HHS Public Access

Author manuscript

J Immigr Minor Health. Author manuscript; available in PMC 2018 February 01.

Published in final edited form as:

J Immigr Minor Health. 2018 February ; 20(1): 107–114. doi:10.1007/s10903-017-0548-x.

Culturally Relevant Human Subjects Protection Training: A Case Study in Community-Engaged Research in the United States

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Abstract

Background—Non-academic members of research teams, such as community members, can perceive traditional human subjects protection training as lacking in cultural relevance. We present a case exemplar of the development of a human subjects protection training for research staff with limited English proficiency and/or no or limited research experience.

Methods—Seven modules were adapted for language, cultural examples, etc., from the standard Collaborative Institutional Training Initiative (CITI) human subjects protection training. Non-academic research staff completed a day-long training in human subjects protection (6 modules) and our research protocol (1 module). We assessed comprehension of content with PowerPoint slides and module quizzes.

Results—All participants successfully passed each module quiz with ≥ 80% correct. Questions answered incorrectly were discussed before proceeding to the next module.

Discussion—To meet the increasing demand for collaborative community-engaged research with underserved minority populations, human subjects protection training protocols can be adapted successfully to reflect real-world situations and provide culturally relevant materials to help non-academic research staff better understand the importance and necessity of research ethics.

Keywords

Community-engaged research; Human subjects protection

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BACKGROUND

All research staff conducting human subjects research in the United States (U.S.), whether supported or not by federal funding, are required by federal mandate to complete some form of responsible conduct of research training as detailed in the 45 CFR 46 or also known as the "Common Rule" (1). For most academic institutions in the U.S., the gold standard human subjects protection training is the Collaborative Institutional Training Initiative (CITI) (2). Others such as the National Institutes of Health's (NIH) Protecting Human Research Participants (PHRP) course are also acceptable (3). Such certificate programs cover the basics of research ethics and protection of human subjects. Using PowerPoint presentations, narrative text, case studies, and quizzes, these programs are developed for individuals with the education and English language capacity to comprehend, complete, and pass the training modules, specifically academics and researchers, graduate students, and research associates. These standard research ethics training modules have been translated into other languages (i.e., Spanish, Japanese, and Korean). However, in community-engaged research, research ethics training issues remain related to cultural and contextual relevance, risks and benefits of research to communities, and areas of confusion to community members engaged in research (4,5). Pearson and colleagues' (5) work with American Indians and Alaska Natives demonstrated that adaptations to human subjects protection training should include issues that are pertinent to ethnic minority communities, references to specific cultures, use of simplified terminology and clarification of concepts, examples relevant to communities (e.g., misuse of data), and topics related to community-level risk and benefits (e.g., discomfort or distress from discussing traumatic events).

Involving communities in research processes is critical for building rapport and trust and for successful research implementation and dissemination (6). Research is now being conducted outside traditional academic settings, and innovative partnerships between community partners and academics are increasing. Community-engaged research approaches, such as community-based participatory research (CBPR) and community-based action research, have been effective in engaging underrepresented minority populations previously excluded from research processes (7,8). A community-engaged research approach is grounded in "mutual interest, need, and respect" (9, p. 1). This approach is based on relationships and involves community members, agencies, and/or people the community values (9). Community is defined as a socially constructed 'unit of identity' in which members share common attributes such as biology, history, interests, values and norms, and/or knowledge of a population (10,11,12). For our paper, community is one connected biologically, in which membership signifies the community into which one is born (e.g., the Lao community) (12). Most importantly, community-engaged research activities such as recruitment and retention, intervention implementation, and dissemination, take place in the community. In addition to CBPR, patient and family engagement is required in comparative effectiveness research funded by the Patient-Centered Outcomes Research Institute (PCORI) (13). Lay persons and community partners are actively involved in the research planning and implementation as key personnel, as well as serving on grant reviews and advisory committees. Community engagement is also strongly recommended by the Council for International Organizations of Medical Sciences (CIOMS) (14). Similar to principles of CBPR, community engagement

early in the research process ensures that the research is relevant and acceptable to the community, as well as contributes to the community's capacity to understand the research process (14).

As the role of community members in research grows, so does concern over the ethical research training they receive (5,15,16). Research in communities may lead to different research ethical challenges than those in traditional academic and clinical settings. For example, underserved populations, with whom much of community-engaged research is conducted, may also experience lower socioeconomic status, education, and literacy, adding to difficulties in trying to understand terminology in ethics training, discomfort completing online training or difficulty accessing the Internet. To ensure understanding of and compliance with research ethics, it is essential to eliminate such barriers and engage underserved populations by using materials appropriately targeted to their needs (4,5). Because community members engaged in research are likely to know research participants as neighbors, friends, business associates, or relatives, maintaining confidentiality and anonymity presents different challenges.

While community research partners must abide by the ethical guidelines required by the federal government, there is less agreement on how to conduct such training and which elements should be included (4). One example is the concern for privacy. In some ethnic groups, a spouse may want to be present during private, one-on-one interviews (17). A community member who is hired to be an interviewer may allow the interviewee's spouse to be present during the interview. This action may be necessary so that the interviewer avoids culturally offending the spouse. For example, the Lao kinship system is traditionally patriarchal, and places strong values on family or communal decision-making (18). The head of the household, often times a male, may make decisions for a woman in terms of medical decisions or in permitting her to participate in research studies on intimate topics (19,20). Non-academic research staff may encounter strain between their role as a community member and their position as part of a research team (15). Although it is possible to navigate these relationships, meeting the expectations of both – community and research – can be challenging and may result in confusion and frustration.

Alternative human subjects protection trainings have been developed to address the needs of community researchers and field research (4,15,21). While these programs address some common themes found in community-based research projects (rules and regulations, informed consent, data/materials management), we found a need for a more tailored approach to encompass the community make-up, language barriers, education level, and interviewer resources for our specific community.

In this paper, we present a case exemplar of the development of a human subjects protection training for non-academic research staff with low English proficiency and limited research experience in a community-engaged study of Southeast Asian women's health in the U.S. The goal of the training was to provide an alternative, culturally relevant human subjects protection training specifically targeting Southeast Asian community research partners.

METHODS

Description of project background

In the summer of 2013, we conducted an exploratory study titled the Southeast Asian Women's Health Project (SEAWHP) to assess Cambodian and Lao immigrant women's knowledge of barriers and facilitators to cervical cancer screening, as well as to examine mother-daughter communication on topics related to women's health issues (Award #R03CA175464-01A1). We hired three bilingual and bicultural research staff from the local Cambodian and Lao community to recruit and consent participants, moderate focus groups, and conduct interviews. Working with the project's Community Advisory Board (CAB), potential research staff from the local Cambodian and Lao communities were identified. The CAB introduced the Principal Investigator (PI; first author) to potential research staff to garner their interest in working on the project. Initially, two Cambodian and one Lao woman were hired. All three of these women were longstanding, well connected, trusted, and respected members of local Cambodian and Lao communities, and spoke English and were fluent in their native language.

All research team members were required to complete the CITI training. After several discussions about what the training entailed (i.e., purpose of training, content, and time required to complete the online training), two of the research staff felt that the training would be too difficult for them to successfully complete. One research staff tried to access the online training, but had challenges operating her computer and setting up a log-in on the website. Thus, she could not begin the training modules. There were no other resources at our university for alternative human subjects protection training.

Development of content

Subsequently, we conducted a literature search for human subjects protection trainings specifically for community members and/or community health workers. There were only a few articles (4,15,21) that provided insight into alternatives for training our research staff at the time. One training was focused on data collection in low-resource settings and only provided a narrative description of the role and expected behaviors of the data collector and basic ethical research principles (21). Other articles provided insight into content that should be considered in research ethics training modules, but the actual training curriculum was either not published at the time of our literature search or only provided a description of their processes to develop a modified curriculum (4,15). None of the trainings were translated into Khmer or Lao, our languages of interest.

Given that our research staff had little or no experience with research, coupled with low English proficiency and education, we felt that developing human subjects protection training was imperative. In Table 1, we outlined challenges and how and why we adapted content for our new training program. We developed human subjects protection training modules based on the CITI training Social and Behavioral Research Modules because CITI was the most common human subjects protection training for NIH grantees and most institutions (2). In addition, the Social and Behavioral Research Modules were most relevant to our exploratory study on health issues among Southeast Asian women. We did not adapt

optional CITI modules that pertained to biological, international, and Food and Drug Administration or Veteran Affairs research. The adapted training modules were written to be relevant to research staff by incorporating scenarios and examples that might happen in community settings with Cambodian and Lao women. By embedding cultural referents from Cambodian and Lao cultures into the content enhanced culturally appropriate delivery (22). Seven modules were created: six on research ethics and one on the study protocol (Table 2). Our human subjects protection training was approved by the Ohio State University Institutional Review Board (IRB). Each module is described below.

Module 1—Basic introduction to research; included descriptions of different types of research, research methods, and the role and responsibilities of research team members. We described the types of research questions (descriptive, difference, relationship), then discussed our study's research questions and what we planned to measure. In addition, we discussed the ways in which data can be collected such as surveys, focus groups, and in-depth interviews.

Module 2—Principles of research ethics, the role of the IRB, and the need for IRB approval. In this module, we clearly described reasons why research ethics are necessary in research with human subjects by providing examples of unjust research performed on specific groups in the past (e.g., Nazi experiments, Tuskegee Syphilis Study). We defined and discussed the importance of respect, beneficence, and justice, as well as defined the IRB and its role in research at the university.

Module 3—Overview of human subjects, vulnerable populations, and coercion. Module 3 covered voluntary participation and avoiding coercion in recruitment activities. Risks and benefits were discussed in the context of research in general, and as it pertained to our study, specifically. For example, participants might face potential stigmatization for participating in a study on a sensitive topic. As such, we discussed how some people in the community might feel that simply talking about cancer might bring on the disease, a belief that some Southeast Asian women have about cancer (23), or that some women may not want others in the community to know that they participated in the study for fear of being stigmatized.

Module 4—Informed consent. This module provided a brief overview of voluntary participation, informed consent, and the specific items to be discussed with potential participants when obtaining informed consent.

Module 5—Privacy and confidentiality. Issues discussed included potential challenges conducting research in a small, close-knit community such as the Cambodian and Lao communities and breach of confidentiality. The group role-played scenarios on dos and don'ts in handling a situation in which a member of the community such as monks, family, and friends, asks about other members who have participated in the study. An example of a scenario on maintaining privacy and confidentiality is presented in Table 3. The PI fully participated in the activities along with research staff and acted out the scenarios with different individuals.

Module 6—Unanticipated problems and reporting requirements. Examples included different types of problems that could arise during the implementation of community-engaged research, such as issues around safety for research staff and participants, or any sort of neglect or abuse that research staff may witness while conducting focus groups in a participant's home. We discussed how to identify unanticipated problems that must be reported to the IRB and what to do when one was unsure if there was a problem (contact one of our research staff). Examples included stolen or lost research materials or equipment and adverse events involving participants (e.g., death or a negative Pap test result after being interviewed by us).

Module 7—Review of study protocol. We reviewed the procedures for recruiting and consenting, administering the baseline questionnaire, facilitating focus groups, distributing participant incentives, and writing summaries (field notes) of focus groups. The PI and research staff discussed in detail each section of questions on the baseline questionnaire and described terms that may be challenging to translate, such as *human papillomavirus*, *hepatitis B*, and *cervix*. Research staff practiced asking each other questions from the focus group moderator's guide. Follow-up discussions about the protocol were conducted with individual research staff as necessary.

Delivery

Three research staff (1 Lao and 2 Cambodian women) attended an intensive day-long training conducted by the PI. The PI presented the training modules on PowerPoint slides, and each research staff received a project binder with slides of all the modules, module quizzes, study protocol, and recruitment (e.g., recruitment flyers, script, and log) and data collection materials (e.g., baseline questionnaire, focus group moderator's guide). Lunch and snacks were provided. At the end of each module, a brief quiz of 3–5 questions was administered by the PI. To assess content knowledge, research staff had to answer 80% correctly to be considered proficient in human subjects protection and ready to participate in the research project. For questions that research staff did not answer correctly, the PI reviewed and discussed the content in the module and answered questions before proceeding to the next module. All three research staff passed the quizzes with at least an 80% correct.

DISCUSSION

Research ethics training is a crucial and obligatory part of conducting research with human subjects and is especially important to consider when working with communities that have limited research experience and English proficiency. Alternatives to standard human subjects protection training programs may be necessary when working with community members unfamiliar with research, difficult to reach, and/or easily marginalized. For our purposes, the training programs in the literature developed as alternatives to CITI and PHRP had the limitation of not providing enough detail for us to use (4,20). Therefore, we developed our own training for our research staff, informed by information gleaned from previous studies. Researchers working in community groups that have no or limited knowledge of research and/or low English proficiency can use this training program as a template.

Our human subjects protection training for Cambodian and Lao research staff presented a unique example of adaptation of the standard human subjects protection trainings into a more culturally relevant and accessible training for community-engaged research. The training emphasized the required guidelines, but gave community members room to provide feedback and work through culturally relevant scenarios.

Locally focused, in-person training, using slides and oral presentations, followed by a question-and-answer period were found to be successful by others (4,24), and is the approach that we used. In-person trainings help develop relationships and communication with the research staff so community members feel comfortable reaching out for clarifications or problem-solving help throughout the study. Locally delivered training programs are more beneficial in community-engaged research because the information presented can be tailored to the trainees' community, knowledge, and practices (24). Culturally adapted scenarios will engage community members to be partners in problem solving.

We recommend that researchers work with their institutional IRB early in the implementation planning process, especially if they anticipate that key personnel may potentially have challenges comprehending and successfully completing the human subjects protection training program. IRB personnel may have resources or look for resources that can help with training research staff. Investigators should also run drafts of research protocol and materials by IRB personnel to obtain constructive feedback prior to submitting the final IRB application. Such anticipatory work will prevent or limit unnecessary delays in starting a study and enable researchers to adhere to human subjects protection guidelines and policies required to maintain essential elements, such as privacy and confidentiality, while culturally adapting the training. Another potential challenge for researchers may be to find a balance between the need to hire individuals with research experience and higher English proficiency who can comprehend and successfully pass the standard human subjects protection trainings or to hire individuals who may be well connected, knowledgeable, and trusted in the community, but may not grasp academic and research concepts quickly. Though it is ideal to hire staff with some research experience, having an individual who is trusted by the community may be more beneficial in the long run in terms of recruitment, enrollment, good will, and community engagement. Individuals can be trained in the research protocol, but an established rapport and trust with community members is not earned through training.

Overcoming the barriers that existing human subjects protection training can present to a community member is one benefit of modifying a training program to incorporate scenarios, information, and training relevant to the trainees' communities and expertise. Because community members do not regularly work in research, they may need additional and ongoing support throughout the project. Access to resources varies, and community members may not have access to computers or the Internet.

Development of human subjects protection training that is culturally adapted is feasible, valuable, and a needed element of community-engaged research (4,7,24,25). A limitation of our training program was that we did not conduct an evaluation of the modules with the

research staff who completed the training. A formal evaluation would better inform content improvement; however, during the training, we did address all questions from research staff regarding research ethics and the study protocol. Further, we only conducted this training with three participants, specifically of Cambodian and Lao ethnic backgrounds. For the field of community-engaged research, our training program is most applicable to minimal risk descriptive and behavioral research in the U.S.

NEW CONTRIBUTION TO THE LITERATURE

In summary, we developed human subjects protection training modules that integrated culturally relevant research ethics scenarios, incorporated teaching methods such as role-playing, and allowed time for discussions and questions to help research staff comprehend content. We found that it was feasible to adapt standard research ethics content and teach it in a way that communities with limited research experience could grasp and use as well as adhere to IRB mandates regarding training on protection of human subjects in research. We also found that ongoing training is important to keep research staff abreast of research protocol and resolve problems experienced in the field.

CONCLUSIONS

Protecting research participants from unethical treatment and violation of rights is a mandated responsibility of all investigators conducting research with human subjects (CITI; NIH). As we increasingly move toward a community-engaged approach to research in underserved minority populations, human subjects protection training protocols must reflect real-life situations that communities may face and provide culturally relevant materials to help community members better understand the importance and necessity of research ethics (4,15). Development of a culturally relevant human subjects protection training is feasible, valuable, and necessary in community-engaged research.

Acknowledgments

We gratefully thank our Community Advisory Board members who have been instrumental in implementing this study. We also thank members of the Cambodian and Lao communities for sharing their experiences with us. This work was supported by Award #R03CA175464-01A1 from the National Cancer Institute; The Ohio State University College of Nursing; and Department of Women's, Gender, and Sexuality Studies. The content is solely the responsibility of the authors and does not necessarily represent the official views of National Cancer Institute or the National Institutes of Health.

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Table 1

Areas of adaptation

Area	Issue	How this was addressed in the modified training
Access	CITI is an on-line training and requires access to a computer and the internet. The amount of time it takes to complete the training varies by individual and may take a committed amount of time to complete.	Delivering human subject protection training in person allowed for immediate questions and clarifications. Scheduling training in person also ensured all research staff could attend and receive the same high quality of training.
Cultural Relevancy	CITI covers a wide range of ethical and educational situations, but does not provide any guidance on culturally specific situations specific to our study participants (e.g. engaging with community elders, gender relations, or how to address culturally taboo topics).	Adapting the CITI training to include culturally relevant topics both provided research staff with solutions to anticipated problems within their community, but also important context into why ethical training is important. By adapting the material into a culturally relevant training we were able to effectively and efficiently deliver the information and better ensure adherence due to greater team member understanding.
Limited English Proficiency	CITI uses research and academic jargon which requires higher level of English proficiency to comprehend and successfully complete the training.	Adapting the CITI training to better reflect a more appropriate reading and cognition level for limited English proficient research staff allowed for better understanding and adherence. Training in which research staff could understand, engage, and apply was key in our adaption.
Research Experience	CITI provides ethical training on research with the assumption that those participating in the training are familiar with the basic terminology, process, and goals of scientific research. There is no adaption for research staff who are not familiar with scientific research or have any experience.	In-person training with research staff allowed for the trainer to gauge the level of understanding of basic research concepts CITI assumes participants possess. Research staff with little or no research experience can better understand ethical research principles when concepts were broken down and explained from a more basic level and in-person.

Table 2

Human subjects training program module description for the Southeast Asian Women's Health Project (SEAWHP)

CITI Social and Behavioral Research	SEAWHP Project Staff Training Modules
Populations in Research Requiring Additional Considerations and/or Protections (Optional)	*Module 3 Protection of Human Subjects:* Define human subjects and vulnerable populations. Describe voluntary participation. Explain coercion and ways to avoid it. Identify how to assess physical and psychological risks. Activities included role-play and discussions using cultural examples.
Introduction	*Module 1 Introduction to Research:* Describe types of research, research methods, roles, and responsibilities of research team members.
Belmont Report and CITI Course Introduction (Optional)	*Module 2 Principles of Research Ethics:* Explain the importance of respect, beneficence, and justice. Describe the Belmont Report and discuss case studies.
Students in Research (Optional)	Not Covered
History and Ethical Principles	*Module 2 Principles of Research Ethics:* Describe the development of research ethics. Provide historical examples.
History and Ethics of Human Subjects (Optional)	*Module 2 Principles of Research Ethics*
Defining Research with Human Subjects	*Module 1 Introduction to Research*: Describe types of research.
Federal Regulations	*Module 2 Principles of Research Ethics:* Describe regulations developed for protection of human subjects.
Basic Institutional Review Board (IRB) Regulations and Review Process (Optional)	*Module 2 Principles of Research Ethics:* Describe the role of the IRB and why the IRB is necessary.
Assessing Risk	*Module 7 Project Protocol:* Discuss risk and benefits in the section on obtaining informed consent.
Informed Consent (2 modules, 1 optional)	*Module 4 Informed Consent:* Define informed consent, describe consent form, and review consent process.
Privacy and Confidentiality	*Module 5 Privacy and Confidentiality:* Define privacy and confidentiality. Describe ways to protect personal health information. Describe HIPAA. Define breach of confidentiality and identify situation when confidentiality is breached.
Social and Behavioral Research (SBR) for Biomedical Researchers (Optional)	Not Covered
Records-Based Research	Not Covered
Genetic Research in Human Populations (Optional)	Not Covered
Research with Prisoners	*Module 3 Protection of Human Subjects*
Vulnerable Subjects-Research Involving Prisoners (Optional)	*Module 3 Protection of Human Subjects*
Research with Children	*Module 3 Protection of Human Subjects*
Vulnerable Subjects-Research Involving Children (Optional)	*Module 3 Protection of Human Subjects*
Research in Public Elementary and Secondary Schools	*Module 3 Protection of Human Subjects*
Vulnerable Subjects-Research Involving Pregnant Women, Human Fetuses, and Neonates (Optional)	*Module 3 Protection of Human Subjects*
International Research	Not Covered
International Studies (Optional)	Not Covered
Internet-Based Research	Not Covered
FDA-Regulated Research (Optional)	Not Covered
Human Subjects Research at the VA (Optional)	Not Covered
Research and HIPAA Privacy Protections	*Module 5 Privacy and Confidentiality*

CITI Social and Behavioral Research	SEAWHP Project Staff Training Modules
Vulnerable Subjects- Research Involving Workers/Employees (Optional)	*Module 3 Protection of Human Subjects*
Hot topics (Optional)	Not Covered
Conflicts of Interest in Research Involving Human Subjects	*Module 6 Unanticipated Problems and Reporting Requirements:* Discuss different types of problems that may arise. Identify unanticipated problems that need to be reported. Describe ways to report to the IRB and what do when unsure. Activities include role-play and discussions using cultural examples.
VA Module (Optional)	Not Covered
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research	*Module 6 Unanticipated Problems and Reporting Requirements*

Table 3

Scenario on maintaining privacy and confidentiality

Person 1: Hey, [insert name], it's nice to see you again!
Person 2: Hi, [insert name].
Person 1: So, Toc told me about your interview with her last night and she mentioned that you had asked her a lot of questions about cancer and STDs.
Person 2: Well, [insert name] I can't discuss that with you. As a researcher, it's my responsibility to make sure that the identity of the people who I speak with is kept private. What they tell me is confidential information. I'm sorry, but I can't talk to you about who participated in this study.
Person 1: It should be okay, right? I mean…it's just between you and me. We're friends. Besides, I was just curious what you said to her. Toc told me that she was so tired and didn't want to continue, but she felt that she had to finish the interview with you.
Person 2: You know, I really can't tell you anything. However, I can tell you that if you are a participant in a study and you wish to stop the interview, you have the right to do so.