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Beyond the Belmont Principles: A Community-Based Approach to Developing an Indigenous Ethics Model and Curriculum for Training Health Researchers Working with American Indian and Alaska Native Communities

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Abstract

Individuals responsible for carrying out research within their diverse communities experience a critical need for research ethics training materials that align with community values. To improve the capacity to meet local human subject protections, we created the research Ethics Training for Health in Indigenous Communities (rETHICS), a training curriculum aligned within American Indian and Alaska Native (AI/AN) context, culture, and community-level ethical values and principles. Beginning with the Belmont Report and the Common Rule that defines research with human subjects (46 CFR 45), the authors convened three different expert panels ($N = 37$) to identify Indigenous research values and principles common across tribal communities. The resulting culturally grounded curriculum was then tested with 48 AI/AN individuals, 39 who also had recorded debriefing interviews. Using a thematic analysis, we coded the qualitative feedback from the expert panel discussions and the participant debriefings to assess content validity. Participants identified five foundational constructs needed to ensure cultural-grounding of the AI/AN-specific research training curriculum. These included ensuring that the module was: (a) framed within an AI/AN historical context; (b) reflected Indigenous moral values; (c) specifically linked AI/AN cultural considerations to ethical procedures; (d) contributed to a growing Indigenous ethics; and (e) provided Indigenous-based ethics tools for decision making. Using community-based consultation and feedback from participants led to a culturally grounded training curriculum that teaches research ethical principles and procedures for conducting research with AI/ANs. The curriculum is available for free and the community-based process used can be adapted for other cultural groups.

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Keywords

Community-based participatory research; American Indians; Alaska Natives; Ethics; Training curriculum; Indigenous communities

Introduction

Community-based participatory research (CBPR) is recognized as an essential means of supporting empirically based programs designed to improve community health through the elimination of health disparities rooted in racial and ethnic inequities (Wallerstein & Duran, 2010). The CBPR approach, which recognizes the community as a critical unit of identity (Israel, Schulz, Parker, & Becker, 2001), is also consistent with most American Indian and Alaska Native (AI/AN) values (Pearson, Parker, Fisher, & Moreno, 2014), and their standards of ethical principles.

Although CBPR has increasingly been applied as a research method involving diverse populations, its application to community-level research ethics concerning human subjects has garnered less attention (Pearson et al., 2014; Shore et al., 2011). Traditionally, the ethical protection of human subjects in the United States has been guided by the principles identified in the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). However, these principles are based on Western epistemologies (Ruiz-Casares, 2014), which are rooted in Western values and individualism, and thus ignore Indigenous values and privilege the individual over more holistic, community/group perspectives. These gaps in the Belmont principles, therefore, result in the failure to consider community-level risks, and constrains the interpretability and direct relevance to ethical implementation of health research in racially, ethnically, and culturally diverse communities (Bromley, Mikesell, Jones, & Khodyakov, 2015; DiStefano et al., 2013; Hebert et al., 2015).

The problems with Western ethical approaches have been particularly evident in Indigenous settings, where tribes retain sovereign rights to govern research that involves their members (Harding et al., 2012). AI/AN values include the same principles of respect, justice, and beneficence/non-maleficence; however, unlike most Eurocentric individualistic approaches, Indigenous communities extend these principles to the rights and welfare of communities. Many researchers now apply non-Western thinking to their research methods, but not necessarily to their research ethics.

Ethics in AI/AN Research

Many tribes have laws regulating research on their lands and have established Institutional Review Boards and tribal Research Review Boards to ensure community review of research. Additionally, several tribes have developed cultural training for non-tribally based researchers to orient them to tribal cultural values and principles (Morton et al., 2013; Schrag, 2006). Despite these additional research review processes, AI/AN communities and individuals continue to experience research harms since ethical treatment has not received

the same attention as research methods (Callaway, 2014; Hodge, 2012; Mello & Wolf, 2010).

Arizona State University's (ASU) 2010 settlement with a tribe located in the Southwestern United States represents one of the most recent examples in which researchers failed to ensure adequate informed consent processes to both the tribe and the individual research participants (Drabiak-Syed, 2010). Initial tribal agreements were assumed to be limited to investigation directly related to diabetes, yet ASU researchers used the blood samples for further studies on mental disorders, consanguinity, and human origins research, taking the agreement as a broad consent to any and all medical research. The ASU principal investigator later labeled the tribe's claims as "hysterical" and indicated that she believed she was doing good science (Bommersbach, 2008).

This distressing episode exemplifies the negative consequences resulting from the misalignment between tribal and Western perspectives on ethical matters rather than just the research methods. The occurrence of research harm despite the promulgation of Federal ethics regulations to protect human subjects has made conducting research with both cultural fit and community relevance challenging for both internally and externally based researchers working with tribal communities. The misalignment between tribal and Western research principles contributes to the challenge of planning and implementing effective culturally centered research within AI/AN communities (Pacheco et al., 2013).

Moreover, restricting human subject training to a Eurocentric individual-level application of the Belmont principles can result in culturally insensitive research, as the ASU example shows. In failing to explicitly incorporate community-level protections derived from AI/AN cultural values, it exposes AI/AN communities to research harms and exploitation (Drabiak-Syed, 2010). Building ethics training using CBPR principles would likely strengthen application of human subject protections through its integration of Indigenous ethical values and principles into research procedures in ways that ensure that investigations reflect the values and merit the trust of AI/AN communities.

AI/AN communities differ in important ways in the values, contexts, and practices that serve as the foundation of culture and delivery of care. For example, substance use assessments may lack specificity without integration of cultural components (Walls, Whitesell, Barlow, & Sarche, 2017). Moreover, context matters; AI/ANs in urban communities may require particular considerations when including these communities in health research (Yuan, Bartgis, & Demers, 2014). Identifying these aspects of service delivery and provision of mental health care could provide key insights into improved uptake, retention, engagement, and fit that serve to improve health and behavioral health outcomes (Whitbeck, Kim, & Lorion, 2006; Whitesell, Sarche, Keane, Mousseau, & Kaufman, 2018), and using a CBPR approach constitutes a key study framework to support adherence to Indigenous ethics values and principles (Parker, 2018; Thomas, Donovan, Little Wing Sigo, & Price, 2011). The implications of this study support the need for further inquiry in the area of Indigenous ethics, particularly as applied to delivery of behavioral health care and social services.

AI/AN community members themselves have become increasingly engaged and involved in research (James et al., 2018), and they are required to obtain human subject research training certification. However, there are problems with the current training. The widely used online training curricula (The CITI Program, 2017) lack AI/AN content, relevant case studies, specific issues related to Federal Indian Law and tribal law, and examples to stimulate an understanding in applying the Belmont principles and Common Rule (45 CFR part 46) guidelines to Indigenous communities. Written for an academic audience, the reading level is also inappropriate for many community-level researchers who would be expected to review and implement research (Jetter, Yarborough, Cassady, & Styne, 2015; Pearson et al., 2014).

In an effort to improve these ethical trainings, we first developed one module—the protection of risk and benefits and tested it in a two-arm randomized comparison study (Pearson, Parker, Fisher, & Moreno, 2014). In this initial study, 50 participants were randomized to take either the Collaborative IRB Training Initiative (CITI) Risk and Protection module or our research Ethics Training for Health in Indigenous Communities (rETHICS) Risk and Protection module. Participants who received the rETHICS module as compared to those who received the CITI module reported higher scores on relevance of the material, higher overall satisfaction, higher mean quiz scores, and a trend toward higher research self-efficacy. CITI requires a passing score of 80%; thus, we used the same criteria in our study (Collaborative Institutional Training Initiative, 2013). We calculated quiz scores based on first attempt and found that 65% of participants in the rETHICS group passed as compared to 35% in the control group, which took the same test as the rETHICS group.

Once participants finished taking the module, we conducted 30- to 45-minute debriefing interviews with 30 of the participants. Participants reported that they were interested in sharing the rETHICS curriculum with their tribe because the examples described potential risks and benefits of research that resonated with their lived experience and stressed the utility of the material in health care and social service settings outside of the research arena. One participant said, “I’m ready to jump into research…I’m really glad I did this.” (Pearson et al., 2014) Another participant suggested the training would be good for academic researchers: “For non-Indians coming into a reservation, I thought it would be good for them to do this training. People coming out don’t know about the sensitivity of elders and the damage they could be doing. Researchers are wanting to do something good, but could cause harm unintentionally.” (Pearson et al., 2014)

From this, initial study, came calls to develop a full human subject training curriculum for conducting research with AI/AN communities. This paper reports on the CBPR process used in developing the full curriculum through identifying and integrating Indigenous ethics values and principles into a research ethics training. The process involved an iterative approach across three diverse and inclusive expert panel member discussions, followed by debriefing interviews from individual participants of the module.

The goal of this research is, therefore, to use CBPR principles applied to the development of a AI/AN population-appropriate human subject training curriculum to help encapsulate Indigenous perspectives that will (a) recognize the autonomy and rights of communities to

engage in, govern, and consent to research; (b) derive benefits from research; and (c) ensure equal access to those benefits tailored to community needs (Baldwin, Johnson, & Benally, 2009; Sharp & Foster, 2002).

Method

Developing the rETHICS Curriculum

The principal investigator, in collaboration with the first author, developed a nationally representative list of AI/AN researchers, including AI/AN community researchers, AI/AN academic researchers, and AI/AN research ethics experts. The principal investigator has worked with AI/AN communities for over 10 years as an allied researcher. A co-investigator is an enrolled tribal member and has over fifteen years of AI/AN research experience in varied roles. The research coordinator is AI/AN and had at least 3 years of AI/AN research experience. The last author is an allied researcher with over 30 years of research ethics experience, including some AI/AN research ethics content expertise. Using their research contacts and a CBPR approach, along with referrals from AI/AN researchers and AI/AN community researchers, the team developed a representative panel of experts to aid in developing the culturally grounded ethics curriculum.

Three expert panels were formed to guide the development of the rETHICS training curriculum. Panel members were recruited to reflect the diversity of communities (rural and urban), diverse scientific expertise, and a variety of research backgrounds across the United States. One group consisted of 12 nationally selected AI/AN community members who had partnered in research with their own or other AI/AN communities (AI/AN Community Expert Panel). These experts provided the basis for identifying Indigenous-specific research ethics values and principles of rETHICS, meeting for 2 days early in the curriculum development process. The discussion covered AI/AN research contexts, and identifying Indigenous research ethics principles and concepts. In preparation for the AI/AN Community Expert Panel meeting, the authors developed a first draft of the curriculum by mapping the requirements delineated in the Federal Policy for the Protection of Human Subjects (1991) (the “Common Rule”) as well as the major ethical principles of research included in the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The authors, the principal investigator, co-investigators, and the research coordinator, removed jargon and adapted the reading level from an average grade level of 20 to a grade level of 10 using the Flesch–Kincaid grade-level assessment available in Microsoft Word, which was applied to each paragraph until the assessment reached the 10th-grade reading level. A tenth-grade level maintained the integrity of content while providing the necessary terminology to converse with IRBs. After the meeting, panelists provided feedback on the first round of curriculum revisions, confirming Indigenous ethics concepts and principles via three webinars.

The second group was composed of 15 AI/AN and ally researchers who had conducted research with AI/AN communities for more than 10 years (Scientific/Academic Expert Panel). The third group convened 10 AI/AN IRB administrators, policy, and ethics leaders (IRB/Policy Expert Panel). The Scientific/Academic Expert Panel and the IRB/Policy Expert Panel members provided insights and feedback on the draft curriculum prepared by the

authors. Their contribution included providing case studies, and examples that showed the unique AI/AN perspectives for informed consent, risk and benefits, respect for persons and beneficence, and recommendations as to how the CFR can be applied in AI/AN communities.

Community Setting

Although 78% of AI/AN live in urban areas, tribal land-based communities are generally in rural areas and have unique sovereign rights. Therefore, to obtain a representative sample of expert panel members, we identified the top ten states with the largest AI/AN populations: Alaska, Arizona, Montana, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Washington, and Wyoming (U.S. Census Bureau, 2010). We then identified the top nine urban Indian populations (American Community Survey, 2012): Chicago, Denver, Houston, Minneapolis, Oklahoma City, New York City, Phoenix, Tucson, and Rapid City. We identified one to three experts from each region using our extensive national network and referrals from colleagues and community partners. When experts fit within more than one criteria, for example, if they lived and conducted research within their tribal or urban community (the criteria for participation in the community panel), were affiliated with a research institute for over 15 years (the criteria for the researcher panel), or served on an IRB (criteria for the IRB/Policy Expert panel), the expert selected the panel they felt was most appropriate for their expertise. In addition, within some regions, such as New York City and the Northeast, appropriate representatives were difficult to identify, and therefore, we selected panelists who were from tribes in the Northeast and who also worked extensively in other tribal communities.

AI/AN Community Expert Panel—The AI/AN Community Expert panelists ($N = 12$) were paid to attend a 2-day meeting in Seattle, WA, through a research grant to the principal investigator funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Human Genome Research Institute. Panelists represented the 10 aforementioned geographic and culturally distinct areas, including both rural and urban settings. In structured group discussions, audio recorded and captured through detailed notes by three masters in social work students, expert panel members reviewed the draft curriculum, identifying how the application of federal regulations may or may not meet the research ethics needs of tribal communities. At the first review of the standard CITI training curriculum, panel members unanimously agreed that we should not be adapting the CITI—thus “interpreting someone else’s interpretation of the Belmont Report and the Code of Federal Regulations (CFR)” but we should create a curriculum directly from the source. Panel members also specified their role was to identify tribal ethics perspectives, practices, and standards that address gaps in federal regulations for AI/AN research settings. The meeting provided a critical starting point to develop an ethics training curriculum for research in Indian Country. The community expert panel discussed each component of the draft modules in depth, the CFR, and identified content that held relevance for AI/AN communities, identifying content that should be highlighted or expanded. Fundamental changes brought forth by the panel members included: (a) establishing the framework from a strength-based empowerment approach; (b) grounding in the importance and relevance of research in AI/AN communities; (c) consensus on appropriate examples,

universal terms, appropriate language, and relevant images; and (d) adjustments to the overall appeal (i.e., font and spacing). All panelists continued to provide iterative, detailed review and oversight throughout the curriculum development process.

Scientific/Academic Expert Panel—We also convened the scientific/academic panel members via three, 2-hour webinars ($N = 15$) with 80% attending all three webinars. Similar to the community panel, the academic panel covered the same 10 geographical–cultural areas and rural and urban settings as the community panel. All panel participants provided active, informed contributions, resulting in expanded understanding and knowledge of ethical research concerns across Indian Country. Those who could not make all three meetings sent in detailed edits and comments to incorporate into the curriculum.

In general, this panel agreed with the consensus of the prior community panel, emphasizing the need to teach researchers (Indigenous and non-Indigenous) how to develop community sensitive review and consent procedures and to include Indigenous community members and scholars throughout the research process. Like the community panel, this panel identified research related to ethical concerns common across geographical areas.

IRB/Policy Expert Panel—We concluded the curriculum review by convening three IRB and policy/ethicist panel webinars, which lasted between 60 and 120 minutes each. Ethics and IRB expert panel members ($N = 10$) participated in reviewing the new culturally grounded AI/AN curriculum and the first draft of the new quiz questions. The expert panelist contributions also ensured the curriculum successfully translated federal regulations for AI/AN communities by: (a) incorporating key concepts of Indigenous values and worldviews in the conduct of ethical research across Indian country; (b) identifying harms from research at the AI/AN community and individual level that have occurred; (c) highlighting the benefits of research and shared skills and strategies to conduct research in a "good way"; (d) presenting ethical research terms and regulations in layperson language; (e) incorporating examples of how research regulations and principles apply to AI/AN individuals as well as communities, highlighting unique considerations for AI/AN communities (i.e., *tribal sovereignty*); and (f) ensuring language, formatting, and case examples provide understandable and relevant content for participants.

Expert Panel Validation—After finalizing the new culturally grounded curriculum based on IRB and policy panel feedback, we requested a final review of the curriculum from all three groups of panel members and a CITI peer review expert. The principal investigator incorporated final edits, and the study was approved by the University of Washington IRB on October 26, 2016.

Summary of Changes Recommended by the Panels

Our focus in this paper is on the Indigenous-specific research values and ethics that emerged from analysis of the complete transcript from the original meeting with the AI/AN Community Expert Panel and detailed notes from the 39 phone debriefing sessions with testing participants. Data from the other expert panels were not included, as the Indigenous ethics principles arose from the AI/AN Community Expert Panel, and were merely

confirmed or refined by the Scientific/Academic and IRB/Policy Expert Panels. The AI/AN Community Expert panelists also provided specific comments about each major section of the Common Rule, but these portions were excluded from the present analysis, as they focused on technical aspects of conveying the existing ethics framework, as opposed to tribal-specific content.

Analysis Approach—We used a combination of grounded theory and content analysis to code the three expert panels' transcripts for major themes and subthemes. The AI/AN Community Expert Panel identified several issues related to AI/AN research contexts that concerned requirements established under the Common Rule. These issues included confidentiality, informed consent, privacy, risks and benefits of research, study design, and types of ethical review related to unique aspects of AI/AN communities and research. These issues are not explored in this paper. Importantly, the panel articulated several Indigenous research-specific principles and concepts, which this analysis explores in detail. To identify the major and subthemes, the transcripts from the 2-day meeting were reviewed through an iterative review process, taking care to examine the context of the panelist statements in the overall discussion to ensure definitions and meaning of the statements were accurately reflected in the analysis. An initial coding framework was developed and applied from the first three rounds of transcript review by the first author. This framework encapsulated overall Indigenous ethics principles or concepts, which could include one or several sentences depending on the complexity of the principle. Double coding was used, as some principles and concepts overlapped, but care was taken to ensure principles were unique and that if double coding was necessary, the concepts or principles clearly mapped onto multiple themes. Three additional rounds of review and framework revision were implemented by the first author, to ensure themes and subthemes were clearly defined and represented in the data. The second and third author then reviewed the coding framework and initial coding structure and confirmed and refined the approach and some minor coding adjustments were incorporated. Upon confirmation of the framework, qualitative analysis of the 39 phone debriefing notes was completed. The notes were brief and focused on several aspects of the curriculum in addition to content. Comments specific to the content were coded using the iterative process previously described. Upon completion of coding, agreement between the initial AI/AN Community Expert Panel transcript and the 39 phone debriefings was noted. Level of agreement was not possible, given the nature of the phone debriefing, which focused on many aspects of the curriculum implementation, testing, and online access. To achieve a quantitative assessment of agreement, in-depth interviews covering the Indigenous principles and concepts would be necessary. However, the agreement establishes that the curriculum accurately represented the Indigenous principles and concepts discussed and defined by the AI/AN Community Expert Panel.

The development of the curriculum took place in three stages. First, the AI/AN Community Expert Panel met for 2 days, as previously noted, to review the human subject training content developed by the research team. These experts included researchers, program managers, tribal college representatives, and tribal research institute directors from across the United States. Originally, the expert panels were given the task of refining the prepared content, with the charge to make it accessible for lay community researchers and assistants.

However, as the AI/AN Community Expert Panel met, it became clear that the existing Common Rule framework required a cultural translation to ensure a comprehensive cultural fit for AI/AN settings. We took detailed notes and recorded the meeting to establish the contextual and cultural factors that were recommended to be included in the final curriculum. Two additional review series were completed using an online meeting application, with the Scientific/Academic Expert Panel and the IRB/Policy Expert Panel. These sessions were recorded, but the focus of the discussion in these sessions shifted to confirming that we had accurately integrated the recommendations by the AI/AN Community Expert Panel and that we did not omit other tribal cultural values or research principles (by the Scientific/Academic Expert Panel) and that the content we developed aligned with the Common Rule and tribal research values and principles (by the IRB/Policy Expert Panel).

Testing—As part of their role, panel members were asked to recruit 3–5 individuals each from their communities across ten regions to test the training module. Testing occurred over 2 months, with a total of 49 participants. Verbal consent was obtained by telephone, upon determining participants met inclusion criteria, including being AI/AN, having access to the Internet and a computer, and meeting geographic quotas (i.e., living on/off reservation and living within AI/AN regions of the United States) to ensure a representative sample. An online consent was confirmed upon login to the online training, which most participants completed from their residence or other private location. All participants were AI/AN; 63% of participants were from urban areas; 73.5% were female; and the average age was 38.2 years (SD = 13.8). From these participants, 39 participants completed phone debriefing, conducted by the research coordinator, which lasted about 30–45 minutes. The debriefing questions included topics such as the accessibility of the online format, the language and clarity of content, and the understandability of the quiz questions, as well as an opportunity to provide open-ended comments on the curriculum.

Results

Overview

Overall, panelists called for a reorientation to research, intended to remind participants in the training that Indigenous people have always been researchers, and that tribal ancestors observed, asked questions, experimented, tested, and engineered and shared new solutions that resolved issues in everyday life to benefit the entire community. Panelists emphasized the critical need to recognize AI/AN communities' contributions to research and science through the accumulation of vast amounts of knowledge about the natural world, and that these practices continue today, to improve life in their respective communities. Panelists emphasized the need to briefly orient participants in the training to tribal sovereignty and the important implications for research.

"Meeting communities where they are" embraced a critical, foundational aspect of the methodology recommended by the AI/AN Community Expert Panel. The research team assumed the responsibility of planning, developing, and supporting the ongoing dialogue necessary to ensure true community participation and engagement. Seeking knowledge and

input in a responsive, authentic manner supported expert panelists in important ways to ensure a comprehensive, even-handed review of ethics principles and curriculum content.

The meeting resulted in several important outcomes, including the need to: (a) create an introduction that ties in AI/AN scientific contributions and AI/AN-specific research; (b) highlight the benefits of research in addition to risk; and (c) construct a curriculum that teaches the trainee how to conduct ethical decision making, balance risks and benefits, reduce risk based on respecting culture, place, time, and the federal regulations. Moreover, these elements should also incorporate the understanding that, for AI/ANs, they do not represent a vulnerable group according to the Common Rule, rather, contextual issues for any group or individual may result in vulnerabilities.

Tailoring Research Ethics Training to Community Needs: Major Constructs

Participants identified five foundational constructs needed to ensure cultural-grounding of the AI/AN-specific research training curriculum. These included ensuring that the module was (a) framed within an AI/AN historical context; (b) reflected Indigenous moral values; (c) specifically linked AI/AN cultural considerations to ethical procedures; (d) contributed to growing Indigenous ethics; and (e) provided Indigenous-based ethics tools for decision making. These constructs include subthemes specific for operationalizing Indigenous ethical principles and values for the AI/AN-specific research training curriculum. Most constructs were also articulated and confirmed by testing participants. The following is a summary of each construct, along with examples.

Construct: Human Subject Protection in Historical Context—AI/AN communities have experienced research harm, as well as harm from unethical medical practices. These historical harms act to reduce AI/AN trust in research. Testing participants and expert panelists agreed that naming the historical harms due to research demonstrates the relevance of ethics principles, particularly in considering research with vulnerable groups such as AI/AN children. For example, one panelist described that:

> Language has been used to restrain and control tribal people. The word “ethics” is not a healthy word for Native people because they have suffered due to the control of religious “ethics.” We don’t need to dumb it down for our people. It’s just got to [include AI/AN norms and contexts] but with the same [human subjects] information
>
> (AI/AN community expert).

Similarly, participants in the debriefings interviews agreed that mistrust is a concern in research with AI/AN communities. As articulated by one participant:

> The curriculum did a good job of conveying the mistrust and why it exists between AI/AN people and those involved with research. This is something that surfaces a lot in our community
>
> (Phone debriefing interview)

Additionally, several participants noted that the coverage of the history of harms made the curriculum more personal and therefore more relevant for their work in AI/AN communities. As discussed by one participant:

> When mentioning the stigmatization of our communities, that was personal for me. What the Nazis did, that was based on how the [AI/ANs] were treated in our country, how people tried to wipe us out. That was all personal for me
>
> (Phone debriefing interview).

Expert panelists noted that it is possible to re-victimize AI/AN participants through unnecessarily portraying AI/ANs as being more vulnerable than AI/ANs are in reality.

Construct: Indigenous Ethics Model—Two constructs related to an Indigenous ethics model and model components. Panelist discussions clarified several themes within the model construct. For example, one theme concerned the need to acknowledge cultural perspectives in considering and developing this model. As one expert noted:

> The role of the healer [in many AI/AN communities] is to respect, protect, reconcile harms, and heal harms
>
> (AI/AN community expert).

Similarly, the quote by this panelist reflected a consensus among participants that:

> [Research offers] opportunities to build trust at multiple levels. Holding [researchers] to high standards [helps to] ensure communities have trust in the research and the process and [to identify] possible benefits
>
> (AI/AN community expert).

Debriefing participants confirmed that developing an AI/AN curriculum requires (a) considering multiple cultural and contextual perspectives of research, particularly Indigenous perspectives; (b) an understanding that the design and implementation of research is a process that occurs at multiple levels; and (c) reflecting the unique cultural perspectives and legal status of AI/ANs. One participant noted that it was key that:

> The cultural information was seamlessly integrated throughout, really as the foundation of the training rather than tacked on at the end
>
> (Phone debriefing interview).

Expert panelists also identified themes that included information reflecting that (a) Indigenous research has taken place since time immemorial; (b) tribal communities have a strong interest in protecting their members from research harm; and (c) risks and benefits of potential participants may look different in AI/AN communities.

Expert panelists recommended including a theme related to Indigenous ethics model components: (a) “do good” or make sure research happens in a good way; (b) take the time and care needed to do research with AI/AN communities; (c) obtain AI/AN community approval prior to conducting research; (d) maintain a high level of ethics standards to build community trust; (e) understand research includes building relationships; (f) develop research methods that include consideration of cultural implications of results and

dissemination; (g) when research involves AI/AN children ensure it includes integration of cultural perspectives; and (h) ensure dissemination meets AI/AN community needs and norms. One participant noted that:

> [It's about] conducting research in a 'good way'. It's so simple, but there's no other way to put it. 'Do good.' That's it
>
> (AI/AN community expert).

These values coalesced into an overall model for Indigenous Research Ethics, with developing and sustaining relationships as a central goal and outcome of research with Indigenous communities.

Construct: Integrating Cultural Considerations into Research—Panelists identified five themes within the construct reflecting cultural considerations necessary to conduct research with AI/AN communities: (a) an expression of ethics concepts from a relational perspective; (b) the inclusion of storytelling as a device for learning; (c) an exploration of the complexity of relationships in AI/AN communities; (d) the need to reframe research to a positive perspective; and (e) the necessity of including structural competencies to implement AI/AN research. Consensus was achieved on all of the above with one exception: Not all participants believed there was a need to reframe research in a positive perspective. In discussing the need to reframe research in a positive way, some ethics panelists articulated the need for research to build capacity within AI/AN communities: "research for the sake of research does not constitute a sufficient justification alone." Other expert panelists noted the need to accurately describe the possible risks and benefits, to ensure the AI/AN communities and the individuals who might participate in research received all the information necessary to consent to participate in research. Panelists agreed that there is a need for both capacity development, which would support positive outcomes from research, while also ensuring a full description of the research risks and benefits.

Panelists identified 11 Indigenous values as being related to research: (a) cultivating inclusivity, by clarifying racial and community definitions; (b) we are all related; (c) caring for our ancestors; (d) consensus development, to support research with AI/AN communities; (e) making research our relative, to help to heal past harms; (f) honoring positionality, such that research roles can shift according to cultural norms and expectations; (g) build trust; (h) develop community capacity; (i) respect cultural protocols; (j) integrate cultural values in research; and (k) ensure equal accessibility to research, to make sure the entire community has the option to participate if desired. In addition, debriefing participants also requested that the curriculum includes (a) definitions to improve content accessibility; (b) the AI/AN concept of time; and (c) how to repair research relationships that have been upset or damaged. Debriefed participants appreciated the cultural considerations included in the first iteration of the training curriculum, noting that its inclusion improved the relevancy of the curriculum.

Panelists agreed that navigating relationships within small communities with specific cultural norms pose a challenge, particularly for researchers who are new to the field. For example, one panelist remarked:

> A person might feel violated or breeched but won't speak up because they don't want the researcher to lose their job because it's their auntie or someone they know who they know needs a job
>
> (AI/AN community expert).

In considering the need to show respect for a community's beliefs on information sharing, a debriefing participant stated:

> Information about people who have passed on and how their data is still sacred was powerful
>
> (Phone debriefing interview).

Overall, testing participants voiced their appreciation for the curriculum adaptations and the need for the culturally relevant examples provided. One participant stated:

> These situations are applicable to everyday situations. I understood a lot of the problems and situations that come up in research. I could relate to it, and the examples throughout the training helped bring the information to life
>
> (Phone debriefing interview).

Construct: Growing the Field of Indigenous Research Ethics—Panelists agreed that developing and refining the field of Indigenous research ethics require attention to multiple issues. For example, panelists stated that giving special consideration to the time frames of review and approval processes, providing a foundation in ethics regulations to researchers, and establishing practices and policies to ensure researcher adherence to regulations all play a role in developing the field of ethics in the context of AI/AN research. Debriefing participants affirmed the need to provide guidance and the opportunity to discuss ethics principles and applications within AI/AN communities among IRB members, researchers, and community members, to continue to develop ethics principles and to expand health research in AI/AN communities. One debriefing participant stated:

> Oftentimes we aren't even in the research. Our data isn't even there. We need to be in the research so that we can be impacted by the results
>
> (Phone debriefing interview).

Construct: Indigenous Tools for Ethical Decision Making—Expert panelists identified 11 tools and approaches to support ethical decision making in health research. Eight of them relate to ethics principles espoused in the CFR: (a) establishing agreement on the culturally sensitive application of research principles as defined in the CFR; (b) developing standard approaches to assessing risks and benefits unique to AI/AN communities; (c) applying AI/AN cultural norms to inform assessment of risks to confidentiality; (d) applying AI/AN cultural norms to inform assessment of the risk of undue influence and coercion; (e) employing cultural norms to inform assessments of equity

throughout the research process; (f) applying cultural and structural assessments to inform AI/AN-specific understandings of vulnerabilities; and (g) applying AI/AN-specific cultural norms and structural contexts to support assessment of research risks to children. Three of the tools relate to Indigenous ethics approaches: (a) incorporating acknowledgements of the relevance of Indigenous ethics values in research processes; (b) utilizing AI/AN-specific research examples as a training tool to improve ethics principle application; and (c) developing visual aids to support community sensitive ethics decision making for Indigenous researchers.

Debriefing participants independently confirmed the need to integrate culture in applying the ethics principles in the CFR. Further, both panelist and debriefing participants confirmed the need to acknowledge and use Indigenous ethics values examples and develop visual aids to support decision making. These participants also identified the need to clearly articulate the gaps and available AI/AN ethics tools to support ethical AI/AN human subject research. One debriefing participant stated:

> There aren't that many researchers on my reservation… We're so far apart, and in different fields. It's not like we can come together to talk about this stuff. This training fills that void
>
> (Phone debriefing interview).

Discussion

In a CBPR approach with nationally representative AI/AN community members, AI/AN IRB administrators and ethics experts, and AI/AN and ally researchers, we developed a culturally grounded human subject training curriculum for research within AI/AN communities—rETHICS. The major constructs revealed were as follows: (a) the AI/AN historical context, (b) components of an indigenous ethics model, (c) AI/AN cultural considerations and research, (d) growing Indigenous ethics, and (e) Indigenous ethics tools for decision making emerged. These constructs include themes specific to operationalizing Indigenous ethical principles and values for the AI/AN-specific research training curriculum, and many were confirmed through comparison coding of notes from debriefing interviews completed with AI/AN community members after completion of the AI/AN-specific curriculum. The following figure illustrates an Indigenous ethics model confirmed by expert panelists (Fig. 1).

The national multidisciplinary team of expert panel members articulated the urgent need, provided the essential content, and supported the process to develop rETHICS that received both acceptability across the expert panelists, and unanimous and comprehensive support from training participants. Previous studies have noted Indigenous-specific ethical research approaches (Whitbeck et al., 2006) and the need to train researchers using culturally grounded approaches (McMahon & Griese, 2018; Walters & Simoni, 2009), including research ethics principles. This new training contributes to the understanding that research implementation requires a multidisciplinary perspective, supported by the CBPR approach, and modeled methods of engaging AI/AN communities using an authentic, meaningful, and realistic process. AI/AN communities articulated the need for a culturally grounded human

subject training. Our study established the universal support and utility of such a training. We saw unprecedented levels of support from AI/AN community organizations and those engaged in AI/AN research, as well as external research agencies such as the funding institute, throughout the application process and culminating in the research design and implementation processes. This approach brought essential changes to our methodology, including an iterative, culturally grounded process that culminated in a human subject training curriculum designed from an AI/AN perspective and designed for AI/AN community researchers.

Furthermore, our process illustrated how community members contribute essential knowledge to support improved research ethics among diverse and stigmatized communities. This community-centered approach to developing culturally grounded content is essential to support the conduct of ethical research in AI/AN communities, and could be a useful approach in other communities that experience discrimination, stigmatization, or have other unique cultural characteristics that may be related to ethical principles or the delivery of training materials. Respecting AI/AN tribal sovereignty and community autonomy is critical to building trust, and while perhaps unique to AI/AN communities, other values that came from expert panel discussions may have broad applicability, including the concepts that: (a) respect for community demonstrates that researchers are invested in the research relationship and that they are working to create an equitable partnership in research; and (b) gaining trust requires active listening, a humble approach, and acknowledging the expertise that each member of the community brings to the research.

Limitations

The most challenging aspect of the study was ensuring a nationally representative sample. Establishing a sampling frame using urban AI/AN community size and tribal representation as well as population size served as a critical tool to ensure the Indigenous ethics values and principles were representative of tribal communities and urban AI/AN populations nationally. There were also several study limitations. We did not collect debriefing data from the full intervention phase of the study. Although we attempted to ensure the testing participants were representative, it may be that there were key constructs or sub-themes related to AI/AN research that we did not capture from the test participants. Our interview probes may not have elicited the full array of responses experienced by participants. Other research could revisit these constructs supporting confirmation, or change over time and explore possible additional constructs and subthemes to strengthen the evidence for Indigenous ethics values and principles. The debriefing notes were limited to brief statements. This resulted in a general confirmation of content validity that lacked sufficient content to establish statistical assessments of agreement between the principles established through the expert panel process and the test participants. Additional studies focusing exclusively on content validity could confirm these initial findings.

Conclusion

The nationally representative test of the AI/AN human subject training curriculum demonstrated that the content provides important supports for AI/AN research capacity

(Pearson, Parker, Zhou, Donald, & Fisher, 2019). This study served to elucidate Indigenous ethics values and principles that served as the basis for the AI/AN human subject training curriculum. Moreover, the results helped to confirm the content validity of the Indigenous ethics values and principles first articulated by AI/AN community research experts and confirmed by AI/AN academic researchers and ethics experts.

As part of the CBPR approach, the AI/AN human subject training curriculum is available for free download online (https://redcap.iths.org/surveys/?s=R3EJPAYD4J). The principal investigator has provided training to AI/AN communities and organizations to support ethics training in their respective networks. For example, over 100 home visitors and program staff were training in September 2018 for a national study of tribal home visitation programs, which provide parenting support to tribal and urban AI/AN communities across the United States to improve parent and child health and mental health outcomes, support early childhood development, and ensure school readiness. Making resources like these available to AI/AN community members fulfills a core component of the overall research approach, supports the development of research ethics capacity development, and furthers overall research capacity within tribal and AI/AN communities in urban settings. Growing the field of AI/AN research relies on making research results accessible to AI/AN communities, researchers, and other stakeholders, which was the charge put forward by the AI/AN Community Expert Panel. These approaches may be useful for other communities considering research ethics capacity development.

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Highlights

- Community-based consultation led to identification of culturally-grounded ethical principles.
- Culturally grounded principles support research with American Indians and Alaska Natives.
- Including culturally based principles in an ethics training curriculum supports research with AI/AN.

Fig. 1.
Indigenous ethics model