Piloting a Nationally Disseminated, Interactive Human Subjects Protection Program for Community Partners: Design, Content, and Evaluation

Stephanie Solomon, Ph.D.[1], Brenda Eakin, M.S.[2], Rosalind Kirk, Ph.D., C.Q.S.W.[3], Patricia Piechowski, M.P.H., M.S.W., M.A.[4], and Barbara Thomas, Ph.D., M.S.W.[3]

Abstract

Funders, institutions, and research organizations are increasingly recognizing the need for human subjects protections training programs for those engaged in academic research. Current programs tend to be online and directed toward an audience of academic researchers. Research teams now include many nonacademic members, such as community partners, who are less likely to respond to either the method or the content of current online trainings. A team at the CTSA-supported Michigan Institute for Clinical and Health Research at the University of Michigan developed a pilot human subjects protection training program for community partners that is both locally implemented and adaptable to local contexts, yet nationally consistent and deliverable from a central administrative source. Here, the developers and the analysts of this program discuss its development, its content, and the results of its evaluation. Clin Trans Sci 2014; Volume 7: 177–183

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Introduction

Today, more and more research involves academic researchers and community members as full partners.[1–3] In addition, research projects increasingly take place in nonacademic settings including health clinics, schools, community centers, and even individuals' homes.[4–6] Community members doing research in community settings face ethical challenges significantly different from those encountered by academic researchers in clinical and laboratory settings[7–11] or even academic researchers in community contexts.

Meanwhile, national mandates from federal agencies and funding sources increasingly require investigators to take part in human subjects protection training programs.[12,13] The research community needs relevant training programs in response to new demands and in order to adapt to the ever-changing and more complex realities of research in the modern world. Academic institutions struggle to provide education to diverse groups in diverse contexts implementing diverse forms of research, often well beyond what is envisioned in the mandates.

Community research partners typically fall under the purview of the requirements of Institutional Review Boards (IRBs), Conflict of Interest Committees and regulations for federally funded research, that frequently require training in the basic elements of human subjects research as well as more general issues of responsible conduct of research and good clinical practices. Meanwhile, they must also act in accordance with their community-based organizational missions as well as community norms and practices.

Existing training programs in human subjects protections provided to community partners generally fall into one of two problematic camps. Either community partners are given the same online training program that has been developed for academic researchers or they are provided with a burdensome and time-consuming local program that is both expensive and frequently lacks recognition by academic institutions' IRBs.[14,15] Neither of these options meets the real needs of community partners or the spirit of the mandates to improve the ethical behavior of those conducting research.[15]

A team at the Michigan Institute for Clinical and Health Research (MICHR), the University of Michigan unit supported by a Clinical Translational Science Award (CTSA), undertook the challenge to address this problem. The goals of the training program were to increase community partners' awareness of, and competency in, the conduct of ethical human subjects research. Although numerous training programs (both online and in person) are currently being developed for community partners with these goals, this training was designed to be unique in several ways. First, it was designed to be both implemented locally and responsive to local community needs, as well as nationally consistent and deliverable from a central administrative source. Second, developers included an evaluation strategy to assess the training. The piloting process involved the development and administration of participant surveys including pre- and posttest instruments to assess participant knowledge of ethics and collect demographic data, as well as facilitator surveys.

An integral evaluation strategy is essential to assess the effectiveness of a training program and to provide valuable information for ongoing improvements to its implementation and content. Although resources were not available to develop and implement a fully comprehensive evaluation strategy (e.g., including measurement of longitudinal outcomes and using a comparison arm), evaluation was viewed as an essential component of this training program's development and implementation from the start.

Methods

Developing content

The initial training program was developed and implemented by two of the authors (Solomon and Piechowski) as a local, face-to-face workshop that was delivered three times to different

[1]Albert Gnaegi Center for Health Care Ethics, Saint Louis University, Saint Louis, Missouri, USA; [2]Translational Research Programs Instructional Designer, University of Michigan, Ann Arbor, Michigan, USA; [3]Michigan Institute for Clinical and Health Research, University of Michigan, Ann Arbor, Michigan, USA; [4]Community Engagement Coordinator, Michigan Institute for Clinical and Health Research, University of Michigan, Ann Arbor, Michigan, USA.

Correspondence: S Solomon (solomon2@slu.edu)

For further inquiries and/or access to the training, please contact Patricia Piechowski M.P.H., M.S.W., at kwikwi@umich.edu.

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audiences of community partners representing community organizations in Flint, Ypsilanti, and Detroit Michigan. The program included three 60-minute modules. Content for each module was originally selected based on existing online human subjects protection programs, and then adapted for an audience of community partners in consultation both with local IRBs and with feedback from local community partners.[16] A pre-post test was developed and implemented for this initial training program and its results analyzed to evaluate basic demographic information and assess the knowledge the participants gained.

Building on the lessons learned from the initial workshop and through the support of a CTSA supplement, the ethics training modules were refined and adapted into a packaged program that could be distributed nationally while still being implemented locally in much the same way that the workshop had been delivered initially. The redesigned program included four modules intended for sequential use, each one building on concepts introduced in previous modules. Knowledge and skill-building activities were added throughout the program and were presented in a highly interactive, participatory, and engaging format. The original third module that focused on informed consent was divided into two modules at this stage enabling inclusion of an interactive activity designed for participants to apply and practice their newly acquired knowledge regarding informed consent.

Materials included in the workshop package were designed to be self-explanatory and easy for both facilitators and participants to use. In addition to the original workshop materials, the adapted program included an implementation manual, four facilitator guides (one for each module), nine short prerecorded lecture videos, and one train-the-facilitator module that included a 15 minute video as well as printed materials. The program package also included an expanded and adapted evaluation instrument intended to assess the effectiveness of the program in training facilitators and increasing knowledge for participants.

The adapted program was designed to be relevant and appropriate to community members. Using the principles of adult learning theory, the program was adapted with recognition that adult learners 1) need to know why they are learning something before they learn it, 2) prefer to learn both theoretically and practically, and 3) are motivated in participatory and active learning contexts.[17–19] The program begins with a module that characterizes current human subjects protections in the context of the history of research abuses (why they are learning this), discusses both the definitions of key concepts in human subjects protections and how they manifest in community contexts (theoretical and practical), and also includes numerous interactive activities such as case-studies, videos, brainstorming, role plays, and discussion groups (participatory and active learning).

An implementation manual was developed to prepare those who would be implementing, adapting, and monitoring the program. The implementation manual explained the core concepts and key characteristics of each module and guided the collection of process and outcome evaluation data. *Core concepts* are elements of the program that must not be altered in order to maintain fidelity and ensure the program's success. This program included five core concepts: 1) incorporating real-life experiences of community partners to illustrate concepts, 2) incorporating activities to increase knowledge and self-efficacy regarding the elements of informed consent, 3) modeling and practicing the steps in obtaining informed consent, 4) building skills in assessment and problem solving regarding potential participants' ability to understand research participation, and 5) utilizing small groups to facilitate high levels of participation, skills practice, and interaction. Participating CTSA sites and their community partners were instructed not to alter, delete, or add to the program's core concepts.

Module 1	
Group introductions	Activity
History of current human subjects protections	Lecture
Belmont Principles	Activity
Recognizing unethical treatment	Activity
Module 2	
Recruitment	Lecture
Why do people feel pressured to participate in research?	Activity
Enrollment	Lecture
What is research?	Activity
Risks and discomforts	Lecture
Risks and benefits of research	Activity
Privacy	Lecture
Strategies to protect privacy	Activity
Do participants *really* know what your study is about?	Activity
Vulnerable populations	Lecture
Who is vulnerable?	Activity
Module 3	
Practice with informed consent	Role Play
Module 4	
Voluntary participation	Activity
Community partner role in the IRB process	Lecture
Communication plans	Activity
Unanticipated events and potential harm	Activity
Conflict of Interest	Lecture
Conflict resolution	Activity
Putting it all together	

Table 1. Overview of curriculum.

Key characteristics are elements of the program that can be adapted and modified without altering the outcome of the program. Modifications to key characteristics can be made to fit the needs of each individual audience. Portions of the training program that could be modified were clearly identified. Some activities included in the modules were recommended but not required. These were clearly marked in all program materials as optional. Additional areas for adaptation included flexibility with meeting times and places, number of participants per group, number of facilitators needed (a minimum of two facilitators per group of 10 or more was recommended), use of prerecorded videos or reading background material, and case studies adapted for particular groups or situations. Facilitators were encouraged to implement the program content with a high level of fidelity, but were also encouraged to adapt key characteristics to be most appropriate to their communities. An overview of the program curriculum is shown in *Table 1*.

To help facilitators present program content in a consistent and concise manner, facilitator guides were created for each of the four modules. These guides provided facilitators with all the instructional materials needed to facilitate the program. Each facilitator guide was structured in the same way with a description of the goals for each activity, a list of learning objectives, a list of materials and preparation needed, time required for each activity, as well as detailed descriptions of the activities including step-by-step instructions, case-study examples, and discussion guides.

Each module also included short lectures that introduced key concepts or provided background material for activities. These could be delivered from a script and PowerPoint slides or by using prerecorded videos. Both options were provided to the pilot sites. The purpose of the videos was to help facilitators across a variety of implementation contexts present information critical to the program in a consistent and engaging manner. The videos were narrated from the script and included animation, photographs, and graphics to illustrate concepts. All videos were short (less than 7 minutes long) and were accessible in mp3 format or on a secure YouTube channel.

Recruitment and delivery

This program was created at a CTSA-funded institution and utilized the CTSA network to initially recruit 11 sites across the country to participate in piloting the program. Collaborating sites were primarily located due to existing relationships among Community Engagement and Research Ethics Cores throughout the CTSA Consortium. Some new partnerships were developed through e-mail and phone conversations stating the specific aims of this project and gauging interest to serve as a pilot test site. Once interest was expressed, a phone meeting was held with collaborators at each site to discuss partnering. Due to IRB delays at one site and implementation with a nontarget population at another, data from nine sites were used for this study.

Each site's collaborators were responsible for choosing their facilitators, and we did not specify any particular role that facilitators must hold. Collaborators were asked to select facilitators who were knowledgeable about good research practices, had a background in health/ethics education or community-engaged research, and had good interpersonal skills. Beyond these skills, we hoped that success depended on facilitators who were properly trained by our materials to present information in a manner that maintained fidelity to the core concepts while being able to accurately adapt program materials to a particular community or need. Some collaborators became facilitators themselves, while others selected colleagues from their institution who met the recommended criteria.

Local facilitators were a key component of this program. To assist in facilitator training, train-the-facilitator materials were created to provide in-depth instruction on how to implement the training program. These included a written training guide and a 15-minute video that provided instruction on using the program materials, demonstrated the role-play activity, and introduced techniques for successful group facilitation.

Similarly, we left it up to our site collaborators to decide how to recruit participants. Participants were recruited at each CTSA site in a manner appropriate to their specific community partners. Some sites used flyers and distributed them through their networks. Some used verbal communication to gauge interest. Others used existing events and trainings already scheduled as a platform for implementation.

We made all materials for the training workshop available to the facilitators online. After gaining access to the program materials, facilitators were offered multiple opportunities for face-to-face facilitator trainings via webinar to assist them in implementing the program. Sites were enrolled in the pilot in a rolling admission cycle with webinar training occurring at multiple times throughout the pilot test cycle. After facilitators from a site attending the training webinars, collaborators at that site were instructed to implement the program within 4 months.

In addition to training on the delivery of the program, we provided guidance on evaluation including the administration of the written survey instrument to participants. The completed surveys were returned using conventional postal delivery.

Evaluation

The evaluation comprised two main components, the first of which is the focus of the following analysis.

1. Participant feedback on process, content, participation, and facilitation and the pre-/postknowledge assessment.
2. Facilitator feedback on process, content, and participation (see Solomon et al, this volume).

Both groups provided demographic data.

Study sample

A *participant* was defined as a person who joined in at least part of the training and was present to complete the pre/post written test at the appropriate time.

A facilitator was defined as a person who implemented the training. Facilitators were identified by collaborators at each site and provided a retrospective survey and other feedback.

Instrument for participants

Participant feedback was collected using a survey instrument administered before and after the training program. The instrument included 21 closed and two open-ended questions administered before the training and 14 closed and four open-ended follow-up questions administered after training. Both instruments included identical knowledge-based multiple-choice items on five topics: the Belmont Principles, Vulnerable Populations, Communicating with Research Participants, Choosing Appropriate Research Participants, and Reporting to IRBs. Participants were given a choice of multiple correct and incorrect answers and an "unsure" option. They were asked to indicate the correct answer(s).

In addition to tracking changes in knowledge, participants were also asked initially about their demographic background (e.g., race/ethnicity, gender, educational attainment, current employment status, age, and research experiences). The postinstrument included items that assessed perceptions about the benefits of the training, the program content, materials, facilitation, and convenience as well as intended behavior changes.

Analyses

All completed surveys were mailed to the University of Michigan where the data were collated and input for analyses. Descriptive statistics were used to compare participants' demographics, background, and perceptions of participation. Correct and incorrect answers to each of the knowledge questions were scored and a mean score calculated for each knowledge question at pre and post. Changes in mean scores for each item were then compared.

Demographics	Participants N = 153	Facilitators N = 16
Gender		
Male	43 (31%)	5 (31%)
Female	94 (69%)	11 (69%)
Age		
20–29	22 (15%)	3 (19%)
30–39	33 (22%)	3 (19%)
40–49	32 (21%)	5 (31%)
50–59	45 (30%)	4 (25%)
60–69	12 (8%)	1 (6%)
70 years or over	6 (4%)	0 (0%)
Race/Ethnicity		
Caucasian or white	53 (38%)	9 (56%)
African American or black	76 (54%)	5 (31%)
Asian/Pacific Islander/Native Hawaiian	6 (4%)	0 (0%)
American Indian or Alaskan Native	1 (1%)	0 (0%)
Multiracial	5 (4%)	1 (6%)
Other	2 (1%)	1 (6%)
Hispanic/Latino		
Yes	16 (11%)	0 (0%)
No	124 (89%)	16 (100%)
Education		
Some high school or HS graduate	7 (4%)	0 (0%)
Some college	31 (21%)	3 (20%)
Bachelor's degree	26 (18%)	1 (7%)
Some graduate education	10 (7%)	0 (0%)
Master's degree	54 (37%)	6 (40%)
Doctoral degree	17 (12%)	5 (33%)

Demographics	Participants N = 153	Facilitators N = 16
Participants Only		
Employment		
Community-based organization	80 (56%)	
Faith-based organization	11 (8%)	
Government	20 (14%)	
University	32 (22%)	
Other	21 (15%)	
Research roles (N = 88)		
Investigator	16	
Research assistant/coordinator	14	
Participant	13	
Data collection	12	
Community partner	3	
Research team member unspecified	28	
Observed or participated in ethically problematic research behavior		
Yes	34 (28%)	
No	71 (58%)	
Unsure	18 (15%)	
IRB involvement/role (multiple answers possible)		
Study author/Role on proposal submitted to IRB	48 (62%)	
Internal member of an IRB	9 (12%)	
Community/external member of an IRB	19 (25%)	
Advisory capacity, not as a member of an IRB	10 (13%)	
Other	11 (14%)	
Prior training in research ethics		
Yes, in a course	72 (55%)	
Yes, but not in a course	12 (9%)	
No	49 (37%)	

Table 2. Participant and facilitator demographics.

For purposes of this study, the sponsoring site, not the individual participant, was chosen as the unit of analysis because pre- and posttest data could not be reliably paired by individual trainee. As part of an effort to encourage participation in the training and assessment process, participants were specifically not identified. Consequently, this study utilized an ecological approach to analyze participants' pre- and posttest performance. This approach may provide insights not easily observable in individual level studies. For example, we think that participants were more inclined to respond truthfully about observing or participating in ethically problematic behavior. In addition, our approach places emphasis on ethics training content, process, and knowledge change by group and by site rather than by individual. Larger samples at the site level would have enabled comparisons between site locations, facilitation, etc.

Results

Training program participants

A total of 153 participants completed the pretest and 146 participants completed the posttest across nine sites in the USA. Demographics for participants and program facilitators are shown in *Table 2*.

Of the 153 participants in the training program, more than two-thirds (69%) were women. The median age group was 40–49 years of age. Over half (54%) were African American with Caucasians as the second largest group of trainees (38%). Over a 10th of the participants identified themselves as being of Hispanic or Latino ethnicity and over half (56%) stated they were employed at a community-based organization. Educational attainment was wide ranging from some high school to postgraduate degrees. Almost half of the participants (49%) reported that they had an advanced degree.

Training site number (*N* = number of participants per site)	Pretest score mean (SD)	Posttest score mean (SD)	*p* value
1 (*N* = 9)	13.5 (2.01)	17.8 (1.40)	0.011
2 (*N* = 9)	13.1 (2.04)	16.2 (1/70)	0.008
3 (*N* = 24)	12.7 (3.33)	15.8 (3/16)	0.005
4 (*N* = 7)	14.1 (1.91)	15.1 (2.18)	0.237
5 (*N* = 18)	9.7 (2.13)	13.4 (2.24)	0.001
6 (*N* = 17)	15.6 (2.00)	18.0 (1.08)	0.001
7 (*N* = 24)	15.0 (2.51)	17.1 (1.53)	0.003
8 (*N* = 13)	14.3 (2.50)	15.3 (2.56)	0.363
9 (N = 21)	9.9 (2.98)	12.9 (3.17)	0.011
Knowledge questions	**Pretest *N* Mean (SD)**	**Posttest *N* Mean (SD)**	***p* value**
Characteristics of research participants	*N* = 153 3.1 (0.9)	*N* = 146 3.23 (0.84)	0.001
History of responsible conduct of research and the Belmont Report	*N* = 153 2.2 (0.96)	*N* = 146 3.66 (0.87)	<0.001
Components of valid informed consent	*N* = 153 2.7 (1.07)	*N* = 144 2.3 (0.81)	<0.001
Vulnerable populations	*N* = 153 2.1 (1.08)	*N* = 143 3.3 (0.82)	<0.001
Communication with the IRB	*N* = 153 2.8 (1.15)	*N* = 142 3.1 (1.01)	<0.001

Table 3. Results of pre- and posttest research ethics knowledge by training site.

Our sample demonstrated the diversity in roles and employment of community partners in ethics training and was therefore indicative of the diversity of community partner involvement in human subject research. Participants played many different roles in the research enterprise, and often multiple roles. Roles listed included coordinator, data collection, investigator, participant, partner, research assistant, and team member, including study coordinator. Of those respondents, some held multiple roles in research.

At the start of the training, many participants reported that they had observed ethically problematic behavior. As shown in *Table 2*, more than one-quarter (28%) of respondents reported that they had observed or participated in ethically problematic behavior, while another 15% reported that they may have. This was also at the start of the training when there may have been less certainty about what constituted unethical behavior.

Participants were equally divided between those who had and those who had not been involved in some capacity with an IRB. Among those who had been involved, the majority (62%) were authors or coauthors of submissions or internal or external members of an IRB or advisors to an IRB or were involved in some other way.

As *Table 2* shows, along with previous research and/or IRB experience, some participants also had previous training in research ethics. Over half (55%) had previous training in an ethics training course, and 88% were either somewhat or very familiar with the material prior to the training (55% and 33%, respectively).

Perceptions of training content

Participants were asked if they thought that important ethical issues had been addressed during the training modules. Almost all (96%) agreed that the topics covered were important although 88% also stated that they had some prior familiarity with the material, possibly discussing relevant ethical issues raised in previous ethics courses. There were 38 responses to open-ended requests for information about potential gaps in the training. Of these, eight were comments about partnering and the need for more information about community-based participatory approaches in research. Others commented on the need to develop a better understanding of research methods. There were some other relevant remarks about IRB criteria, language, culture and more time needed on some specific topics such as informed consent, the use of compensation, and how to approach "uninformed or undereducated populations."

Perceived usefulness and benefits of training

Almost all participants who responded considered that the training program had been useful to them. A number of potential benefits were identified by participants. A majority reported that they had gained knowledge of ethical protections history (80%), while reports on knowledge gained of informed consent components were also high at 73%. Equally, 72% and 71% of comments, respectively, were about having an increased confidence working with research participants and having learned proper procedures for obtaining informed consent.

Intended behavioral changes

Although there are substantial differences between intentional behavior change and actual change, when asked how this training program would impact their behavior, virtually all of those who responded to this question (74) reported that they would be better able to recognize and/or address unethical behavior after having completed the training program.

Knowledge gained

The pre-post knowledge tests were scored and weighted according to a set of predetermined correct answers. The test was made up of five questions, with a maximum score of four points per question, for a maximum test score of 20 points. *Table 3* outlines the test scores. The mean test score for the group as a whole was 12.79

at pretest and showed a statistically significant ($p < 0.1$) increase at post to 15.62. Mean scores range from 0–5 and significance is based on *t*-tests for each question. Overall test scores showed a significant knowledge change between pre and post ($p < 0.001$), although on one knowledge question (components of valid informed consent), participants demonstrated a statistically significant drop in correct answers at posttest. We address possible reasons for this in Discussion section. The percentage of participants who indicated that they were "unsure" of answers dropped markedly after the training.

Significance was established using Wilcoxon signed ranks tests of differences in mean pre- and posttest scores by sponsoring site. *Table 3* shows that mean pretest scores relative to mean posttest scores were mostly in the expected direction for each site. Further analyses determined that pretest scores were significantly different in comparison to posttest scores for seven of the nine sites.

After analyzing the overall pretest and posttest scores, we analyzed site pretest and posttest performance on questions by topical area. Five questions (a topical area) were asked in regard to the Belmont Principle. The results (not shown) indicated that the topical area pretest scores relative to their posttest scores were mostly in the expected direction for each site (e.g., posttest score > pretest score). The differences were significant for eight ($p < 0.03$) of the nine sites; the pretest and posttest scores for the Belmont Principle topical area were not significantly different at site 9. Similar findings were noted for the topical area that asked questions about vulnerable populations. The analyses helped identify weaknesses in item design as well as variation in significance levels by site and topic. Some of the limitations are discussed below but we are aware of the limitations arising from sample size to site-level analysis.

Discussion

As a pilot study of this model of developing, disseminating, and evaluating an interactive human subjects protections program for community partners, the process and data illustrated many lessons. Some qualitative data and lessons from facilitators are presented in the companion piece to this paper. From the data gathered from the participants, several important things can be learned.

First, participants admitted a surprising level of observation of or participation in unethical behavior, with over a quarter of participants sure that they had contributed to or witnessed unethical behavior and another 15% admitting the possibility. This demonstrates that community members engaged in research are being exposed to ethical challenges at high levels and that programs that help them identify and address them are necessary and valuable.

Second, over one-fifth of the participants indicated that they had research roles outside of those that were usually expected of community members. This suggests that efforts to teach and understand the ethical challenges of community partners should widen in scope. Further, participants' multiple roles suggest that ethical challenges resulting from role conflicts, both between research roles and between research and community roles, are probably a larger problem than expected.

Third, the data showed that many participants had prior experience with human subjects protections and research ethics trainings. While this could be seen as a limitation of this program if it were intended to be delivered to novice community partners, the presumption behind this training program was that current training efforts are insufficient. As such, the goal was to test whether or not this program was perceived as useful and effective, even to those who had previously participated in federally required training programs. The data appeared to bear out this hypothesis. In spite of previous trainings and sometimes even extensive experience with IRBs, participants found this training program useful and beneficial, i.e., not redundant. In addition, in spite of previous trainings, participants significantly increased their knowledge from baseline. It is unclear whether this was because they had forgotten their previous training or never absorbed it in the first place. Without follow-up, it is also impossible to test whether participants would retain the knowledge gained from this training program or if it would result in behavioral change.

Finally, the data indicate that participants experienced as artificial the current ways of treating training in human subjects protections as distinct and isolable from other ethical issues in research. When asked what the program was missing, participants mentioned numerous topics that we had not intended to convey, but which they may not have been receiving elsewhere. These topics included the ethical values of community engagement and ethical approaches to research partnerships for community partners. They clearly saw these issues as intimately connected to the protection of human subjects, while current training programs and regulations do not.

Important insights also arose from the limitations of this study and its evaluation. First, the analyses were conducted on a group basis rather than matched pairs. Thus, the results do not demonstrate whether individuals increased their knowledge from the training, but only that groups increased knowledge in aggregate. In the future, if an individual pre-post design is implemented, the focus will be on *both* ensuring matches between pre- and posttest scores *and* protecting confidentiality.

In addition, there was ambiguity in the wording of some of the knowledge questions, which requires caution when interpreting these results. For example, a central challenge to knowledge assessment in ethics education is distinguishing between two meanings of the word "should." It could refer to the broad realm of what one should do (ethically) or the narrower realm of what one must do according to rules and regulations. These two meanings of "should" were not clearly distinguished in the pre- and posttest questions or the training itself, leading to answers with ambiguous interpretations. This ambiguity is the best interpretation of the diminished amount of correct answers to the "Components of valid consent" question, which provided options that were both ethically desirable but optional and options that are mandated by the regulations. This is an important lesson for our future iterations of the training program and evaluation to distinguish to participants the distinction between ethical behavior and compliant behavior.

Finally, the significant, positive changes in mean knowledge scores from pretest to posttest are important, indicating that the training program did make a difference. However, the size of the change needs to be treated with great caution because of the stated limitations of question design, variations in administration, and unknown impacts of the variation among site participants' backgrounds. Site differences may have made an impact on total mean scores. For example, this sample may have had a higher than usual number of participants with knowledge of IRB at one particular site, increasing the pretest score.

Evaluation, which is usually not carried out for these sorts of training programs, can demonstrate the match between

intended and actual outcomes, as well as offer perspectives on training content and process. Thus, even with these limitations, evaluation data from this human subjects training program are instructive. When reviewing the pre- and postknowledge tests, it appeared that the training resulted in statistically significant positive outcomes overall, albeit not a large shift. The reliability of the results is strengthened by the consistency between the perspectives of participants and their course facilitators regarding perceptions of the training. The next phase of analyses, where appropriate and sufficiently resourced, would involve triangulating data from these two sources—the perspectives of the facilitators and participants—to validate the identification of any related issues. It would also be valuable, in a future iteration, to explore further whether and how any of the characteristics of the participants (e.g., advanced degree, IRB experience) were related to learning outcomes. These data could potentially be used to tailor the training content to the needs of the particular participant groups.

Finally, the evaluation of this training program should not be limited to learning outcomes, but designed to capture other longer term outcomes, such as community capacity building or networking resulting in research collaborations among group participants, etc.* Resources allocated to support program changes and evaluation to support the ongoing improvement of training design and implementation are needed to conduct this work.

Conclusions

The goal of this project was to develop and evaluate a nationally disseminated, interactive human subjects protection training program for community-based researchers, collaborators, and staff that would be found relevant and useful while meeting national training requirements. A broader goal is to increase the ethical quality of community-based research while engaging and preparing community partners for better relationships with IRBs.

A locally delivered training like this one allows for individualized and tailored implementation to meet specific local needs but requires that underpinning core elements of knowledge, attitudes, and practice are covered. If this data and others like, it can demonstrate that a locally delivered, face-to-face training like this is effective and valuable to its participants, it should be acknowledged by IRBs and given recognition as an adequate training for community partners.

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*Many of these unintended outcomes are discussed in "Piloting a nationally disseminated, interactive human subjects protection program for community partners: Unexpected lessons learned from the field" in this issue.