIHB) meeting. The first day set the table with information. During the second day, Tribal leaders provided good input after taking time to process the details. Mr. Shogren recommended the *All of Us* program use a similar format for longer meetings.

Mr. Shogren expressed concern that even though *All of Us* is not actively recruiting from AI/AN communities, the research program does allow self-identified Tribal participants into the

program and retains the data. During this period of trying to determine Tribal collaboration, such involvement may not be appropriate. These concerns are a result of building the process after it had already started, said Mr. Shogren. How should *All of Us* handle Tribal participants who walk into a local CVS and want to sign up? Should the research program completely embargo that data or turn people away until *All of Us* has time to develop a process for Tribes?

Dr. Tabak said the issue is a conundrum, and NIH would appreciate any TAC guidance. Eric Dishman, Director of *All of Us*, said the research program will embargo all Tribal data until a solution is clear. Mr. Dishman would prefer to inform Tribal participants that the data is under embargo.

Lyle Best, M.D., Technical Advisor for the Great Plains Area, asked about compensation or incentives. Mr. Dishman said the program offers \$25 to those who come in to give a blood draw and urine sample. TAC members also discussed how *All of Us* could work with AI/AN researchers as equal partners.

Dr. Wilson wrapped up the session by proposing a two-step approach: The TAC might appoint or nominate a technical advisor from each Indian Health Service (IHS) area. These technical advisors would go into deep detail with Mr. Dishman and the *All of Us* team. Findings from the technical advisors would go to NIHB or the National Congress of American Indians (NCAI) for Tribal leadership approval.

- **THRO Report**
David R. Wilson, Ph.D.

Dr. Wilson highlighted plans and accomplishments for the THRO, including new staff, congressional activities and the NIH Strategic Plan for Tribal Health Research. The year also has included consultations on intellectual property and data sharing/management.

Dr. Wilson noted that policies that affect and apply to biomedical research were established decades ago. THRO staff members want to present these issues to the TAC and Tribal communities to determine how these policies support or inhibit Tribal participation. THRO can bring feedback from Indian Country back to NIH to improve the biomedical research process.

Work also continues on the NIH Tribal Consultation Policy and the consultation protocol to ensure that THRO and NIH staff members conduct these activities in a consistent manner, added Dr. Wilson. Other U.S. Department of Health and Human Services (HHS) divisions are waiting on this document to incorporate successful ideas from the THRO and to create standard procedures across operating divisions.

Venturing outside of HHS, THRO staff sat on a Senate Committee on Indian Affairs roundtable this year to discuss how the office addresses health disparities in Indian Country. THRO also coordinated with other NIH offices to take the AI/AN summer interns to Congress to meet with representatives and understand the legislative branch of government.

Dr. Wilson also highlighted site visits to the Blackfeet and Yakima Nations and the monumental signing of the Navajo Nation data-sharing agreement.

Upcoming activities include the FY 2018 AI/AN portfolio analysis and the Traditional Medicine Summit in November in partnership with the National Center for Complimentary and Integrative Health (NCCIH). Additional collaborators include Indian Health Service, Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention (CDC). Dr. Wilson also expects participation from SAMHSA.

The event will include 1 1/2 days of closed sessions with traditional healers. The second half day will feature an anthropologist from the National Museum of the American Indian. The second day also will include open sessions with staff from the NCCIH. The conversation will highlight work on Eastern traditional medicine to give summit participants an idea of how NCCIH might develop a portfolio related to Native American traditional medicine. The 2020 summit will examine how IHS and SAMHSA can use traditional medicine effectively and how research can support those efforts.

Ms. Sundberg requested a pre-meeting discussion on the agenda and a focus on plant-based medicines. Dr. Wilson said the event subcommittee, comprised of medicine men and women and members of the community, will develop the agenda during the closed session. As conversations continue about the agenda, Dr. Wilson will share information with the TAC. The event space holds 100 people and the budget includes an honorarium for the traditional healers. Dr. Wilson asked for a list of TAC members who want to attend the summit so THRO staff can factor that information into the logistics.

During the question-and-answer portion of the presentation, Dr. Best encouraged more NIH program officers to visit Tribal communities such as Emmonak. Breannon Babbel, Ph.D., National At-Large Proxy for Debbie Danforth, said future TAC meetings in Indian Country should include similar site visits. TAC members also asked THRO staff to develop a liaison role to help point Tribal communities to the federal agencies that might help address mental health, obesity or other critical issues.

- **BUILD-funded Biomedical Learning and Student Training (BLaST) Program**

Karsten Heuffer, DVM, Ph.D., FHEA

BLaST Principal Investigator
Associate Dean of Veterinary Medicine
University of Alaska, Fairbanks

Arleigh Reynolds, DVM, Ph.D., DACVN

BLaST Principal Investigator
Director of One Health
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The BLaST program stands for Biomedical Learning and Student Training Program. It is part of NIH's Diversity Program Consortium, an effort launched by a report about nine years ago from an advisory committee to the director on diversity in the biomedical research workforce. BLaST seeks to address the underrepresentation of rural students in the biomedical workforce.

The program targets rural/indigenous students, particularly Alaska Natives, as well as institutions in the lower 48 states. The program relies on Research Advising and Mentoring Professionals (RAMPs) to create a supportive community that fosters student research and careers in biomedical research. Rather than focusing on Ph.D., R01-funded research, the program encourages students to succeed and contribute to a healthy community and healthy research or health-related research in Alaska and beyond.

Dr. Reynolds highlighted the RAMPs, the cornerstone of the program. About 21 percent of the incoming University of Alaska, Fairbanks, students are Alaska Natives. In 2013, prior to when the program began, only about 9 percent of the graduating students were Alaska Natives. That number has since increased to 13 percent.

RAMPs help rural/indigenous, nontraditional students navigate work/life balance and other challenges that can get in the way of graduating. Those challenges include jobs, families, single parenthood, and limited math/science skills due to the quality of the schools in small, rural communities. Available daycare would allow part-time students to participate in the program, added Dr. Reynolds.

RAMPs help students navigate these challenges while staying true to themselves. Students participating in undergraduate research can get assistance with experiments, proposals, lab techniques and other strategies. RAMPs also provide academic advising and psychosocial support.

UAF has expanded the BLaST program to campuses in Juneau, Sitka and Ketchikan. UAF also has new partners in Colorado, Arizona, New Mexico and Montana.

Following the presentation, NIH TAC members asked questions about RAMPs training and salaries, housing for nontraditional students and strategies for matching students with mentors. Dr. Reynolds said the NIH TAC can assist the program by helping NIH program officers understand that BLaST defines student success differently. Rather than focusing on the number of graduates, Ph.D. candidates and other data, Dr. Reynolds and Dr. Hueffer want the students to identify and reach their own goals. For some students, that could be nursing.

Dr. Wilson offered to talk to Dr. Hueffer and Dr. Reynolds further and take program recommendations back to the National Institute of General Medical Sciences.

- **Congress 101**
Donna Crews
Legislative Analyst
Office of Legislative Policy and Analysis

Ms. Crews discussed the legislative players and processes that affect NIH appropriations. NIH invites lawmakers to visit the Institutes and Centers to ask questions, see where funds are going and understand how legislation impacts research. NIH enjoys bipartisan support, and appropriations have grown over the years.

Reviewing recent and upcoming elections and turnover on Capitol Hill, Ms. Crews noted the diversity of the 116th Congress. New members on Capitol Hill include the first two Native American women elected to Congress. The 116th Congress also includes 35 physicians and scientists. The discussion provided insight on the typical congressional office and upcoming issues on the political landscape.

TAC members asked questions about when and how to secure more funding for THRO issues. Suzanne Sisley, M.D., Technical Advisor for the California Area, discussed the challenges of getting support from the National Institute on Drug Abuse (NIDA) to study medically active plants. The balance of the funding goes to studying plants such as cannabis for drug abuse and not as medicine.

Dr. Wilson said NCCIH might be a better source of funding. Kathy Etz, Ph.D., a Program Director for NIDA, added that multiple Institutes conduct cannabis research. Dr. Sisley said other plants in addition to cannabis have been criminalized as studies focus only on harmful effects and addiction. Some of those plants can serve as medicines too. Ms. Sundberg discussed food science and obesity. Ms. Crews said researchers tackle obesity as well as diabetes within the National Institute of Diabetes and Digestive and Kidney Diseases.

- **Discussion of “American Indian and Alaska Native Research in the Health Sciences: Critical Considerations for the Review of Research Applications” Document**

Kathy Etz, Ph.D.

Director, Native American Programs

Program Director, National Institute on Drug Abuse

Dr. Etz sought feedback from the TAC on the Critical Considerations document, which aims to improve the review of AI/AN health research grant applications to the NIH by helping reviewers understand the implications of sovereign nation status for research.

These implications include the unique context as well as approvals for research, data sharing, data ownership, scientific approaches, community engagement, and potential exemptions to NIH policies. After considering the scientific review criteria of the NIH, reviewers will understand how AI/AN research might look a little bit different. The document includes examples of helpful and unhelpful reviewer comments.

To develop the document, NIH hired under contract these four AI/AN scientists who are funded by the agency:

- Karina Walters, MSW, Ph.D.
- Melissa Walls, Ph.D.
- Denise Dillard, Ph.D., and
- Judith Kaur, M.D.

A team of NIH staff worked with the writers. An external review committee that was comprised of about 20 people, who are focused on AI/AN research, reviewed the document and provided feedback.

TAC members did not receive the information in time to provide comments during the in-person meeting. The committee and Dr. Etz agreed that TAC members would provide written comments on the document by September 5 and participate in a conference call on September 6. TAC members want to address such issues as dissemination of the document as well as metrics to determine whether the document makes a difference in the review process.

- **TAC Update and Discussions**

TAC members wrapped up the in-person meeting with a review of comments received on the draft NIH Tribal Consultation Policy. TAC members also discussed feedback from the data sharing/management and intellectual property consultations that occurred during the year.

- **Topic 1: Tribal Consultation Policy**

Reviewing comments for the draft NIH Tribal Consultation Policy, THRO Policy Analyst Ted Keane noted that much of the draft policy is based on CDC, SAMHSA and HHS policies.

Written comments from National At-Large Delegate Chief Lynn Malerba, highlighted the functionality of *Federal Register* notices for communicating with Tribes. Chief Malerba's written comments said if there will only be a *Federal Register* notice, then there should also be an all-Tribes call with a webinar to understand what the issue is. Dr. Dillard agreed and requested more time than 45 days. Dr. Wilson said more than 45 days could be a challenge due to collaborations with NCAI or NIHB.

Dr. Roubideaux discussed NIH's use of 'request for information' notices (RFIs). Most agencies send 'Dear Tribal Leader' letters and include an e-mail address for Tribal feedback. Dr. Wilson said sending the letter would cut down on response times and help THRO staff collect comments immediately after consultation. The Tribal consultation protocol will now include the Dear Tribal Leader letter and e-mail as the sole mechanism.

Other written comments from Chief Malerba focused on Tribal resolutions being the catalyst for consultation procedures. Some Tribes may have other mechanisms to express formal Tribal governing body actions. TAC members recommended review of the issue by NIHB and NCAI. Dr. Roubideaux agreed to share the information with NCAI for clarification.

TAC members also questioned how communications, that are part of the decision-making process within an agency, affect transparency and trust. Dr. Wilson said NIH and THRO work hard to be as transparent as possible and share information as needed within the confines of federal law. Confidential information, such as a TAC member's home address, does not go out to the public.

Another comment noted that not all Tribes have treaties, and some were never signed by the federal government. The federal government, however, has the same treaty and trust obligations for all Tribes. Mr. Keane said the draft NIH Tribal Consultation Policy might benefit from a revision. So instead of the text reading: A legally binding and written document that affirms the government-to-government relationship between two or more nations, that it instead read something like between the federal government and one or more federally recognized Tribes.

Dr. Wilson said NIHB and NCAI can review this language as well. The NIH Office of General Counsel will also look at the consultation policy. Lastly, the policy will be the topic of the 2020 NIH Tribal Consultation.

- **Topic 2: Tribal Consultations on Data Sharing and Management and Intellectual Property**

Mr. Keane highlighted these themes from the Data Sharing and Management Policy Consultation.

- Theme Number 1: How is Tribal sovereignty considered in data sharing and management? This question raised the concept of ‘data on loan.’ This concept, used by the Navajo Nation, implies that data always belongs to the Tribe, said Dr. Wilson. It is loaned out to people for analyses and to make sense of what the data mean, but if the Tribe wants the data back or if there is an infraction in ethics, the Tribe can pull that data back into the community. Mr. Keane said one potential option would be to include a third-party storage arrangement to be able to enforce those procedures.
- Theme Number 1 also highlighted the NCAI term ‘indigenous data sovereignty,’ which is the right of a nation to govern the collection, ownership, and application of its own data. NCAI calls for consultation on this issue whenever it is brought up, said Dr. Roubideaux. Mr. Keane noted as a possible resource the U.S. Indigenous Data Sovereignty Network. Dr. Roubideaux prefers the term ‘data governance’ because the issue affects Tribal Nations.
- Theme Number 2: How does the existing data sharing and management policy respect Tribes? Mr. Keane said one comment noted how policies can be updated or adjusted to actively respect Tribes – particularly regarding genetic data. And as Dr. Roubideaux said, Tribal consultation should occur as these issues arise.
- Theme Number 4: Research findings must be communicated appropriately to the community. One step that might be taken is a current review of clinicaltrials.gov for ongoing studies that should have the findings disseminated back to the community, said Mr. Keane.

“Communicated appropriately” could look different depending on the research. Some types of dissemination might be better suited for regular cycles, reporting what has been happening in year one, two or three. Dr. Babbel noted that during some research studies, researchers might not have any findings to report on for some time. Regular updates on ongoing research would keep Tribal communities in the loop, said Dr. Babbel. Dr. Sisley added that researchers could

establish clear timelines of when a Tribe would receive a study update or final data. Researchers and Tribes could establish these timelines at the beginning of the process as part of informed consent documents.

Another comment highlighted the role of traditional foods in research, and communication and relationship building between research participants and collaborators.

- Theme Number 5: Why is it important for these populations to be included in the research?

Among the RFI responses, one comment said NIH should communicate potential benefits to the individual participants as well as to the community, and that the distinction should be clear before research begins. Mr. Keane said institutional review board (IRB) guidance for how researchers are allowed to communicate potential risks and benefits plays a huge role in this issue as well.

Dr. Sisley said some IRBs drill research studies down to such generic language, no one wants to join a trial or otherwise participate. IRBs worry about coercion while researchers seek broader language to create more incentive.

- Theme Number 6: It is important for the NIH to consult with Tribal Epidemiology Centers regarding data sharing and management with AI/AN Tribes and communities. In addition to consulting, however, TAC members said NIH should encourage infrastructure, capacity-building and training. Dr. Wilson said the language also should include Tribal health organizations.
- Theme Number 7: How do the NIH data sharing and management policies distinguish different types of data?

This topic led to discussions about adding a comment or response on how NIH protections around genomics or other types of data can protect Tribes from harm regarding non-health related analyses, said Mr. Keane. Analyses that are not necessarily in line with health research analyses can be damaging and stigmatizing.

Dr. Wilson said this complicated issue involves tiered types of data. Genomic data around specific disease conditions is very personal and may require a different level of data-sharing requirements.

TAC members said Tribally owned or operated data repositories might be a good strategy for

addressing some of these concerns. One such example is the Alaska Area Specimen Bank, said Dr. Wilson.

Dr. Best said journals want the data in publicly available data repositories. Because of policies related to this community, however, the journals know they cannot have that data and will not demand it, said Dr. Wilson.

Tim Thomas, M.D., Alaska Area Proxy for Donna Galbreath, asked for greater clarity on publicly available data. Is it a free for all or publicly available as long as researchers complete appropriate steps? These important details are similar to the data-sharing plans of many of the grants at NIH, said Dr. Wilson. A data-sharing plan can establish that data cannot be shared per a community's request or requirements.

Mr. Keane next addressed the themes from the Intellectual Property Consultation.

- Theme Number 1: The need to develop protocols on how researchers respectfully collect, handle, and dispose of biosamples such as hair, blood, or tissue. The first theme also included language to specifically capture medically active plants because wild plants are not necessarily covered under patent laws, but they might be able to be protected under intellectual property rights in this Tribal health research paradigm.
- TAC members discussed educating researchers on the importance of cultural sensitivity when involving Tribal members in biomedical research. Members also discussed the Collaborative Institutional Training Initiative (CITI) training, which mentions intellectual property. Dr. Roubideaux said the CITI training needs updating given the new Common Rule updates and the requirement to follow Tribal law.
- Theme Number 3: The importance of cultural sensitivity in informed consent for researchers working with Tribal communities. TAC members said consent is focused more on the individual level, whereas intellectual property rights are handled at the community level. Discussing cultural sensitivity and informed consent might be better suited in a discussion about informed consent rather than in a discussion about intellectual property, which is more in line with how to protect a community's right over intellectual property rather than an individual.

Dr. Roubideaux said with Tribes, there is an individual as well as community concern. An individual might sign up for the *All of Us* Research Program and agree to provide genetic

material. But if that person is a citizen of the Navajo Nation, there are limitations on that consent.

Broad consent means the person consents to have his or her data taken but he or she also consents to specific future uses. Those future uses impact the individual and the Tribe. So there has to be coverage for both of those issues, said Dr. Roubideaux.

- Theme Number 5: How the NIH policies support recognition of Tribal laws that govern biomedical research on Tribal lands, and research involving Tribal members outside of Tribal lands. Dr. Wilson said there are Tribes that do not have laws around this but do have procedures that must be recognized.

Dr. Roubideaux said the Common Rule update says that researchers with federal funding must follow federal, state and Tribal law. But that does not say that the researcher only listens to Tribes that have laws or research codes. Researchers must listen to Tribes due to the government-to-government relationship. The law is just a way to hold the researcher accountable.

- Theme Number 6: NIH support for building research capacity in Tribal communities, including the partnerships between institutions and researchers. Regarding intellectual property, it seems like that is a complex environment, the partnerships that exist there, said Mr. Keane.

TAC members discussed the importance of having these conversations on the front end. Ms. Sundberg also noted the implications of anything that is gathered. Tribes should know up front the impact research will have on the community. Dr. Roubideaux referred the TAC to NCAI, which wrote a letter on intellectual property rights. The letter is available on the NCAI Policy Center Website under Research Recommendations.

Mr. Keane also highlighted these standalone concerns:

- RFI comments called for a technical assistance module aimed at increasing understanding of intellectual property rights and biomedical research among the Tribes. Rather than a webinar, this would be information available at any time, said Mr. Keane. Dr. Wilson recommended posting material on partner websites.
- Establish a Tribal intellectual property rights point of contact at NIH.
- Focus on the central authority for IRB guidelines at HHS for cultural sensitivity

training. This could manifest within the research applications.

- Researchers should seek Tribal council approval where IRB availability is limited. Dr. Roubideaux said researchers should seek Tribal approval through whatever means the Tribe has established for research review. Dr. Thomas added that Tribes need more education so researchers cannot just come into Native communities waving paperwork from an IRB.
- An intellectual property Points to Consider document should include case examples that involve medically active plants. The document should broaden awareness of intellectual property and explain when to ask more questions.
- Create a system of accountability for enforcing intellectual property protocol.

In its letter to NIH on intellectual property, NCAI said NIH has a lot of different ways to help enforce things for Tribes or help require things for Tribes in the process.

When researchers want to apply for patents, they must notify NIH, said Dr. Roubideaux. At that step, NIH could have a checkbox that says did this research involve any data from Tribes? And if so, researchers would need proof that the Tribes agreed to it.

Even during the funding announcement stage, NIH could require researchers to provide evidence that they have negotiated intellectual property rights with a Tribe. The researchers also should demonstrate due diligence. When the patent, the intellectual property as a result of the research, gets recorded and there is potential to file for patent, the NIH could have a process to ensure that Tribal rights are protected, said Dr. Roubideaux. Tribes need NIH assistance throughout the process.

The TAC will discuss goals for 2020 during the next monthly conference call. Regarding conference call and meeting attendance, members suggested a reminder for TAC members who have missed too many meetings.

Ms. Sundberg agreed to prepare a letter for Dr. Tabak regarding TAC feedback on the site visit to Emmonak and the outcome of the meeting discussions. Following the closing prayer, the meeting adjourned at 5:00 p.m.

- **Action Items**

- Dr. Wilson offered to take BLAST program recommendations back to the National Institute of General Medical Sciences.

- TAC members will provide written comments on the Critical Considerations document by September 5 and participate in a conference call on September 6.
- The TAC will discuss goals for 2020 during the next monthly conference call. Regarding conference call and meeting attendance, members suggested a reminder for those who have missed too many meetings.
- Ms. Sundberg agreed to prepare a letter for Dr. Tabak regarding TAC feedback on the site visit to Emmonak and the outcome of the meeting discussions.

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August 22, 2019

List of Attendees

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