

Tribal Consultation on Intellectual Property in Biomedical Research
Sparks, Nevada
June 24, 2019

Meeting Summary

Welcome and Introductions

**Aaron Payment, Ed.D., Tribal Chairperson, Sault Ste. Marie Tribe of Chippewa Indians
Chairperson, NIH Tribal Advisory Committee (TAC)**

The consultation began at 9:00 a.m., with welcoming remarks from Aaron Payment, Ed. D., Chairperson of the Sault Ste. Marie Tribe of Chippewa Indians. The session included participants in the room and via conference call. Following the opening blessing, Chairperson Payment, who also chairs the NIH TAC, asked for introductions around the table.

This morning session also included remarks from David Wilson, Ph.D., Director of the NIH Tribal Health Research Office (THRO). The TAC initiated and proposed the consultation on intellectual property, said Dr. Wilson. Tribal communities often avoid engaging in biomedical research due to numerous concerns about commercialization.

THRO recently released the first NIH Strategic Plan for Tribal Health Research, which will help staff pinpoint the needs of Tribal communities. The first point in the strategic plan stresses increased communication and engagement. Consultation on intellectual property is part of that goal. NIH is invested in communicating with Tribal leaders and demystifying science and biomedical research to help Native communities benefit from discoveries occurring at NIH. Further, NIH remains the world's primary funding source for biomedical research, and Tribal Nations should leverage those discoveries as well, said Dr. Wilson.

Dr. Wilson invited consultation participants to review the strategic plan and engage in ongoing conversations on data sharing/management during the upcoming Department of Health and Human Services Regional Tribal Consultations. The sessions on data sharing/management will focus on the kinds of information that require protections.

NIH Programs and Policies on Intellectual Property

Dr. Wilson turned the session over to Mark L. Rohrbaugh, Ph.D., Director of Technology, Transfer and Innovation in the Office of Science Policy. Dr. Rohrbaugh reviewed inventions, patents and NIH intellectual property policies, basing the discussion on a recent webinar.

NIH seeks fundamental knowledge about the nature and behavior of living systems and leverage the application of that knowledge to enhance health, reduce illness and lengthen life. This mission guides the agency's efforts regarding patents and intellectual property. NIH uses intellectual property to transfer technology. Transferring technology can occur through publications, data research results, and discussions about findings. At times, it is appropriate to patent inventions or copyright materials that

come out of research. Intellectual property can advance the broader mission and serve the goals of the research participants.

Dr. Rohrbaugh stated that unlike tangible property, intellectual property is a creation of the mind. A person has produced something through research and mental processes. Intellectual property remains protected by U.S. and international laws regarding trademarks, patents, copyright, trade secrets and so on. Intellectual property systems aim to foster an environment that supports and protects creativity to benefit the public. The process helps creators or inventors earn recognition while supporting the commercialization of products, when appropriate.

A patent is an intangible property right given to an inventor. Patents come from the U.S. Patent and Trademark Office. Patents now last 20 years from the date that a regular patent application was first filed. Other processes exist for filing patents internationally. Efforts to enforce or keep others from infringing the patented materials must go through the federal courts.

Dr. Rohrbaugh's discussion included the types of patents, general requirements, and limits. The discovery of certain genes that lead to a propensity for alcohol addiction cannot be patented. In contrast, a specific way of using that information with a tangible device or specific methods could be patentable. Chairperson Payment noted the nuances in the regulations because traditional medicine typically is not distilled to a pill.

NIH also has guiding principles regarding genomic data from humans and other organisms. Human data is much more highly protected. The greatest public benefit will be realized when large-scale genomic data are made available in a timely manner to the largest number of investigators. Informed consent can designate how a party agrees for his or her data to be used.

Tribal Discussion

After reviewing the consultation policy, Chairperson Payment began the discussion period with questions about traditional practices. Some cultural practices are protected information and not for publication. Some Tribes, for instance, rely on oral traditions and have cultural beliefs against putting things in writing. Chairperson Payment also encouraged Tribes to develop institutional review boards (IRBs) to further protect data and craft memoranda of understanding (MOUs) with students or institutions that want to conduct research in Native communities. MOUs help all parties clarify data uses and restrictions, such as disaggregating data. These steps can keep researchers from simplifying or misstating data and reaching spurious conclusions, said Chairperson Payment.

Chairperson Payment also noted that a 20-year patent protection can seem exploitative because pharmaceutical companies can charge exorbitant prices until a patent expires, and the product becomes part of the public domain. On the other hand, if a company provided the money and resources for product research and development, the company wants to recoup that investment.

The session also addressed the disposal of human samples. Chairperson Payment expressed that Tribes should develop protocols on how researchers dispose of hair, blood, tissue or other biospecimens respectfully. Chairperson Payment next opened up the discussion for questions and invited conference call participants to submit their comments via e-mail.

Shirley Murphy of the Pine Ridge Reservation said that Tribal researchers and scholars have wrestled with the difference between traditional and Western knowledge. Ms. Murphy also discussed spending a lot of time as a researcher refuting terms and ideas. Western researchers, for instance, often label misunderstood concepts as “primitive.” These negative perceptions and other issues prevent Tribal members from enjoying and contributing to mainstream research.

Gloria Simeon of the Orutsarmiut Traditional Native Council in Bethel, Alaska, said that Native villages have been a gold mine for research for many years, typically without informed consent. These Tribes provided easy access for researchers because Tribal members did not know which questions to ask, said Ms. Simeon. Ms. Simeon also noted that commercial ancestry services look at genetics as well as health disparities and often share specimens for secondary or tertiary bioresearch. Ms. Simeon expressed concerns about biobanking and biopiracy. She also noted a need to develop informed consent documents and resolutions to protect Tribes.

Dr. Wilson stated that Tribal members can engage and fight for community needs by sharing concerns with NIH. NIH can use that information to develop more comprehensive and responsive policies. THRO remains committed to hearing Tribal voices. Tribal leaders also continue to push for culturally appropriate research, added Chairperson Payment. Members of the NIH TAC stress the need to train grant reviewers and advance understanding so that researchers know how to conduct studies in Indian Country. These and other efforts can create a framework for appropriate research. Chairperson Payment understands NIH is genuinely interested in getting it right, although staff must take the time to understand historical trauma and other Tribal concerns. Tribes must communicate positively and persistently to encourage such understanding.

Dr. Wilson asked Dr. Rohrbaugh how Tribal communities should start addressing the intellectual property process. When should these conversations begin with researchers who seek partnerships in Native communities? And when are patents pursued during the research process? Dr. Rohrbaugh said that these kinds of discussions should occur before research begins. Researchers and Tribal leaders should communicate about the effects of intellectual property and its uses, the potential for abuse and opportunities. These conversations will help Tribal leaders shape the results and use of the research in a way that meets community needs and traditions.

Dr. Rohrbaugh stated the patents process usually begins during the middle of research or at the end when researchers or communities identify potential inventions and make that information publicly available. Early discussions can help Tribal leaders understand where the process might go and the implications. Ms. Murphy also encouraged the consultation participants to reframe how Tribal communities view the U.S. Patent Office and the federal government overall. Ms. Murphy added that the issues remain complex because each Tribe operates as a collective and must consider future generations.

Victoria Sutton, a member of the NCAI Policy Research Center Advisory Council, recommended using cooperative research and development agreements (CRADA) between the federal government and the private sector or developing entity. Within that agreement, parties pre-decide how to share intellectual property or collaborative work. Dr. Rohrbaugh further stated that under a CRADA, the government gives first rights of any invention or intellectual property in advance of research commencing. Tribes can develop similar agreements with a university or organization. Similarly, Chairperson Payment noted the

use of MOUs between the Sault Ste. Marie Tribe and student researchers. These documents establish ownership of the data and the appropriate uses of the data at the end of the study. Tribes can develop these agreements and set terms and conditions as part of data sovereignty.

A question submitted via e-mail asked whether the applicability of the data policy being developed was limited to instances where NIH funding is involved or whether the policy expanded to non-NIH funded instances. Dr. Wilson said that intellectual property is established in federal law and applies to government funding as a whole and is beyond NIH funding. The consultation process helps NIH demystify the policies that currently exist.

Another question asked was how the NIH policy takes into account the applicable provisions of the United Nations Declaration on the Rights of Indigenous People (UNDRIP) in terms of recognizing that within Tribal territories, Tribal law is the primary law that governs biomedical research. Further, with respect to uses of biomedical research involving Tribal property outside of a Tribal territory, the free, prior and informed consent of the Tribe must be obtained before such use can occur. Although unfamiliar with UNDRIP, Dr. Rohrbaugh said these would be conditions and policies with respect to collaboration with researchers who are funded with the U.S. government. The policy would not apply to other circumstances.

Dr. Wilson added that most of the Tribal communities that have policies around research work through IRBs, and those policies are specific to the research project. The policies include getting an approval on how researchers conduct studies and they provide stipulations on how researchers communicate results and findings back to the community. Most IRB policies do not address how the Tribal community and researchers share potential inventions.

Dr. Rohrbaugh also said that under federal law, an inventor owns his or her invention. Ownership of an invention is not given to the institution or community with which the inventor works. The inventor must, in advance, assign rights in that invention to the institution that will control and own those rights.

Yvette Roubideaux, M.D., who serves as Director of the NCAI Policy Research Center, asked if Dr. Rohrbaugh had found, within the consultation process, good ideas for modifying the NIH policy to help protect Tribal sovereignty and ownership over data and research. Noting that the process had just begun, Dr. Rohrbaugh appreciated the Tribal discussion. Dr. Wilson added that the consultation process is the first step. NIH wants to identify and address problems in order to make the policy process easier. NIH will post all comments and recommendations on the THRO website after the consultation and the follow-up Request for Information processes. THRO will also post NIH's responses.

Ms. Murphy stated these issues trace back to traditional law – transferring indigenous concepts into a piece of Western knowledge. Ms. Simeon requested boilerplate resolutions or conditions that others can use to develop individual Tribal policies. Other Tribal leaders called for reciprocity and NIH-funded projects that promote capacity building in Tribal communities. NIH can require institutions and researchers to have a real partnership in Indian Country, the leaders said.

Dr. Wilson highlighted the Native American Research Centers for Health (NARCH) program funded out of the National Institute of General Medical Sciences. This year, at least 12 young Native scientists have participated in a weeklong immersion process at NIH, thanks to NARCH-funded programs across the

country. THRO also seeks to increase the participation of NIH Institutes and Centers to diversify the disciplines in biomedical research.

Ms. Sutton noted that NCAI has developed a guide for conducting genetic research in Tribal communities. The U.S. Patent and Trademark Office should know about this guide and avoid issuing patents to those who have not followed Tribal protocols, said Ms. Sutton.

Wrapping up the consultation, Dr. Wilson said the record will be open for 30 days after the consultation, and a Request for Information will also go out after the consultation. In the spirit of reciprocity, Tribal comments and feedback will shape strategies to help NIH engage Native communities, increase Tribal participation in biomedical studies and eliminate unethical research.

Whereupon, the consultation concluded at 11:12 a.m.

Action Items

- A Request for Information will go out after the consultation.
- NIH will post all comments and recommendations on the THRO website after the consultation and the follow-up Request for Information processes. THRO will also post NIH's responses.

Attendees at NIH Consultations on June 24, 2019

Loren Birdrather, Blackfeet Tribe
Sheldon Boyd, Mille Lacs Band
Christie Byces, Chickasaw Nation
Vanesscia Cresci, California Rural Indian Health Board
Christine Crossland, U.S. Department of Justice - NIJ
James DeLaCruz, National Indian Child Welfare Association
Devin Delrow, National Indian Health Board
Abigail Echo-Hawk, Urban Indian Health Institute
Sherry Ely-Mendes, Pyramid Lake Paiute Tribe
Gwynne Evans-Lomayesva, National Congress of American Indians
Richard Graymountain, San Juan Southern Paiute Tribe
Steven Hatnu, NAMUS
Haley Hammond, Picayune Rancheria of Chukchansi Indians
Herold Hammond, Picayune Rancheria of Chukchansi Indians
Jeremy Hayward, Redding Rancheria
Jennifer Hughes, Hobbs Straus Dean and Walker
Ashley Johnson, Leech Lake Band of Ojibwe
Laura Laitinen-Warren, Oneida Nation
Travis Lane, Inter-Tribal Council of Arizona
Shirley Murphy, Taspan Consulting
Luis Neuner, Karuk Tribe
Sonya Oberly, Nez Perce Tribe
Melissa Oppenheim, Confederated Tribes of the Goshute Reservation - Goshute Housing Authority
Aaron Payment, Sault Ste. Marie Tribe of Chippewa Indians
Michael Peercy, Chickasaw Nation
Robert Pete Sr., Cedar Band of Paiutes of the Paiute Tribe of Utah

Rachele Peterson, University of Arizona
Laura Platero, Northwest Portland Area Indian Health Board
Yvette Roubideaux, National Congress of American Indians
Tim Seward, Hobbs Straus Dean and Walker
Chris Shields, Chickasaw Nation
Rosenda Shippentower, Umatilla Tribe
Gloria Simeor, Orutsararmiut Native Council
Michele Smith, Pyramid Lake Paiute Tribe
Debra Souza, PWD, Picayune Rancheria
Sharon Stanphill, Cow Creek Board of Umpqua Indian Tribe
Andy Stern, National Oceanic and Atmospheric Administration/National Weather Service
Victoria Sutton, Lumbee/NCAI Policy Advisory
Kim Taylor, Pamunkey Indian Tribe
Alberta Unok, Alaska Native Health Board
Patricia Whitefoot, Yakama Nation
Monica Yellowhair, University of Arizona