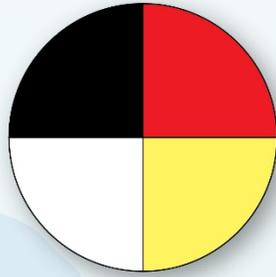

AMERICAN INDIAN AND ALASKA NATIVE RESEARCH IN THE HEALTH SCIENCES:

*Critical Considerations for the
Review of Research Applications*



AMERICAN INDIAN AND ALASKA NATIVE (AI/AN) RESEARCH IN THE HEALTH SCIENCES: CRITICAL CONSIDERATIONS FOR THE REVIEW OF RESEARCH APPLICATIONS

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National Institutes of Health Specially Appointed Committee to Review AI/AN Research in the Health
Sciences: Critical Considerations for the Review of Research ApplicationsA-1

Foreword

To assist reviewers in understanding the unique context of applications proposing research in American Indian and Alaska Native (AI/AN)¹ communities so that they can provide the most informed reviews, the Tribal Health Research Office of the National Institutes of Health (NIH) and a working group of NIH staff commissioned the writing team of Karina L. Walters, Melissa L. Walls, Denise A. Dillard, and Judith S. Kaur to develop a resource to guide NIH reviewers in assessing AI/AN-focused grant applications. This document is in response to and consistent with the needs identified by multiple groups, including the NIH Tribal Advisory Committee (TAC), Native American Research Centers for Health investigators, and the National Institute on Drug Abuse Native Scholars Working Group.

The document was developed through a multi-stage process that began with commissioning authors to develop a manuscript in collaboration with an NIH staff team, which then was reviewed by a working group that included external scientists and NIH staff. The document was revised and sent back to the working group and the NIH TAC for comments. The comments, suggestions, and guidance from these sources were integrated into the final version (members of the working group and TAC can be found in [Appendix A](#)). We thank the TAC and working group for their contributions and for helping to ensure that this document more broadly reflects the views of those working in this field.

What Is the Purpose of This Document?

The purpose of this document is to provide critical considerations for NIH reviewers as they assess applications focused on AI/AN populations. It provides context for applicants' AI/AN-focused research to help reviewers interpret and understand the information being presented. While the primary audience is reviewers and the document is crafted to reflect this, applicants must ensure that they provide reviewers with the information necessary to assess an application, including appropriate justifications. As such, this document has implications for applicants as well.

Given the cultures, experiences, and sovereign statuses of tribal nations, research with AI/AN populations may require unique research or administrative partnerships, exceptions to existing NIH policies, and alternative strategies to ensure that research is conducted in an ethical and meaningful manner that will benefit AI/ANs. Added complexities are inherent in the processes of AI/AN-focused health research; as a result, grant applications submitted to the NIH in this research area often present unique considerations for reviewers.

If reviewers do not adequately consider the unique complexities of AI/AN health research, they could inadequately evaluate and critique this research, causing the NIH to lose opportunities to support innovative and beneficial health research. By gaining knowledge on the unique perspectives and indicators of successful research common to AI/AN-focused projects, reviewers will be able to more effectively assess applications.

The need for diversity in science, including both a more diverse workforce of researchers and a greater diversity among research participants, has been documented. The journal *Nature* dedicated a special edition in September 2014 solely to this subject area (“Diversity: A Nature and Scientific American

¹ “AI/AN” will be used throughout the document to reference the Indigenous peoples of the United States from the contiguous U.S. and Alaska. “Indigenous” will be used in reference to theories, methods, and approaches in conducting research with AI/AN communities. While Native Hawaiian and Pacific Islander groups are not explicitly discussed, as they are not members of federally recognized sovereign nations, a number of the considerations presented here will prove relevant to the assessment of applications proposing to work with these groups.

Special Issue,” 2014, Volume 513, Issue 7518). The diverse science conducted with AI/ANs has provided exciting and innovative advances in scientific theories and methodologies with clear influences on practices, policies, and products to improve human health. Several illustrations of these impacts are shown in **Box 1**. The appropriate review of AI/AN research applications ensures that this diversity will continue to advance science.

Box 1. Case Examples of AI/AN Research and Significant Advances to Science and Population Health

Oral Rehydration Therapy

The White Mountain Apache community partnered with researchers in groundbreaking field trials to demonstrate the effectiveness of the Oral Rehydration Therapy (ORT) treatment used to prevent dehydration, especially due to diarrhea. This high-impact study was the result of community-engaged scholarship that addressed a tribally identified health issue and was led by a respected academic partner, Dr. Mathu Santosham (Johns Hopkins University). Since this study, it has been estimated that ORT has saved more than 50 million lives worldwide.

Pharmacogenomics

A community-based participatory research project in Alaska found genetic variation in AI/ANs that would predict a lower mean warfarin dose requirement compared to non-AI/AN people. This finding supports anecdotal clinical evidence and could be used to prospectively identify dosage and prevent side effects such as bleeding (Fohner et al., 2015).

AI Vietnam Veternal Treatment

Research with AI Combat Veterans revealed that tribal members who engaged in ceremonies prior to deployment were less likely to meet criteria for post-traumatic stress disorder compared to peers who did not participate in ceremonies. Similar protective effects of traditional AI ceremony involvement were observed after combat experiences (Manson, n.d.), thus demonstrating both the preventive and stress-buffering effects of ceremony. This research contributed to federal approval of funding and billing for 13 traditional ceremonies for AI Veterans at Department of Veterans Affairs hospitals and in community settings (Manson, n.d.; Novins et al., 2004; Gurley et al., 2001; Manson, 1997).

Considerations in AI/AN Research

Factors that contribute to the uniqueness of AI/AN research are discussed below to provide a knowledge foundation and then are considered more specifically later in the document as they relate to review criteria. These factors are distinct, but intertwined.

Tribal Sovereignty

The terms “American Indian” and “Alaska Native” have both racial/ethnic and legal/political connotations. Ethnologically, “American Indian and Alaska Native” refer to persons with “origins in the original peoples of North, Central, and South America and [who] maintain tribal affiliation or community attachment,” including persons who self-identify as AI/AN but may or may not be enrolled in or eligible for enrollment in a state-recognized or federally recognized tribe (Office of Management and Budget, 1997, <https://www.whitehouse.gov/wp-content/uploads/2017/11/Revisions-to-the-Standards-for-the-Classification-of-Federal-Data-on-Race-and-Ethnicity-October30-1997.pdf>).

In contrast, the political and legal usage of “American Indian and Alaska Native” reflects a unique government-to-government relationship between the United States and federally recognized tribes as sovereign nations with all of the rights, protections, and trust responsibilities the United States is obligated to uphold by treaty, law, and congressional mandate. The distinction between the racial/ethnic and legal/political definitions is of further importance because the former implies self-identification as AI/AN regardless of tribal enrollment, whereas the latter relates to tribal enrollment in a federally recognized tribe or, in some cases, documentation of descendance from an enrolled member. Investigators conducting NIH-supported AI/AN research have used both self-identification and evidence of tribal enrollment as approaches to recruiting AI/AN people.

Sovereignty means that each tribe has the inherent legal and political authority to govern itself and includes the ultimate decision-making power to enforce research regulations within their territories. **No decisions about a tribe’s lands and citizens can be made without the explicit participation and consent of the tribe** (Thierry et al., 2009). Indeed, sovereignty is the basis for many research policies and processes (Warne and Frizzell, 2014), and this sovereign status gives tribes legal rights and privileges that are distinct from racial and ethnic groups.

Tribal Rights in Research: Tribal sovereignty extends to regulatory rights that, on tribally governed lands, have implications for research, including for Institutional Review Board (IRB) requirements, Community Research Boards (CRB), and exemptions from some NIH and other research policies (for example, those related to data ownership and data sharing). Understanding the implications of these rights in terms of how they impact research is imperative to evaluating research applications proposed in this area of inquiry. The recent update to the *Federal Policy for the Protection of Human Subjects/Final Rule* (the revised Common Rule) acknowledges research laws and codes passed by a tribe’s governing body, along with state and local law, in its requirements (Code of Federal Regulations [CFR], Title 45, Part 46, Section 46.101(f), Subpart A [45 CFR 46.101(f), Subpart A]). IRBs or CRBs often require that all manuscripts or presentations generated from the data receive approval before they are shared.

AI/ANs, however, do not all live on federally recognized tribally governed lands. In AI/AN research conducted off tribal jurisdiction-based lands, tribal sovereignty and rights may be viewed and addressed differently than in research projects set in tribal jurisdiction-based lands. Although the context is different off tribal lands, practices developed under tribal jurisdiction have influenced research processes for urban- and non-tribal-jurisdiction-dwelling urban and rural AI/ANs (James et al., 2018).

Other Foundational Issues

Research History: Unethical and inappropriate studies in AI/AN communities (Examples: **Box 2**) contribute in some cases to a general mistrust of research and researchers. This mistrust, combined with sovereign nation status, has resulted in tribes requiring unique research processes and protections. Many of these processes include tribal government and community engagement, as discussed below.

Box 2. Case Examples of Ethical Research Violations in AI/AN Communities

Arizona State University

Beginning in 1990, researchers at Arizona State University engaged in research with the Havasupai Tribe based on tribal interest in diabetes in their community. Tribal members who consented to participate believed that they were donating blood solely for this purpose. However, researchers published papers on the inbreeding, alcoholism, and migration pathways of tribal members that directly conflicted with cultural teachings and creation stories. This led to a lawsuit that was settled in 2010, though the distress and ongoing mistrust of researchers among many Havasupai and members of other tribes lives on (Harmon, 2010; Sterling, 2011).

Center for Research on the Acts of Man

In 1979, researchers were asked to enumerate trends in alcohol use among members of a northern AN community in response to concerns over rising rates of alcohol-related problems. Upon completion of a written report to the community summarizing their findings, the research team also issued a press release carried by a national news syndicate with the headline, “Alcohol Plagues [Tribal Group].” This simultaneous release of findings precluded collaboration with or opportunities for community members to address the validity or interpretation of the results. Indigenous people of the region saw the study as shaming, feeding stereotypes of AN people and alcohol, and decontextualized from the root socioeconomic causes of alcohol-related problems. The community suffered rapid negative economic consequences, including a massive reduction in their Standard and Poor’s credit rating subsequent to this national news coverage (Manson, 1989).

Community Engagement: Successful AI/AN research involves consistent community engagement, partnership, and shared leadership that ideally begins at the inception of the project and is sustained through the completion and dissemination of research findings. Community engagement is defined as “the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people” (Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Committee on Community Engagement, 1997). This approach requires development of a partnership, including cooperation, negotiation, and collaboration among partners and a commitment to addressing local health issues (Wallerstein et al., 2018). Engagement may appear in many forms, as elaborated upon later. Community-Based Participatory Research (CBPR) is one of these forms, but not all communities will choose this approach to engagement (see Approach section).

Small Study Populations: While not always the case, many AI/AN proposals involve smaller sample sizes than reviewers may be accustomed to and could be limited to a single tribe. Research with small populations of AI/ANs will have challenges similar to those associated with any small sample research, including potential contagion in intervention research, the necessity of using different design/methodology, or finding appropriate statistical approaches. Reviewers may need to balance considerations of generalizability or other limitations associated with small sample research with public health impact as they relate to AI/AN health research and other positive factors because the work proposed often can benefit a population that suffers disproportionately from health disparities. Moreover, as detailed later, small samples can also drive the field toward innovations in methods and statistical analysis.

AI/AN Diversity: Contrary to some representations of AI/ANs as a homogenous group, they are members of distinct and diverse tribal nations. The Bureau of Indian Affairs Federal Registry now recognizes 573 tribes, and states recognize more than 60 additional tribes. More than 167 Indigenous languages continue to be used in the United States (Siebens and Julian, 2011). Diversity among AI/AN tribal cultures, practices, beliefs, traditional ceremonies, and origin stories has implications for health research. The unique culture of a tribe can impact all aspects of research, including the selection of research questions, the approach and study design, and the interpretation and dissemination of findings. What works in one tribe might or might not work with another, culturally distinct, community.

Additionally, AI/ANs have experienced rapid urbanization. Currently, 7 of 10 AI/ANs live in urban areas, compared to 45 percent in 1970 and 8 percent in 1940. Unique aspects of urban AI/AN research, where hundreds of tribes may be represented, include complex sampling and measurement strategies, broad inclusion of AI/AN community and agency personnel, and possibly multiple IRB review processes (e.g., tribal, university, and urban-serving AI/AN organizations) (see James et al., 2018, for a consideration of unique research issues for urban AI/ANs).

Avoiding Gatekeeping—The Flexibility Imperative: Reviewers might believe that AI/AN-focused research proposals must contain particular components or address particular topics to be deemed “acceptable.” Although it is true that certain structures or approaches may differ for tribal research and some tribes share common views, reviewers should not assume that what is research-appropriate for one tribal community is appropriate or even feasible for another tribal community or an urban AI/AN community. Communities may choose to address research questions or engage in research in ways that reviewers might not expect. Respect for different AI/AN communities’ perspectives and autonomy to make that decision can facilitate effective reviews. Moreover, the expectation or assumption that a community must approach research in a certain way or only study certain topics when that is not the community’s wish can be harmful to the review.

Broader Benchmarks: Benchmarks for a successful research project might be different in AI/AN research, given the noted considerations associated with tribal sovereignty and rights, research history, and the importance of community engagement. These might include dissemination of findings to the community, which will impact the time available to produce journal publications; documented success in community engagement; development of research infrastructure, possibly including ensuring that community members are more knowledgeable about research; sharing of resources; efforts toward sustainability of programs or services; or mentoring.

What Are Relevant Considerations in Evaluating the Scientific Merit of AI/AN Research Applications at the NIH?

It is essential to note that this document is not prescriptive or exhaustive. The great diversity of AI/AN tribes and communities precludes a universal approach to research (e.g., Hiratsuka et al., 2012). Instead, this document is intended to elucidate insights and key considerations for NIH reviewers when evaluating AI/AN-focused research proposals. The document is organized around the review of Research Project Grants (RPG/R01/R03/R15/R21/R34) but has implications for all NIH research mechanisms. The factors outlined above will be discussed in further detail in this document, and case examples of potentially unique aspects of AI/AN health research will be provided. Many of the examples incorporate tribal or community input and adaptations beyond what is typically seen in “conventional” applications for funding.

While the intent of this document is to assist reviewers in understanding the implications of the unique AI/AN context for research, it remains incumbent on applicants to assist reviewers in understanding when and how these contexts influence their research. Further, as expected in any outstanding application to the NIH, applicants must justify their approach within the unique context and describe the benefit or value added to science of their research.

The following considerations are organized according to the NIH review criteria and begin with the NIH overview guidelines for evaluating the significance of proposals, which are directly excerpted from the NIH criteria (Definitions of Criteria and Considerations for Research Project Grant [RPG/R01/R03/R15/R21/R34] Critiques; <https://grants.nih.gov/grants/peer/critiques/rpg.htm>) and presented in blue text below. The criteria are followed by points to consider for AI/AN research and, in some instances, case examples. Finally, text boxes are provided that contain paraphrased examples of reviewer comments from summary statements associated with NIH applications focused on AI/AN health research and populations followed by guidance regarding the usefulness and adequacy of the example comments. In some cases, the examples illustrate misconceptions or misunderstandings; in others they reflect sound and thoughtful review. Some examples may be relevant to more than one issue or review criterion. *These examples and the accompanying insights are intended to be illustrative, not comprehensive.*

Significance

NIH Overview Guidelines for Evaluating Significance

- ❖ Does the project address an important problem or a critical barrier to progress in the field?
- ❖ If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- ❖ How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Points to Consider for Reviewers Regarding the Significance of AI/AN Applications

- ❖ **Considerations of generalizability may need to expand beyond solely considering whether the answers to the research questions generalize to other samples or populations.** Reviewers may need to consider whether the science is significant because the research processes, analytical strategy, or other aspects, such as innovations in design/methodology, can inform and expand research with other populations or expand science in some other way.
 - Core aspects of within-culture, small-sample research (e.g., application of novel methods, small sample-size solutions) can be generalized beyond the cultural group under study.
 - The methods or innovative analytical strategies that are used or the constructs that are examined might generalize to other populations.
 - Lessons learned about AI/AN history, traditions, worldviews, and culturally meaningful risk and resilience (e.g., cultural frameworks for health [Kagawa-Singer et al., 2014]) can have analogues across cultures.
- ❖ **Studies seeking to expose newfound information within AI/AN communities and cultures are significant.** The process of scientific learning is at various stages of development across populations. In many cases, there is limited epidemiological, biomedical, prevention, intervention, or other background information for AI/AN peoples about topics or issues that are widely studied in non-Native contexts.
 - Vis-à-vis evaluating the state of the literature, reviewers might evaluate whether “first step” approaches are significant for AI/AN communities; studies that might appear incremental in other fields could be essential to moving science forward for AI/AN communities.
 - A disease or health problem that is not yet apparent (e.g., HIV, diabetes in some tribal regions, or intravenous drug use) may be a significant target for prevention when many risk factors are present.
 - The *process* of research with AI/AN communities may be significant in that it can inform best practices in community engagement orientations, approaches, and models (see CBPR in the [Approach](#) section).
 - Determinations of significance should be informed by community perspectives regarding the health concerns that they prioritize or deem significant.

- ❖ **Sample size is considered an approach issue, not a significance issue.** Reviewers often comment on sample size when reviewing the significance of a project, but, as it should be considered under approach, it is addressed there in this document.

Examples Relevant to *Significance* in the Summary Statement

NOTE: Appropriate/constructive and inappropriate/inadequate reviewer comments are shown below. Each of the reviewer comments is paraphrased to reflect comments similar to those that have appeared in the summary statements of submitted applications and is shown in italics. Guidance is provided following each example of a reviewer comment.

Appropriate/Constructive Comments	Guidance
<i>Research exploring the effects of mental health on other comorbidities has not focused on Indigenous populations where the need is greatest.</i>	This comment indicates the significance of developing a body of knowledge for a unique population, as well as indicating that a health disparity in this area further contributes to the significance of the project.
<p><i>This project could potentially benefit the larger field of substance abuse research.</i></p> <p><i>This study could yield an inexpensive way to capture risk for disease in this population and other populations.</i></p>	These comments indicate that an aspect of the study could generalize to other populations and suggest how this could contribute to the general body of knowledge.
Inappropriate/Inadequate Comments	Guidance
<p><i>Some reviewers indicated that the significance was reduced because the results would have limited generalizability beyond AI/ANs.</i></p> <p><i>Concerns remain as to whether the findings will be generalizable beyond this study population; this weakness limits the significance.</i></p> <p><i>Although a small number of participants is justified, this may limit interpretability and generalizability of the results.</i></p>	Applicants must demonstrate the significance of a project in the face of results that might not generalize to other populations. However, reviewers should be careful not to conflate generalizability with significance. Reviewers should evaluate the overall significance of the project and balance the contribution to advancing science for the AI/AN population with generalizability to other populations. In addition, applicants should help reviewers understand how aspects of the scientific project might generalize to research with other populations, even if the specific answers to the research questions will not generalize.
<i>Similar work has been done with other groups, and it is not clear how the AI/AN population is different.</i>	Applicants must help reviewers understand why models developed and supported for other populations might not be similar to AI/AN populations. If this case is made effectively, reviewers should understand that science is sometimes at different stages for different populations. Although similar work might have been done with other groups, important differences might exist; therefore, it is important to evaluate outcomes in studies that explore these differences.

Investigator(s)

NIH Guidelines for Evaluating Investigators

- ❖ Are the project directors (PDs)/principal investigators (PIs), collaborators, and other researchers well suited to the project?
- ❖ If the applicants are Early-Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training?
- ❖ If the applicants are established researchers, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- ❖ If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise? Are their leadership approaches, governance, and organizational structures appropriate for the project?

Points to Consider for Reviewers Regarding Investigators of AI/AN Applications

- ❖ **Evaluations of productivity and prominence in a scientific field may need to consider the multiple demands of research within AI/AN communities.** Productivity, as typically measured by the NIH, may not be reflective of the time required to build and maintain tribal and community relationships and multiple and sometimes competing stakeholder interests (e.g., tribal leaders, federal funders, community members) or the time and effort required to obtain tribal resolutions and approvals and overcome staffing and infrastructure challenges in under-resourced settings.
 - As community engagement is an essential component of AI/AN research (see **Foreword**), PIs and other researchers may demonstrate productivity through investment in the community. Indicators of community productivity may include dissemination of findings through lay publications, presentations, and social media; community-organizing activities; policy-related papers, presentations, and testimony; and trainings, courses, or curricula that may influence health care and health-related behaviors (Harawa et al., 2017).
 - Given the effort required to satisfy complex demands, the number of scientific publications produced during funding periods and overall careers may be fewer for researchers focused on AI/AN populations.
 - The team science approach found in much of AI/AN research may produce publications with multiple authors that reflect culturally based inclusive processes rather than a lack of independent productivity.
 - Given the factors that could potentially affect editorial impressions of significance, such as small samples and the developmental state of the science, publications focused on AI/ANs may appear in less familiar or less high-impact or prestigious journals.
- ❖ **AI/AN PIs and other researchers may work in community-based settings, tribal operating divisions, or in Tribal Colleges and Universities (TCUs),** where job titles, demands and promotion practices may not correspond with those typically found in research-intensive institutions (see **Box 3**).

- Indicators of career progression in tribal or community-based settings might include increasing levels of responsibility (e.g., promotion to supervisory positions) or high-profile service within the community or setting (e.g., board memberships). Thus, they may not correspond to promotion, tenure, or other benchmarks established at research-intensive institutions.
- Teaching obligations and expectations to mentor students or interns are often greater in TCUs, less research-intensive institutions, and community-based settings. Faculty may have administrative and service responsibilities within the surrounding community (Tippeconic and McKinney, 2003).
- At all types of institutions (major universities and research institutions, TCUs, etc.), faculty of color and those from underrepresented groups, including AI/ANs, bear a disproportionate burden of service (Pololi, Cooper, and Carr, 2010).

Box 3. Case Example of Investigators Within a Community-Based Setting

Southcentral Foundation is a tribal health organization in Anchorage, Alaska, with its own research department. Researchers with terminal degrees who are PIs have the job title of Senior Researcher. Senior Researchers lead teams comprised of master's-level researchers and Research Interns, many of whom are AI/AN, and mentorship is a core job expectation. Progression from Senior Researcher I to Senior Researcher II is based on increasing levels of funding, numbers of peer-reviewed publications, and service on organization-wide quality improvement and other committees, as well as local and national committees focused on tribal health research.

- ❖ **A wider breadth than depth in area of expertise** may be evident in the PIs' biosketches compared to non-AI/AN-focused researchers.
 - Some PIs who successfully conduct research in AI/AN communities are asked by community leadership to partner on multiple projects across an array of health conditions. These requests are often based on an established trust relationship and a desire to expand the partnership to address other community priorities and needs.
 - Including multiple investigators, co-investigators, or consultants with specialized scientific and community knowledge on the study team is common.
 - The experience of the team, specifically with respect to conducting research in tribal contexts and perhaps in the particular community specified, should be considered.
- ❖ **Community members may be included as investigators or PDs.** Experts in the local community and culture are important for ensuring feasibility, as well as respect for tribal protocols, laws, and requirements.
 - A community member's strengths may not be reflected in a typical NIH biosketch. Reviewers should also consider their investment and role in the community (e.g., an Elder² and/or elected tribal leader) and contributions in similar roles through employment (e.g., community health worker) (see **Box 4**).

² In AI/AN culture, Elders are held in very high esteem and are repositories of cultural and philosophical knowledge and the transmitters of such information.

- Community members, including community advisory boards or AI/AN research staff regardless of formal educational credentials, may be essential members of the team. As such, they may sometimes be authors of peer-reviewed research publications, depending on the wishes of the community.
- Tribes may desire community members to be included as project staff for the purpose of building local research capacity.

Box 4. Case Example of Community Member Investigator

A White Mountain Apache Tribal member is a researcher within the Center for American Indian Health, Johns Hopkins Bloomberg School of Public Health. She has worked as an interventionist for the Apache Tribe for more than 20 years, oversees case managers, and facilitates the activities of the local community advisory board and Elders Council. She is also the Center’s primary liaison to the Tribal Council and Tribal Health Board. In addition, she is a co-author on 22 publications with university partners (Center for American Indian Health, 2018).

- ❖ **Members of investigative or training teams may not be located where the research will take place**, given the rural and geographically dispersed nature of many AI/AN communities. Physical proximity is neither necessary nor sufficient for sound partnerships or training relationships. However, a plan for having a physical presence in the community is important. Reviewers should evaluate the plan for managing distance, with the understanding that, in some cases, physical proximity may be necessary, while in others, the distance can be effectively managed (see **Box 5**).
 - Investigators engaged in AI/AN communities and research may use long-distance training for those in the community working on the project and less frequent face-to-face meetings interspersed with teleconference and email contact in lieu of living in the community.
 - For mentorship and training grants, mentors with expertise in AI/AN research may not be at the investigator institution; as a result, training and mentorship may take place with mentors from different institutions than that of the trainee. It is not uncommon for trainees to develop a mentorship team across the country for both substantive and AI/AN-specific research mentorship and trainee development.

Box 5. Case Example of a Distance Training and Collaboration Network

Funded continuously since 2003, the Native Investigator Development Program has used a structured, skills-based approach to mentor postdoctoral AI/AN scientists without requiring relocation. Faculty and mentees are located across the nation and convene for multiple 2–3-day meetings in Denver, Colorado, or Seattle, Washington, over a 2-year period. Weekly contact between mentors and mentees is maintained by email or telephone. In the first 6 years of the program, 10 individuals completed the program, and graduates produced 57 publications and became PIs, co-PIs, or project leaders on 12 NIH grants (Manson, Goins, and Buchwald, 2006). In a social network analysis, Native Investigator Development Program mentees and faculty collaborated on 106 manuscripts and 83 grant applications between 1998 and 2007 (Buchwald and Dick, 2011).

Examples Relevant to <i>Investigator</i> in the Summary Statement	
<p>NOTE: Appropriate/constructive and inappropriate/inadequate reviewer comments are shown below. Each of the reviewer comments is paraphrased to reflect comments similar to those that have appeared in the summary statements of submitted applications and is shown in italics. Guidance is provided following each example of a reviewer comment.</p>	
Appropriate/Constructive Comments	Guidance
<p><i>Tribal members have integral roles in achieving the project goals. Their input and vision in planning the project are clearly reflected, and they are engaged in the ongoing research and project activities.</i></p>	<p>This comment relates to the need for researchers and the community to work together, further acknowledging how community members can move this work forward.</p>
Inappropriate/Inadequate Comments	Guidance
<p><i>The investigators on this project are quite different in terms of accomplishments and experiences and this raises a concern.</i></p>	<p>AI/AN applications might include co-investigators (including PIs) who represent different and necessary roles on the team, including those with more community or more scientific expertise. The accomplishments and experiences of these investigators will vary and should be evaluated according to the role that they are taking on the project (e.g., PIs representing community expertise should be evaluated in terms of their experiences and accomplishments in the community).</p>
<p><i>The collective expertise of the PI and team is appropriate, but there is concern that the PI, an expert in substance abuse interventions does not have expertise in diabetes interventions. Instead a consultant is providing that expertise.</i></p>	<p>It is common for a community to ask a PI they trust to lead a project in their community for which the PI does not have extensive expertise. In this case, the PI has expertise about the community and how to work effectively with them. Consultants and other investigators often are brought onto the team to ensure that the appropriate scientific expertise is present in addition to this necessary expertise and critical trust in how to work with this particular community.</p>
<p><i>The PI reports limited publications and only one first-authored publication in the last 3 years.</i></p>	<p>PIs working in AI/AN communities have extensive demands on their time in terms of being present in the community, attending community events and meetings, and the need to disseminate results to the community, all of which also reflect productivity. First-authored publications are not the only measure of productivity for PIs working with AI/AN communities.</p>
<p><i>The partners are separated by long physical distances in an area where there are limited transportation resources. The weather at some times of year might increase the transportation challenges.</i></p>	<p>AI/AN populations often are located in areas that are remote from research institutions with scientific expertise. As such, it is often unavoidable to have a study team that is a long distance away. Applicants should not be judged on distance, but rather their plan to handle any challenges that might be presented due to distance.</p>

Innovation

NIH Guidelines for Evaluating Innovation

- ❖ Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- ❖ Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- ❖ Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Points to Consider for Reviewers of AI/AN Applications

- ❖ **Reviewers may encounter innovative theoretical and conceptual approaches in AI/AN studies.**
 - For example, the application of AI/AN-specific holistic approaches to health and wellness by incorporating mind, body, heart/emotions, spirit, and relational worldviews and behaviors is novel, expanding the research beyond single-disease outcomes and allowing research to explore multiple underlying mechanisms.
 - Building on personal, cultural, and communal strengths and resources that are available and potentially sustainable in tribal communities can reflect innovation.
 - Indigenous methodologies and approaches reflect AI/AN logic, worldviews, and knowledge based upon the unique ontology, epistemology, methodology, and axiology of AI/ANs (Tuhiwai Smith, 1999; Wilson, 2001). Indigenous approaches consider the social, historical, and political factors within AI/AN communities and contexts (Walters et al., 2017); emphasize AI/AN voices; and identify and address issues that are of highest priority to AI/AN people (Martin and Mirraoopa, 2003).
- ❖ **Consideration of Indigenous cultural constructs can offer innovations in measurement of health-related risk and protective factors.** The relevance of widely identified risk and protective factors for health in non-AI/ANs is not fully determined in AI/ANs. In fact, there is compelling evidence that previously unanticipated and thus innovative risk and protective factors are related to health outcomes. AI/AN research is doing much to lead the field in analyzing the social, cultural, historical, and spiritual determinants of health and well-being. (**Box 6**).
- ❖ **Studies within AI/AN communities have fueled innovations in the development and/or application of methodological and statistical techniques suitable for small sample research** (Etz and Arroyo, 2015). This includes mixed-methods approaches to intervention evaluation, applied solutions for analytic issues, addressing statistical power (e.g., imputation, Bayesian approaches) for statistical analysis, and reducing measurement error (Fok et al., 2015).
- ❖ **AI/AN studies often lead the field in community-engaged research approaches**, and these might reflect an innovative aspect of the research.

Box 6. Case Examples of Innovations in Conceptualization and Measurement of Risk and Protective Factors

Conceptualization Example: The Indigenist Stress-Coping Model

Researchers at the Indigenous Wellness Research Institute developed an Indigenist-centered stress-coping framework (Walters and Simoni, 2002). This framework provides a conceptual heuristic for identifying AI/AN-specific cultural protective factors that buffer the impact of risk factors such as traumatic events, including discriminatory events, and stressors on various health outcomes.

Risk Factor Example: The Historical Loss Scale

Historical trauma represents cumulative and ongoing traumatic events and policies specifically targeting AI/AN communities, including the loss of tribal lands and involuntary relocation; forced boarding school attendance; systematic removal of AI/AN children from their families; and prohibition of AI/AN languages, religions, and cultural practices. The Historical Loss Scale, developed in collaboration with AI Elders in the upper Midwestern United States, assesses the frequency of thoughts about a variety of cultural losses attributed to historical trauma (Whitbeck et al., 2004). Perceptions of cultural losses are associated with negative health outcomes, including psychological distress and substance use (Walls and Whitbeck, 2011; Whitbeck et al., 2016).

Protective Factor Example: Awareness of Connectedness

Researchers and community members of the People Awakening Team in Alaska developed the Awareness of Connectedness Scale as a way to operationalize Indigenous notions of “connectedness,” or the interrelated welfare of an individual, their family, nature, and community as an important protective mechanism (Mohatt et al., 2011).

- ❖ **Studies with AI/AN often integrate traditional practices, medicine, or knowledge** and this can be a source of innovation.
- ❖ **AI/AN studies may include technology innovations that place them at the forefront.** A recent review describes enthusiasm and creativity in adapting or developing mobile technologies across Indigenous communities, in some cases as a way to address distance barriers and a “digital divide” (e.g., Jones et al., 2017).
- ❖ **Research-testing culturally based interventions may show innovation** in the context of the little research that has tested these interventions for AI/AN populations. Culturally based intervention research falls along a spectrum, from interventions developed from the ground up to selecting evidence-based programs with cultural congruence to cultural adaptation of existing programs (e.g., Okamoto et al., 2014).
- ❖ **In intervention research, innovation may lie in balancing the tensions between cultural specificity and identifying principles and practices that might generalize to other populations,** thus moving beyond efficacy testing to identifying processes of adaptation and key ingredients in interventions that resonate across cultures.
- ❖ **Innovation can stem from capacity-building efforts** to facilitate local support to conduct research, train for academic research skills and capacity, and/or foster innovation in existing health systems.

Examples Relevant to *Innovation* in the Summary Statement

NOTE: Appropriate/constructive and inappropriate/inadequate reviewer comments are shown below. Each of the reviewer comments is paraphrased to reflect comments similar to those that have appeared in the summary statements of submitted applications and is shown in italics. Guidance is provided following each example of a reviewer comment.

Appropriate/Constructive Comments	Guidance
<p><i>While the overall approach is not overly innovative, this project will take advantage of studying a protocol that is new for the AI/AN population. Because of this, the study is innovative.</i></p> <p><i>While many of these questions have been explored for other populations, examining developmental trajectories in an indigenous group is novel.</i></p>	<p>AI/AN research might be at a different stage relative to scientific advances in a field overall, and thus innovation for this population might need to be assessed relative to knowledge of the population, rather than relative to the overall field.</p>
<p><i>The major innovation in this application is the theoretical basis and use of AI-specific theory. The project is based in a holistic (mind, body, spirit, emotions, and community connections) approach and explores the role of historical trauma in both mental and physical health.</i></p>	<p>Innovations might relate to the application of culturally specific theory in AI/AN applications.</p>
<p><i>While the introduction of historical trauma is potentially novel, it is unclear how it might be addressed during intervention. It is unclear whether the intervention will specifically target historical trauma or will only be assessed in the outcomes. If it is part of the intervention, it is critical to ethically plan for its inclusion.</i></p> <p><i>The focus on historical and contemporary oppression and trauma could be helpful but could also increase the experience of historical cultural losses. The investigators must attend to the nuances and ethical issues surrounding this.</i></p>	<p>While culturally specific theory and the use of culturally relevant constructs might reflect innovation, they can also introduce a weakness if applicants are not clear on how these constructs and theories will enhance the project and whether they do not attend to ethical issues.</p>
Inappropriate/Inadequate Comments	Guidance
<p><i>Similar work has been done in other ethnic communities, though there is innovation in the way the constructs are related to health outcomes.</i></p> <p><i>This work is not particularly innovative because programs like this are in place throughout the United States, though they have not been used by this community.</i></p>	<p>As noted above, although similar work might have been done with other populations, testing similar approaches with a new population can be innovative in some cases, especially if processes or relationships between constructs are expected to differ. Applicants should be careful to clearly articulate this innovation despite work in other populations, and reviewers should be open to persuasive arguments.</p>

Approach

NIH Guidelines for Evaluating Approach

- ❖ Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- ❖ Are potential problems, alternative strategies, and benchmarks for success presented?
- ❖ If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

Points to Consider for Reviewers of AI/AN Applications

- ❖ **Community engagement is a critical component of AI/AN research** (see **Foreword**). Reviewers of applications with AI/AN communities might consider whether the proposed approach will balance scientific methods with the AI/AN communities' needs and willingness to participate and partner in proposed designs.
- ❖ **CBPR/Tribally Based Participatory Research (TBPR) are approaches to research focusing on relationships and co-learning with mutual benefit** (Minkler and Wallerstein, 2003) through collaborative exploration (Blacksher, et al., 2016) rather than a specified set of methods or techniques (Wallerstein and Duran, 2006). Although CBPR/TBPR are sometimes viewed as a “gold standard” for AI/AN research, new partnerships may require support and time to develop, and some communities or projects may request consultation rather than collaboration. As noted in the **Foreword**, rather than assuming a singular approach to community engagement, reviewers should look for evidence of investigator attention to AI/AN contexts, how community members have been involved in the AI/AN proposal, how local preferences for involvement in the conduct of the study are followed, and how a proposed study addresses community needs. Formative work to explore the acceptability of different types of research, such as genetic research and feasibility pilots, may be first steps.
 - Potential, though not exhaustive, examples of evidence of community engagement include letters of support clearly describing engagement processes, tribal resolutions, and/or memoranda of understanding.
 - Reviewers may see partnership development, work to disseminate findings to the community, and other components of CBPR/TBPR or community engagement reflected in timelines, budgets, and research approach strategies. This engagement likely will take time and funds.
 - Community member involvement in data collection and interpretation is a cornerstone of many AI/AN studies. Grants that provide funding to employ tribal research workers can build local research capacity and facilitate deep involvement of tribal members in research processes and protocols. Community members also can lend their cultural expertise to the project.
- ❖ **Reviewers may be more likely to encounter wellness- or strengths-focused, holistic applications in AI/AN research in contrast to disease- or disorder-centric proposals.** AI/AN communities evince tremendous strengths and resilience and increasingly have indicated their desire to ensure that these characteristics are reflected in research (Baldwin, 1998; Fixico, 2013; Kahn et al., 2016; Mohatt et al., 2004; Wolsko et al., 2007; Rasmus et al., 2016). The notion of AI/AN *survivance*

(Vizenor, 1999) as active survival, rejection of victimhood, and assertion of intellectual autonomy provides a critical underscoring of positive orientations.

- ❖ **Cultural constructs may be incorporated** in the approach and include traditional values, practices, diet, and activities; AI/AN identity; respect for Elders; and strong family and community ties, among others (Gone and Calf Looking, 2011; Greenfield and Venner, 2012; Guillory and Wolverson, 2008; Jones and Galliher, 2007; Kading et al., 2015; Kulis et al., 2012; Walters and Simoni, 2002).
- ❖ **Reviewers may not always see standardized, widely validated measures as the central measurement strategy in AI/AN-involved applications**, as grant applications with AI/AN communities might include measures used in prior tribal or other research and/or measures specifically developed for the research project (see also **Innovation**). When standardized measures are not feasible or appropriate, reviewers should evaluate the proposed non-standardized measures, assessing the process of developing the measures and the anticipated or demonstrated quality, merit, and rigor of the measure for the specific population and/or construct proposed. Applicants should ensure that they include justifications for the measurement strategies they have selected.
 - An ongoing tension in AI/AN research is the desire for locally specific, culturally meaningful operationalization versus the use of widely known measures for comparability and generalizability of results across settings (Beals et al., 2003). Some risk and protective factors, for example, may be specific to cultures or non-majority groups, including cultural, racial, or ethnic discrimination; historical trauma; or engagement in Indigenous traditions or spirituality (see **Box 6**).
 - For AI/AN research in urban settings, the sheer number of tribes represented in the data set poses measurement challenges where researchers often adapt or create new measures that capture meta values or constructs that could be successfully applied universally across tribes (e.g., connectedness; urban AI identity attitudes).
 - The tension between specificity and generalizability can permeate multiple phases of measurement, from conceptualization of constructs to operationalization of data collection to interpretation of findings (Walls et al., 2017).
- ❖ **Although small sample research can present unique challenges, small samples should not de facto equate to the research approach being flawed, especially since small samples are often inherent in AI/AN research.**
 - Small sample research is important in that the research questions posed in such contexts often address major health inequities for AI/ANs and other underrepresented groups (Etz and Arroyo, 2015).
 - Investigators must propose rigorous scientific approaches when faced with small samples, but reviewers are encouraged to exercise flexibility rather than assuming that only one approach can provide appropriate rigor, thus overlooking evidence presented to support a different perspective.
- ❖ Many AI/AN cultures are composed of small, close-knit communities that emphasize inclusivity and communal approaches, and they may be reluctant to randomize assignment. These characteristics mean that randomized clinical trials may not be acceptable, possible, or desirable. Blinded trials also may be challenging, as transparency can be an important component of building or rebuilding trust. Reviewers may see variations on the randomized controlled trial (RCT) or pre-experimental approaches that balance cultural values and scientific rigor with feasibility and acceptability.

- Alternative research designs to the RCT may represent methodological rigor for study of health interventions in certain AI/AN settings. Alternative designs include interrupted time series, rollout randomization designs such as dynamic wait-listed and stepped wedge, regression discontinuity, and other quasi-experimental designs. Community preferences and ethics, as well as scientific perspectives related to feasibility, intervention approach, and efficiency, are all important considerations defining rigor. These alternative designs are able to estimate intervention effects with limited bias, allowing researchers to operate in greater congruence with community values and rigor.
 - Randomization of individuals, families, or groups through purposeful exclusion from interventions that are viewed as beneficial can raise ethical concerns in small, close-knit AI/AN communities. It can also conflict with cultural values that may include sharing of opportunity, inclusion, and communal approaches.
 - Implementation of an RCT is not always feasible. For example, group randomization may not be pragmatically possible in small communities or on the level of population health research.
 - Implementation of an RCT is not always desirable from scientific perspectives. RCT assumptions cannot always be met for health inequity interventions that often adopt community, population health, or multi-level, or structural approaches, where the social unit of analysis is clusters of individuals. For example, bias is introduced if sample sizes differ across clusters or the numbers of clusters are fixed. This is often the case among tribal groups with limited numbers of communities of varying sizes. RCTs are also inefficient in their use of statistical power, in contrast to many of these alternative designs, and a poor match to the small populations and samples that characterize much of the AI/AN research, increasing the likelihood of underpowered studies.
 - Unintended consequences of a metric holding the RCT as the singular gold standard for causal interpretation in all research settings can limit progress to address current AI/AN health inequities. It can unintentionally privilege particular intervention approaches that are more amenable to RCT frameworks, such as individual-level interventions, over other promising, more context responsive interventions, and can privilege study settings and populations that can produce large, easily accessible sample sizes over smaller, more difficult-to-reach groups facing some of the most extreme health inequities in the United States. This limits the capacity to study effective solutions to the challenges of potentially greatest societal importance.
 - Alternative approaches to RCT designs may at times provide opportunities for measuring diffusion of treatment (e.g., measuring the impact of an intervention on non-experimental group community members or networks; note also potential contributions to **Innovation and Significance**).
 - Note also that preferences about research designs or situations are not universal; in contrast to what is presented above, some communities may see advantages to, possess capacities for, and desire using an RCT.
- ❖ **Reviewers may see novel statistical approaches**, such as Bayesian analysis, that are sometimes more suited to analyzing data from small samples.

- ❖ **Sampling in AI/AN communities may be complex due to variation in definitions of tribal membership and other factors.** As some tribes may not be federally recognized and also vary in how they define membership, the ethics and politics of membership in AI/AN communities can have implications for sampling in research. Although some researchers have used tribal enrollment rosters, others rely on self-identification as AI/AN. Common sampling frame strategies, such as telephone listings or addresses, may be problematic for AI/ANs, as landlines have often been replaced by prepaid cellular phones and addresses are often nontraditional in reservation settings. The implementation of novel or modified non-probability sampling approaches across various modes of research may strengthen sampling approaches.
- ❖ **Though approximately 70 percent of AI/ANs live off reservations, urban AI/ANs constitute less than 2 percent of the population in many of the metropolitan statistical areas in major cities, and they do not cluster in any of the cities by neighborhood** (AI/ANs cluster at less than 1 percent for any neighborhood enclave); thus, a random sample for survey purposes is simply not cost-effective or efficient. In fact, no clear sampling frame exists for urban AI/AN populations—the sizes and boundaries are simply unknown.
 - Typically, an ideal sampling procedure would yield a sample that is independent of its starting point and an unbiased sample of the underlying population with a known degree of consistency from which confidence intervals could be computed. However, urban AI/AN research typically has a revised goal: to devise a way of obtaining a sample that minimizes selection biases and produces a cross-section of the target population or one that covers the heterogeneity of the target population. Quite often, this leads to creative mixed sampling practices, such as uniting dual-frame sampling approaches (agency lists and volunteer lists) with modified targeted, partial network, and respondent-driven sampling procedures to address non-coverage, overrepresentation, and the other selection biases that are inherent in non-probability sampling designs. Implementation of mixed sampling approaches may strengthen urban sampling strategies.
- ❖ **Qualitative, quantitative, and mixed methods approaches may be used when appropriate for the research questions and the associated research design.** Qualitative and mixed methods approaches may be more common in AI/AN research in response to fewer studies and the resultant need for exploratory and explanatory investigations. Qualitative data also may help contextualize and interpret quantitative findings. Many qualitative approaches permit deep collaboration and partnership between the researcher and the participant that honors human experience and story (e.g., life history approaches, auto- or reflexive ethnographies, ethnodrama, etc. [Denzin and Giardina, 2016; I-Poems, Listening Guide Method; Gilligan, 2015]). Despite this, reviewers should not make assumptions about one approach being more appropriate than another, but should instead evaluate the investigator’s justification for the approach and ensure the approach can effectively address the research question.
- ❖ **Reviewers should be sensitive to the possibility that customary data collection practices may violate cultural or spiritual religious practices/freedoms in some tribes.** In some cases, investigators may need to propose alternative approaches that differ from what might be used in other populations due to these restrictions. Examples of potentially challenging standards include (1) collection of certain bio-samples (i.e., cord blood, hair); (2) observational measures in homes or of ceremonial areas or practices that may be taboo or raise undue tensions; and (3) not respecting the need for passage of time before interviewing families after a death. In these cases, reviewers should

consider whether alternative approaches may be able to address the question, though they may be non-standard.

- ❖ **Alternatively, some AI/AN communities will support the collection of data that other AI/AN communities might not be willing to support.** If appropriate letters of support or other material indicating community support are included with the application, reviewers should not make assumptions or draw their own conclusions about the cultural appropriateness of collecting a certain type of data. The community and tribe should be able to collect the data they deem important. The reviewer should focus on assessing the scientific merit of the data to address the research questions.
- ❖ **Timelines may reflect that more time is necessary to complete projects.** Research conducted with AI/AN communities can take longer than other research. This can happen for many reasons, including the formative phase time for building the team and gaining multiple levels of tribal and institutional IRB approvals; sometimes more time is needed for sample recruitment due to rural, isolated settings or the need for recruiting to ensure a larger sample. It can also take more time for publication development, as participatory research, co-reporting of results, and obtaining tribal approval for publications can take longer than the standard publication process.

Examples Relevant to Approach in the Summary Statement

NOTE: Appropriate/constructive and inappropriate/inadequate reviewer comments are shown below. Each of the reviewer comments is paraphrased to reflect comments similar to those that have appeared in the summary statements of submitted applications and is shown in italics. Guidance is provided following each example of a reviewer comment.

Appropriate/Constructive Comments	Guidance
<p><i>An asset-based intervention with AI/AN communities is innovative and important.</i></p> <p><i>In contrast to prior work, which is deficit-focused, this study uses a strengths-based approach to evaluate positive development.</i></p>	<p>AI/AN communities often value a strength-based perspective. As such, reviewers might see this approach taken more often in AI/AN research.</p>
<p><i>Even if the pilot study is not efficacious, the CBPR activities and scholarship will yield important experience and knowledge.</i></p>	<p>The strength of the approach can stem not only from what will be learned from the results, but also from other aspects of AI/AN projects.</p>
<p><i>Using culturally appropriate definitions to measure well-being is innovative. It will shed light on unique constructs that may be strengthened to achieve better health outcomes.</i></p> <p><i>The research methods and strategies are a strength as they include the development of culturally grounded measures; innovative sampling methods; and an approach that reflects the best practices in Community Based Participatory Research.</i></p> <p><i>This application does not consider the cultural appropriateness of existing measures for the AI/AN sample.</i></p>	<p>Given the unique culture and influences on outcomes for AI/ANs and the need for community engagement in research, reviewers might see novel approaches to research or are likely to see measures that are developed specifically for this population. Failure to consider cultural appropriateness might be a weakness.</p>
<p><i>This application does not demonstrate community engagement, ensure that the community helps to interpret the outcomes, or include a plan to share the outcomes with the community. This is a big concern.</i></p>	<p>Community engagement is an important component of successful AI/AN research.</p>
Inappropriate/Inadequate Comments	Guidance
<p><i>It is not clear how many AI/ANs will be able to use the proposed technology (smartphones, tablets, computers) or whether service will be reliable, especially in remote communities. While the preliminary data indicate that many have computers and cell phones, those data depend on who responded to the survey, and this may be geographically limited and self-selected.</i></p>	<p>While AI/AN communities might have lesser access to technology platforms or might not have reliable service, reviewers should not assume that this is a fatal flaw but should assess the information that applicants provide about how they will overcome this challenge. Reviewers should take care to not penalize AI/AN research if proper arrangements have been made, as less access to technology or other conditions that pose challenges can be inherent to where much of the population resides.</p>

<p><i>There are no letters of support from families. The letters of support are from existing Community Advisory Board members, who are all professionals, or from other professionals (e.g., directors, officials) in the community. Letters of support from the families of youth or from the youth themselves, who are the target of the intervention, would strengthen the application.</i></p>	<p>Letters of support are an important indication of community engagement. However, beyond tribal resolutions or tribal council approval for research, there are no established standards for who should write these letters. As such, reviewers must be careful when evaluating letters to not introduce their own bias for who should write letters and instead be sensitive to what is appropriate in a given community.</p>
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Environment

NIH Guidelines for Evaluating Environment

- ❖ Will the scientific environment in which the work will be done contribute to the probability of success?
- ❖ Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed?
- ❖ Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Points to Consider for Reviewers of AI/AN Applications

- ❖ **Applications are likely to include a description of the resources available in the tribal community.**
- ❖ **Research in a relatively resource-poor research environment does not automatically lead to inadequate research outcomes.**
 - Consider proximity to, knowledge of, and involvement with local participant populations as important environmental contributors to feasibility, as well as translational potential.
 - Research projects within AI/AN communities can provide examples of overcoming resource challenges to make noteworthy scientific and other contributions.
- ❖ **Similar to investigators and research teams, research sites for AI/AN-focused proposals also may be rural and geographically dispersed or urban.** This geographical reality for many AI/AN communities has been successfully addressed via multiple channels (e.g., videoconferencing, regular in-person visits) in research across many fields and disciplines and need not be considered an insurmountable challenge.
- ❖ **Infrastructure to support research projects may be in development.** PIs and other researchers may work in community-based settings, including TCUs, where resources vary from those typical of research-intensive institutions (see also [Investigators](#)).
 - The promise of capacity building for (later) larger-scale and more complicated types of designs and resource-intensive data collection and processing, such as clinical trials and genetic studies, may be important investments with considerable long-term payoffs, given the very limited participation in research of AI/ANs nationwide.
- ❖ **Research Capacity and Infrastructure may be an explicit goal.** While not necessarily related to a proposed study's ability to address immediate specific aims, in some instances, tribal communities may desire research capacity components that will facilitate sustainability of future research projects. These components can provide the tribe with knowledge of and familiarity with the research and research processes, enabling the tribe to increase its ability to express sovereignty over the research. These items could include IRB development, training community members in research administration, and access to research publication databases.

Examples Relevant to *Environment* in the Summary Statement

NOTE: Appropriate/constructive and inappropriate/inadequate reviewer comments are shown below. Each of the reviewer comments is paraphrased to reflect comments similar to those that have appeared in the summary statements of submitted applications and is shown in italics. Guidance is provided following each example of a reviewer comment.

Appropriate/Constructive Comments	Guidance
<p><i>The project aims to develop capacity in a variety of areas, including organizational, technical, and community health through a process to be carried out over the course of the project timeline.</i></p> <p><i>Access to an AI/AN health information system through the research-intensive partner at no cost will provide support to all the participants involved in the grant and allow an increase in the availability of support for student research internships.</i></p>	<p>Building research capacity and infrastructure can be a strength in AI/AN research.</p>
<p><i>The strong collaborative arrangement between the tribe and research-intensive partnering institution enables a secure environment for the tribal members' medical records.</i></p> <p><i>Participation of the community-based tribal facility provides the necessary partnership and expertise to achieve the project aims with the target AI/AN population.</i></p>	<p>Strong partnerships can support an appropriate environment for the research project.</p>
Inappropriate/Inadequate Comments	Guidance
<p><i>The geographical distance between the tribal community and partnering research-intensive institution may diminish the presence of the research-intensive partner in the tribal community. This is a minor weakness, since the tribal community and research-intensive partner have a long history of successful collaboration.</i></p>	<p>Given where tribes reside, there are often long distances between project sites and research institutions. While this comment notes that this is only a minor weakness and the long history of successful collaboration allays the concern, the reviewer may be introducing unconscious bias by noting this as a concern. Many scientific projects are successfully implemented across multiple locations, demonstrating that research can be conducted across distances. While the applicants should present a plan to manage the challenges introduced by distance, AI/AN-focused health research should not be penalized for geographical realities that cannot be changed but can be effectively managed.</p>

Not as many AI/ANs have cell phones or use media compared to other populations, and this might create challenges for the uptake of the intervention.

This comment may or may not be accurate, and the applicant should ensure that they provide data on usage for the community in which they will work. The comment potentially penalizes the proposal for a challenge in some tribal areas and introduces bias on issues that are common in many contexts of AI/AN health research. Applicants should anticipate this challenge to their research and include how they will address it, noting that some limitations cannot be overcome completely but can be managed. Applicants must also justify why the use of this technology is preferable to other approaches, despite associated challenges.

Overall Impact

NIH Guidelines for Overall Impact

- ❖ Reviewers will provide an Overall Impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five core review criteria (Significance, Investigator, Innovation, Approach, Environment), and additional review criteria (e.g., Human Subjects and as applicable for the project proposed).

Points to Consider for Reviewers of AI/AN Applications

- ❖ **When an AI/AN application receives a review that notes that the constraints that can exist when conducting research in AI/AN communities are weaknesses, such comments can accumulate into a perceived overall major weakness of the application.** Even when these multiple “cuts” are acknowledged as minor, as when things cannot be changed or it is noted that the PI has done the best they can in the face of the challenges, the comments can lead to an application scoring poorly overall, due not to a major flaw or a belief that the science is not rigorous, but to constraints that pose challenges. Researchers are able to conduct rigorous and meaningful science despite the constraints that may exist.
 - Examples of these minor weaknesses or situations that cannot be changed include the distances between investigators and the research location, sometimes hard-to-retain samples, and small sample sizes. Although any one of these might not dramatically impact the evaluation, taken together, they can decrease enthusiasm. Reviewers should be open to information provided by applicants that demonstrates effective strategies to manage these challenges and maximize high-quality science.
- ❖ **Innovations in theory, methodology, and research design in AI/AN projects could have impacts on multiple disciplines and fields.** For example, research projects could inform other research focused on patient-centered outcomes, as well as the process of culturally tailoring interventions, or could have implications for research with Indigenous people from other countries.
- ❖ **A project can be judged likely to have a major scientific impact even if it appears to lack innovation, given that innovation is in part dependent on the state of the science for a population.**
- ❖ **The evaluation of the Overall Impact could be extended beyond implications for science to also consider the likelihood of the project to exert a sustained, powerful influence on the tribal community and address community health concerns through science.**
- ❖ Reviewers should be careful not to make assumptions based on their knowledge of AI/AN communities concerning what any one AI/AN community might want from research or to suppose that particular components must be present for the research to be “acceptable.” Given the history of research in AI/AN populations, reviewers are often eager to ensure that research abuses do not occur. This is an important goal. If, however, there is evidence (such as letters of support) in the application to support the investigators’ claims about the desire for the research and the research plan, reviewers should accept these without bias and not be influenced by their own beliefs about

what is appropriate research in AI/AN communities. We refer to this bias as **Gatekeeping**, which can be a prevalent issue in the peer review of AI/AN-focused research.

- Although it is true that certain structures for research will be different in tribal research, reviewers are charged with evaluating applications as they are written, without assumptions about the community that are not included in the application.

Examples Related to Overall Impact in the Summary Statement (including Gatekeeping)

NOTE: Appropriate/constructive and inappropriate/inadequate reviewer comments are shown below. Each of the reviewer comments is paraphrased to reflect comments similar to those that have appeared in the summary statements of submitted applications and is shown in italics. Guidance is provided following each example of a reviewer comment.

Appropriate/Constructive Comments	Guidance
<p><i>If successful, the project could provide a strong community-based model to address support for mental health in tribal communities.</i></p> <p><i>The proposed collection of data will provide the tribal community with a better understanding of the local risk factors and disease burden. These data can provide an understanding of the underlying factors for the disease disparity as well as some of the mitigating causes.</i></p>	<p>Data collection to assess community issues or models not previously utilized in these communities could have large impacts on current research approaches.</p>
Inappropriate/Inadequate Comments	Guidance
<p><i>This is an ambitious and culturally sensitive project, but the urban-based researchers may not be aware of all of the logistical challenges if they have not tried to use cell phones in rural and remote areas in AI/AN communities. Due to the impoverished areas with lack of reliable transportation, there are concerns that the backup plan to contact subjects with a certified letter may have serious problems.</i></p> <p><i>The AI populations may be transient, and locating them may not be possible.</i></p> <p><i>The unique aspects of this population, the geographic location, and the specific focus on addressing AI/AN-related issues result in some issues with the research design.</i></p>	<p>There are realities of AI/AN communities that cannot be changed. As such, reviewers must be careful when noting these realities and indicating that they are weaknesses in the research design, when they are in fact real-world challenges. Applicants should include a plan for managing them. If reviewers consistently include the geographic, technological, and other barriers to conducting AI/AN research as a weakness, the effect can be “death by a thousand cuts,” resulting in the evaluation and scores of proposals being harmed by the accumulation of multiple minor issues that in some cases cannot be changed but can be managed through careful research and planning.</p>
<p><i>These models reside in a linear framework of time, focused on the current generation and moving forward. The cyclical nature of time is not captured; neither is the importance of connection to ancestors or the interdependency represented by the concept of the seven generations. These are critical to understanding the effect ancestral connections have today on youth, families, and communities.</i></p>	<p>This description appears to make assumptions about how AI/AN research must proceed, suggesting that it needs to be cyclical rather than linear. If the applicant has presented sufficient evidence that the community supports the research, then the linear approach should not be questioned. The reviewer should evaluate the models in the context of the project at hand.</p>
<p><i>It is unclear whether tribes have the capacity to give informed consent for the mapping of their genomes.</i></p>	<p>AI/AN research often requires tribal approvals; as such, tribes are likely the appropriate body to give consent, though individual consent for participation in the research is still an obvious requirement. If a tribe approves a project that includes genome mapping and the individual consent forms are appropriate, this is likely sufficient to meet the standards for human protection and appropriate consent. In addition, questioning the ability of a tribe to guide research efforts that involve its populations can recall historical concerns that tribes have had regarding research and impede the</p>

	beneficial evolution of attitudes and understanding that tribal populations have for scientific research.
<p><i>While tribal support for the project is presented, indicating support for a harm reduction approach in substance abuse treatment, it is unclear that a harm reduction approach is truly consistent with AI/AN values.</i></p>	<p>While some tribes or AI/AN people may prefer an abstinence-based approach to substance abuse treatment, if the letters of support indicate that the community is supportive of this approach, then this is sufficient. Assuming that the community has values other than those that are included in the letters of support, even if those values are different from other communities that a reviewer has knowledge of, constitutes gatekeeping.</p>

Additional Review Criteria

While not part of the review criteria that are scored separately by reviewers, the following areas are also evaluated in the review of applications. The guidance on these criteria is: “As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.”

Human Subjects Protections

NIH Ethical Guidelines for Protection of Human Subjects

- ❖ For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials.
- ❖ For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: (1) the justification for the exemption, (2) human subjects involvement and characteristics, and (3) sources of materials.
- ❖ For additional information, see the Guidelines for the Review of Human Subjects.

Points to Consider for Reviewers of AI/AN Applications

- ❖ **The 2017 revised Common Rule, page 7258, clarifies that tribal governments can develop laws related to the protection of human subjects that are more protective than the Common Rule and that these laws must be followed by federally funded researchers in activities involving these populations.**
 - Tribal governments may develop their own informed consent standards that provide additional protections to subjects that investigators would have to follow.
 - If a tribal government requires review by more than one IRB by law in multi-institutional research, the single IRB review requirement does not apply.

The following points are not part of the NIH policy on human subjects and, as such, are not evaluated in review. However, reviewers should be aware of these unique features of research that *may* apply for *some* tribes. Reviewers are not asked to evaluate whether the investigators have considered these factors, as each community will have its own approach. Rather, reviewers may encounter these features in applications and should be sensitive to how they may impact the design and conduct of a study.

- ❖ **Some tribal protections extend beyond the protection of the individual.**
 - For tribes, protection of human subjects often extends to the community level (Hull and Wilson, 2017). Reviewers may encounter community- and tribal-level protections in addition to individual protections.

- Protection might extend to lands (including fauna, flora, and water) and tribal territories.
- Epistemologically, protections may extend to ancestors, the present generation, and future generations that might be impacted by the research.
- Protections extend to cultural knowledge and traditional guardianship of that knowledge. Tribes have the right to protect, maintain, control, and develop their sacred, traditional, and cultural knowledge and expressions of intellectual property (see United Nations Declaration on the Rights of Indigenous Peoples at <https://indianlaw.org/implementing-undrip>).

❖ **Tribal sovereignty is the basis of authority to establish research regulations.**

- Some tribes may have their own IRB; others will use the national/regional Indian Health Service (IHS) IRB (or may require both university and tribally sanctioned IRBs—see **Box 7**); and others may defer entirely to the university IRB. Some tribes may have another regulatory authority, such as a tribal council or research board that provides approval of proposals. Some tribes might also have their IRBs or other types of regulatory boards (e.g., Research Review Board, Community Advisory Board) provide additional required functions such as review and approval of presentations and/or publications.
- Community members, including those not elected or appointed (e.g., Elders, consumers, content experts), customary leaders (e.g., inherited or inspired), and/or knowledge keepers (e.g., cultural societies, traditional healers) may also play an important role. In some cases, it is important for a research project to gain approval and/or engagement from such sources in addition to elected tribal leadership (e.g., the Tribal Council).
- In some tribes or AI/AN communities, research protocol codes or research agreements are created as a primary means of clarifying and confirming mutual expectations and commitment by and between AI/AN communities and researchers. These codes or agreements can also indicate a plan to enact in case disputes arise.
- Some aspects of urban AI/AN research may be subject to tribal authority. Although tribes, as a general rule, do not assert authority over the research participation of tribal members who live outside tribal jurisdiction lands, if the recruitment targets a particular tribe or will be generalized to a particular tribe, then the tribe should be consulted and may expect researchers to elicit tribal review, oversight, and support.
- Urban AI/AN communities may desire a review process or seek regional IHS AI/AN IRB oversight, and/or they may designate a university IRB as their IRB of record. Additionally, a “community” in urban settings may consist of AI/ANs living in a geographic area and may include different sectors of the community that have a stake in the proposed research, including stakeholder groups, consumers, local government bodies, and AI/AN urban health-related organizations. Researchers often partner with AI/AN organizations located in the area, sometimes including Urban Indian Health Programs (41 across the United States), their review bodies or advisory boards, and in some cases the IHS IRB boards serving the region. IHS IRBs exert authority over research conducted at IHS facilities or with IHS staff, patients, or resources.
- Lack of any formal research protocols, review committees, or IRBs in a particular tribal or urban AI/AN site does not relieve the researcher of the obligation to seek and secure community consultation to adequately assess risks to subjects and the potential for community harm.

Box 7. Challenges to Complex IRB Protocols

The People Awakening team faced a very complex human subjects review process involving three IRBs, six regional tribal boards, and numerous village councils. At the time, research that involved more than one tribal group needed to obtain a multiple project assurance (which was available from the IHS IRB), as well as gain approval for conducting the research from each tribal group. According to federal law, each village in Alaska is a tribal group, resulting in more than 250 tribes. Because the NIH had very little experience with statewide research in Alaska, the research team worked with the Office for the Prevention of Research Risk to gain permission for the Alaska Native Tribal Health Consortium IRB to represent the tribes in each of the regions (Mohatt et al., 2004).

❖ Respect for proper handling of biological materials and other data.

- Standards and expectations for managing data and biological samples (i.e., tissue, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, or other bodily fluids) vary across tribes and communities. As a result, some human subjects proposals may include a description of culturally appropriate handling and/or agreed upon disposal or return of these materials.
- Reviewers should not make any presumptions about whether tribes will want to engage in **genetic research** and should look for appropriate letters of support to indicate tribal wishes. Some tribes may choose to participate; others may choose not to pursue this line of research.
- Given the potential for privacy violations as well as stigmatization, data sharing protocols should consider protection of risk to individuals and the community from the storage and use of health-related data (including video, digital, and print media).

❖ Respect for participants' and communities' privacy and confidentiality.

- It can be difficult to maintain privacy and confidentiality in AI/AN communities that have closely tied familial, clan, and community networks. Applications may indicate the steps they will take to mitigate the possibility of confidentiality violations of the community and of individual participants. Sometimes this means hiring staff from outside the community.
- Frequently, tribes may decide to ensure community safety and mitigate potential harm to the community by providing dissemination guidelines that include policies to restrict publication of community-level identifiers (e.g., omitting a tribal name) in presentations and publications (Hull and Wilson, 2017).
- In other cases, participants (or communities) may want to be acknowledged for their research participation; in such cases, the conditions under which participant or site identities could be publicly acknowledged should be specified.

❖ Data Safety Monitoring Plans and Boards

- Data Safety Monitoring Plans may include safeguards to protect the confidentiality of sensitive, personal data; avoid unnecessary invasive or culturally prohibitive procedures when less invasive procedures are available; and exclude participants at significantly increased risk of being harmed by the intervention.

- Given ethical guidelines to ensure the respect for communities, AI/AN-related Phase III clinical trials warrant AI/AN research expertise on Data Safety Monitoring Boards (DSMBs). Having AI/AN-focused researchers as part of the DSMB may help contextualize any data considerations, data safety concerns, and monitoring.

Resource Sharing Plan

NIH Guidelines for Resource Sharing Plan

- ❖ Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan](#); (2) [Sharing Model Organisms](#); and (3) [Genome Wide Association Studies \(GWAS\)/Genomic Data Sharing Plan](#).

Points to Consider for AI/AN research

- ❖ **In general, review of scientific merit should not be related to data sharing policies.** Data sharing policies may, in some rare cases, have implications for scientific merit. For example, if scientific rigor would be enhanced by pooling data, this should be noted. However, any weaknesses introduced due to data sharing plans should be weighed against tribal policies and preferences for data sharing, as well as the overall significance of the research for the community, regardless of any potential additional value gained through data sharing. Per the NIH data sharing policy, exceptions are permissible to protect the rights and privacy of research participants or as indicated by other laws or regulations.
 - As sovereign entities, many (but not all) tribes have regulations, policies, or practices addressing data sharing and ownership. Data sharing options may include open use, restricted use (which requires an application process and agreements about keeping the data safe), use in either a physical or virtual data enclave, no sharing, or no storage for future use. Institutes and Centers within the NIH have approved each of these types of data sharing options, including no sharing of the data.
 - Data sharing agreements are negotiated between the grantee institution and their research partners. Grantees then explain the approach they have taken to the NIH, which then either approves or rejects the data sharing plan. The NIH is not directly involved in the negotiation of data sharing agreements.
- ❖ **Data sharing plans may include cultural and other considerations, as well as the environments within which the data were collected.** As previously mentioned, tribes may have different beliefs and approaches to sample collection and data sharing (see **Box 8**). The following scenarios are examples of what could be considered in the data sharing plan:
 - De-identified data, which include AI/AN heritage, may or may not be considered to have a potential for group harm (i.e., identifying a region or that the study deals with a tribal community). In some cases, stigma could arise from publications on AI/AN if the results are not reported appropriately; thus, it could be important to not share even de-identified data or to share only via an approval process.
 - Some tribes and tribal members may have cultural, spiritual, or religious beliefs that emphasize the body's remaining intact or whole, and removal of bodily fluids and hair or the donation of tissues may mean specific protocols must be followed for both collection and storage (e.g., Burhansstipanov et al., 2005; Hiratsuka et al., 2012).

- Some tribes or AI/AN people may want specimens returned after use or upon the death of the participant or want the disposal or destruction processes to involve ceremony or other respectful treatment.
- Tribal entities may consider data sensitivity but authorize sharing, given the potential benefit to the community or other considerations.
- Data sharing plans in applications also could state that the specific terms of data sharing will be subject to tribal approval pending ongoing discussion and negotiation.

Box 8. Example: Data Sharing

The Indigenous Wellness Research Institute (IWRI) houses data for academic and community partners, and some of these data sets are available for public access. Public access includes a standard access approval procedure as well as a project-specific tribal and PI approval process. Interested applicants contact the IWRI Data Management Team (DMT) with clear specifications relative to their data analytic plan, their own human subjects' approval procedures, and their outline for adherence to IWRI and tribal data use and confidentiality standards, including any particular restrictions identified by tribal partners relative to data access and usage for a particular data set. Upon approval by the DMT, the researchers sign a contract agreeing to follow confidentiality procedures, submit reports of progress, and permit the DMT, the PI, and the tribal partners to review all final papers and presentations prior to submission or publication.

- ❖ Resource sharing plans also may take into account cultural and other considerations.
 - Some tribes have regulations, policies, or practices addressing disposition of resources, such as equipment.
 - Some AI/AN research codes specify that, if any patents result from research, the tribal community should be a co-owner and share in the benefits. Research on traditional practices, medicines, and ceremonies could pose concerns about others profiting without appropriate permissions, acknowledgement, or profit-sharing.

Budget

NIH Guidelines for Evaluating Budget

- ❖ Is the requested budget realistic for the conduct of the project proposed?
- ❖ Is the budget considered to be sufficiently justified by the project described in the application?

Points to Consider for Reviewers of AI/AN Applications

In many cases, AI/AN-focused research incurs additional fiscal and time costs for multiple needs, including but not limited to longer recruitment periods; staffing to accommodate protracted timelines, given community and cultural needs; and transportation needs. Specifics are included below, and reviewers can better assess applications by keeping these potential needs in mind.

- ❖ **Travel is essential to obtain tribal approval** for data collection, intervention implementation and results dissemination, but is also important in creating and maintaining trusting and productive relationships with leaders and community members. Given the rural and widely dispersed geography of many tribal communities, travel costs to communities may be high, involving many miles of travel. Costs to rent a four-wheel-drive vehicle may be necessary, given the unpaved nature of many roads.
 - In Alaska, many communities are accessible only by plane or boat, and the average price of a plane ticket is typically much higher than between two large cities in the continental United States.
 - Lodging options also may be limited and above the estimated General Services Administration costs.
- ❖ **Requests to cover costs provided through indirect funding in other settings may be justifiable**, given limited or developing research infrastructure.
 - These costs may include fees for tribal review and approval through an IRB or other committee.
 - Funds to provide computers, printers, phone minutes, and cell phones may be essential for project success, depending upon the resources available in the community setting.
- ❖ **Other costs may be justifiable**, given cultural and community practices.
 - For community gatherings, it may be customary to provide food in establishing or recognizing relationships. Sharing of foods is vital in preserving and celebrating culture and is important in research to build trust and bring researchers into the community. Costs to provide food for focus groups and town halls to introduce projects, recruit participants, and share progress and results are considered to have a programmatic purpose and are not considered entertainment, as they are likely essential to ensuring the success of project activities involving group gatherings. Per NIH policy, these costs may be allowable and either must be in the approved budget or approved by the awarding Institute or Center.
 - Other costs might also be justifiable that would be unusual in other contexts, such as paying for minutes on phones if the study requires frequent contact or texting or paying for transportation to participate in the study.

- ❖ **Giving away gifts also may be customary at community gatherings** and may include door prizes, raffles, or small items given to attendees.
- ❖ **Monetary and other participant incentives may account for higher costs for travel and other potential logistical burdens to participants.** On the other hand, unduly high incentives may be coercive in resource-poor environments.
 - Tribal IRBs and other tribal review committees (where they exist) may closely examine incentives in the context of local customary practices, and decisions by outside entities could be inappropriate and run the risk of appearing paternalistic.
 - Reviewers could recommend review and approval by the tribe or tribal entities when unsure if amounts are appropriate.

Final Summary

This document seeks to aid NIH peer reviewers in appropriately and effectively assessing applications focused on AI/AN health research. Reviewers, along with researchers applying for NIH funding, AI/AN communities, and the NIH itself, share the goal of gaining and applying new knowledge to improve health. Unfortunately, progress toward achieving this goal has been uneven in its inclusion of AI/AN peoples. By gaining knowledge on the unique research context and the indicators of successful research common to AI/AN-focused projects, as supported by this document, reviewers can improve review of research that can help achieve health equity and ensure that collective scientific knowledge will expand.

There is no “one size fits all” approach and no prescriptive or exhaustive list of considerations. By definition, research seeks new knowledge, and the scientific landscape is constantly changing. As such and as science evolves and changes, attention should be paid to how advances impact the issues discussed in this document.

References

- Baldwin, J.A. (1998). "Conducting Drug Abuse Prevention Research in Partnership with Native American Communities: Meeting Challenges Through Collaborative Approaches," *Drugs & Society* 14(1–2): 77-92.
- Beals, J., Manson, S.M., Mitchell, C.M., Spicer, P., and the AI-SUPERPFP Team. (2003). "Cultural Specificity and Comparison in Psychiatric Epidemiology: Walking the Tightrope in American Indian Research," *Culture, Medicine and Psychiatry* 27: 259–289. doi: 10.1023/A:1025347130953.
- Blacksher, E., Nelson, C., Van Dyke, E., Echo-Hawk, A., Bassett, D., and Buchwald, D. (2016). "Conversations About Community-Based Participatory Research and Trust: 'We Are Explorers Together,'" *Progress in Community Health Partnerships: Research, Education, and Action* 10(2): 305-309.
- Buchwald, D.S., and Dick, R.W. (2011). "Weaving the Native Web: Using Social Network Analysis to Demonstrate the Value of a Minority Career Development Program," *Academic Medicine* 86(6): 778-786.
- Burhansstipanov, L., Bemis, L., Kaur, J.S., and Bemis, G. (2005). "Sample Genetic Policy Language for Research Conducted with Native Communities," *Journal of Cancer Education* 20(1 Suppl.): 52-7.
- Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). "Principles of Community Engagement: Second Edition," National Institutes of Health, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry, Clinical and Translational Science Awards. NIH Publication No. 11-7782, available at www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf.
- Davis, S.M., and Reid, R. (1999). "Practicing Participatory Research in American Indian Communities," *The American Journal of Clinical Nutrition* 69(4 Suppl): 755S–759S. doi: 10.1093/ajcn/69.4.755S.
- Denzin, N.K., and Giardina, M.D. (Eds.). (2016). *Ethical Futures in Qualitative Research: Decolonizing the Politics of Knowledge*. New York: Routledge.
- Diversity: A Nature and Scientific American Special Issue (2014), *Nature* (2014). 513(7518): 279-454.
- Etz, K.E., and Arroyo, J.A. (2015). "Small Sample Research: Considerations Beyond Statistical Power," *Prevention Science* 16(7): 1033-1036.
- Fixico, D.L. (2013). *Indian Resilience and Rebuilding: Indigenous Nations in the Modern American West*. Tucson: University of Arizona Press.
- Fohner, A.E., Robinson, R., Yracheta, J., Dillard, D.A., Schilling, B., Khan, B., and Tiwari, H.K. (2015). "Variation in Genes Controlling Warfarin Disposition and Response in American Indian and Alaska Native People: CYP2C9, VKORC1, CYP4F2, CYP4F11, GGCX," *Pharmacogenetics and Genomics* 25(7): 343.
- Fok, C. C. T., Henry, D., and Allen, J. (2015). "Maybe Small Is Too Small a Term: Introduction to Advancing Small Sample Prevention Science," *Prevention Science* 16(7): 943-949.

- Gilligan, C. (2015). "The Listening Guide Method of Psychological Inquiry," *Qualitative Psychology* 2: 69-77.
- Gone, J.P., and Calf Looking, P.E. (2011). "American Indian Culture as Substance Abuse Treatment: Pursuing Evidence for a Local Intervention," *Journal of Psychoactive Drugs* 43(4): 291–296. doi: 10.1080/02791072.2011.628915.
- Greenfield, B.L., and Venner, K.L. (2012). "Review of Substance Use Disorder Treatment Research in Indian Country: Future Directions to Strive Toward Health Equity," *The American Journal of Drug and Alcohol Abuse* 38(5), 483-492. doi: 10.3109/00952990.2012.702170.
- Guillory, R.M., and Wolverton, M. (2008). "It's About Family: Native American Student Persistence in Higher Education," *The Journal of Higher Education* 79(1), 58-87.
- Gurley, D., Novins, D.K., Jones, M.C., Beals, J., Shore, J.H., and Manson, S.M. (2001). "Comparative Use of Biomedical Services and Traditional Healing Options by American Indian Veterans," *Psychiatric Services* 52(1): 68-74.
- Harawa, N.T., Manson, S.M, Mangione, C.M., Penner, L.A., Norris, K.C., DeCarli, C., Scarinci, I.C., Zissimopoulos, J., Buchwald, D.S., Hinton, L., and Pérez-Stable, E. (2017). "Strategies for Enhancing Research in Aging Health Disparities by Mentoring Diverse Investigators," *Journal of Clinical and Translational Science* 1: 1-9.
- Harmon A. "Indian Tribe Wins Fight to Limit Research on Its DNA," *New York Times*, April 21, 2010.
- Henry, D., Dymnicki, A.B., Mohatt, N., et al. (2015). "Clustering Methods with Qualitative Data: A Mixed-Methods Approach for Prevention Research with Small Samples," *Prevention Science* 16(7): 1007-1016. doi: 10.1007/s11121-015-0561-z.
- Hiratsuka, V., Brown, J., and Dillard, D. (2012). "Views of Biobanking Research Among Alaska Native People: The Role of Community Context," *Progress in Community Health Partnerships: Research, Education, and Action* 6(2): 131-139. doi: 10.1353/cpr.2012.0025. PMID: 22820223.
- Hong, L., Page, S.E. (2004). "Groups of Diverse Problem Solvers Can Outperform Groups of High-Ability Problem Solvers," *Proceedings of the National Academy of Sciences of the United States of America* 101(46): 16385-9. doi: 10.1073/pnas.0403723101.
- James, R.D., West, K.M., Claw, K.G., Echo-Hawk, A., Dodge, L., Dominguez, A., Taulii, M., Forquera, R., Thummel, K., and Burke, W. (2018) "Responsible Research with Urban American Indians and Alaska Natives," *American Journal of Public Health* 108(12): 1613-1616.
- Jones, L., Jacklin, K., and O'Connell, M.E. (2017). "Development and Use of Health-Related Technologies in Indigenous Communities: Critical Review," *Journal of Medical Internet Research* 19(7): e256.
- Jones, M. D., and Galliher, R. V. (2007). "Ethnic Identity and Psychosocial Functioning in Navajo Adolescents," *Journal of Research on Adolescence* 17(4), 683-696.
- Kading, M.L., Hautala, D.S., Palombi, L.C., Aronson, B.D., Smith, R.C., and Walls, M.L. (2015). "Flourishing: American Indian Positive Mental Health," *Society and Mental Health* 5(3): 203-217. doi: 10.1177/2156869315570480.

- Kagawa-Singer, M., Dressler, W., George, S., and Elwood, W. (2014). "The Cultural Framework for Health: An Integrative Approach for Research and Program Design and Evaluation," Office of Behavioral and Social Sciences Research, National Institutes of Health, Bethesda, MD.
- Kahn, C.B., Reinschmidt, K.M., Teufel-Shone, N.I., Oré, C.E., Henson, M., and Attakai, A. (2016). "American Indian Elders' Resilience: Sources of Strength for Building a Healthy Future for Youth," *American Indian and Alaska Native Mental Health Research* 23(3): 117-133. doi: 10.5820/AI/AN.2303.2016.117.
- Kulis, S., Hodge, D.R., Ayers, S.L., Brown, E.F., and Marsiglia, F.F. (2012). "Spirituality and Religion: Intertwined Protective Factors for Substance Use Among Urban American Indian Youth," *The American Journal of Drug and Alcohol Abuse* 38(5), 444-449. doi: 10.3109/00952990.2012.670338.
- Manson, S.M. (1997). "Ethnographic Methods, Cultural Context, and Mental Illness: Bridging Different Ways of Knowing and Experience," *Ethos* 25(2), 249-258.
- Manson, S.M. (1989). "Barrow Alcohol Study: Emphasis on Its Ethical and Procedural Aspects [Special Issue]," *American Indian and Alaska Native Mental Health Research* 2(3), 5-6.
- Manson, S.M. (n.d.). *Bridging Different Ways of Knowing: Funding Traditional Practices for Navajo Combat Veterans*. [Video File]. Retrieved October 31, 2018, from www.youtube.com/watch?v=gu2XhLhmSsc.
- Manson, S.M., Goins, R.T., and Buchwald, D.S. (2006). "The Native Investigator Development Program: Increasing the Presence of American Indian and Alaska Native Scientists in Aging-Related Research," *Journal of Applied Gerontology* 25(1 Suppl.): 105S-130S.
- Marsiglia, F., Gallagher, J., Secakuku Baker, D., Booth, J. (2014). "Community Engagement and HIV Prevention with American Indian/Alaska Native Communities: Working with the Whole Person." In: Rhodes S. (ed.) *Innovations in HIV Prevention Research and Practice through Community Engagement*. New York: Springer, pp 105-134. doi: 10.1007/978-1-4939-0900-1_6.
- Martin, K.L., and Mirraabooa, B. (2003). "Ways of Knowing, Being and Doing: A Theoretical Framework and Methods for Indigenous and Indigenist Research," *Journal of Australian Studies* 27(76): 203-214.
- Minkler, M., and Wallerstein, N. (Eds.) (2003). *Community-Based Participatory Research for Health*. San Francisco: Jossey-Bass.
- Mohatt, N.V., Fok, C.C.T., Burket, R., Henry, D., and Allen, J. (2011). "Assessment of Awareness of Connectedness as a Culturally-Based Protective Factor for Alaska Native Youth," *Cultural Diversity and Ethnic Minority Psychology* 17(4): 444.
- Mohatt, G.V., Rasmus, S.M., Thomas, L., Allen, J., Hazel, K., and Hensel, C. (2004). "Tied Together Like a Woven Hat: Protective Pathways to Alaska Native Sobriety," *Harm Reduction Journal* 1(1), 10.
- Mohatt, G. V, Hazel, K. L., Allen, J., Stachelrodt, M., Hensel, C., and Fath, R. (2004). Unheard Alaska: Culturally Anchored Participatory Action Research on Sobriety with Alaska Natives. *American Journal of Community Psychology*. 33(3-4), 263-273.
- National Institutes of Health, "Definitions of Criteria and Considerations for Research Project Grant (RPG/R01/R03/R15/R21/R34) Critiques," available at

<https://grants.nih.gov/grants/peer/critiques/rpg.htm>. “Novalene Goklish,” (n.d.). Center for American Indian Health. Accessed on February 4, 2018, caih.jhu.edu/about/our-people/novalene-goklish.

Novins, D.K., Beals, J., Moore, L., Spicer, P., Manson, S.M., et al. (2004). “Use of Biomedical Services and Traditional Healing Options Among American Indians: Sociodemographic Correlates, Spirituality, and Ethnic Identity,” *Medical Care* 42: 670-679.

Okamoto, S.K., Kulis, S., Marsiglia, F.F., Steiker, L.K.H., and Dustman, P. (2014). “A Continuum of Approaches Toward Developing Culturally Focused Prevention Interventions: From Adaptation to Grounding,” *The Journal of Primary Prevention* 35(2): 103-112.

Pololi, L., Cooper, L. A., and Carr, P. (2010). “Race, Disadvantage and Faculty Experiences in Academic Medicine,” *Journal of General Internal Medicine* 25(12): 1363-1369.

Rasmus, S., Allen, J., Connor, W., Freeman, W., Board, N. T. C. A., and Skewes, M. (2016). “Native Transformations in the Pacific Northwest: A Strength-Based Model of Protection Against Substance Use Disorder,” *American Indian and Alaska Native Mental Health Research*, 23(3): 158.

Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, 62 *Federal Register* 58782 (October 30, 1997) (Notice of decision), available at www.federalregister.gov/documents/1997/10/30/97-28653/revisions-to-the-standards-for-the-classification-of-federal-data-on-race-and-ethnicity

Siebens, J., and Julian, T. (2011). “Native North American Languages Spoken at Home in the United States and Puerto Rico: 2006–2010,” *American Community Services Briefs* 10(10).

Sterling, R.L. (2011). “Genetic Research Among the Havasupai: A Cautionary Tale,” *Virtual Mentor* 13(2): 113.

Thierry, J., Brenneman, G., Rhoades, E., and Clifton, L. (2009). “History, Law, and Policy as a Foundation for Health Care Delivery for American Indian and Alaska Native Children,” *Pediatric Clinics of North America* 56(6): 1539–1559.

Tippeconic, J.W., and McKinney, S. (2003). “Native Faculty: Scholarship and Development.” In Maenette, K.P., Benham, A., and Stein, W. J. (Eds.), *The Renaissance of American Indian Higher Education: Capturing the Dream*. New York: Routledge, Taylor, and Francis Group, pp 241-256. Retrieved from books.google.com.

Tuhiwai Smith, L. (1999) *Decolonizing Methodologies: Research and Indigenous Peoples*. New York: Zed Books Ltd.

“United Nations Declaration on the Rights of Indigenous Peoples,” (n.d.). Indian Law Resource Center, available at indianlaw.org/sites/default/files/Declarations_Booklet_2012_LRSpreads.pdf.

Vizenor, E. (1999). *Manifest Manners: Narratives on Postindian Survivance*. Lincoln: University of Nebraska Press, p. vii.

Wallerstein, N., Duran, B., Oetzel, J., and Minkler, M. (eds., Third Edition) (2018). *Community-Based Participatory Research for Health: Advancing Social and Health Equity*. San Francisco: Jossey-Bass.

Wallerstein, N.B., and Duran, B. (2006). “Using Community-Based Participatory Research to Address Health Disparities,” *Health Promotion Practice* 7(3): 312-323.

Walls, M., Whitbeck, L., and Armenta, B. (2016). “A Cautionary Tale: Examining the Interplay of Culturally Specific Risk and Resilience Factors in Indigenous Communities,” *Clinical Psychological Science* 4(4): 732-743. doi: 10.1177/2167702616645795.

Walls, M., and Whitbeck, L. (2011). “Distress Among Indigenous North Americans: Generalized and Culturally Relevant Stressors,” *Society and Mental Health* 1: 124-136.

Walls, M., Rumbaugh Whitesell, N., Barlow, A., and Sarche, M. (2017). “Research With American Indian and Alaska Native Communities: Measurement Matters,” *Journal of Ethnicity in Substance Abuse* 1-21. doi: 10.1080/15332640.2017.1310640.

Walters, K.L., and Simoni, J.M. (2002). “Reconceptualizing Native Women’s Health: An ‘Indigenist’ Stress-Coping Model,” *American Journal of Public Health* 92(4): 520-524.

Warne, D., and Frizzell, L. B. (2014). “American Indian Health Policy: Historical Trends and Contemporary Issues,” *American Journal of Public Health* 104(S3): S263-S267.

Whitbeck, L., Adams, G., Hoyt, D., and Chen, X. (2004). “Conceptualizing and Measuring Historical Trauma Among American Indian People,” *American Journal of Community Psychology* 33: 119–130.

Whitbeck, L., Chen, X., Hoyt, D., and Adams, G. (2004). “Discrimination, Historical Loss, and Enculturation: Culturally Specific Risk and Resiliency Factors for Alcohol Abuse Among American Indians,” *Journal of Alcohol Studies* 65: 409-418.

Wilson, S. (2001). “What Is an Indigenous Research Methodology?” *Canadian Journal of Native Education* 25(2), 175-179.

Wolsko, C., Lardon, C., Mohatt, G.V., and Orr, E. (2007). “Stress, Coping, and Well-Being Among the Yupik of the Yukon-Kuskokwim Delta: The Role of Enculturation and Acculturation,” *International Journal of Circumpolar Health* 66(1): 51-61.

Additional Resources (not cited in text):

Reports or Guidelines

Sahota, P.C. (n.d.). “Research Regulation in American Indian/Alaska Native Communities: A Guide to Reviewing Research Studies,” National Congress of American Indians.

“Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS),” (2012). Australian Institute of Aboriginal and Torres Strait Islander Studies, available at aiatsis.gov.au/research/ethical-research/guidelines-ethical-research-australian-indigenous-studies.

“Indigenous Research Protections Act,” (n.d.). Indigenous Peoples Council on Biocolonialism, available at www.ipcb.org/publications/policy/files/irpa.html.

“The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” (1979). The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education, and Welfare, available at www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

“Guidelines for Health Research Involving Aboriginal People (2007-2010),” CIHR, available at www.cihr-irsc.gc.ca/e/29134.html.

International Ethical Guidelines for Health-related Research Involving Humans, 4th Edition. (2016). Council for International Organizations of Medical Sciences and World Health Organization. Geneva, available at cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf.

“Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada,” (2014). In: *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, CIHR, available at www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#toc09-1.

“Walk Softly and Listen Carefully: Building Research Relationships with Tribal Communities,” (2012). NCAI Policy Research Center and MSU Center for Native Health Partnerships.

“United Nations Declaration on the Rights of Indigenous Peoples,” (2008). United Nations, available at www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf.

Journal Articles

Chadwick, J.Q., Copeland, K.C., Daniel, M.R., et al. (2015). “Partnering in Research: A National Research Trial Exemplifying Effective Collaboration with American Indian Nations and the Indian Health Service,” *American Journal of Epidemiology* 180(12): 1202-1207.

Chino, M., and DeBruyn, L. (2006). “Building True Capacity: Indigenous Models for Indigenous Communities,” *American Journal of Public Health* 96(4): 596-599.

Echo-Hawk, H. (2011). “Indigenous Communities and Evidence Building,” *Journal of Psychoactive Drugs* 43(4): 269-275.

Harding, A., Harper, B., Stone, D., O’Neill, C., Berger, P., Harris, S., and Donatuto, J. (2012). “Conducting Research With Tribal Communities: Sovereignty, Ethics, and Data-Sharing Issues,” *Environmental Health Perspectives* 120(1): 6-10.

Hiratsuka, V.Y., Beans, J.A., Robinson, R.F., Shaw, J.L., Sylvester, I., and Dillard, D. (2017). “Self-Determination in Health Research: An Alaska Native Example of Tribal Ownership and Research Regulation,” *International Journal of Environmental Research and Public Health* 14(11): 1324.

Hull, S.C., and Wilson, D.R. (2017). “Beyond Belmont: Ensuring Respect for AI/AN Communities Through Tribal IRBs, Laws, and Policies,” *The American Journal of Bioethics* 17(7): 60-62.

Kelley, A., Belcourt-Ditloff, A., Belcourt, C., and Belcourt, G. (2013). “Research Ethics and Indigenous Communities,” *American Journal of Public Health* 103(12): 2146-2152.

Mohammed, S.A., Walters, K.L., LaMarr, J., Evans-Campbell, T., and Fryberg, S. (2011). “Finding Middle Ground: Negotiating University and Tribal Community Interests in Community-Based Participatory Research,” *Nursing Inquiry* 19(2): 116-127.

Mohatt, G.V., Hazel, K.L., Allen, J., et al. (2004). “Unheard Alaska: Culturally Anchored Participatory Action Research on Sobriety with Alaska Natives,” *American Journal of Community Psychology* 33: 263. doi: 10.1023/B:AJCP.0000027011.12346.70.

Schnarch, B. (2004). “Ownership, Control, Access, and Possession (OCAP) or Self-Determination Applied to Research: A Critical Analysis of Contemporary First Nations Research and Some Options for First Nations Communities,” *Journal of Aboriginal Health* 1(1): 80-95.

Sharp, R.R., and Foster, M.W. (2002). “An Analysis of Research Guidelines on the Collection and Use of Human Biological Materials from American Indian and Alaska Native Communities,” *Jurimetrics* 42(2): 165-186.

Sharp, R.R., and Foster, M.W. (2002). “Community Involvement in the Ethical Review of Genetic Research: Lessons from American Indian and Alaska Native Populations,” *Environmental Health Perspectives* 110 (suppl 2): 145-148.

Federal Regulations

Indian Entities Recognized and Eligible To Receive Services from the United States Bureau of Indian Affairs, 83 *Federal Register* 34863 (July 23, 2018) (Notice), available at www.federalregister.gov/documents/2018/07/23/2018-15679/indian-entities-recognized-and-eligible-to-receive-services-from-the-united-states-bureau-of-indian.

“Federal Regulations for Protection of Human Research Subjects (45 CFR 46).” (2018). U.S. Department of Health and Human Services, available at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Federal Policy for the Protection of Human Subjects, 82 *Federal Register* 7149 (January 19, 2017) (Final Rule), available at www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects.

Steneck, N.H., and Zinn, D. (2007). “Introduction to the Responsible Conduct of Research,” Office of Research Integrity, U.S. Department of Health and Human Services, available at ori.hhs.gov/ori-introduction-responsible-conduct-research.

Appendix A

National Institutes of Health Specially Appointed Committee to Review AI/AN Research in the Health Sciences: Critical Considerations for the Review of Research Applications

Chair:

Spero Manson, Ph.D.

University of Colorado Denver

Committee:

Jim Allen, Ph.D.*

University of Minnesota, Duluth

Alison Ball, Ph.D.

Colville Confederated Tribes Health and Human Services

Allison Barlow, Ph.D., M.P.H.

Johns Hopkins University

Annjeanette Belcourt-Dittloff, Ph.D.

University of Montana

Ronny Bell, Ph.D., M.S.

East Carolina University

Francys Crevier, J.D.

National Council of Urban Indian Health

Abigail Echo-Hawk, M.A.

Urban Indian Health Institute

Kevin English, Dr.P.H., M.P.H.

Albuquerque Area, Southwest Tribal Epidemiology Center

Robert Foley, M.Ed.

National Indian Health Board

Kimberly Fowler, Ph.D.

National Council of Urban Indian Health

Lonnie Nelson, Ph.D.

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Stacy Rasmus, Ph.D.*

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Donald Warne, M.D., M.P.H.

North Dakota State University

Nancy Rumbaugh Whitesell, Ph.D.

University of Colorado, Denver

*Did not attend in person.

