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Engaging Institutional Review Boards in Developing a Brief, Community-Responsive Human Subjects Training for Community Partners

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Abstract

BACKGROUND—Engaging community partners as co-investigators in community-based participatory research (CBPR) requires certification in the rules, ethics, and principles governing research. Despite developments in making human research protection trainings more convenient and standardized (e.g., self-paced Internet modules), time constraints and the structure of the content (which may favor academic audiences) may hinder the training of community partners.

OBJECTIVES—This paper is motivated by a case example in which academic and community partners, and stakeholders of a community-based organization actively engaged the leadership of a pediatric hospital-based Institutional Review Board (IRB) in implementing a brief, community-responsive human subjects training session.

METHODS—A two hour, discussion-based human subjects training was developed via collaborations between the IRB and the community and academic partners. Interviews with trainees and facilitators after the training were used to evaluate its acceptability and possible future applications.

CONCLUSIONS—Local Institutional Review Boards have the potential to assist community partners in building sufficient knowledge of human subjects research protections to engage in

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specific projects, thereby expediting the progress of vital research to address community needs. We propose the need for developing truncated human subjects education materials to train and certify community partners, and creating formally organized entities within academic and medical institutions that specialize in community-based research to guide the development and implementation of alternative human subjects training certification opportunities for community partners.

At the core of community-based participatory research (CBPR) approaches are the development of equitable community-academic partnerships and co-ownership of data and results [1–4]. Achieving equitable partnerships requires significant investment in mutual training and skill-building. Whereas some skills and knowledge can be shared through ongoing collaboration, the transmission of other skills and knowledge, such as those concerning research ethics, are more time sensitive and can pose a potential obstacle to the beginnings of CBPR projects. Before research activities can take place, all members of a team must achieve certification in the protection of human subjects through adequate training, particularly if they are to be involved in recruitment, consent/assent of participants, data collection, and analysis.

One method often pursued to expedite research education for academic and community research partners alike is online training in the protection of human subjects. Online trainings, such as via the University of Miami online Collaborative Institutional Training Initiative (CITI; www.citiprogram.org), are self-paced, can be completed anywhere there is Internet access, and provide a standardized certification experience that is recognized across many institutions. However, online trainings may not be “community responsive” because some training modules still require several hours to complete, the trainings may be written in language that assumes familiarity with research terms and methods, and the modules may contain information on research procedures and requirements that are not germane to the specific research project under consideration [5].

This paper was motivated by a real example in which the academic and community partners worked with an institutional review board (IRB) to achieve human research protection training certification for a short program evaluation project. The collaboration between the community and academic partners began after they met at a community health center forum focused on programs and research addressing lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth health disparities. The community partners approached the academic partners with a desire to evaluate the effects of their arts-based youth program on the mental health and self esteem of LGBTQ youth. As joint principal investigators, the community and academic partners secured a small pilot grant to support the evaluation efforts. The project was funded for one year only, thus creating fiscal and time constraints that necessitated a quick training. This process paper describes the development of a brief human subjects training for community partners engaged in CBPR projects. Quotations from brief follow-up interviews and e-mail correspondence with all 8 of the community partners who attended the training are provided as appropriate as a means of bolstering the rationale of the training and evaluating the training’s success and potential future applications.

Development of the Training

Upon receiving funding for the project the academic and community partners discussed the rationale and purpose for human research protection certification and introduced CITI as training system utilized by the academic institution. The community partners understood the value of the certification process and the need to devote adequate time to understanding the history of human subjects research, ethical principles and regulatory requirements. One community co-investigator recalled:

> I had just finished reading a really powerful story about Henrietta Lacks in [*The New York Times*]. Doctors had taken cells from her cervix without her consent. Her cells contributed so much to science… and nothing was really given back to her or her family. That gave me a little bit more context for why we had to do the training before we could begin anything in this project.

Based on the short timeline of the evaluation project, it was readily apparent that having the community partners complete the training around their busy schedules (which often included schoolwork and part time jobs in addition to their work with the CBO) would make it difficult to meet the project deadlines. The team briefly considered an option whereby the academic partners could guide the community partners through all aspects of the online training step-by-step, but as one community research assistant said, “it would have been hard to know what to do on [CITI] without you sitting with us and talking us through step by step, and even that would have taken a really long time.”

Fortunately, the academic institution (Boston Children’s Hospital) had an office dedicated to community health, and a newly formed Center for Collaborative Community Research (C-CORE; http://www.childrenshospital.org/research-and-innovation/research/centers/center-for-collaborative-community-research) to provide assistance in the development and implementation of a alternative human research protection training for the community partners. C-CORE is aimed at reducing childhood and adolescent health disparities through pediatric hospital, public health, school, and community health center partnerships. Although not all institutions may have an equivalent to C-CORE, researchers should consider working with community health or community outreach liaisons at their institutions when planning CBPR projects, navigating the IRB approval process, and organizing human subject protection trainings for community partners. The presence of the community health office and C-CORE was a boon to the team because the staff in these offices were aware of previous instances in which CBPR and community-engaged research projects were delayed or had to be modified due to required ethics training certification. This provided the research team with actual cases to present to IRB staff and to make a stronger case for why alternate pathways towards certification were needed.

The IRB director and staff were responsive to our request and recognized that developing a brief training could also aid future researchers using CBPR approaches. To create a tailored training, the academic partners shared with the IRB the funded grant proposal and working drafts of the IRB application, and had two meetings to discuss potential adverse events and the design of the safety plan. In addition, e-mail correspondence between the IRB, academic partners, and community partners were used to develop training materials to address

potential issues that could arise in data management and engaging participants in the community space. Working closely with the IRB helped to refine the language of the consent and assent forms and scripts, and devise additional systems of maintaining confidentiality in the face of potential adverse events (e.g., disclosure of suicidal ideation, exposure to domestic violence) prior to submitting the application for IRB review.

The IRB also consulted with staff at affiliated schools, specifically Harvard T.H. Chan School of Public Health and Harvard Catalyst (an institution-wide clinical and translational science center) to create a one-time, 2-hour-long training that reviewed the basics of human subjects protections, their history, and vignettes that were focused on situations that could arise in the current study. The workshop was ultimately led by staff from Harvard T.H. Chan School of Public Health, attended by both the academic and community partners and the director of the Boston Children's Hospital IRB, and was held in the office of the CBO. Table 1 contains the key components of the training, the content covered under each component, and questions that guided the discussion with the community partners. Because of the tailored nature of the training, the IRB director made clear that the certification received by the community partners was conditional to this one project. If the community partners became investigators or research staff on another project or at another research institution, they would have to confer with the appropriate IRB staff about required trainings and possibly complete online or in-person modules to meet institutional certification requirements. However, one of the goals of the training was to build a knowledge base that might make any subsequent trainings easier to comprehend and accomplish.

Training Components

As displayed in Table 1, the training was focused on six sets of questions that map onto components generally reviewed in basic human research protection certification. In contrast to online trainings, which primarily provide web content to review and quizzes, the current training was primarily focused on learning material through discussion. The first five components reviewed (1) the definition of human subjects research, (2) the meaning and origins of ethics and federal laws to protect research subjects, (3) ethical responsibilities of researchers (and community partners, specifically), (4) the purpose of IRBs and IRB review, (5) and issues with obtaining informed consent and youth assent. The third component in particular was focused on making the training community responsive by recognizing that academic and community partners have different areas of expertise and different relationships with research participants. Attendees had multiple opportunities to compare and contrast their role as youth workers and their roles as research assistants and co-investigators.

The discussion format helped to crystallize the importance of ethical and regulatory obligations for confidentiality and participant safety, as well as to help the community partners see how their current experiences and procedures overlapped with what would be expected of them as members of the research team. As one community research assistant noted:

> We talked a lot about confidentiality. That was a little hard, because we usually talk a lot about each other and the troupe members in the program... During the training,

> it was useful to think about [confidentiality] and compare anything that was shared in this study to something like coming out. If a friend came out to you as gay, you wouldn't go and tell other people that this person is gay. When we're doing research with [the youth] we can think about what they say as 'coming out', so we wouldn't share this with anyone else. It was also helpful to know that we can talk with other members of the research team if we just HAD to talk about something we heard in an interview.

The final component of the training was focused on special considerations when involving adolescents in research, with a focus on discussing vignettes that were based on potential events and issues (e.g., adverse events) that could arise in the current study. This was particularly helpful when discussing the procedures of the safety plan. One community co-investigator remarked,

> [When a youth is potentially suicidal] we usually invite the youth in for a private meeting with us and make sure they're in a safe place, that they know whom they can reach out to, and that they have a plan for what they can do. But most of all I just make sure I give them support.

In the context of the training, the team was able to discuss why they would be required to take additional steps to ensure the safety of the research participant if needed, such as taking the youth to the emergency room or engaging in mandated reporting procedures. This discussion prompted the team to review and make further changes to the safety plan, with IRB staff input, so that the team could create a plan that satisfied to concerns of the multiple investigators and stakeholders.

At the conclusion of the workshop, the participants in the training reflected on how the training and discussions reiterated the strengths of the CBPR approach. By discussing how they would respond to a situation, they were able to highlight the complementary areas of expertise among the community and academic partners, and understand the commonalities of their interests in protecting the youth-- both as valuable participants in research and as thriving program participants. A common thread of the final discussion was the need for reciprocal support throughout the research project. Community partners could rely on the substantial knowledge of the academic partners when questions of research process and ethics arise, and academic partners could rely on community partners for guidance about how to engage participants in research without interfering with their regular program participation and support-seeking. Involving the IRB in the course of creating the training also reassured the team that the IRB was just as much a facilitator as a regulator of the research process.

Outcomes from the Training

All of the community partner attendees reported that they enjoyed the training. In particular, they noted that they benefited from the opportunity to ask specific questions about how human subjects research regulations apply to the current research project. The community partners appreciated the basic nature and shorter duration of the training, which was respectful of their current skills and knowledge of research and their limited availability. The training was delivered at the CBO and certified all the community partners within 2 hours,

thus evincing its convenience and efficiency. One strength of the workshop was the ability of the trainers to include vignettes that assisted the team in learning the ways in which research regulations apply to the specific study at hand. Because the training can be easily tailored to include vignettes that apply to a wide range of vulnerable populations (e.g., incarcerated youth) and research designs, this training should be tested as an education alternative for CBOs engaged in other research projects. Since the development of the training for this project, Harvard Catalyst has created a guide ("Community Partner Human Subjects Training Guide," available by contacting regulatory@catalyst.harvard.edu) to structure future implementations of the training and to serve as a model for other institutions who are interested in alternative methods for training community partners in human research protections.

Although the training was deemed sufficient by the Boston Children's Hospital IRB to certify the community partners for their roles as investigators and research assistants on the current project, this certification was not transferable to other institutions. However, the brief training may be a reasonable alternative for achieving certification for community partners in one-time projects, or projects requiring the mobilization of a large staff for recruitment, consent/assent, and data collection. The team suspected that the in-depth discussion during the workshop, coupled with the practical experience conducting research in the current study, would provide a strong knowledge base to assist the community partners in completing subsequent ethics training if needed in the future. Approximately 6 months after the training, one attendee accepted a position at a community health center as a research assistant. Although the community health center did not accept his certification and he had to complete several CITI training modules, he noted, "It was easier to do the CITI training because I could think about some of the examples we discussed." In addition, one of the community research assistants from the current project has since become a research assistant on a subsequent project with the team. Because of the overlap in study content areas, the IRB recognized the previous training as meeting the ethics certification.

Discussion

Fiscal and time constraints and the presence of less relevant or arcane subject matter can delay the process of having community partners complete standardized human subjects research training requirements. This process paper describes a potential pathway to achieving research ethics certification through an efficient, well-tailored, community responsive approach. The resulting training program contributes to other emerging curricula to educate and certify community partners to become engaged in CBPR projects. Notably, Spencer-Hwang and colleagues developed a similar, 4-hour-long training program to certify co-investigators from a CBO for an environmental health study.[5] The current training expands upon this work by demonstrating that community partner trainings can be brief (e.g., 2 hours), yet still provide adequate discussion and consideration for the complexities of research with vulnerable youth populations.

Components from the current training are provided as a means to spark new discussions and research into the use of such methods in the development of CBPR partnerships. Brief trainings may be well suited to CBPR projects because they facilitate quick certification for

community partners who may only ever be engaged in a limited number of research projects, and an efficient means of training a large number of community partners under time constraints. Two factors facilitated the development of an alternative path to research ethics certification for community partners: (1) working directly with IRB officials at all stages of the IRB application and submission process, and (2) having a community liaisons office at the academic institution. The team recommends that other researchers work with their IRBs to devise abbreviated research ethics trainings for community partners in order to reduce barriers to CBPR projects. *The Harvard Catalyst Community Partner Human Subjects Training Guide* can be used as a basis for the development of such trainings [6].

The team's efforts were heavily scaffolded by C-CORE at Boston Children's Hospital. Having a dedicated entity that is focused on CBPR within a research institution can be a major asset to investigators who are interested in conducting health research with vulnerable populations. In place of an actual center for CBPR, having a formally organized network of CBPR researchers within or across institutions, or developing a community-academic advisory board could fulfill a similar purpose, prevent information silos, and help to lobby for alternatives to standard research ethics trainings. It is important to note that such abbreviated trainings may not be considered a substitute for the extensive substantive material and knowledge testing encountered in established online training mechanisms, such as CITI. It was thus not surprising that one community research assistant who attended the brief session was required to complete CITI training before assisting with other research projects at a different institution. However, in this particular case, the brief training provided adequate background knowledge to expedite the completion of the standardized, full online training.

Standardized research trainings cover the broad range and scope of issues and dilemmas that academic investigators and staff may encounter throughout multiple projects or their entire careers. By contrast, brief, topical trainings may be more consistent with the reality that many CBOs are primarily concerned with serving their priority populations, and may only be engaged in a limited range of research and evaluation studies [1,7]. The flexibility of brief trainings means they can be easily tailored to the content of the research collaboration, which allows for a more critical discussion and consideration of issues that community and academic partners are most likely to encounter. Whereas web-based trainings focus on the development of individual knowledge, brief trainings can help to clarify and synergize the contributions and strengths of the academic and community partners. Through discussions of vignettes, academic and community partners can assess how their differing approaches to logistical and human research issues can be respected and integrated in practice.

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Table 1

Training Components of the Brief Harvard Catalyst Workshop to Train Community Research Partners in Research Ethics

Question Addressed	Training Content	Discussion Questions
1. What is human subjects research?	• Definitions of research and human subjects • Review of study designs	• What is the design of the current project? • How are data being collected?
2. What do we mean by ethics and ethical conduct? Why do we have federal guidelines in order to protect research subjects?	• Definition of ethics and discussion of values (personal, community, society, federal) • Federal and institutional structures that regulate research (i.e., Dept. of Health and Human Services, Office for Human Protections Research, other federal agencies, Institutional Review Boards) • History of how rules were developed (e.g., Nazi experiments, Tuskegee Syphilis Study) • Recent tragedies generating distrust of research • Historical documents underlying current guidelines (e.g., Belmont Report)	• What are your experiences with research? • What are your communities' experiences with research? • What are common perceptions about research?
3. What are my ethical responsibilities as a community partner?	• Belmont Report principles	• What is the mission of your organization with respect to youth? • In what ways does the research fit/not fit with your mission? • What can we do to ensure that the research conforms to the principles of the Belmont Report and that it does not violate the mission of the organization? • What risks and benefits does the current study pose?
4. What is an Institutional Review Board (IRB)?	• IRB structure, responsibilities, and membership • Definitions of vulnerable populations and conflicts of interest • Components of an IRB application	• Are there any potential conflicts of interest? How can you manage potential conflicts of interest? • Are the youth in the organization members of vulnerable populations? • What information is required and what design decisions need to be made in order to complete the IRB application?
5. What is informed consent/ assent, and why is it necessary?	• Definitions and distinctions between consent and assent, minors and adults, and initial and ongoing consent • Rationale for components of a consent and assent form • Connections between consent/assent and Belmont Report • Definition of confidentiality • Adverse events and safety plans	• What information is the minimum information required in order to sufficiently obtain informed consent or assent for this study? • Is it possible to obtain waiver of parental consent for this study? • What unique issues regarding confidentiality may be faced by participants in this study?

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Question Addressed	Training Content	Discussion Questions
		• What are potential adverse events, and what systems are in place to prevent adverse events and support participants if such events occur?
6. What are special considerations when involving adolescents in research?	• Vignettes based on potential events and issues that could arise in the proposed study (e.g., disclosure of potential suicidality; protecting information about a youth's sexual or gender identities in the face of a parent's inquiry about the study)	• Sharing of how the academic and community partners would each respond to the vignette, and a discussion of how academic and community partners can work together in response to the issues raised in the vignette

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