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Capacity Building from the Inside Out: Development and Evaluation of a CITI Ethics Certification Training Module for American Indian and Alaska Native Community Researchers

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Abstract

Current Human Subject Research training modules fail to capture ethically relevant cultural aspects of research involving American Indian and Alaska Native (AI/AN) community members. Applying a Community Engaged Research (CEnR) approach, we adapted the Collaborative IRB Training Initiative training module “assessing risk and benefits.” In a two-arm randomized controlled trial, followed by debriefing interviews, we evaluated module acceptability and understandability (test scores) among 40 reservation-based community members. Participants who took the adapted module, compared to those who took the standard module, reported higher scores on relevance of the material overall satisfaction, module quiz scores, and a trend toward higher self-efficacy. Implications of the efficacy of this approach for enhancing ethics training and community participation in research within AI/AN and other cultural populations within and outside the United States are discussed.

Keywords

American Indian and Alaska Native (AI/AN); Community Engaged Research (CEnR); culturally responsive human subjects training

COMMUNITY ENGAGED RESEARCH

Community Engaged Research (CEnR) plays a significant role in conducting research with minority communities (Friedman Ross et al., 2010). It represents a broad spectrum of practices that include equal partnership with community members in the development and

evaluation of human subjects' protections and research design, implementation, analysis, interpretation and dissemination. CEnR principles bring mutual respect, community voice and ways of knowing to guide research agendas and develop interventions from cultural perspectives that resonate with the study population (Cochran et al., 2008; Minkler & Wallerstein, 2008). Studies have credited CEnR with increasing underserved and minority populations' involvement in research (Alvarez et al., 2006), attending to issues of mistrust (Christopher et al., 2008), increasing intervention success and sustainability (Trickett, 2011; Wallerstein & Duran, 2010), tackling complex social and health issues, changing health and environmental policy (Israel et al., 2010; Minkler et al., 2008; Wallerstein & Duran, 2010), and creating community-academic power shifts (Friedman Ross et al., 2010; Wallerstein & Duran, 2008a). Furthermore, CEnR has improved the science of research through enhancing external validity (Boyd-Ball, 2003; Mohatt et al., 2004), producing culturally relevant, reliable, and valid measurement tools (Minkler, 2005), improving qualitative and quantitative data analyses (Dubois et al., 2011), and expanding scientific knowledge by incorporating world views beyond western epistemologies (Wallerstein & Duran, 2010).

COMMUNITY ENGAGED RESEARCH WITH AMERICAN INDIAN AND ALASKA NATIVE COMMUNITIES

Tribes have inherent sovereign authority to govern their lands and may elect to manage federal health programs and other federal contracts in their communities under Public Law 93-638, The Indian Self-Determination and Education Assistance Act of 1975 (Deloria, 2002). The practice of engaging community members was therefore established in American Indian and Alaska Native (AI/AN) communities well before it was labeled by the academic community (B. Duran & Duran, 1999). Indigenous CEnR (ICEnR) embraces the emic (insider) perspective (Baldwin, Johnson, & Benally, 2009) that deemphasizes the voice of "external experts" (Smith, 2001; Caldwell et al., 2005). ICEnR focuses on the protection of tribal interests (Baldwin et al., 1999; Beauvais, 1999; P. A. Fisher & Ball, 2003) and acknowledges historical trauma, tribal sovereignty, and other contextual variables (Brave Heart-Jordan & DeBruyn, 1995; E. Duran & Duran, 1995) throughout the research process. ICEnR also requires academic partners to understand and respect the fundamental rules and laws of tribes. Studies have shown that when collaborations between researchers and AI/AN communities acknowledge and work within a historical framework they have the greatest likelihood of producing lasting change (P. A. Fisher & Ball, 2002; Stubben, 2001). Overall, cyclical and continuous involvement of community members characterizes the ICEnR process (Baldwin et al., 2009). Each step in the process includes building and sustaining collaborative relationships; developing, implementing and evaluating the research together in culturally acceptable ways; and disseminating research findings from a tribal perspective. While best practices are still emerging, challenges remain in identifying the specific elements of ICEnR that are needed to build community research capacity and improve health outcomes (Wallerstein & Duran, 2008b).

COMMUNITY ENGAGED HUMAN SUBJECT RESEARCH TRAINING NEEDS

To be of value, research must be scientifically valid and socially responsible (Emanuel, Wendler, & Grady, 2000; Emanuel et al., 2004; C. B. Fisher, 2004; Foa et al., 1997). As

community members assume active partnership in the research process, they join investigators in the obligation to ensure studies meet the highest standards of research design and human subjects protections (Council for International Organizations of Medical Sciences [CIOMS] in collaboration with the World Health Organization [WHO], 2002; Dubois et al., 2011; Hyatt et al., 2009; NIH, 1979; US Department of Health and Human Services, 1980; World Medical Association, 2008). A number of excellent opportunities exist for broad training in research ethics and design including the Collaborative IRB Training Initiative (CITI), Family Health International certification training (Family Health International 2009), National Institute of Health Protecting Human Research Participants guide (NIH, 2008) and other university-based training designed for scientists who have been academically trained. However these training modules were developed specifically for members of the scientific community and largely reflect a biomedical ethics framework focused on knowledge production and academic institutional ownership with little to no direct relevance to CEnR (Flicker et al., 2007). The few training approaches developed specifically for community training in human subjects protections and research are often narrow in scope focusing on responsibilities of project field staff, primary data collection methods, and policy advocacy (Carroll-Scott et al., 2012; Goodman, Dias, & Stafford, 2010).

HUMAN SUBJECTS TRAINING CHALLENGES TO ICENR

Available human subjects training modules fail to resonate with AI/AN community members. In programs of ICEnR research in which the first two authors have been involved, community partners complete the CITI behavioral and social science web-based training. The training may take several days and up to 15 hours to complete. After taking the CITI training, community partners have often raised concerns about the jargon, lack of cultural and contextual relevance, absence of discussion about community risk and benefits, and questioned their own ability to apply the concepts to the research for which they provide oversight. Similar concerns over standard training adequacy for community member human subject trainings have been reported by other research teams (Hatcher & Schoenberg, 2007).

Informed engagement of AI/AN community partners in the ethics review of research protocols plays a critical role in ensuring that community-based research avoids cultural misunderstandings, including tribal stigmatization, or culturally inappropriate, irrelevant, and disrespectful science that may lead to mistrust and damage the long-term viability of the partnership (Hyatt et al., 2009; Mohatt & Thomas, 2006). Assessing risk and potential benefits, establishing data control and ownership, and identifying research dissemination policies and practices represent the most important concerns within AI/AN communities (Mohatt & Thomas, 2006; Noe, Fleming, & Manson, 2003; Sahota, 2010). Identifying AI/AN community concerns requires community capacity building, open dialogue between institutional and community-based researchers, community benefits from the research, and respecting the community partners' voice in the research process (Fantuzzo, McWayne, & Childs, 2006; True, Alexander, & Richman, 2011).

There is a critical need for procedural models that guide the development and evaluation of community-responsive research ethics trainings for American Indian tribes and other

cultural minorities. As a first step toward addressing this need, the research reported in this article applied a CEnR procedural model to develop and evaluate a culturally responsive research ethics training module that was more accessible and relevant to AI/AN community research partners.

Methods

In this study, with permission of Collaborative Institutional Training Initiative (CITI; citiprogram.org) partners, we used a CEnR approach to adapt and evaluate a social and behavioral science CITI human subjects training module incorporating Pacific Northwest tribal perspectives. The CEnR module adaptation process proceeded in three phases: (1) investigators prepared materials for community partner review including identifying module core components that mapped on to the code of federal regulations (CFR) and illustrative examples; (2) three expert panels met to select a module and adapt the selected module to meet the needs of CEnR; and, (3) a parallel randomized-controlled study evaluated the acceptability and reliability of the adapted version compared to the original version among 40 AI/AN community members. The study was approved by two academic institutional review boards, the institute of the principle investigator and by a regional tribal college located on a northwest Indian reservation. We begin this section with a description of the expert panel members and the process of module mapping, selection and revision. This is followed by a description of the randomized controlled trial.

EXPERT PANEL MEMBERS

Module adaptation followed a deliberate, iterative process. We recruited three expert panels to guide the adaptation process including community, scientific, and ethics panels. To recruit panel members we sent emails to our network of AI/AN colleagues and scholars collaborating with AI/AN communities in the Pacific Northwest. We also presented our requests at regional and university AI/AN ethics meetings. *Community Panel* members ($n = 4$) were coastal and plains Pacific Northwest tribal members who had obtained human subject protection certification and conducted research in their tribal communities. *Scientific Panel* members ($n = 4$) were AI/AN and Ally scholars from universities and research institutes with 10–30 years of experience conducting research with AI/AN rural and urban communities. One member designed a human subjects training for academics working with Southwest AI/AN communities. *Ethics Panel* members ($n = 4$) included an administrator from an area Indian Health Board, a university IRB administrator, an AI/AN ethicist, and an AI/AN policy analyst. One panel member was among the original authors of the CITI. All panel members were reimbursed \$300 to review and edit project materials before and after meetings, and attend up to two 2-hour webinars. Given the long distances between tribal communities, we found using Webinar technology to be an excellent means of engagement.

MODULE SELECTION AND IDENTIFYING CORE ELEMENTS

The CITI human subjects protection modules were first developed at the University of Miami in 2000 to assist institutions fulfill the US Department of Health and Human Services mandate that all key personnel engaged in research must obtain human subjects protection training (NIH, 2001). Originally the CITI training consisted of single module basic course

focused on biomedical content from experts at a single institution. Now in its tenth iteration, the CITI expanded their content experts across multiple institutions and expended to three basic courses (i.e., biomedical, social, and behavioral), refresher courses, three good clinical practice courses, a health information privacy and security course (HIPS), a laboratory animal research course, six responsible conduct of research (RCR) courses, and a bio-safety and bio-security course. Face and content validity is obtained through a peer review process of over 80 core developers across 65 institutions. The developers meet semi-annually to review the courses and make editorial changes (CITI, 2000).

Much of our work resides in the social and behavioral science arena thus we decided to begin with the CITI Social and Behavioral Sciences Human Subjects training which includes 16 modules. In order to assist our AI/AN partners with opportunity to prioritize modules for cultural adaptation, we removed seven modules that primarily reviewed federal laws or designations and have limited mutability for cultural adaptation. Another six modules, although important, focus on critical issues for specific populations (i.e., children, prisoners). Our focus was to first address human subjects ethics modules relevant to all populations. Therefore, we began with the Informed Consent, Assessing Risks and Benefits, and Privacy and Confidentiality modules. Each module addresses a specific topic (i.e., informed consent, privacy and confidentiality, assessing risk and benefits) and has an introduction describing the purpose and learning objectives, primary headers describing the ethical construct, and sections detailing definitions, issues and examples of specific ethical issues.

To adapt the three modules and ensure cultural relevance, cultural equivalence, and generalizability we followed strategies applied for cultural adaptation of survey instruments (Alegria et al., 2004) and interventions (CDC, 2008). The first step, in this process was to identify the core principles and elements (Alegria et al., 2004; CDC, 2008) of each module by constructing a matrix that mapped the major constructs, definitions and examples in each of the three CITI modules to Subpart A of the Code of Federal Regulations governing human subject research (US DHHS, 2009). This process ensured that modifications made in the adaption phase would retain core regulatory elements and reflect the foundational moral principles of beneficence, respect, and justice outlined by the National Commission in the Belmont Report (NIH, 1979). The first and second authors worked synchronously on independently coding and revising each module's ethics matrix. This was followed by a final review conducted by the third and fourth authors.

MODULE SECTION, PANEL REVIEWS, AND MODULE ADAPTATION PROCESS

During our first expert panel review with the AI/AN community members, we reviewed all three modules and community members discussed preference and importance of each module. Members prioritized the assessing risk and benefit module as they believed this was where researchers often made the biggest mistakes. Also they stated this was where community researchers are often referred to in reviewing research protocols. Once we identified this module we began the adapting process.

We conducted three panels to achieve an iterative revision process. For each panel, one week prior to each webinar, panel members received: (1) a brief summary of the project; (2)

instructions on their role in adapting the module; (3) the original CITI module; (4) a merged version of the module using Word track-changes made by any previous panel(s); and (5) the core element matrix. The audio-recorded webinar format ensured a well-documented, focused, in-depth discussion. Webinars began with a brief review of the core element matrix, followed by a section-by-section review of the track-changed version with comments noted from previous panel reviews. The original version without track changes was available as a reference. Suggested changes were made directly and confirmed by the group. After each discussion, an investigator reviewed the webinar tape and made any additional revisions, followed by a second investigator who confirmed that revisions accurately reflected panel recommendations. All changes were sent back to the expert panel for final approval.

The Community Panel provided the first level of review. They made recommendations for changes that would meet the needs of local AI/AN communities, bring AI/AN culture and lived experience into the revision process and most importantly, identified AI/AN individual and community level risk and benefits. The investigators and the panel reviewed the core element matrix and then reviewed the module section by section. Changes to the original module were made via track changes editing in Word. The track-changed version was return to the panel for additional comments.

The Scientific Panel conducted the second review. This panel worked from the community panel track-changed version, verified the revisions reflecting the scope of ethical issues confronting university-based researchers in AI/AN communities, confirmed recommendations by the Community Panel, refined and added examples reflective of the AI/AN culture, and provided face validity on all revised materials. Changes were incorporated into a revised track-changed module with changes emailed for a second review.

The Ethics Panel provided the third level of review. These panelists compared the original module with the recommended changes and certified that the changes met human subjects' certification criteria. They also provided additional ethical issues specifically confronting research with AI/AN communities e.g., tribal approval processes.

FINAL ADAPTATION STEP: REFINEMENT AND ANALYSIS

After the Ethics Panel met, the fourth step—refinement— was to pull all the changes together in a coherent curriculum. The IRB administrator and the first author met twice. They reviewed all the language and examples. They refined and simplified the language and ensured the core principles and elements were retained. This stage also included deciding on maintaining the module's original structure and all main headers with only two minor modifications and replacing all original photos with images reflective of AI/AN culture. In the final, fifth step we sent the final version out to all panel members for their review. Only minor editorial comments were suggested.

Once the final modifications were made, two coders independently coded the changes mapping comments to the code of federal regulations (CFRs) and categories within the assessing risk and benefit module: invasion of privacy, breach of confidentiality, balancing risks & potential benefits, minimizing and managing risk, assessing risk, probability and

magnitude of harm). We modified 56% of the text in the original module. The word count increased by 718 words (2003 to 2721), primarily adding in statements pertaining to community level risk and tribal oversight. Statistically, as compared to the original module the adapted version increased in the number of paragraphs (102 versus 122), sentences (90 versus 121), and sentence per paragraph (2.1 versus 2.2) and increased in Flesh-Kincaid grade 12.6 versus 13.1. There were no changes in characters per words (5.4 for both). However there was a decrease in number of passive sentences (26% versus 22%) and Flesh reading ease score (33.2 versus 31.6).

A summary of selected new and major modifications, including our coding for the changes made is illustrated here (DOI: 10.1525/jer.2014.9.1.S1). We made a total of 62 changes in four categories: (1) “focused the topic relevant to AI/AN populations as compared to a general population” ($n = 12$)—this includes reference to AI/AN culture and frames the content on ethical issues salient to work in AI/AN communities; (2) “clarified concepts” includes removing jargon, simplifying language, or expanding an explanation ($n = 22$); (3) “examples relevant to AI/AN populations” ($n = 11$)—examples include those that have occur often or are more reflective of events in AI/AN communities, i.e., misuse of data, focus on events likely in community settings versus a technologically advanced setting (4) “community protection” ($n = 17$)—provides community-level risk and benefit issues to address a critical gap in ethical training pertinent to AI/AN communities. A table of all changes and coding for the changes may be accessed at <http://www.iwri.org/projects/>.

RANDOMIZED CONTROL TRIAL

RCT Participants—We conducted a parallel two-group randomized control trial (RCT) to evaluate the acceptability and reliability of the adapted risk-benefit module compared to the original module among 40 AI/ AN Pacific Northwest community members. Data was collected from November 2012 to January 2013. Participants were AI/AN who: (a) were 18 years or older; (b) had never taken the CITI training; (c) were currently participating or interested in conducting research; (d) resided on or near a Pacific Northwest reservation or native village; and (e) had access to a computer and the Internet.

Procedures—Members from our three expert panels sent recruitment flyers to their AI/AN community networks with some communities choosing to post the flyers on their websites, Facebook pages and at local tribal colleges. Interested persons contacted study staff by phone, email, or in-person. Study staff screened participants and obtained oral consent. Random assignment to condition was based on a computer-generated allocation sequence of 12 blocks with five different sizes generated (sizes 2–10). After participants were consented, they were assigned the next sequential study identification number by the study coordinator. Participants were blind to the intervention. An information statement and link to the module were provided to each participant. Participants were asked to complete the module in five days. The day after the module was completed staff called or in some cases the respondent called staff and scheduled a 1-hour debriefing interview. Participants received \$75 for their time.

Measure—After reading the module, respondents answered the five original CITI quiz questions and four investigator-designed and panel reviewed community-level risk and benefit multiple choice questions. This allowed us to compare both groups on the original items as well as the community-sensitive risk-benefit questions. The original as well as the new questions may be accessed at (DOI: 10.1525/jer.2014.9.1.S1).

To determine how well the module was received by the participants and the extent to which the components met their needs, participants responded to three acceptability and feasibility Likert-type scales (Ayala & Elder, 2011; Babbie, 2007) on *relevance* of the materials (5 items, Cronbach alpha $\alpha = .78$: i.e., subject covered, information reflective of culture, quality of the information conveyed) (Kalbach, 2009); *self-efficacy/ confidence* (3 items, $\alpha = .84$: i.e., use ethical principles to review research study designs, assess consent form, and make recommendation to ensure consent); and *satisfaction* (4 items, $\alpha = .92$: i.e., readability of the materials, visual appearance, quality of information). Responses were on a 5-point scale ranging from not at all to extremely relevant, confident, and satisfied as appropriate. We also recorded the time it took to take the quiz and to review the module. In the debriefing interviews, staff reviewed the module with participants, asked whether they had any difficulty understanding the topic areas, and asked follow-up questions pertaining to relevance, self-efficacy, comprehension, and technical difficulties. Staff typed responses into a data collection form and read the responses back to the participants to ensure accuracy.

Data Analysis—We hypothesized that participants trained on the culturally-responsive version compared to those trained on the original CITI risk-benefit module would demonstrate significant reduction in the time it took to complete the module and higher levels of: (a) comprehension of the core elements (quiz scores), (b) self-efficacy in their ability to apply the concepts to their research activities, and (c) satisfaction and relevance of the materials.

We evaluated the difference between the standard and culturally-responsive module arm at posttest participant outcomes and were conducted using χ^2 and Independent samples t-tests with unequal variance for dichotomous and continuous outcomes, respectively. Scales were summed and means compared. We computed Cronbach alpha to assess each scale's reliability coefficient. Power analyses were based on the continuous measure quiz score as the outcome, with a standard deviation of .16 and .80 power to detect a .15 difference in scores. The power calculation indicates that 19 respondents were required in each arm, resulting in a total sample of 38.

The first and second authors also independently analyzed the open-ended debriefing questions with five major themes emerging (agreement = .92%): (1) overall positive response to the study; (2) relevance of the material presented; (3) self-efficacy; (4) technical problems encountered; and (5) readability challenges and implications. Results within and between study arms are summarized below.

Results

Of the 54 people who contacted the study staff, 44 (81.5%) were eligible and randomized. Of the respondents who were randomized, 40 (90.9%) logged into the CITI website and took the training module. Respondents were primarily female (80.6%), with a mean age of 26.7 (SD = 11.2, range 19–60). Demographic information and description of work experience are provided in Table 1. There were no significant differences between the adaptation and standard module groups among these variables.

Table 1 also provides mean scores, standard deviations for outcome measures and test statistics for differences between respondents trained on the adapted and standard modules. Module quiz scores are represented as percent correct for all 9 items, then for the 5 original items and 4 new items. Respondents trained on the adapted as compared to the standard module had significantly higher overall quiz scores, higher scores for the 4 new items, and a trend toward higher scores on the 5 original items. Respondents who took the adapted module, as compared to those who took the standard module reported significantly higher scores on overall relevance of the material, overall satisfaction, and module quiz scores. Although, there was only a slight trend in overall group difference in self-efficacy total scores, respondents who took the adapted version as compared to respondents who took the original version were significantly more likely to report that they were mostly or extremely confident (versus not at all, a little, or somewhat confident) in their ability to assess risk and benefits in research study design.

We conducted 30 debriefing interviews (*adapted module, n = 17; standard module, n = 13*) that confirmed the differences seen in quiz and survey responses. The majority of respondents, who took the culturally-adapted module, appreciated the relevance of the materials. In particular, five respondents noted that the example in the adapted model highlight the risk of potential trauma resulting from interviews conducted at an old Indian boarding school resonated with their lived experience. Four respondents stated they were interested in sharing the culturally adapted module with others and/or their tribe and five respondents stressed the utility of the material in health care and social service settings outside of the research arena. Several ($n = 5$) noted an increase in self-efficacy. One person said, “I’m ready to jump into research in the next year and I’m really glad I did this.”

During debriefing respondents who took the original version also articulated confidence in weighing risks and benefits in research, however, these respondents tended to note the lack of AI/AN examples or cultural relevance. For example, one respondent stated, “[The module material] didn’t go into the depth that you need. It was like, ‘this was it.’ It was like giving someone water but none of the Kool-aid mix. This goes especially for Native American reservations. It didn’t say anything about certain communities, poverty, social status, [or] religious beliefs. It didn’t say you have to watch who you are asking. It didn’t say that you should talk to the right people to know about them.” Another respondent stated, “the pictures really didn’t make sense”.

Debriefed respondents from both study arms expressed frustration with the technical difficulties. In particular, logging into the CITI website took a very long time and was

burdensome for respondents. They also expressed difficulty with the vocabulary and the long sentences, and the time needed to understand the materials. Many respondents said they appreciated learning about the protection a Certificate of Confidentiality provided. Respondents also 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.” Overall the response to the study was very positive. As one person who took the adapted version stated, “You guys are putting really important information in your module.”

Discussion

Our research study established a community engaged procedural model to develop culturally-responsive ethics education tools for AI/AN community researchers. This procedural model may provide guidance in further adapting ethics training materials involving AI/AN and can inform modifications appropriate for other ethnic minority groups. In this study, we found the culturally-adapted CITI social-behavioral risk-benefit module led to improvements in respondents quiz scores, overall reported relevance, satisfaction with materials, and self-efficacy in ability to assess risk and benefits in research study design. The qualitative data gathered through cognitive debriefing interviews confirmed these quantitative results.

Increasingly, AI/AN communities expect and require researchers to adhere to tribal standards honoring community knowledge and benefits (Whitefoot, 2008) with the expectation that tribal partners fully participate in every phase of research including development, implementation, interpretation, and dissemination of findings. AI/AN communities have the legal authority and responsibility to protect their members and the tribe itself from research harms and ensure they can gain the maximum possible benefits from research (Sahota, 2011). This study confirms the acceptability, applicability, and utility of a culturally relevant human subject training curriculum for tribal communities and will increase informed CEnR for both academic and community partners. It can also serve as a model to provide adaptations to other minority communities. Further, ethics review boards both outside and within AI/AN communities could benefit from these enhanced ethics training materials in the development and application of appropriate review standards.

Best Practices

We have identified three salient best practices for research efforts in AI/AN communities. First, culturally-relevant human subject protections training materials will ensure biomedical and social-behavioral research adequately addresses AI/AN protections. Scholars and AI/AN communities have found programs based on both an understanding of power and history and that build upon community strengths and cultural restoration, resonate with AI/AN and thus have the most transformative effect (Brayboy & Castagno, 2009; Castagno & Brayboy, 2008; North Central Regional Center for Rural Development, 2007). Pluralistic ethical requirements drawn from both communities and academic researchers produce

transcultural ethical frameworks and training curricula (Mzayek & Resnik, 2010). The results of this study further demonstrate the utility of including community voice in ethics training materials.

Second, the inclusion of AI/AN ways of knowing and lived experiences provide AI/AN community researchers the opportunity to participate in non-stigmatizing research activities (Miranda et al., 2005), and to better address the unique issues facing their communities (Becker et al., 2005). Tribal communities that restore cultural knowledge and develop community strengths foster transformation of individuals, families, communities, systems of care, and social structures (Goodkind et al., 2010).

Third, CEnR methodology and mixed methods provide an important set of tools to make cultural adaptations of ethics materials possible to a wide range of community members who are engaged in the research process. CEnR offers a valuable means for integrating both academic and community knowledge by translating and testing the core components of empirically supported trainings with communities, while integrating culturally supported norms and practices to enhance the translation in local context. This process strengthens acceptability and may enhance sustainability fit within the values and social systems of AIAN communities, support cultural revitalization, and remain highly utilized and sustained over time (B. Duran & Walters, 2004; Smith, 2001).

Limitations

With over 566 diverse federal and 200 state-recognized tribes as well as multiple unique urban AI/AN communities, our Pacific Northwest regional focus may not fully capture AI/AN human subject training concerns. However, our study included voices from urban expert panel members and rural community members from federally and state-recognized tribes as well as from tribes still fighting for recognition. Technical difficulties logging into the module may have impacted respondent participation. The clarity of log-in procedures must be a focus when implementing online data collection efforts in any community, but such challenges have particular implications for resource-poor environments where computer time may be limited, connectivity issues exacerbate already complicated log-in procedures, and participants have other competing demands. Future efforts should include a streamlined log-in to reduce respondent burden and improve module testing. Participants voiced a need to improve readability of the adapted module material. This additional adaptation will require another layer of modification in future efforts. It would also be imperative to include readability in quantitative and qualitative measures testing future revisions. Finally, we recognize using a CEnR process to adapt a full human subject curriculum would require intensive time and labor resources. However, we believe this is an essential step for ensuring the conduct of ethical research, as well as developing research infrastructure and capacity serving AI/AN living across the United States, a group at risk for expanding health disparities.

Research Agenda

The support for this study was overwhelmingly positive with AI/AN community members, IRB administrators, academics, and ethicists all expressing the need for a culturally

responsive human subjects training. We adapted one module; however, it would be necessary to adapt the entire training curriculum to formulate a cohesive ethics training framework. As human research training becomes more reflective of community, it potentially increases tribal involvement in research, reaching more community members and reducing mistrust (Struthers et al., 2005).

Developing training materials and programs that are collaborative, community driven, mutually respectful, and nationally supported offer the most promising potential for long-term success and sustainability (Friedman Ross et al., 2010; Herrenkohl et al., 2008; Weahkee, 2011). To the extent more communities of color are empowered and engaged in the research process, training that ensures ethical competencies and informs partners of community-level protections will strengthen research efforts and provide a foundation for human subject protections.

Educational Implications

This culturally responsive ethics training module would enhance and strengthen the research knowledge and participation of AI/AN. It would also inform other researchers wishing to work with AI/AN researchers about ethical concerns and provide a framework for conducting research with AI/AN communities. Furthermore, this established procedural model of working with community groups to develop a culturally responsive ethics education tools would be generalizable to different modules for research involving AI/AN and to develop training for other ethnic minority groups. Future adaptations should be responsive to the cultures in which the training would be provided.

Accessible and culturally responsive protection of human subject training constitutes an imperative for ensuring true participation of community members in all aspects of CEnR. As community partners continue to recognize research risk and benefits this may provide important policy implications and research at the tribal, state, and federal level. A completed, fully adapted curriculum could be used to identify ethical issues and decision making concerning research within AI/AN communities. Furthermore, since an adapted CITI behavioral and social science version would meet the certification requirements for training in human subjects' research, academics conducting research in AI/AN communities would also benefit from taking the training.

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Biographies

Cynthia Pearson has collaborated with American Indian (AI) communities in designing and implementing community based prevention interventions and in the development of tribally approved research policies (data use agreement, research and publication guidelines). She has developed expertise in designing community-based health interventions from an ecological perspective that emphasize social, political, environmental, and historical determinants of health. She has nine years' experience creating trusting long-term working relationships through collaboration with Pacific tribal communities.

Myra Parker is an enrolled member of the Mandan and Hidatsa Tribes from the Fort Berthold Indian Reservation in North Dakota. She has worked with tribal leaders and tribal program directors in Arizona and in the Pacific Northwest. Her work focuses on data sharing agreement development with tribes and tribal organizations, cross jurisdictional agreements and public health impacts, as well as development of community-based participatory research methods in tribal communities.

Celia B. Fisher is the Marie Ward Doty Endowed University Chair and Professor of Psychology, and Director of the Fordham University Center for Ethics Education. She directs the Fordham University Training Institute on HIV Prevention Research Ethics and serves as a member on the numerous committees. Dr. Fisher is the author of *Decoding the*

Ethics Code: A Practical Guide for Psychologists, co-editor of eight books, and over 150 publications on ethics in medical and social science research and life-span development. Dr. Fisher research interest is related to ethical issues and human rights, health disparities and well-being. Dr. Fisher received the Lifetime Achievement Award for Excellence in Human Research Protection in 2010. She was named a Fellow of the American Association for the Advancement of Science in 2012.

Claudia L. Moreno is a Latina who has experience in community-based research in HIV/AIDS, partner abuse and interventions research in HIV prevention with Latinas and also with heterosexual couples at risk for HIV. She has been involved in research projects in Latin America and in the Latino community in New York and New Jersey. Her passion is qualitative research, grounded theory and community-participatory research. She is a faculty member and mentor at the HIV Prevention Research Ethics Training Institute at Fordham University.

TABLE 1
Comparison of Demographics, Acceptability, and Quiz Scores at Posttest by Study Arm among 40 AI Community Members.

	Total	Adapted Module	Standard Module	Test Statistic	P-value
Age, years (M, SD)	36.7 (11.2)	34 (10.7)	39.4 (11.3)	1.49	
Female	29 (80.6)	15 (83.3)	14 (77.8)	0.18	
College Degree	13 (36.1)	7 (38.9)	6 (33.3)	0.12	
Number of Years Conducting Research (M, SD)	1.2 (2.4)	1.2 (2.6)	1.2 (2.3)	0.07	
Live in a Reservation Community	28 (77.8)	13 (72.2)	15 (83.3)	0.64	
Work in a Reservation Community	34 (94.4)	16 (88.9)	18 (100)	2.12	
Research Interest ^δ					
HIV/AIDS	5 (12.5)	2 (10.0)	3 (15.0)	0.23	
Substance use	13 (32.5)	8 (40.0)	5 (25.0)	1.03	
Sexual health	10 (25.0)	5 (25.0)	5 (25.0)	0.00	
Violence	13 (32.5)	7 (35.0)	6 (30.0)	0.11	
CVD, obesity, diabetes	11 (27.5)	4 (20.0)	7 (35.0)	1.13	
Environmental health	14 (35.0)	6 (30.0)	8 (40.0)	0.44	
Acceptability^τ					
Relevance: Overall Score (M, SD)	74.2 (18.4)	82.7 (13.5)	65.8 (19.1)	3.06	**
Subject relevancy ^{δδ}	23 (63.9)	13 (72.2)	10 (55.6)	1.08	
Reflective of culture ^{δδ}	22 (61.1)	15 (83.3)	7 (38.9)	7.48	**
Quality of information ^{δδ}	25 (69.4)	16 (88.9)	9 (50)	6.41	**
Appropriate examples ^{δδ}	23 (63.9)	15 (83.3)	8 (44.4)	5.90	*
Interesting ^{δδ}	19 (52.8)	13 (72.2)	6 (33.3)	5.46	*
Satisfaction: Overall Score (M, SD)	75.4 (17.8)	81.4 (18.8)	69.4 (14.9)	2.11	*
The way information was conveyed ^{δδ}	23 (63.9)	15 (83.3)	8 (44.4)	5.90	*
Readability of the materials ^{δδ}	24 (66.7)	15 (83.3)	9 (50)	4.50	*
Quality of information provided ^{δδ}	26 (72.2)	16 (88.9)	10 (55.6)	4.98	*
Visual appearance ^{δδ}	24 (66.7)	13 (72.2)	11 (61.1)	0.50	
Self-efficacy: Assessing Risk & Benefit (M, SD)	72.2 (14.6)	76.3 (14.0)	68.1 (14.6)	1.71	^

	Total	Adapted Module	Standard Module	Test Statistic	P-value
Reviewing research designs ^{δδ}	24 (66.7)	15 (83.3)	9 (50)	4.50	*
Assessing consent forms ^{δδ}	17 (47.2)	10 (55.6)	7 (38.9)	1.00	
Recommendation to ensure consent ^{δδ}	21 (58.3)	12 (66.7)	9 (50)	1.03	
Module Quiz Scores: Overall (M, SD)	69.3 (19.7)	75.7 (16.0)	62.9 (21.2)	2.15	*
Quiz score 5 original quiz items	67.7 (26.1)	75.6 (23.3)	60.0 (26.7)	1.90	^
Quiz score 4 new quiz items	72.4 (25.9)	81.9 (20.7)	63.8 (27.5)	2.29	*

Data reported as frequency (N) and percent (%) unless otherwise noted by M = mean, SD = standard deviation.

t test and chi square test were conducted as appropriate;

^ P < .10

* P < .05;

* P < .01.

δ Research Interest categories are not mutually exclusive.

τ total N = 36, missing cases were distributed equally with two cases in each arm.

δδ 5-point Likert scale responses dichotomized at mostly or extremely compared to not at all, a little, somewhat. Data reported are numbers and percent reporting mostly or extremely confident.