

Supporting Ethical Research Involving American Indian/Alaska Native Populations

VIRTUAL WORKSHOP

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OHRP Virtual Workshop: August 26, 2021

Welcome Address

- *Rachel L. Levine, M.D.; Assistant Secretary for Health, Department of Health and Human Services (HHS)*

Yvonne Lau (Director of the Division of Education and Development, Office of Human Subject Protection [OHRP], HHS) introduced herself and welcomed everyone to the workshop. She explained that its purpose was to help investigators, sponsors, and Institutional Review Boards (IRBs) navigate the unique challenges of working respectfully and successfully with American Indian and Alaska Native (AI/AN) populations. OHRP was privileged to have the Assistant Secretary of Health (ASH), Dr. Levine, present to deliver a welcome address.

Dr. Levine said she was pleased to join the session. HHS is working to implement President Biden's [Executive Order](#) on advancing racial equity and support for underserved communities, and research plays a critical role in this effort. We cannot know how our policies and programs are benefitting or harming populations without sound and ethical research, she observed.

We know that, historically, research has not always benefitted subjects. Memories of the horrific Tuskegee experiment perpetuate mistrust in research enterprise. It is critical that research proceed with the utmost respect for subjects' autonomy. Within HHS, OHRP is specifically dedicated to protecting research participants and promoting ethical research.

This workshop underlines HHS's commitment to stand with marginalized communities, helping to ensure that their health and wellbeing benefit from research and that they are treated with respect. The Assistant Secretary closed by conveying her best wishes for a productive and impactful meeting.

Introduction

- *Moderator: Jyoti Angal, M.P.H., C.I.P.; Director, Clinical Research, Center for Pediatric and Community Research, Avera Research Institute, Avera McKennan Hospital and University Health Center*

Ms. Angal said it was an honor to moderate the session and introduced the four distinguished speakers. (Visit workshop [website](#) for biographical information.)

The goal of this workshop is to provide the research community with a practical framework for conducting and reviewing human subjects research involving AI/AN populations. The discussion will focus on the importance of including the ethical perspectives of indigenous communities in planning, reviewing, and conducting research with their community members.

Native Communities, Investigators, and Research Sponsors: Navigating Organizational, Political, and Cultural Differences

- *Spero Manson, Ph.D. (Pembina Chippewa); Distinguished Professor of Public Health and Psychiatry, Colorado Trust Chair in American Indian Health, and Director, Centers for American Indian and Alaska Native Health, Colorado School of Public Health, CU Anschutz Medical Campus*

Dr. Manson called the discussion “timely and important.” He highlighted two egregious examples of research that underline the urgent need for the workshop’s lessons. The Barrow Alcohol Study, conducted at Tulane University in the late 1970s, resulted in a report to a major conference and a *New York Times* article that stigmatized AN study participants as a “generation of despair” that was “likely to be extinguished.” The Eskimo tribe that participated in the research saw its municipal bond rating drop from A to C plus, making it difficult for them to access urgently needed funding. A more recent example is the betrayal of the Havasupai tribe, who contributed biospecimens for a study of possible genetic causes of diabetes only to find that these specimens were used without their permission for a variety of purposes the tribe would not have approved. Reports of this research outraged AI and AN communities across the country, precipitating essential conversations about how research should be done.

The speaker reviewed a series of Presidential executive orders and initiatives, beginning with President Reagan, intended to affirm a respectful government-to-government relationship between Indian tribes and the federal government. President Clinton expanded and encouraged the effort, and many IRBs were founded in native communities to ensure an appropriate partnership between researchers and participating communities. Under President Obama, a variety of [helpful guidance](#) was produced to foster federal cooperation with tribes, including agency-specific handbooks on consultation.

Organizational differences. Successful consultation on research must take into account significant organizational, political, and cultural differences among tribal communities, investigators, and research sponsors. For example, in universities and the federal government, Dr. Manson noted the following organizational characteristics:

- Decision-making is hierarchical and rule-driven;
- The process emphasizes efficiency, replicability, and written documentation around those elements;
- Leadership is formal and centralized, often free of any sense of the context in which the work is to be done;
- Analytic thinking is prominent and assumes an answer; and
- Instrumental competence is highly valued, and standard for assessment.

Tribal communities are organized very differently:

- Decision-making is horizontal, precedent-oriented, and consensual. Potential conflicts are expected.
- The process is fluid, iterative, recorded orally, and benchmarked by key events (not necessarily in chronological time).
- Leadership is shared, diffused, and ascribed rather than attributed to individuals.
- The emphasis is on distributive cognition and assumes multiple answers. Important perspectives, knowledge, and understanding are distributed across the community. There may be multiple answers to a question.
- Authority is rooted in collective competence of the community, not attributed to an organizational locus.

Political differences. Political differences also abound. In universities and the federal government, Dr. Manson explained:

- Representation is seen as a collective of individual constituents.
- The objective is to govern or to control individuals and groups of individuals.
- Competence stems from delegated authority and flows from administrative license.
- Accountability is couched in terms of blameworthiness and liability.
- Obedience is assured through instruction and compliance.

Again, the politics of tribal communities provide a contrast:

- Representation is seen as a body politic, not a collection of individuals.
- The objective is to manage interdependent relationships among members of tribal communities.
- Authority is rooted in moral and social responsibility.
- Accountability framed as obligation to and acceptance by others.
- Conformity to these expectations is fostered by adherence to shared values and various ways of reminding tribal leaders of their obligation.

Cultural differences. The speaker also characterized the cultural differences that may be found in the non-tribal world as opposed to within tribal communities. He suggested that the non-tribal world tends to:

- be egocentric,
- prize privacy and anonymity,
- emphasize majority opinion,
- be goal-directed and value problem-solving per se, and to
- perceive time as a limited commodity to be managed.

In contrast, tribal communities tend to:

- be sociocentric;
- seek cooperation and de-emphasize conflict;

- stress mutuality, belonging, and solidarity;
- tolerate differences among community members and expect they will be honored;
- encourage common vision and shared principles; and
- be cautious, deliberate, and patient, assuming that events will unfold rather than be dictated at the outset.

Addressing points of tension. Dr. Manson identified six major points of tension in research planning and implementation that must be addressed in order to build a true partnership between AI/AN communities and the research team. These include:

- *Review and approval of the research itself.* Participating communities must have the opportunity to understand and influence the nature of the questions to be addressed, the kind of data collected, and the way the process will unfold.
- *The distribution of resources.*
- *The manner of informed consent.*
- *The nature and extent of accountability and control.*
- *Data ownership and sharing.* Assumptions about ownership needs to be “decolonized” so that tribal participants share new knowledge gained through the research.
- *Requirements for continued collaboration.* To be fruitful, partnerships should be long-term, not short-term.

Several examples illustrate successful navigation through organizational, political, and cultural differences to accomplish research. Data sharing agreements have been negotiated successfully and implemented respectfully, allowing tribal communities and sponsors to meet their mutual expectations and obligations. Dr. Manson cited agreements negotiated by Washington State University with the Fairbanks Native Association and, for a different grant, the Southcentral Foundation. A memorandum of agreement between the Seattle Indian Health Board and the University of Colorado Anschutz Medical Campus also illustrates meaningful cooperation. Also, the speaker noted that the Tribal Health Research Office within the office of the Director of the National Institutes of Health has gone to great lengths to implement an effective consultation process to inform its procedures.

One of biggest challenges at present, given the groundwork that has been laid for successful collaboration and the examples set by successful research, is to ensure that federally sponsored researchers “do their homework” on the protocols, guidance, and examples that have been developed for their use.

From Inception to Planning and Designing Research with AI/AN Populations: Recommendations for Investigators

- *Amy Elliott, Ph.D.; Chief Clinical Research Officer, Avera Research Institute, Avera McKennan Hospital & University Health Center, Professor & Co-Division Chief, Research, Dept. of Pediatrics, University of South Dakota School of Medicine*

Dr. Elliott focused her remarks on lessons learned through the experience of the Avera Research Institute, which has a 72,000 square mile footprint in the Midwest. The institute has worked with many tribes on research intended to improve health.

The Safe Passage Study. The speaker described the approach used to complete a major study of the causes of elevated rates of infant mortality among American Indians in South Dakota, called the Safe Passage Study. Safe Passage was a large, complex study of maternal and child health in which 12,192 pregnancies were enrolled. By working closely with participating tribes “from day one,” researchers were able to achieve 86 percent compliance for study visits. Two cultural issues had to be addressed:

- *Sensitivity around the collection of tissue and bloods, especially post-mortem.* This issue was addressed by providing several options for individual choices on the consent form.
- *Concerns related to genetic studies.* These were addressed by providing a separate informational sheet so that people could understand how genetic data would be used.

These attempts to address cultural concerns thoughtfully were rewarded by a very high consent rate. The vast majority of subjects – 98.8 percent – gave consent for the use of DNA for research purposes, and a similar majority – 97.8 percent – consented to the use of placental tissues for research.

Lessons learned. Dr. Elliott prefaced her summary of lessons learned with a pertinent quotation from an article by Gratton and Erickson (2007): “The most productive, innovative teams were led by people who were both task- and relationship-oriented. What’s more, these leaders changed their style during the project.” She counseled researchers to keep their relationship with tribes in mind constantly, remembering that it is a “privilege and honor” to work with them. At the same time, it is important to keep getting the necessary tasks done. You should have a sense of urgency, but also take the time to build a solid foundation. In this regard, she cited the title of Covey’s memorable article, “Moving at the Speed of Trust.”

Keys to successful collaboration cited by the speaker include:

- Communication!
- Having champions at every level of the organization (for example, within tribal government, health care organizations, and community agencies).
- Making everyone know they are part of a team. Demonstrate that their input matters and will influence what happens.
- Giving regular feedback so people know how things are going. Send thank yous and keep people updated. Whether you did or did not get the grant you applied for together, let your partner know as soon as you do.

Dr. Elliott also stressed the need for the research team members to understand their own organizational culture and how it does or does not match the culture of the community where they are working. This knowledge can help in recognizing biases that may affect the partnership or the research itself. The research team needs to understand its role and maintain an appropriate balance between overextending its reach and claiming to have all the answers, and failing to share the expertise it has, which is a benefit for tribal participants. It is important to be honest about the long-term goal of the research and appropriate indicators of success or failure. It is also important to appreciate the fact that “all of us operate in multiple cultures.”

Language barriers may be an impediment to mutual understanding. People think in different languages. Disciplines, organizations, and professions all have languages of their own. It is important to notice how much translation is happening in conversations about the research and make sure that discussions about the research are proceeding at a pace that allows everyone to keep up with the complexities of the conversation. It will be useful to find the best words that exist in potential subjects’ languages for the concepts being discussed.

Making it work. In closing, Dr. Elliott offered succinct advice for “making it work”:

- Listen, listen, listen. It may feel as if you are hearing the same message over and over, but if so, there’s a reason people feel the need to repeat it: It’s important!!! Don’t tune out, but instead consider the nuances of the message.
- Strive for infallible follow-through. Do not drop the ball. Become known as someone who is reliable and will get things done.
- Realize that this specific project or idea isn’t the most important task on the plate of either your staff or participating community members. Everyone has a lot going on.
- Stay humble. Always keep in mind the larger context in which the work is proceeding.

Supporting Research with AI/AN Populations: Utilizing the Resources Available from the Indian Health Service

- *Rachael Tracy, M.P.H.; Research Director, National Institutional Review Board, Chair, Division of Planning, Evaluation, and Research, Office of Public Health Support, Indian Health Service*

Ms. Tracy explained that the mission of the Indian Health Service (IHS) is more comprehensive than just providing health services. It is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. Its research program has the specific aim of supporting national health research, including human subjects research protections and research related to health problems and the delivery of care to AI/AN people.

Research oversight. After reviewing the role of IRBs and pertinent Federal legislation in general, she explained that research with human participants that is conducted in IHS facilities or using IHS staff or resources must be approved by an IHS IRB. This is true regardless of whether the sites are tribal or urban since both fall under the IHS Federal-Wide Assurance (FWA). The IHS has one national IRB and eight area IRBs. Ms. Tracy also noted that tribal and urban

facilities may obtain their own FWA with OHRP independent of IHS; in fact, IHS encourages, supports tribal and urban health programs that want to do so.

There is quite a variety of ways tribes handle review of research. While some tribes do administer their own IRBs (for example, the Cherokee Nation and the Chickasaw Nation), others rely on a Tribal College or a University IRB. For example, the Lummi Nation works with the Northwest Indian College IRB for review of research taking place in their community. Still other tribes rely on IRBs provided through independent tribal organizations. For example, Pueblos in New Mexico work with the Southwest Tribal IRB (located at the Albuquerque Area Indian Health Board), while the California Rural Indian Health Board IRB reviews research for member tribes. In all, there are over 50 known research oversight entities used by tribes. Also, some tribes who do not have an IRB might have a research review committee that serves a similar function, while others conduct review through their Tribal Councils or Health Departments.

Working with IRBs. Ms. Tracy urged researchers to reach out to IRBs and give them as much advance notice of the proposed study as possible. Representative IRBs (whether IHS or tribal) have the best knowledge of the local community and can minimize potential harms and misunderstandings. These types of IRBs provide an extra layer of protection and often require additional steps and considerations.

The speaker also noted that tribal members and tribal communities may mistrust researchers. Educating communities about the purpose and role of IRBs and having the support of a local IRB may encourage more people to participate in research.

Issues in human subjects protection. Ms. Tracy highlighted specific concerns that arise in ethical review of human subjects research that involves AI/AN members.

In regard to equitable selection of subjects, she noted that some tribal IRBs consider their entire population as “vulnerable.” For example, the Navajo Nation does not allow expedited or exempt research on this ground. Full board review is required for all research.

Ms. Tracy also observed that tribes are becoming increasingly involved in the informed consent process. Common concerns are a lack of contact information and an inappropriate reading level for the subjects.

A major emphasis is placed on databases; both the data collection process and how data will be used must be clear. Tribes need meaningful ownership and control over data collected from their members. Data collected for a given study must not be used for another study without prior tribal approval. Also, tribes want review and input into publications while still in draft form.

It is also important to tribes to ensure that participants are not coerced into participating either by potential loss of services or huge incentives. Also, the tribe itself must not be coerced into participation and should have a clear understanding of what assistance it is expected to provide (for example, funding, staffing, and facilities).

Researchers and sponsors must secure the full awareness and consent of tribal authorities within community involved. This requires a tribal resolution or letter of support. If healthcare sites are involved, each area will have its own process for approval.

Reviewing Research with AI/AN Populations: Training Resources for IRBs and Ethics Review Committees

- *Cynthia Pearson, Ph.D.; Professor, School of Social Work, Adjunct Professor, American Indian Studies, Director of Research, Indigenous Wellness Research Institute National Center of Excellence, University of Washington*

Dr. Pearson described the process of developing and validating a new training program for the conduct of ethical research with AI and AN communities. Known as Research Ethics for Health in Indigenous Communities, or rETHICS, the NIH-funded curriculum addresses the following learning objectives:

- Understand the role of IRBs in relation to tribal oversight.
- Define the three principles of the *Belmont Report* from an Indigenous perspective.
- Identify signs of equitable partnerships Importance of Research preparedness and building relationships.
- Apply the code of federal regulations (CFR) at a community level:
 - individual vs. group harms,
 - privacy and anonymity/confidentiality.
- Define “vulnerable groups/population.”
- Identify essential tools that facilitate the conduct of ethical research with AI/AN communities.

The curriculum is grounded in indigenous knowledge and values. Development was guided by a panel of community members, a scientific panel composed of indigenous scholars and allies (each with more than 15 years of experience working with AI/AN), and a policy panel that included IRB members, tribal IRB administrators, and regional and national policy experts.

The community panel stressed the importance of respecting tribal sovereignty in any research involving tribal members. This refers to each tribe’s inherent right to make their own laws, enact regulations, and determine what research can take place on their lands. Tribal sovereignty means that the tribe can:

- Approve or deny requests for research;
- Decide how research is reviewed and conducted;
- Require research activities to stop;
- Review research reports, press releases, or publications before they are publicly shared;
- Negotiate exclusive or shared ownership of research results;
- Decide if, how, and what cultural knowledge or practices are shared; and
- Restrict use of tribal identifiers in research reports.

IRB oversight also applies to federally funded research with human subjects. The IRB

- Has the authority to approve, require modifications, or disapprove all research activities,
- Requires that information specifically mentioned in the Common Rule at CFR 46.116 be given to the subjects,
- Conducts continuing review of research, and
- Determines whether risks to subjects are minimized through the use of sound research procedures that do not unnecessarily expose subjects to risk.

If *either* the IRB or the tribe says “no,” research must be stopped until the concern is addressed.

The Belmont principles and the indigenous perspective. Dr. Pearson explored the implications of each of the three ethical principles articulated in the Belmont Report – beneficence, respect, and justice – in the context of an equitable partnership for research with AI/AN participants. Members of indigenous communities participating on the rETHICS panels stressed that the *intent* to confer a benefit for native people is not enough. The principle of *beneficence* can only be realized in the context of established trust and equitable partnership. She explored the question on what would indicate that

- trust and an equitable partnership have been established?
- the researcher has contacted the appropriate leaders?
- the letter in hand is the letter of authority?

Indicators of a partnership will differ depending on the tribal approval process. Processes are different across tribes and type of studies, and they may change over time. The ability to follow an appropriate process and do it well depends on the length of the relationship between the research team and the tribe, as well as the number of people the researchers have consulted and their roles within the tribe.

Formal documentation of the partnership may be a tribal resolution, a Memorandum of Understanding (MOU), or a Memorandum of Agreement (MOA). The necessary paperwork, if required, may be processed through the grants and contracts department or another tribal authority. Multiple letters of support from leaders across the tribe are a good indication of a quality partnership. Another indicator is the distribution of funds: are they all in the academic partner’s hand? If so, the level of partnership is questionable.

The principle of *justice* is also salient. *Procedural* justice requires that research procedures be fair and non-exploitative. *Distributive* justice holds that those who experience the risks of study participation should also experience any benefits. Tribes want to ensure that research benefits tribal members.

Respect must be shown to the community as well as to individuals. The tribe must be given the necessary time, space, and privacy to decide if the research will take place on their lands. The community must be given enough information to enable them to make that choice. It is also important to bear in mind that, as always, consent occurs *throughout* the research project, not just at the outset.

Research settings. When researchers are working with AI/AN participants in urban settings, approval to proceed should be based on meaningful discussions with urban AI/AN leadership, rather than with each of the tribes to which subjects belong. When research is conducted off tribal lands, individual rights take precedence. However, any use of tribal identifiers must be approved by the tribe, and any research activities that take place on tribal land still require tribal approval.

Offering community-level benefits. While research ethics traditionally places the focus on benefits that accrue to individual subjects, in AI/AN communities, community-level benefits are important. Examples of possible benefits to the tribe or community include:

- *Relationship* - Ties and trust have been developed with academic researchers; researchers help with data access and grant development.
- *Knowledge* - The community gains additional knowledge about the strengths and vulnerabilities of its members.
- *Treatment* – Research offers an opportunity to learn what types of interventions are helpful to community members and to adapt or create culturally appropriate interventions.
- *Materials or resources* – The tribe has access to the intervention manual; salaries are covered for participating local staff; infrastructure for staff is provided.
- *Training opportunities* – Opportunities to train existing and future local staff are included.
- *Empowerment* – The project offers prestige and an opportunity to strengthen partnerships across agencies. The tribe co-owns data and products.

Assessing risk. Members of AI/AN communities may perceive risks that are invisible to the researcher. They can help identify and reduce these risks. For example, a researcher invited elders into a specific building for discussions and did not realize the building was an old boarding school in which many atrocities were carried out. It carried painful memories for the individuals. If the researcher had involved the community, members could have prevented this harm. Community review of the protocol may help to reduce risks associated with any of the following:

- Words used and their connotations,
- The place where research activities are conducted,
- The people conducting and implementing the research, and
- Proposed partners, sites, or places.

Private and public data. The concept of what is private and what is public may also play out differently in tribal settings. Different communities and cultures may vary in unexpected ways. For example, while federal research regulations generally do not consider observations of public behavior to require approval, some indigenous ceremonies that take place in public are nevertheless considered sacred and should not be recorded without the explicit permission of the tribe or tribes.

Anonymity and confidentiality must also be considered at the community level. Protecting the identifiers of AI/AN communities (i.e., the name of the tribe or geographical area) is just as important as protecting the identifiers of a participant. For example, many Alaska Native villages are very small, so stating a geographic area or town may serve as an identifier. Similarly, if the researcher claims to be working with the largest tribe in Washington state, it is easy to find out which tribe they mean.

Essential tools. Data sharing agreements are an essential tool and facilitate the conduct of ethical research with AI/AN communities. These agreements address all facets of study data. They may, for example:

- State that the tribe owns the data;
- Grant the university a royalty free, nonexclusive right to use the data to publish reports and other academic publications in furtherance of the aims of the project;
- Set forth regulation of data access, collection, protection, storage use, and reporting requirements; or
- Describe how disputes will be resolved.

Research and ethics protocols are also helpful. Researchers and tribe representatives can work together to craft a research partnership protocol that sets forth principles, obligations, and responsibilities, guiding partners through all phases of the research process.

Panel Discussion

Ms. Angal posed questions for group discussion.

- ***All of the speakers mentioned the fact that establishing a relationship takes time. However, the traditional grant framework does not allow much time. As a new researcher, how do you find champions and lay the groundwork for a successful study?***

Dr. Pearson suggested that smaller grants may offer the opportunity to build a relationship over time. She also benefitted from an association with the Indigenous Wellness Research Institute, where part of her job was to learn from AI/AN community members and attend events. This type of experience is invaluable.

Investigators new to AI/AN communities should do their homework, reach out to established investigational teams, and solicit guidance, said Dr. Manson. He suggested that was also helpful to link up with major health advocacy organizations that can help researchers understand constituents' highest priorities; this will enable investigators to better align their interests with those of the communities in which they want to do research. It is important to reach out to key organizations and find champions. Talk to program officers and build a relationship with them. The speaker noted that recent NIH policies allow more latitude for strategic planning before project implementation, which is helpful in this regard.

It is important to have the conversations needed to build a relationship before an appropriate funding opportunity appears, advised Dr. Elliott. It will be much more difficult to understand the tribe's priorities and provide information about the investigator's institution once a specific opportunity is on the table. "Good ideas will find their funding avenue."

- ***All of you have several years of experience working with AI/AN communities. How have you changed?***

The past 45 years have offered a gradual accumulation of lessons learned, Dr. Manson observed. He had to swallow anxiety at reaching out to novel settings, listen, and learn: "Nothing ventured, nothing gained." He counseled, "Do not fear failing in an authentic fashion." Native people will be forgiving when others are respectful and recognize the importance of indigenous knowledge.

Dr. Pearson spends time every month going out to communities and listening. She has learned to be humble. "It's okay if you get your hand slapped. Learn from it. That's growth, and it's a good thing."

For Ms. Tracy, the biggest change over the past 25 years has been learning patience. She has had to learn how to "settle down and go with the flow." She's learned not to be afraid to reach out and have a conversation, or to just "hang out" and be part of community. You don't always have to go to them with your agenda, she said; you can just go and learn, always with humility and respect.

While Dr. Elliott wanted research to be tribally driven, she had to be told by a tribal council to speak up and explain some of the available options. Listen well, she said, but also offer your expertise, giving useful information in an understandable way. There is a reason you are at the table.

- ***What concerns do you see in working with urban communities of AI/AN? Some investigators seek to avoid the complexity of securing tribal approval for research by working with people living in urban settings.***

Dr. Pearson observed that it is important to respect individual autonomy as well as tribal authority. If you are an American citizen abroad and want to participate in research, you will not ask the U.S. government for permission to do so. As long as you simply identify an individual as an American Indian, there is no problem. Once you identify them by tribe, however, you need to get tribal approval. This would be analogous to using personal identifiers without permission. Similarly, genomic studies can yield data specific to a tribe.

While he agreed with Dr. Pearson's points, Dr. Manson said it is sometimes helpful to have conversations with the tribal communities to which constituents belong in order to gain a better understanding of the differences in the tribal and urban settings. There are urban Indian health boards that can also serve as points of contact for research review. To assume full license to proceed with a study without local input or review would be "foolish," he said.

Ms. Tracy noted that many researchers often approach the IHS for guidance when they are planning research with AI/AN people in urban communities, and the IHS tries to advise them on

appropriate touch points. Some urban Indian organizations may not have the capacity, interest, or jurisdiction to participate, but others will welcome the opportunity to have a voice in the research. Urban health boards may include representatives for various tribes, but it is important to realize, while honoring the representatives' perspective, that the tribe may have a different point of view. Talking with one tribal representative is not consultation.

As a healthcare provider, the Avera Institute often needs to make decisions about whether to include a patient in a study in a short amount of time. Sometimes, Dr. Elliott said, the patient qualifies for a study, but follow-up will be needed on tribal land. It is important to reach out and have an open conversation about how this should be handled, but it still can “get murky.”

In closing, Ms. Angal observed that there is “more work to be done” on the critical issues raised in this workshop. Dr. Lau thanked everyone for their participation, noting that much of the work being done in this area applies to other areas as well. She hoped that research going forward will benefit from the valuable insights on partnering with communities presented here.

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Resources

Indigenous Cultures Institute. <https://indigenoucultures.org/>

Indigenous Wellness Research Institute. Research templates: <http://iwri.org/resources/research-resources/research-templates/>

National Congress of American Indians.

Consultation Letters and Materials by Federal Agency:
<https://www.ncai.org/resources/consultation-support/consultation-letters-and-materials-by-agency>

Consultation Support Center: <https://www.ncai.org/resources/consultation-support>

Research Ethics Training for Health in Indigenous Communities.

Free curriculum: <https://redcap.iths.org/surveys/?s=R3EJPAYD4J>

Training toolkit and license to distribute: <https://els2.comotion.uw.edu/product/rethics---research-ethics-training-for-health-in-indigenous-communities>

University of Arizona.

Tribal Consultation policy: <https://www.naair.arizona.edu/research-engagement-guidelines>

Urban Indian Health Institute. <https://www.uihi.org/>

Urban Indian Organizations listed by the Indian Health Service.
<https://www.ihs.gov/urban/urban-indian-organizations/>

Agenda:

Supporting Ethical Research Involving American Indian/Alaska Native Populations

OHRP Virtual Workshop

Thursday, August 26, 2021, 1:00 – 3:00 PM (EDT)

For details and access to the webcast, visit

<https://www.hhs.gov/ohip/education-and-outreach/educational-collaboration-with-ohip/workshops/ohip-hosted-workshops-aug2021>

Time	Sessions
1:00-1:05 PM	Welcome Address Rachel L. Levine, M.D. <i>Assistant Secretary for Health, Department of Health and Human Services</i>
1:05-1:10 PM	Introduction Moderator: Jyoti Angal, M.P.H., C.I.P. <i>Director, Clinical Research, Center for Pediatric & Community Research, Avera Research Institute, Avera McKennan Hospital & University Health Center</i>
1:10-1:30 PM	Native Communities, Investigators, and Research Sponsors: Navigating Organizational, Political, and Cultural Differences Spero Manson, Ph.D. (<i>Pembina Chippewa</i>), <i>Distinguished Professor of Public Health and Psychiatry, Colorado Trust Chair in American Indian Health, and Director, Centers for American Indian and Alaska Native Health, Colorado School of Public Health, CU Anschutz Medical Campus</i>
1:30-1:50 PM	From Inception to Planning and Designing Research with AI/AN Populations: Recommendations for Investigators Amy Elliott, Ph.D. <i>Chief Clinical Research Officer, Avera Research Institute, Avera McKennan Hospital & University Health Center, Professor & Co-Division Chief, Research, Dept. of Pediatrics, University of South Dakota School of Medicine</i>
1:50-2:10 PM	Supporting Research with AI/AN Populations: Utilizing the Resources Available from the Indian Health Service Rachael Tracy, M.P.H. <i>Research Director, National Institutional Review Board, Chair, Division of Planning, Evaluation, and Research, Office of Public Health Support, Indian Health Service</i>

2:10-2:30 PM	Reviewing Research with AI/AN Populations: Training Resources for IRBs and Ethics Review Committees <i>Cynthia Pearson, Ph.D. Professor, School of Social Work, Adjunct Professor, American Indian Studies, Director of Research, Indigenous Wellness Research Institute National Center of Excellence, University of Washington</i>
2:30-3:00 PM	Panel Discussion