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Views of Academic and Community Partners Regarding Participant Protections and Research Integrity: A Pilot Focus Group Study

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Abstract

When community partners have direct interaction with human research participants, it is important to consider potential threats to participant protections and research integrity. Few studies have directly compared the views of academic and community partners. This pilot focus group study explores the views of academic partners (APs) and community partners (CPs) regarding challenges to the protection of research participants and research integrity in community-engaged research (CEnR). Data are analyzed to understand how APs and CPs define and think about ethical problems and how meaning and analysis may differ between the two groups. Findings have implications for the development of research ethics training materials for academic-community research partnerships and IRBs; best practices for CEnR; and future research on ethical issues in CEnR.

Keywords

community engagement; human subjects protections; research integrity; community partner views

Community-engaged research (CEnR)—defined broadly as research that involves collaboration among stakeholders whose common goal is to improve health (Clinical and Translational Science Awards Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, 2011)—can take a variety of forms across a broad spectrum, from consultation to action research. Community engagement at any level can present unique ethical challenges. Specifically, when community partners—individuals from nonacademic settings who collaborate with university investigators to develop and implement research projects—are involved in recruiting participants, obtaining informed consent, or collecting data (i.e., have direct interaction with human research participants), it is important to consider potential threats to participant protections and research integrity (Anderson et al., 2012).

Many academic researchers have discussed the unique ethical challenges inherent in CEnR in the form of published case studies or reflections on experience, focusing not only on human research protections and research integrity but also on partnership development and collaborative decision-making (Bastida et al., 2010; Brugge & Cole, 2003; Gikonyo et al., 2008; Minkler, 2004). There is also growing attention to IRB review of CEnR (Flicker et al., 2007; Malone et al., 2006; Shore, 2007; Shore et al., 2011; Silverstein et al., 2008).

Prior Research on the Views of Academic Researchers

Most empirical studies exploring specific threats to the protection of research participants and research integrity in CEnR employ qualitative methods. In large part, like the case studies, these focus on the perspectives of academic researchers. For example, Shore (2006) interviewed researchers about the relevance of the traditional Belmont principles of respect for persons, beneficence, and justice to their experiences with CEnR. Participants recommended that future research explore how researchers grapple with ethical dilemmas in the field. Terpstra et al. (2011) conducted focus groups with academic investigators and staff members, asking about their experiences employing community health workers (CHWs) to recruit participants, obtain informed consent, and collect data. Participants discussed that the tendency of CHWs to be “natural helpers” and the fact that they are often viewed by community members as health care providers created a “difficult balance that CHWs needed to maintain between the requirements of a research study ... and the expectations of the communities participating in the research” (p. 3). They also noted that such conflicts potentially compromise adherence to recruitment protocols and fully informed consent. Researchers cited examples in which the belief of CHWs that research was beneficial to the community had led them to ignore inclusion and exclusion criteria or share health information with control group participants. Academic researchers also noted that maintaining confidentiality is difficult when CHWs interact with research participants who are part of their regular social networks. Lastly, academic partners also noted that CHWs sometimes took on too much responsibility attempting to help research participants, which stretched them beyond their research roles.

Prior Research on the Views of Community Partners and Field Staff

A few studies have explored community partners’ general perceptions of research. For example, Goldberg-Freeman et al. (2007) interviewed representatives from community-based agencies and conducted focus groups with community residents. Findings centered on the importance of involving community partners in decisions about research priorities and dissemination of findings. Other studies have focused explicitly on ethical issues related to participant protections and research integrity. Brugge and Cole (2003) interviewed community research partners and identified ethical dilemmas arising from inequality within the partnership, community partners’ desire to “defend” their community, the discovery of “unflattering” data, and difficulties in meeting community expectations and producing “tangible benefits.” Interestingly, when specifically asked about recommendations regarding what IRB training should include in order to better prepare community partners for challenges in the field, many participants were unable to answer, and those who did had extremely diverse suggestions. A process evaluation of human research protection education in a CEnR project found that community leaders “questioned the level of caution we proposed to exercise in the data collection process as well as the importance and relevance of policies and procedures designed to protect confidentiality and human participants in general” (Hyatt et al., 2009, p. S528).

A few other studies have examined the views and behavior of individuals working in the field in community-engaged projects, targeting individuals whose primary role involves direct contact with research participants through recruitment, informed consent, and/or data collection. These are not usually the same “community partners” who are engaged in the development of the research study, and tend to be affiliated with community organizations (e.g., social service agencies, health clinics, schools, or community coalitions). Rather, these are lay (research-naïve) individuals selected for these tasks due in large part to their similarities—superficial or otherwise—to potential research participants. Alexander and Richman (2008) conducted a small focus group study to explore how “research extenders”

(REs) (defined as street-level workers who recruit and gather data in community-based research projects and are hired because they share important characteristics with the target population of the research) understand “responsible ethical conduct” as it relates to their work. They found that in the face of both practical and ethical issues, REs have a “general disinclination to think in terms of rules” (p. 80). REs tended to be suspicious about researchers’ intentions and the appropriateness of certain aspects of research; for example, protocols that required the collection of a lot of personal information from participants were considered by some REs as “unnecessary or manipulative” (p. 81). REs were also concerned about their ability to maintain existing relationships with community members while conducting research work. The authors argue that “standard ethics training and guidance do not speak directly to the realities of the community research work of REs” (p. 84) and recommend “more targeted and nuanced training approaches” (p. 83).

In a similar study with community research workers operating in both traditional/ institutional and community settings (streets, participant homes), Richman and colleagues report on challenges to the boundaries between the workers and participants, threats to their safety, and fabrication and falsification (although very few of the interviewees reported involvement in this or other ethically questionable behavior) (Richman, Alexander, & True, 2012). They found that closer physical proximity to participants—that is, working in communities rather than traditional institution settings—resulted in experiencing greater challenges related to these themes.

In a comparison of community and academic research teams, Brugge et al. (2010) found that community data collectors more frequently used data tracking forms incorrectly. True, Alexander, and Richman (2011) found that community research workers (defined similarly to research extenders) acknowledged falsifying or fabricating data, knowingly enrolled individuals not meeting eligibility criteria, or doing things that they had been told not to do during training.

The Current Project

Together, these studies suggest room for improvement in human research protections and research integrity training for community research partners. Published case reports and empirical studies also suggest that academic researchers and community research partners may interpret, analyze, and resolve issues of research ethics and integrity differently. However, no study was identified that directly compared the views of academic and community partner perspectives regarding specific challenges to human participant protections and research integrity that arise during the conduct of research.

This pilot focus group study explores the views of academic partners (APs) and community partners (CPs) regarding challenges to the protection of research participants and research integrity in CEnR. Data are analyzed to understand how APs and CPs define and think about ethical problems and how meaning and analysis may differ between the two groups. Findings have implications for the development of research ethics training materials for academic-community research partnerships and IRBs; best practices for CEnR; and future research on ethical issues in CEnR.

Methods

Participant Eligibility Criteria

For the purposes of this study, APs were broadly defined as faculty members or nonstudent research staff affiliated with any Chicago-area university. AP participants were required to have previous experience with CEnR projects, be currently involved in the implementation

of a CEnR project, or be in the process of developing a CEnR partnership. Individuals were eligible for participation in a CP focus group if they represented their community in the development of a CEnR project or partnership, had served on a community advisory board, or had experience recruiting participants, obtaining informed consent, and/or collecting data from participants on a CEnR project *or* if they (most likely through a community-based agency with which they are affiliated) were planning to get involved in a CEnR partnership in the near future.

Recruitment

During the spring of 2010, participants for both AP and CP groups were recruited simultaneously using convenience methods. Announcements were sent through local area listservs and e-mail groups related to CEnR. Rather than recruiting for groups separately, since APs might be more active on such listservs/email lists, all announcements outlined eligibility criteria for both groups and encouraged list members to share the information with other academic and community partners and colleagues. Interested individuals contacted the author either by e-mail or phone for more information about participation.

Development of Focus Group Guides

The focus group discussion guide for the AP groups (see supplementary online document) was developed by the author in consultation with the University of Illinois at Chicago (UIC) Center for Clinical and Translational Science (CCTS) Community Engagement and Research Core (CERC) Subcommittee on Ethics and Community Engagement. The primary goal of the focus group study was to inform the development of human research protections training materials for CEnR partners (available at www.go.uic.edu/CIRTIfication). Topics and questions were based on an extensive literature review, personal experience with CEnR, informal conversations with/anecdotal evidence from other researchers conducting CEnR, and input from the UIC CCTS CERC Community Engagement Advisory Board (CEAB).

The AP groups were asked to discuss issues related to human research protections that had arisen in their own CEnR experience, were *anticipated* based on past experience, or that they had learned of from colleagues or the research literature. The conversation was unstructured, and participants were prompted to provide specific examples whenever possible (see Table 1).

In order to gather CP perspectives on issues specifically raised by APs and provide a focus for the discussions (especially since it was anticipated that some participants might be new to research), the focus groups were iterative. Preliminary analysis of the AP groups occurred prior to the delivery of the CP focus groups, and discussion questions and case studies were developed based on major themes identified (see Table 2). Real stories shared by APs as well as concerns about potential problems served as the basis for the discussion cases used in the CP groups; however, significant details were altered or existing case studies modified so that particular projects, investigators, or community partners would not be identifiable.

Use of discussion questions and cases generated from the AP groups stimulated lively discussion in the CP groups. This strategy focused the conversation and provided insight into the ways that CPs think and talk about specific concepts relevant to human research protections such as privacy, voluntariness, appropriate inclusion/exclusion criteria, and data integrity.

Focus Group Implementation

Four separate focus groups were conducted: two groups with APs and two groups with CPs. Each focus group discussion lasted approximately 90 minutes. All four groups were

moderated by the author with an assistant for note taking. All sessions were digitally recorded and transcribed; participants were informed of the recording and provided verbal consent to participation prior to the start of the focus group. (This study was approved as exempt research [Research Protocol #2009-1024] by IRB #2 at the University of Illinois at Chicago.) Participants in the CP groups were paid \$25 each as a thank you for their time, and refreshments were served (AP groups were served refreshments only).

Data Analysis

In addition to the previously mentioned preliminary analysis, after completion of the CP groups, an in-depth analysis of all four focus groups was conducted by the author in which major coding categories (domains) and subcategories (components) were refined. Domains and components were reviewed and combined or separated in order to organize the data in Microsoft Word files. Themes and patterns were identified within each category, and illustrative quotes were selected (Knafl & Webster, 1998). Raw data, categories, and themes were presented to a working group on community engagement and ethics (names listed in acknowledgments) to check reliability of interpretation by the author.

Findings from AP and CP groups will be presented separately and organized by parallel themes. Conclusions and recommendations will be presented based on findings from all groups.

Results

Academic Partners

A total of eleven individuals participated in two AP focus groups. The first group had five participants; the second group had six. These eleven participants represented five Chicago-area academic institutions. Ten APs had experience with multiple CEnR studies; one served in an administrative role facilitating community-academic partnerships. Minimal demographic information was collected. Participants included nine women and two men; six were African American, and five were white. Because this was a small local pilot study, it was arguably necessary to limit the amount of information collected about individual participants in order to encourage open discussion. Therefore, information was not collected regarding the specifics of CEnR projects or community partners (however, all participants conduct health-related research, defined broadly). This anonymity allowed researchers to speak candidly regarding problems and challenges.

Ethical challenges discussed by APs can be organized into four major overlapping themes: the importance of trust; applying research norms in CEnR contexts; challenges to informed consent and recruitment; and concerns about scientific integrity.

THE IMPORTANCE OF TRUST—APs feel that it is important to address negative views or concerns that CPs may have about research early in the relationship in order to promote trust. This can be done by

addressing misnomers that are out there regarding researchers, addressing stereotypes they've already preconceived about research. Also what is in it for them. They're already overburdened. Community groups, they already have a lot on their plates ... (AP Group 2)

Consistent with the foundational principles of community engagement (Clinical and Translational Science Awards Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, 2011), APs also identify that clarifying

expectations of all individuals and organizations involved in the research partnership is critical to success.

Giving the community partners ownership, collaborating up front, before you get together ... Because they know their audience, they know better the needs and differences of their audience. *We* think this is what they want, but they may not be interested in giving up that information or maybe that's not something that they're even dealing with. (AP Group 2)

We have to tell them just what happens up front, what happens when research is winding down, there may not be a chance to sustain it, what it will mean, all that stuff, the norms of how external funders, how some of those things operate. Then they can decide if it works for them or not. (AP Group 1)

According to APs, developing rapport is key to ensuring that CPs feel comfortable speaking openly and asking questions. This is part and parcel of respecting CPs as equal partners in the entire process, but as the next quotes highlight, this can also have a significant impact on the experiences of research participants.

[Community partners] are uncomfortable sometimes saying "I don't know," because they feel like they're supposed to know already. The specific example I'm thinking of had to do with a rheumatoid arthritis study. And because we use "RA" everywhere ... A patient came in, said they had "reactive arthritis," and the worker assumed because it was RA it was the same thing. Just thought it was a new or different word. So making sure that people are comfortable clarifying ... that they ask, basically. Because it can be a real problem. (AP Group 1)

Providing the overall picture of a study and letting everyone know where and how they fit in was also described as a way to demonstrate respect for CPs.

When you come to the table, everybody that's a part of it, they need to understand what their role is—not just what their job is—but this is my role in the project—so you get more of a buy-in. Because what I get a lot is that, okay, I'm doing this, well why is she doing that, because nobody's ever actually gone over the entire protocol—only "you're going to go out and you're gonna do a survey and that's it, don't worry about what's gonna happen after, all you have to do is consent and survey." And in a way that belittles and it minimizes their input into the process. (AP Group 2)

APPLYING RESEARCH NORMS IN CENR CONTEXTS—APs discussed challenges they face with regard to standard research norms in CEnR. For example:

[T]he worldview of many people [in the communities] that I work with ... it is completely ridiculous to them to draw someone apart from their family or group, and it may be in some ways insulting or you may not get the right information actually you're hoping to find. (AP Group 2)

In such a context, simply telling CPs to "respect privacy" or "maintain confidentiality" during training may not be sufficient to ensure adequate participant protections. Specific protocols—as well as discussions about what will actually work in practice—are needed.

Educating CPs regarding the purpose of research rules and regulations is also important. As one AP said:

They [community partners] need to understand the rules that we have in place and why we have them. I think very often those rules do not apply ... in their way of how they conceptualize what they are doing. They already have an internal ethics

system that they built and are adhering to and our structured one may seem quite ridiculous to them. But having no concept of why we're throwing out this 10-page form that they have to sign. They need to know there are reasons that we have these rules and we are forced to adhere to them. (AP Group 2)

APs also discussed challenges that have arisen in the context of data interpretation when outcomes are defined differently by APs and CPs.

I've known of projects where at the end of the project, the community thought it was of value and that it was something that should be sustained, but the people from the academic side, because we are focused on p values and clinical, statistical significance, it turned out that once the data was analyzed it did not seem as though the intervention made a significant difference. But people who lived in the community saw a change in their neighborhood and wanted the program sustained and the institution says we're pulling out because the data doesn't show. Even though people in [the] community think it's working, it's not enough. (AP Group 1)

Overall, APs demonstrated sincere understanding and empathy with the views of their CPs. However, they wrestle with how to reconcile community norms with standard practices and research regulations while maintaining scientific integrity and good relationships with their CPs.

CHALLENGES TO INFORMED CONSENT AND RECRUITMENT—Several APs reported struggling to train CPs to properly recruit participants and obtain informed consent. In many cases, these difficulties stem not from lack of skills, intellect, or qualifications on the part of the CPs but rather from their relationship to the individuals whom they are recruiting. For instance, CPs may face challenges recruiting people they know or people who view them as trusted community members.

There's a community agency that's been recruiting for me for one [study], and they call me every now and then with someone asking, can this person qualify for this study? And it's always no. Some exclusion criteria. And I'm always thinking, gosh, did I not do a good enough job explaining the inclusion/exclusion criteria? And for a while I'd keep reviewing it with them, and I'd resend it, and all that stuff, and I realized now, they're not dumb, they know. They just can't be the one to formally deny the person because they're too close. So they need me to say, "oh the doctor said we can't, we called her, we asked, but she said no." So, once I realized that, I stopped sending them the inclusion criteria every month ... It took me a while to figure that out. (AP Group 2)

APs also discussed how CPs' knowledge of potential participants might bias the recruitment process and threaten data integrity. One shared a story about a CP who dismissed some potential participants outright, saying

"This is a good person to be in [the study]" or "This isn't a good person. I know she has the disease but she's not gonna be good, you're gonna have a problem with her." And that's one of the instances I ran into. The person at the front desk, she was like, "You don't want to talk to her. Oh no." (AP Group 2)

APs could see how someone without research training might view this sort of "screening" as improving the project outcomes, but had not anticipated something like this happening and were therefore at somewhat of a loss regarding how to respond without appearing to disrespect CP input.

CONCERNS ABOUT SCIENTIFIC INTEGRITY—APs noted examples from their own experience that involved CPs not adhering to protocol instructions. In some cases, CPs may

disagree with protocol requirements and simply not follow them, rather than speak up when they have good reason to think that a particular strategy will not work in their community. One AP relayed the following story:

The protocol says ... You're gonna go door to door. And then the [community partner] wasn't going door to door because she said nobody was letting her in. So she was meeting them in the Laundromat. I was like, "We didn't say nothing about meeting in the Laundromat." And she said, "Well, that wasn't working for me." She says, "You all didn't ask me before you decided on door to door. You should have talked to me first because I could have told you that was a dumb idea ... I got the addresses, I know where they live because I know everybody and I went to where I could find people. You told me to get people." (AP Group 2)

If CPs do not comply with the research protocol, not only might the validity of results may be compromised, but participants may lose trust in the research. This is highlighted in the following example:

I've had a community partner go out to do a procedure in a [research participant's] home, and ... there was a person who was trained, but they brought along another person. And we initially contacted the [participants] and let them know one person will come to your home. But now, they're comfortable knowing that one person is coming to the home, but at the visit, two people are coming to the home. And they both appear to be inept because, ... they didn't read the information, they didn't pay attention to training, and then they brought another person along with them to do the visit. And the [participant], they're used to, they know what should be going on in the visit, going on for each, all the procedures. So the person had to ask the [participant], constantly, well what do I do next, what do I do next, and that was horrible and it got back to us. That didn't go over well, because then [participants] don't want to continue to participate, they don't want this person back in their home, and other issues after that. ... That was just a big mess. (AP Group 2)

Based on these key themes that arose in the AP groups, four discussion questions and six case scenarios were developed for use with the CP groups. Some of these are presented in Table 2.

Community Research Partners

Thirteen CRPs participated in two focus groups (the first group had four participants; the second group had nine). These thirteen participants represented eight Chicago-area community-based organizations. Seven had been previously involved in the conduct of community-engaged research; six were in the process of initiating community-academic partnerships that had not yet evolved into concrete research projects. Some of the participating individuals reported that they had completed formal human subjects protection training at some point, but we did not track this information. As in the AP groups, minimal demographic information was collected from participants. Eleven participants were African American, one was Latino, and one was white. Participants included nine women and four men.

As discussed above and presented in Table 2, themes and subthemes that emerged from the AP focus groups were used as the basis of discussion questions and cases that were then used with the CP groups. Three of these—the importance of trust, applying research norms in CEnR contexts, and challenges to informed consent and recruitment—are presented here.

THE IMPORTANCE OF TRUST—Because the concept of trust permeated discussion in the AP groups, the CP focus groups started with a series of brainstorming questions aimed to

get at views on trust in research (see Table 2). CPs discussed both risks and benefits of research participation. Although past abuses of research participants were acknowledged as affecting trust, potential physical harm is not a primary concern when it comes to research in their communities. Instead, CPs focused on honesty, transparency, information-sharing, and inclusion. CPs want information not just about individual-level risks and benefits but also about the purpose and potential of the research. They want to know what is going to happen with the information that researchers gather from their communities: how is it going to be used to help people in their communities or other communities suffering from similar health issues; how is it going to be kept safe; and how can they be sure it is not going to be misused (e.g., sold to marketing agencies).

Several CPs expressed that researchers had not taken the effort to educate people in their communities about research.

I think more people would be engaged in research if people would take the time to explain what it is, how it works, because there's a lot of unknowns and depending on how it gets presented, if it gets presented in a very scientific way it's going to turn people off because you don't get it. So I think, it's presentation, it's education. And people will be more willing if they're more educated. (CP Group 1)

CPs also expressed that researchers should be clear on the terms of participation and not “abandon” research participants and/or partners. They relayed stories of studies that had lasted longer or included more follow-up than initially noted as well as studies that ended early without explanation. As one CP expounded:

But if you're not getting any follow-up in regard to this information that you're giving out, that defeats the purpose of why you were in there, and that's why people get to the point of, I did this same crap back in 1995, I got no response from that, why should I do this now in 2010 ... Because that's one of the things that we found out in our community about universities. Universities will come out and do studies and ask us all these questions and do this in our community, and then they would never get back and tell us what they found out. They wrote grants, they made money, they did whatever they wanted to do, but we never got any information. (CP Group 2)

Overwhelmingly, they emphasized that researchers need to share the results of research with those who participate.

I think you ought to make the research findings available appropriately, and when I say appropriately, I mean in a way that the individuals and organizations who are participating, so that when they receive that information, they can use it. I don't need to see a scholarly publication, if I'm talking about something with a group of under-nourished adolescents. They may not appreciate it or understand, but the output oughta match the intended audience. (CP Group 1)

Even if it's just a newsletter saying our findings were XYZZZ, what we're gonna do with it and just a simple newsletter in the mail, based on what we ... yeah, what we went through. (CP Group 2)

In both CP groups, the Tuskegee Syphilis Study emerged early in the conversation, but CPs also brought up the fact that minorities have historically been excluded from research participation and therefore have been excluded from some of the benefits of research. In one group, a direct connection was made between this exclusion and persistent health disparities among African Americans.

We are the last ones. We are the first ones, they highlight us and say we have these disease and all that but when it comes to the research for finding a cure for this, we are the last ones they demonstrate it to. (CP Group 2)

CPs see the value of the data being collected for research purposes and want those who participate in research and provide data to benefit as much as those who conduct research. In the words of one CP:

You see that what has been done with us, they pick our brain and use our intelligence, and our facts about whatever it is we know about us and then turn around and profit from it and we never find out anything about it. (CP Group 2)

In discussing the potential benefits of research, CPs also cited barriers to research participation that prevent certain individuals and populations from sharing the benefits of research.

A lot of people sometimes want to participate but don't know and understand the basics, but they might not have the carfare to get there, or they might now, you know, can't finagle themselves to get there if they have some kind of issue. So I think it's important when we consider whatever it is we're doing whether it's a written survey or whatever do we make it as plain and basic as we can not to frighten anyone off. (CP Group 2)

It also seems that, especially in biomedical research/clinical trials, lack of certainty regarding what's going to happen after the research ends—or experiences of abandonment—keep people from participating.

Well, I know that in one of the research projects that a friend of mine was involved in that did involve medication they were able to get medication ... for their high blood pressure ... but once that research project was over that person wound up having to pay for that medication. You know while they were on that research it was free, but when you wind up having to pay for medication, we're talking about this *new* medicine that's out, we're talking about big money. (CP Group 2)

And also, the doctors ... the PIs [doing] that research, do they continue to follow that patient or have someone to follow that patient once they're out of that program or project and do they have some issues still going on? (CP Group 2)

APPLYING RESEARCH NORMS IN CENR CONTEXTS—The case of Mary (Table 2, Case 1) generated the most discussion in both groups. CPs clearly understood that in her role as a data collector, Mary has an obligation to keep what she sees to herself. They knew that for Mary to even mention to her cousin that she saw Joe at the clinic was a violation of his privacy and a violation of the rules of research—and could potentially get Mary into legal trouble. But most participants also admitted that if they were in this situation, they would certainly be tempted to look at Joe's survey, and a few even stated that they would say something to their cousin. Given this, the conversation quickly focused on how this unfortunate sighting could have been prevented. CPs discussed the importance of training related to health information and privacy in the context of a study like this, but the overarching sentiment in both CP groups was that such a situation should have been anticipated and that Mary should not have been involved in this way in her own community. In addition, participants felt that because the client base of the clinic was so specific, this made it difficult to protect participant privacy regardless of the specific information collected in the survey. This led to a broader discussion about the potential privacy and confidentiality risks that arise when doing research in one's own community. As one CP stated:

She needs to be way out of her community or even out of the city. You know 'cause she's gonna know too many people in the community Look, I go somewhere, everywhere and I still see people I know. (CP Group 2)

CHALLENGES TO INFORMED CONSENT AND RECRUITMENT—CP focus groups discussed several cases based on topics that arose in the AP focus groups (Table 1, Cases 2 and 3). As hoped, these cases prompted discussions about trust, voluntariness, bias, and adherence to inclusion/exclusion criteria. As many of the CPs who participated in the focus groups were fairly savvy and experienced, the “right thing to do” in each case was quickly identified. For example, in Case 2 (Table 1), participants in both groups immediately recognized that Elizabeth’s saying “yes” to Bill did not meet the requirements of voluntary informed consent. But they also immediately saw how the pre-existing relationship Bill has with Elizabeth could engender trust, thereby making her overly willing to participate but also reluctant to refuse to participate due to concern for loss of services for her child or simply discomfort.

In discussing Case 3, most CPs expressed confidence that in a similar situation they would prioritize adherence to study criteria over emotion and desire to help the young mother. A few said they would want to “bend the rules” (Group 2); in the words of one animated participant, “no IRB training could make my heart any harder than it is” (CP Group 2). CPs acknowledged that sometimes the responsibilities or missions of community organizations compete with research priorities, but that these conflicts should be considered at the level of the project, not the individual participant.

Discussion

Academic investigators struggle to address some of the practical issues that arise in the field in CEnR that potentially threaten the safety or privacy of research participants or the integrity of the research. They are not always sure about solutions or even how to initiate discussion. Many of the issues identified in the AP focus groups are not the typical research ethics conundrums and stem from underlying issues related to collaboration, team management, and communication. Challenges can be complicated by the desire of APs to be sensitive to CPs’ input and community knowledge, but sensitivity can come at the expense of open, honest communication and the responsible conduct of research.

APs may also perceive that CPs don’t always understand the rules for research. The CPs who participated in the focus groups community partners demonstrated a sophisticated understanding of research rules but sometimes saw a disconnect between these rules and common sense or community norms. These are not insurmountable differences but rather issues that need to be addressed prior to study implementation. In some cases, privacy for example, more work is needed regarding how to operationalize research norms into best practices for the CEnR context. Tailored training materials and tools are needed.

Our focus groups with APs and CPs also highlight the diversity of community partners, community-academic partnerships, and CP roles in CEnR studies. This diversity must be highlighted in the development of training materials and suggestions for best practices.

Some of the cases discussed in the focus groups (particularly those not reported in this paper) were very “cut and dried” and did not foster conversation about ethical dilemmas. It is not clear how these simpler cases would have worked with a more naïve group of community partners. But this pilot study demonstrated that even when solutions are fairly clear, cases can prompt discussion of broader ethical issues among CPs.

This pilot study has several limitations. The results are not generalizable to all APs and CPs involved in CEnR but rather reflect only the experiences of those in the study sample. Unfortunately, there were a small number of participants in a small number of groups, and participation was not diverse in terms of race and ethnicity (APs were white and African American; CPs were primarily African American, and Latinos were not well represented in any groups). These focus groups were exploratory in nature, and a great deal of content was covered in a very short period of time; groups were not able to get very deep into any one topic. Furthermore, data coding was done by the author only. However, the iterative structure of the groups allowed for comparison of academic and community partner views, and findings provide insight into ethical issues that require further exploration. Preliminary conclusions can inform the development of best practices for CEnR; training materials for community-academic research teams and IRBs; and a research agenda for human research protections in CEnR.

Best Practices for CEnR

While the ability to draw strong conclusions from these pilot data is limited, three practical suggestions can be made. First, it appears that open dialogue is foundational not only to successful academic-community partnerships but also to participant protections and research integrity. Open dialogue should focus on the expectations of all partners as well as CPs' previous experiences with and perceptions of research and academic researchers. It is important that academic-community teams develop a level of comfort that encourages CPs to participate as equal partners—and this includes raising concerns about potential ethical issues or questions about features of the study protocol. Open dialogue is needed among team members about values and interpretations of the ethical principles that are the foundation of human research regulations.

Second, academic investigators should take time to consider the real-world conditions of any proposed CEnR projects and the potential challenges to participant protections and data integrity. Concerns and potential safeguards should be discussed with CPs. For example, thought should be given to the relationship between the person doing the recruiting, informed consent, and data collection and the potential participants to identify potential power dynamics, discomfort, or privacy issues. Community-academic teams should have frank discussions about potential threats to voluntariness, understanding, and privacy.

Lastly, it is important that APs clearly communicate to CPs the connection between protocol adherence and respect for research participants who are members of their community. Research participants sacrifice their time and energy to contribute to research for the good of their community, and scientific integrity—which is the responsibility of all members of a research project—is key to ensuring that their contributions are not wasted.

Educational Implications: Training for Community-Academic Research Teams

Human research protection training is federally mandated for anyone directly involved in research and interacting with research participants. This includes engaged community partners. However, there are no specific guidelines and little professional consensus as to what must be included in such training. Existing training programs and materials are primarily geared toward graduate students and junior researchers and therefore assume a certain level of research experience and knowledge of research methods and standards. Like the federal regulations, training content is tailored to clinical research and therefore not always relevant to ethical issues that arise in CEnR (Anderson et al., 2012). Existing training materials cannot account for the complexity of research that is conducted in community

settings, and individual research investigators/projects do not have the resources to develop audience-appropriate materials from scratch. This pilot research is a first step in determining content for such tailored training programs.

The focus group discussions bring to light the fact that community-engaged academic researchers also need and want tailored tools and training on human research protections and research integrity issues in CEnR. Many of the ethical issues identified in the focus groups are beyond the narrow scope of issues outlined in the federal regulations or discussed in traditional research ethics training courses. For example, APs raised issues related to initiating relationships (e.g., how to explain why you as an outsider of the community are interested in a particular community and research topic); professionalism (e.g., respecting participants' time; avoiding inappropriate cell phone usage); good employment practices (e.g., conducting background checks of community research partners; hiring data collectors or recruiters as university employees versus providing funds to community organizations to pay their staff); sustainability (e.g., securing funding; identifying and providing benefits for community partner organizations); and scientific integrity (e.g., considering inclusion/exclusion criteria that allow community partners to satisfy their obligations to their community without compromising scientific integrity).

Ultimately, it is important to think about how best to train community academic teams, and how to help APs and CPs teach each other, rather than thinking about academic researchers and community partners as needing distinct training. While there are no one-size-fits-all solutions, community-academic teams might benefit from case studies or questions that could serve as conversation starts to elucidate meaningful dialogue.

Educational Implications: Training for IRBs

We had initially had hoped that there would be time in the AP focus groups to talk about IRB-related challenges, but this was not possible. There is growing discussion about what IRBs need to know about CEnR and what, if any, unique criteria should be applied to the review of CEnR. Importantly, these discussions and any recommendations need to be mindful of the narrow scope of IRB responsibility and should not encourage mission creep. These focus groups suggest that perhaps the unique risks to privacy, confidentiality, and voluntariness that can arise in CEnR might be a critical starting point for IRB education.

As mentioned above, many institutions fulfill training mandates with programs that are a poor fit with the needs of frontline CPs. IRBs also should explore potential alternative options for training community-based field staff that address the unique issues of CEnR and consider revising policies that do not allow for more appropriate alternatives.

Research Agenda

More empirical research on ethical issues in CEnR is needed to gather the perspectives of a wider range of individuals and different types of community partners (both individuals and organizations). Identification of problems that are peculiar to specific designs (e.g., intervention, survey, or clinical) is also needed. Future research should also address the perspectives of IRB members and administrators. Quantitative research is needed in order to determine the most prevalent issues and the potential harmful effects on research participants, communities, and academic-community teams. Qualitative research can help ethicists and community-academic research teams better understand the nature of the ethical problems that arise in the field. Identification of highly contextualized “research conundrums” can serve as the basis for future training and research. Theory and methods from communication research could be very useful in addressing some of these issues.

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Biography

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TABLE 1**Academic Partner Focus Groups: Sample Prompts.**

What challenges to human subjects protection have arisen in your community-engaged research projects? Try to share concrete examples. These could be related to (privacy and confidentiality or another topic discussed earlier in the group), or something else. I am looking for examples across all phases of research. Keep in mind, your examples don't need to fall into the category of "serious adverse events." They may be violations of proper procedures or research integrity, or unprofessional behavior more broadly.

Are there practices related to human subjects protections, or more generally related to research integrity, that the community partners with whom you work resist or have difficulty understanding?

What issues related to research ethics and human subjects protection are most important for community research partners to learn about before they get into the field?

TABLE 2

Themes from AP Groups and Discussion Questions/Cases for CP Groups.

Theme (AP GROUPS)	Discussion Case Summary (CP GROUPS)
The Importance of Trust	
<i>Subtheme: Trust</i>	What words or phrases come to mind when you hear the word “research”? What are some reasons that people in your community might want to participate in a research study? What are some reasons they might NOT want to participate in a research study? What do you think are some of the rules of research/what are rules that researchers need to follow?
Applying Research Norms in CEnR Contexts	
<i>Subtheme: Privacy and confidentiality</i>	Case 1: Mary is employed as a data collector on a survey to find out more information about the needs of people living with HIV in her community. She sits in the lobby of a community clinic that serves many HIV+ people and asks everyone who walks by if they would be willing to fill out a brief health survey. While she is working, she sees her neighbor, Joe, who has also been romantically involved with her cousin Sandy for a few months. Mary asks Joe to complete a survey. He agrees, but Mary is not sure that Joe recognizes her. Mary is supposed to place each survey in a sealed envelope and not look at the answers. (<i>adapted from “Ethical Protections in Community-Engaged Research,” Michigan Institute for Clinical and Health Research, Stephanie Solomon and Patricia Piechowski-Whitney</i>)
Challenges to Informed Consent and Recruitment	
<i>Subtheme: Inclusion/exclusion criteria</i>	Case 2: You work for a local social service organization. A researcher asks for your help to recruit women to participate in a focus group on family nutrition. Eligibility criteria include having at least 2 children between the ages of 5 and 18. Each participant will be paid \$40 and a free meal will be provided. A young mother who volunteers at the agency sees the flyer and asks you if she can participate. When you tell her that she is not eligible because her children are not the right ages, she asks, “Are you sure? I could really use that money to buy food for my baby.”
<i>Subtheme: Recruiting people you know</i>	Case 3: Bill runs several programs for youth at a community-based organization. He is well-liked by all the children he works with and their parents. He has been asked by the head of the organization to help recruit parents to participate in a research study on parenting. One day Bill approaches Elizabeth, a mother of one of the 12 year-olds in his computer club, and asks her if she’d be interested in participating in the study. When he hands her the 3-page consent form, Elizabeth quickly says, “I don’t need to read this whole thing. If you think this study’s okay, just sign me up!”

Note: For reasons of space, these summaries have been shortened from those actually used in the CP focus groups.