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Research Ethics Education for Community-Engaged Research: A Review and Research Agenda

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Abstract

Community engagement is increasingly becoming an integral part of research. “Community-engaged research” (CEnR) introduces new stakeholders as well as unique challenges to the protection of participants and the integrity of the research process. We—a group of representatives of CTSA-funded institutions and others who share expertise in research ethics and CEnR—have identified gaps in the literature regarding (1) ethical issues unique to CEnR; (2) the particular instructional needs of academic investigators, community research partners, and IRB members; and (3) best practices for teaching research ethics. This paper presents what we know, as well as what we still need to learn, in order to develop quality research ethics educational materials tailored to the full range of stakeholder groups in CEnR.

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"Community engagement" refers broadly to what the Carnegie Foundation for the Advancement of Teaching describes as "collaboration between institutions of higher education and their larger communities (local, regional/state, national, global) for the mutually beneficial exchange of knowledge and resources in a context of partnership and reciprocity" (http://classifications.carnegiefoundation.org/descriptions/community_engagement.php?key=1213).

Community engagement is a growing area of interest in many health-related disciplines; it is also integrated into an increasing number of federally funded research programs, including the National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA) (Hood et al., 2010) and other extramural research grants from NIH and the Centers for Disease Control and Prevention (CDC) (for example, see http://www.cdc.gov/prc/). NIH has adopted the broad term "community-engaged research" (CEnR) to describe research that involves collaboration among stakeholders whose common goal is to improve health, regardless of the specific types or degrees of engagement (Clinical and Translational Science Awards Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, 2011). We apply this term to "research that provides communities with a voice and role in the research process beyond providing access to research participants," and consider engagement to include studying the views of community members regarding research protocols, community advisory and review boards, hiring community members as part of a research team, and including community members as co-investigators (DuBois et al., 2011).

We are a group of representatives of CTSA-funded institutions and others who share expertise in research ethics and CEnR (see Table 1, which delineates the numerous roles that the authors play in CEnR ethics, research ethics education, and research ethics curriculum development). We convened via multiple teleconferences over the course of about one year. Our initially identified goal was to identify, develop, and disseminate research ethics educational programs and materials that could meet the unique needs of community-academic research partnerships.

As a first step, we attempted to reach consensus regarding learning objectives, content, and approaches for research ethics instruction, tailored instructional materials, and quality measures. Our discussions have highlighted the fact that there is limited evidence regarding: (1) the particular instructional needs of academic investigators, community research partners, and IRB members; (2) best practices for teaching research ethics; and (3) effective ways to integrate CEnR's unique ethical issues into research ethics education. Based on our collective experiences, review of relevant literatures, and extensive deliberation, this manuscript presents what is known, as well as what still needs to be learned, in order to develop quality research ethics educational materials that are tailored to the full range of stakeholder groups in CEnR. In order to provide background and context for our recommendations regarding best practices and a research agenda, we will first outline unique ethical issues that arise in CEnR; describe the various stakeholder groups that require ethics education specific to CEnR; and present current standard methods of delivering research ethics education and discuss their limitations for community research partners.

Unique Ethical Issues that Arise in CEnR

There are numerous ethical issues that are unique to CEnR or that manifest uniquely in the CEnR context. Many of these have not been fully explored from all stakeholders' perspectives; gaps in knowledge and lack of solid guidance makes integration of these issues into research ethics education difficult. Here we categorize these ethical challenges as a first step in determining topics of salience for research ethics education for all stakeholder groups.

Partnership Challenges

Many ethical problems that arise in CEnR are not directly related to participant protections or scientific integrity; rather, they stem from the fact that academic and community partners sometimes have overlapping but incongruent goals, disparate power and access to resources, or different work and communication styles (Lindau et al., 2011; Shore, 2006; Silka & Renault-Caragianes, 2006). For example, community organizations may feel overburdened by academic partners' requests for input on formal products such as grant proposals or manuscripts, particularly if they have a limited number of paid staff members. Partner organizations may be eager to deliver services to community members and feel stifled by the sometimes slow pace of research and intensive attention to process. Successful collaboration requires a strong mutual commitment to power-sharing and open communication about the collaborative process, inherent assumptions, and stakeholder goals (Heitman & McKieran, 2004).

Community vs. Academic Expertise

Community and academic researchers have different kinds of expertise. Although respecting partners' expertise is a central tenet of ethical engagement (Fisher & Goodman, 2009; Fisher & Ragsdale, 2006), negotiating decisions when experts conflict can be challenging. Threats to the protection of participants or the integrity of the research process may arise from the fact that community partners view their communities from a unique vantage point; they have knowledge about their members that academic researchers cannot learn simply from studying the community, and articulating these community dynamics to outsiders may be difficult. For example, community partners working as recruiters in community-based drug trials have observed that study inclusion/exclusion criteria sometimes do not reflect the realities of participants' lives (Fisher et al., 2012; True, Alexander, & Fisher, 2012). However, they may not feel empowered to communicate their concerns to investigators. Life experiences may also attune community partners to certain things about which university-based investigators may be naïve, such as when a participant may be lying in order to enroll in a study. Problems may arise if community partners do not feel comfortable scrutinizing potential participants in order to verify eligibility or to make screening or eligibility decisions beyond strictly adhering to written protocol instructions.

There has long been a perceived tension between "good science" and community engagement (Buchanan, Miller, & Wallerstein, 1997). Particular protocol features, such as the collection of a large amount of personal information, may create suspicion about researchers' intentions (Alexander & Richman, 2008). Community partners may also question the fairness of certain research methodologies such as the use of a control group (Fisher & Wallace, 2000). If academic researchers do not adequately explain the reasons for certain methodological decisions, community partners may question their integrity or even their scientific expertise.

Risks to Groups

Traditional clinical research ethics frameworks focus almost exclusively on risks to individuals. Ross et al. (2010b) have highlighted risks to individuals *qua* community (group) membership (if the individual self-identifies as a group member or is externally identified) and risks that occur to the group *qua* group as key considerations in CEnR. Harms to individuals can occur during the research process when a person is labeled and recruited because of membership in a group. For example, in a culture where blood carries special meaning, if blood samples are taken for a research study, individual participants may be at risk for stigmatization within their community. Harms to individuals can also result from research outcomes if findings about a group are attributed to an individual member. For example, because research has shown that BRCA1 and BRCA2 genes are more prevalent in persons of Ashkenazi Jewish heritage, increased risk for breast cancer is attributed to *any* woman who describes herself as Ashkenazi Jewish (whether or not she participated in the research), potentially resulting in increased insurance premiums (Weijer, 1999). CEnR can also pose risks to individual agency as a result of group membership. For example, if the leader of a disease group has had a negative research experience, he or she may refuse to provide a researcher with access to the group for a project that may be of significant benefit to the group, leaving others in the group entirely unaware of the opportunity (Ross et al., 2010b).

Risks to communities also include potential disruptions to group structure and function. For example, internal conflict resulting from disagreement over aspects of a community's research participation can lead to diminished group cohesiveness. The following example demonstrates potential disruption to both internal and external relationships as well as group agency. The Havasupai Native American tribe was concerned about growing rates of diabetes in their community and gave blood samples to investigators whom they had asked to conduct genetic research on diabetes. Ultimately, the investigators concluded that novel genetic factors were not a primary factor in the Havasupai's diabetes problem. These same blood samples were also used to study genetic factors in other diseases, including schizophrenia, and may have also been shared with researchers at other institutions. The samples were also used to determine that the tribe originated in Asia and migrated across the Bering Strait to what is now Arizona. This finding significantly threatens the tribe's traditional collective belief that they originated from the Grand Canyon. However, neither tribe leaders nor the individuals who provided the samples gave consent or even knew about these additional uses of the blood samples (Ross et al., 2010b).

Threats to Informed Consent, Voluntariness, and the Integrity of Data

Community partners' specific roles and general stature within their communities can influence participants' perceptions of a study and their decisions to enroll (and continue participating) (Gikonyo et al., 2008). It is often argued that community involvement leads to increased trust, higher participant enrollment, and perhaps even improved informed consent (Minkler, 2004; Quinn, 2004; Strauss et al., 2001). However, much as academic investigators may be misperceived as bringing services to communities of research interest, community research partners may be mistakenly viewed as service providers, that is, individuals who "know best" and have participants' best interests at heart and resources to offer (Terpstra et al., 2011). Bean and Silva (2010) make a comparison between peer recruiters and clinician-researchers, whose preexisting, trusting relationships with potential participants create potential conflicts of interest in recruitment (Fisher, 2012; Levine, 1992).

Even if an individual community partner does not hold a formal leadership position in a community, close proximity and likeness to potential research participants may create subtle peer pressure to participate. It has been suggested that peer-driven recruitment shares some

of the characteristics of network marketing (e.g., similar to home-based sales parties to sell jewelry, cosmetics, or housewares). When a potential participant is approached by a recruiter who is also a peer, the participant assumes the recruiter is playing the role of peer first and recruiter second (Phillips, 2010). This perception mediates potential participants' concerns about risks and benefits and ultimately their willingness to participate in a research study.

Community partners may struggle to balance the expectations of their community members with the requirements of a research study and expectations of their academic partners (Brugge & Cole, 2003; Terpstra et al., 2011). There is increasing pressure from federal funders to meet recruitment goals, and much CEnR is conducted in vulnerable communities where participation in research has been historically low. Pressure to meet recruitment goals (and perhaps a perception that enrolling participants is more important than providing complete information and ensuring understanding and voluntariness) can lead to protocol violations, de-emphasis on risks, pressuring friends and family to participate (Terpstra et al., 2011), or falsifying data (True, Alexander, & Richman, 2011).

Expectations of Benefits

Despite being presented with similar information, people associate a variety of different benefits with research participation (e.g., development of programs and services, direct health-related feedback). Recent research suggests that perceptions about benefits may vary among racial/ethnic groups (Lakes et al., 2011). To complicate matters, CEnR projects often do include both research and nonresearch activities (e.g., direct service provision, community health education). This may lead community partners to conflate research and service, not because they do not conceptually understand the difference, but because their primary goal is to obtain services for their communities, and they believe the programs offered to be beneficial (or at least better than nothing) (True, Alexander, & Richman, 2011). A desire to provide presumed benefits to community members may lead partners to target certain subgroups or kinds of people, such as those individuals whom they think are deserving or who will be more compliant, thus creating selection bias (Terpstra et al., 2011).

Potential Conflicts of Interest

Community partners may be employed by or otherwise affiliated with community organizations that are involved in research partnerships, or they may be hired by an academic institution explicitly to liaise with the community for research purposes. No matter their role in or specific contributions to the research, their primary employers, their priorities, and their allegiances may vary (Alexander & Richman, 2008; Terpstra et al., 2011). For example, community partners may interact within their community as service providers or caregivers in addition to being engaged in research. They may be health care providers, public health professionals, teachers, community organizers, medical assistants, or social workers; these dual roles may present competing personal or professional obligations (Fisher et al., 2012; True, Alexander, & Fisher, 2012). They may also be fathers, grandmothers, writers, or housepainters, and their nonresearch roles may value social and ethical norms that differ from research norms, creating ethical ambiguity or conflicts of interest (Anderson, 2010). They may have other interests that could impact the ways in which participants are recruited. For example, members of a patient advocacy group may have personal interests in seeing a study reach enrollment goals if they or family members share the medical condition being studied, and this could lead to an emphasis on benefits and de-emphasis on risks during the informed consent process (Landy & Sharp, 2010).

Moral Distress

Research suggests that community partners can experience moral distress, defined in the nursing literature as "the inability of a moral agent to act according to his or her core values and perceived obligations due to internal and external constraints" (Ulrich, Hamric, & Grady, 2010), when conducting research in communities in which they live and/or work. Moral distress can arise when community partners learn certain information about their communities (e.g., high rates of disease and disability) and become concerned about the circumstances of research participants with whom they interact, particularly if they are members of the same community (Simon & Mosavel, 2010). They may feel a sense of responsibility for things that are beyond their research role—at potential peril to themselves and participants. Community partners may be frustrated by their inability to provide immediate assistance to members of their communities due to limited resources and/or the fact that the primary goal of research is not service provision (Fisher et al., 2012; True, Alexander, & Fisher, 2012). A propensity to want to help can compromise study findings (e.g., randomization) and informed consent (Terpstra et al., 2011). Moral distress may also lead to feelings of disempowerment, particularly when community partners disagree with recruitment approaches, inclusion criteria, or other aspects of study design.

Control over Interpretation and Dissemination of Research Results

When it comes time to interpret and disseminate findings, academic and community partners may have competing agendas. Academic investigators may focus on generalizable claims in order to secure publication or additional funding, while community groups may focus on the local relevance of findings and want to use data for securing services or changing public policy. Partners may have conflicting ideas regarding how and where data are presented as well as what data should be published (Ross et al., 2010a).

Who Needs Research Ethics Education?

Efforts to provide appropriate education and skills training in research ethics are typically motivated by two separate but related goals. The first is an essential role of academic institutions: to ensure that everyone involved in conducting research has the knowledge and skills needed to meet high standards of safety, ethics, and accuracy. The second goal is to comply with federal mandates for instruction on the protection of human participants in biomedical and behavioral research and the responsible conduct of research—mandates that initially developed in response to misbehavior, fraud, and scandal.1 There are several different stakeholder groups that require research ethics education.

Community Research Partners

The label "community research partners" can be applied to organizations *as well as* individuals, as both have responsibilities for the protection of research participants and the integrity of the research process. For federally funded research that involves human

[1]In the 1980s, Congressional hearings on prominent biomedical researchers' reported fraud led Congress to seek to protect U.S. taxpayers' money through increased federal oversight. In 1989, NIH created an Office of Scientific Integrity, and the Department of Health and Human Services (HHS) created its Office of Scientific Integrity Review to investigate allegations of misconduct. In 1982, these two offices were merged into the HHS Office of Research Integrity (ORI), which was given responsibility for "the oversight of research misconduct inquiries and investigations, education and training in the responsible conduct of research, activities designed to promote research integrity and prevent misconduct, and research and evaluation programs" (http://www.ori.dhhs.gov/about/ORI_Mission.shtml). At the end of the 1990s, the failure of IRBs at several major academic research institutions to provide adequate review and maintain appropriate records led to a temporary shutdown of federally funded research at these institutions. In 1999, the NIH Office for the Protection from Research Risks (OPRR) was reorganized and renamed the Office of Human Research Protections (OHRP) and became part of the Office of the Assistant Secretary for Health (OASH) at HHS. One of OHRP's first efforts to improve the quality of research protections was to require research institutions to provide education to IRB members and researchers, focusing on the protection of research participants (http://www.hhs.gov/ohrp/education/).

participants, education is mandated for anyone "responsible for the design and conduct of the study" (NOT-OD-00-039, Required Education in the Protection of Human Research Participants). Many academic institutions extend this requirement to any individual who will directly interact with research participants or data, regardless of the project's funding source. Institutions fulfill this mandate in a variety of ways and are not required to use any particular curriculum; for example, they may require an existing "packaged" program2 or may choose to develop their own program to meet the federal requirement. Federal policy has implications not only for individuals who will be involved in the day-to-day activities of research but also for organizational leaders (who may not be as involved).3

The specific research roles of community partners may span the full range of ethical responsibilities, including identifying and recruiting eligible participants; obtaining informed consent; maintaining privacy and confidentiality; collecting, tracking, and collating data; and reporting adverse events. Community partners may also contribute to the development of research questions, study design and methods, and study materials. All of these critically impact study safety and integrity. Although community partners may have significant clinical, service, or other educational experience, they may have little or no prior research experience and will therefore require ethics education early on in a partnership. Unfortunately, education is too often considered to be a compliance requirement that must be fulfilled before the real work of research can start—and therefore limited to knowledge of the federal regulations. We disagree with this narrow approach to research ethics education. A successful CEnR partnership involves a process of "co-learning" in which both community members and researchers are perceived as experts (Fisher, 1999, 2005). Community partners have specific knowledge of community strengths and vulnerabilities. They possess unique perspectives from which to critique the scientific and social value of a proposed study and inform investigators about the value orientations that guide their reactions to planned procedures (Fisher & Goodman, 2009; Fisher & Ragsdale, 2006). If well educated about the ethical challenges that arise in research and the best practices to address them, community partners can serve as a robust link in the chain of protection of research participants and research integrity. Compliance with regulations and certification to conduct research are important goals. However, the primary goals of research ethics

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[2]OHRP's policy requires institutions to certify that their IRB members and approved investigators have received appropriate education in the protection of human research participants, ethical practice standards, and federal policies. As this mandate coincided with the increased interest in online educational programs, NIH developed an online training module for its intramural researchers soon after the policy was announced. Many universities accepted completion of that NIH module for their own researchers' certification. Around that same time, a national group of IRB directors and ethics educators envisioned a more comprehensive, adaptable, and "trackable" system of educational modules that universities could modify to meet their own needs. In March 2000, Dr. Paul Braunschweiger at the University of Miami and Karen Hansen at the Fred Hutchinson Cancer Center in Seattle founded the Collaborative IRB Training Initiative (CITI, now "Institutional" instead of "IRB") (https://www.citiprogram.org/aboutus.asp?language=english). Ten content experts joined the collaboration, which developed twelve modules on the protection of human research subjects in biomedical research. In December 2000, the CITI course was made available to research institutions by subscription, effectively creating a national standard for research ethics training. As of November 2011, over 1,100 institutions worldwide rely on the CITI program for training and certification in the protection of human subjects in research in multiple languages, and additional modules are available in research integrity/responsible conduct of research, good clinical practices (GCP), privacy and HIPAA, and the humane care and use of animals in research.

[3]From a regulatory standpoint, an institution (for example, a community-based social service organization or a community-based health clinic) is considered to be "engaged" in research when the involvement of their employees or representatives includes: (1) receipt of federal funding in the form of a grant, contract, or cooperative agreement; (2) "direct intervention for research purposes" with participants that involves invasive or noninvasive procedures or manipulation of the environment; or (3) interaction with participants through "protocol dictated communication" (i.e., recruitment, informed consent, data collection) (Guidance on Engagement of Institutions in Human Subjects Research, http://www.hhs.gov/ohrp/policy/engage08.html). Before becoming engaged in federally supported research that is subject to the Common Rule (Title 45 Part 46, Code of Federal Regulations, Protection of Human Subjects), an institution must hold (or obtain) a Federalwide Assurance (FWA) from the Office of Human Research Protections (OHRP) of the Department for Health and Human Services (HHS). The institution must certify that the research has been reviewed, approved, and will undergo continuing review by an IRB (this can be the IRB of another institution or an independent IRB if an organization does not have its own IRB). In establishing an FWA, an institution assumes responsibility for promoting the rights and welfare of research participants and agrees to comply with all applicable laws, regulations, and policies as well as ethical guidelines for research.

instruction for CEnR partners should be to promote knowledge and understanding of good research practices and ultimately create—as theologian Paul Ramsey advocated in his seminal work on research ethics (1970)—true "co-adventurers" in the research enterprise.

Academic Investigators

Most university-based investigators have likely completed research ethics educational requirements prior to getting involved in a CEnR project. Some institutions may also require continuing human research protections education or refresher courses, and many professionals seek out additional training relevant to specific methods, populations, and topics. However, research ethics courses may not address ethical issues and standards of practice that are unique to CEnR, and CEnR education may not relate ethical issues that arise in practice to federal research regulations. Academic investigators are often not aware of the specific ethical challenges that community research partners face in the field, nor do they necessarily have ready solutions. Academic investigators require specific ethics education relevant to the CEnR context.

Community-Academic Research Partnerships

Educating community partners in isolation—for example, through web-based educational modules—limits opportunities for dialogue, questions, and the direct application of concepts to the research project on which they will be working. Any disconnect or separation between ethics education and protocol-specific training may send a subtle message to community partners that ethics education is merely a requirement to be met. Ideally, ethics education should be delivered to academic-community research *partnerships*, and the comprehensive educational needs of all partners should be discussed at the onset of the partnership. Ethics instruction should be role-specific but should also situate individuals' roles in context within the overall project team.

Institutional Review Boards

IRBs are comprised of individuals with a variety of disciplinary backgrounds. This means that many IRB staff and members are not familiar with the particularities of CEnR. This lack of familiarity creates challenges for investigators in presenting their work to IRBs as well as deficits in IRB review of CEnR projects (Flicker et al., 2007; Guta et al., 2010; Khanlou & Peter, 2005; Malone et al., 2006; Shore, 2007; Wolf, 2010). For example, a misunderstanding of CEnR may lead an IRB to harbor misgivings about the competencies of community partners and therefore require "more" rather than "more relevant" training (Dolor, Smith, & Neale, 2008; Yawn et al., 2009). This can create administrative burdens for community partners and exacerbate mistrust among all parties (Solomon & Piechowski, 2011). IRBs that are unfamiliar with CEnR may be limited in their ability to assist CEnR teams in tackling ethical problems that emerge during study design (e.g., deciding whether or not to include a control community) or project implementation (e.g., handling potential breaches of confidentiality). Proposed changes to the federal regulations for human research (Department of Health and Human Services, 2011) may provide more flexibility for behavioral and social science research, and community-academic partnerships will be looking to local IRBs to help them understand how the regulations may affect their research.

Open dialogue between community-academic partnerships and IRBs can increase the appropriateness and rigor of ethical review of CEnR (Wolf, 2010). University-based investigators should educate IRB members regarding the unique aspects of their work and negotiate alternative training strategies for their community partners (Dolor, Smith, & Neale, 2008). IRBs should also be involved in efforts to educate community partners about research, especially institutional policies and procedural requirements. The extensive amount of external oversight that is characteristic of research may be unfamiliar to

community partners, and bringing IRBs and community partners together can put a human face on what is often an enigmatic review process (Hyatt et al., 2009).

How Should Research Ethics Education Be Delivered?

There are significant gaps in knowledge regarding best practices for research ethics instruction

Although NIH requires education for individuals in certain research roles, NIH does not endorse any particular instructional programs. Institutions are considered to be in the best position to determine what programs are appropriate for their needs. NIH does not delineate specific content that should be included in education (NOT-OD-00-039, Required Education in the Protection of Human Research Participants). The evidence base for what constitutes effective instruction in the protection of research participants and scientific integrity is weak (Antes et al., 2009; Antes et al., 2010; Heitman et al., 2007). Instructional programs currently utilized by academic institutions have not been well evaluated; no "gold-standard" has been identified, although certain programs are considerably more popular than others (Braunschweiger & Goodman, 2007). In education on the responsible conduct of research,[4] there is significant variability in topics covered (Epstein, 2008; Grossman et al., 2004) and no unified approach to instruction (Sunderland et al., 2011).

One size does not fit all

The most urgent need may be for educational programs tailored to the unique needs of community partners. Due to the variety of roles, communities, research topics, designs, and partnership structures, an effective curriculum must be flexible and responsive to the ethical challenges of local contexts and learning needs. At the same time, IRBs have been more apt to recognize consistent, one-size-fits-all training programs. While some may criticize these "packaged" educational products, they are effective at providing a low-cost, low-commitment, and highly efficient way to streamline and track the delivery of education to a large number of individuals, hence their popularity with academic institutions. The widespread use of the online Collaborative Institutional Training Initiative (CITI) Program has created the impression for many institutions that CITI is ***the*** required training program. In their efforts to cover the core elements of research protections, educators may overlook the fact that NIH policy gives individual institutions responsibility and authority for identifying what needs to be taught and how best to provide instruction but does not prescribe a particular curriculum.

Community research partners are obviously different from academic partners in some important ways, but little work has been done to identify their specific research ethics educational needs. Several academic institutions, government bodies, and research teams have created research ethics educational materials specifically for community research

[4]Following a policy update issued in November 2009, NIH now requires that all trainees, fellows, participants, and scholars receiving support through an NIH training, career development award (individual or institutional), research education grant, or dissertation research grant receive substantive instruction (defined as eight or more hours—in person/face-to-face and not online) in the "responsible conduct of research" (RCR) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html). NIH policy defines RCR as "the practice of scientific investigation with integrity," which "involves awareness and application of established professional norms and ethical principles in the performance of activities related to scientific research." (Required RCR instruction covers broad nine topic areas, including conflict of interest; policies regarding human subjects, live vertebrate animal subjects, and safe laboratory practices; mentor/trainee responsibilities and relationships; collaborative research including collaborations with industry; peer review; the acquisition, management, sharing, and ownership of research data; research misconduct (fabrication, falsification, and plagiarism) and policies for handling misconduct; responsible authorship and publication; and the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research. These new topics areas reorganized and expanded upon earlier recommendations to emphasize policy in human and animal research and laboratory safety; the social role of biomedical scientists, ethical issues in biomedicine, and the social and environmental impact of research (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

partners, but these are primarily project, population, or institution specific and therefore must be adapted for use with other types of partners (see Table 2). We are not aware of any curriculum that has been thoroughly evaluated or is endorsed by recognized research ethics experts that is widely accepted by IRBs as a substitute for the standard human subjects protection training required of all key research personnel. While institution-based and community-specific trainings may continue to proliferate and be shared, a national consensus on the basic minimal requirements for content, preferred formats and modes of delivery, and standards for assessment of research ethics education for community partners is needed to provide guidance and consistency, as well as facilitate recognition and acceptance of alternative trainings by IRBs.

There is often a disconnect between training offered by an institution in fulfillment of the requirements and the information and skills that are actually needed to work on a CEnR project. For example, preliminary research has shown that CEnR studies may have more data accuracy and completeness problems than those that use traditional academic-based research assistants (Brugge et al., 2010), but standard research ethics education rarely covers data integrity issues in any detail as research personnel working in academic settings learn these norms and skills through other means. Common sense also suggests that community partners must have basic “research literacy” before they can truly contribute to research—or benefit from instruction on more advanced or specific topics like ethical principles or informed consent (Goodman, Dias, & Stafford, 2010; Ross et al., 2010c). Much of the research ethics instruction offered by academic institutions may not be perceived by community partners as relevant or useful; this assertion is based on published reports (Alexander & Richman, 2008) as well as our own experience and that of colleagues.

In many settings, modifying curricula initially designed for academic researchers or graduate students is not always a viable or appropriate solution (Merritt et al., 2010). Current standardized programs contain much information that is not directly relevant to CEnR studies (especially those that do not involve medical intervention), and many do not include practical information that people involved in the day-to-day work of community-based studies need to know in order to do their jobs well (True, Alexander, & Richman, 2011). For example, research ethics education may deliver the message that protecting participant confidentiality is important but not necessarily explain how to accomplish this when working in the community—literally on the streets and out of cars—and interacting with research participants who are part of their regular social networks (Edwards, Lund, & Gibson, 2008; Terpstra et al., 2011). There is often a disconnect between how recruitment, informed consent, and data collection tools are developed for institutional review board (IRB) submission and how they are implemented in the field. Written research protocols tend to focus on the language in the consent form but omit details of the recruitment and informed consent *process* that are essential for those who will actually be doing that work. Community research partners are not always provided with adequate guidance regarding what to do once they get in the field, the specific challenges they may face, or tools for resolving dilemmas (Fisher et al., 2012; True, Alexander, & Fisher, 2012)—for example, how to handle if a potential participant slams a door in their face, insists that they want to participate but will not take the time to read the consent form (or have it read to them), or appears to lie to meet inclusion criteria.

Formal instruction is not enough to ensure compliance with rules

Mentoring and leadership from experienced community and academic investigators as well as institutional policies and climate can also influence the ethics and integrity of research (Clinical and Translational Science Awards Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, 2011). However, even

less is known about how to change institutional climate than how to provide optimal research ethics education (Geller et al., 2010).

The following recommendations for best practices and a research agenda result from our extensive review of the theoretical and empirical literatures related to research ethics education and ethical issues in CEnR. Through the group writing process, we have identified certain areas where evidence is sufficient to support concrete recommendations. We have also identified significant gaps in knowledge, suggested which gaps deserve priority, and offered specific research strategies for filling those gaps.

Best Practices

Ethics Education Across Stakeholder Groups

We have argued that community research partners, academic investigators, and IRB members need research ethics education that is CEnR-focused and tailored to their learning needs. However, while the specific instructional needs and learning styles of these stakeholder groups may be different, we argue that their instruction should not occur in isolation from each other. Opportunities for information exchange are crucial and should be encouraged. Time should be taken to engage in co-learning regarding the people, institutions, and communities involved in the partnership in order to foster a culture of scientific integrity and transparency.

Specific Recommendations for Educating Community Research Partners

Every community is unique, and each research protocol is different, but ultimately unifying principles, unified approaches, and core tools are needed. Therefore, any curricular materials or resources developed specifically for community partners should emphasize consistency with traditional standardized programs in terms of learning objectives and topics, but they should also be flexible enough to allow customization to community and project contexts and learning needs. Research ethics education should be tailored to partners' unique roles, responsibilities, backgrounds, and learning styles. While research is needed to identify optimal instructional methods and content, we can make some preliminary recommendations in these areas (see Table 3).

First, to decrease burden, education should be focused on the specific research context. Content should be relevant to immediate roles and responsibilities, research design and setting, and participation population. Second, education for community partners with no or limited research experience should be as protocol-specific as possible. Individuals who are new to research cannot be expected to extrapolate broad ethical principles or relate examples from other research settings to their specific situations. Program materials should anticipate those ethical dilemmas that may reasonably occur during fieldwork, and instructors should teach to these specific issues. Key process issues related to scientific integrity, such as what constitutes falsification/fabrication of data, accurate completion and handling of data forms, and tracking participant data and incentive payments, should be covered. Third, research ethics education should include hands-on opportunities to practice new skills (e.g., approaching a potential participant and obtaining informed consent) and receive concrete feedback. In order to minimize burden, instruction regarding such operational issues could be provided in the form of on-the-job training by a variety of experts, including research subject advocates (RSAs),5 experienced clinical research coordinators, or community-engagement specialists located centrally within academic institutions. Fourth, community research partners involved in day-to-day fieldwork activities should have ongoing opportunities for discussion among themselves and with study investigators to debrief. Ideally, this dialogue will create a feedback loop about ethical issues that arise in practice and strategies for addressing them. These discussions should also include approaches to

managing feelings of moral distress (and stress more generally). Fifth, ethical issues that are unique to CEnR should be integrated into educational programs for all stakeholder groups. Before this can be accomplished, more research is needed to determine the most salient problems, characterize the dilemmas, and identify potential ethical solutions that are consistent with the values of both academic researchers and community partners. Lastly, research ethics education should focus on communication; an important goal of education for community partners should be empowerment to ask questions and speak up when they see potential ethical pitfalls.

Research Agenda

Research ethics education should be evidence-based both in terms of the topics covered and instructional methods employed. To this end, we propose the following research agenda and emphasize that studies in all of these areas could greatly benefit from a partnership approach (see Table 4).

First, there is a critical need for large-scale evaluations of existing, quality research ethics educational programs for all stakeholders but community partners in particular. Experimental methods should be used to identify which instructional methods (e.g., online programs versus face-to-face training; individual role versus team-based approaches) are most effective for each group.

Second, more information is needed regarding community partners' various research roles in order to more appropriately tailor education to specific levels of engagement.

Third, further exploration is needed to determine how university-based investigators, community partners, and IRB members may differently define, approach, and resolve ethical issues. Some fundamental differences in professional culture, expertise, and the interpretation of research risks and benefits may influence ethical analysis. This groundwork can identify areas for educational focus, particularly in terms of communication, and support development of tools such as models for facilitating consensus when partners fundamentally disagree about the translation or prioritization of basic ethical principles.

Fourth, further investigation of prospective participant views of research is needed. Such work may uncover research practices that are scientifically sound but inconsistent with community values. Such practices may create participation barriers due to community concerns regarding threats to autonomy, group stigmatization, or participant distress. These concerns may not be readily discerned through professional logic or scientific inference. Such research will require investigator openness to community knowledge and opinion that may challenge traditional scientific procedures and perspectives and require novel and unconventional yet rigorous methodologies (Fisher, 1999, 2005; Fisher et al., in press; Goldberg-Freeman et al., 2007).

[5]Since the creation of the Research Subject Advocate (RSA) role by NIH in 2000, RSAs have filled a variety of needs in human research protection programs at academic centers, ranging from direct advocacy work with participants, to auditing, improving the transparency of research, and educating researchers in human research protections (National Center for Research Resources Division for Clinical Research Resources, 2005; Neill, 2003; O'Lonergan, 2003). Within CTSA-funded institutions, Research Subject Advocacy has increasingly been organized around best practice functions that include the integration of human research protection policies and educational activities across institutional entities and acting as a resource to research participants and investigators (CTSA Regulatory Workgroup, 2008). Some RSA programs also train community research partners regarding the protection of research participants. Other RSA programs, particularly those that are too large to engage participants individually, use their RSA resources to host broad outreach programs designed to raise the visibility of research, engage communities in setting priorities, educate partners and communities about the potential benefits and risks of research, and explain the protections and procedures in place to protect research participants (Winkler, 2011).

Fifth, some specific challenges to the protection of participants and the integrity of the research process that arise in the field in CEnR projects require systematic investigation. Currently, published case studies rather than rigorous research are the primary source of information regarding unique ethical issues in CEnR. National surveys of CEnR projects could identify common problems and describe differences among various research designs, populations, and settings. Qualitative research with stakeholders could identify areas in need of ethical clarification. Below we outline four broad areas of exploration that could greatly contribute to the development of content for CEnR ethics education (numbered as 5.1–5.4).

5.1 Information regarding the nature of financial relationships among academic institutions/investigators, research projects, community-based agencies, and individual community partners should be collected. Details regarding contractual agreements, employment status, salary, and benefits as well as arrangements for sharing power, resources, and decision making among stakeholders are crucial to understanding the full picture of CEnR ethics (Alexander & Richman, 2008).

5.2 More research is needed to determine how dual roles (i.e., community partners' research and nonresearch roles) or competing priorities can create conflicts of interest that pose harm to research participants and/or the integrity of research data. The potential effect of recruitment through community-based organizations on participants' perceptions of voluntariness, the understanding of key elements of informed consent (e.g., right to withdraw, benefits), and breaches of confidentiality must be examined (Anderson, 2010). Research is needed on research participants' perceptions of "insider" (e.g., community partners) versus "outsider" (e.g., graduate research assistants) recruiters and the effects of these perceptions on participant enrollment and retention, quality of informed consent, voluntariness, trust in research, compliance with study requirements, data quality, and perceived value of research (Alexander & Richman, 2008; Simon & Mosavel, 2010). This information can inform best practices for the training, selection, and compensation of individuals who recruit research participants and obtain informed consent process (Molyneux, Kamuya, & Marsh, 2010; Simon & Mosavel, 2010).

5.3 A better understanding of actual harms to individuals *qua* community membership as well as harms to communities is needed. Research can identify strategies for mediating these risks (Fantuzzo, McWayne, & Childs, 2006; Fisher et al., in press; Mohatt & Thomas, 2006) as well as potential guidelines for considering community-level risks in the IRB review process.

5.4 Research is needed on moral distress. This could explore questions such as how competing responsibilities are balanced, particularly when service providers (or individuals with a service orientation) are involved in recruitment, informed consent, and data collection (Fisher et al., 2012). Strategies for identifying and reducing moral distress could be incorporated into research ethics education.

Educational Implications

Throughout this manuscript, we have documented how currently available research ethics education programs fail to meet the needs of all groups that have a role in CEnR—community research partners, academic investigators, and IRB members. Ideally, curricular materials and activities should reflect the realities and particularities of CEnR; identify potential areas of difference and disagreement among stakeholder groups; recognize and promote the value of protecting research participants, the integrity of the research process, and the quality of data; and embrace CEnR principles of co-equal partnership. Robust,

tailored educational resources and opportunities can enhance the potential of community partners to be effective agents for the ethical conduct of research and support the self-determination of communities and individuals to engage and participate (or not) in research.

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TABLE 1

Authors' Related Roles and Experience.

Current or Past Experience	Authors
Member or chair of IRB	Anderson, Solomon, Heitman, DuBois, Kost, Ramsey, Ross
Research ethics consultation service	Anderson, Solomon, Heitman, DuBois, Kost, Ammerman, Ross
Principal Investigator on CEnR project	Fisher, Kost, Ramsey, Ammerman, Ross
CEnR a primary area of research	Fisher, Kost, Lawless, Ramsey, Ammerman (CEnR ethics: Anderson, Solomon)
Member of Community Advisory Board	Anderson, Solomon, Lawless, Ramsey, Jones, Ammerman
Member of advisory board for CEnR project	DuBois, Fisher, Kost, Lawless, Jones, Ammerman
Involved in development of research ethics curriculum	Anderson, Solomon, Heitman, DuBois, Fisher, Kost, Lawless, Ramsey, Jones

TABLE 2

CEnR Ethics Education (in alphabetical order).

Curriculum	Reference/Web Address (Organization)	Description
CIRTification: Community Involvement in Research, Training in Human Research Protections	http://go.uic.edu/CIRTification (University of Illinois Chicago in partnership with Northwestern University, University of Chicago, Rush University, & Loyola University of Chicago)	• Uses train-the-trainer model and includes participant workbook • Intended for the spectrum of CEnR partners/roles • Developed by one of this paper's authors (EA)
Ethical Protections in Community-Engaged Research	Solomon, S., & Piechowski, P. (2011). Developing community partner training: Regulations and relationships. *Journal of Empirical Research on Human Research Ethics*, 6(2), 23–30. (University of Michigan)	• To be used for group instruction • Developed by one of this paper's authors (SS)
Ethics and Research in the Community	http://ori.hhs.gov/education/products/mass_cphs/training_staff/index.htm Alexander, L., & Richman, K. (2008). Ethical dilemmas in evaluations using indigenous research workers. *American Journal of Evaluation*, 29(1), 73–85. (Office of Research Integrity, Bryn Mawr College, Massachusetts College of Pharmacy and Health Sciences)	• Completed online • Available in Spanish • Intended for research workers in community-based trials
Faith Moves Mountains	Hatcher, J., & Schoenberg, N. (2007). Human subjects protection training for community workers: An example from "Faith Moves Mountains." *Progress in Community Health Partnerships*, 1(3), 257–265. (University of Kentucky)	• Intended to be delivered in-person • Project- and role-specific
Field Training Guide	Merritt, M., Labrique, A., Katz, J., Rashid, M., West, K., & Pettit, J. (2010). A field training guide for human subjects research ethics. *PLoS Medicine*, 7(10), 1–4. http://www.jhsph.edu/sebin/u/p/Field%20Guide_25Feb10.pdf (Johns Hopkins University)	• Brief written guide • Intended for field workers/data collectors in community-based trials
Keeping Research on Track: A Guide for Aboriginal & Torres Strait Islander Peoples about Health Research Ethics	http://www.nhmrc.gov.au/publications/synopses/e65syn.htm (Australian Health and Medical Research Council)	• Intended for Aboriginal and Torres Strait Islander peoples
Project TRES: Training in Research Ethics & Standards	http://www-rohan.sdsu.edu/~gra/grad/research/projecttresinfo.html Terpstra, J., Coleman, K., Simon, G., & Nebeker, C. (2011). The role of community health workers (CHWs) in health promotion research: Ethical challenges & practical solutions. *Health Promotion Practice*, 12(1), 86–93. (San Diego State University)	• Available in web-based or hard copy format for use as either a stand-alone, directed self-study training or in conjunction with group training • nitially developed for community health

Curriculum	Reference/Web Address (Organization)	Description
		workers (CHWs)/ Promotores
Protecting People Who Participate in Research	http://www.hpdp.unc.edu/training (University of North Carolina–Chapel Hill)	• Set of approximately 30 slides developed by two authors (BJ, AA) as alternative IRB training
Research Ethics Training Curriculum for Community Representatives	http://www.fhi360.org/en/RH/Training/trainmat/ethicscurr/index.htm (Family Health International)	• Designed for individual or group learners (recommend 2 full days of instruction) • Available in English, French, Spanish, and Portuguese • Online self-study in English • International research context

TABLE 3

Best Practices for Research Ethics Education for Community-Engaged Research.

Recommendations	Curricular Elements and Activities
Educate community partners together with academic researchers and institutional groups involved in research review	• Opportunities for information exchange among academic, community partners, and IRBs • Team training • Case-based discussions
Focus on ethical and regulatory requirements that relate to specific research project	• What do learners need to know for their roles and responsibilities? • What is relevant to the research design? • What is relevant to the setting and participant population? • Review of population-specific regulatory requirements for informed consent (e.g., children and assent) • Eliminate discussions of issues pertinent only to biomedical clinical trials if research involves survey methods only
Integrate ethics education with protocol-specific training	• All examples should be relevant to research protocol • Anticipate specific ethical dilemmas that may arise in field • Cover process issues related to protocol adherence and data integrity • Review actual study informed consent document • Discuss what to do when someone does not meet inclusion criteria but insists they want to participate • Review best practices for recordkeeping and documentation
Provide hands-on opportunities to practice new skills	• Role plays to practice recruitment and informed consent
Offer opportunities for ongoing education and discussion about ethical issues	• Establish a continuous feedback loop between field staff and investigators • Weekly field staff meetings with standing agenda to discuss recruitment problems, stress, and distress
Review ethical issues unique to CEnR	• Partnership challenges • Risks to groups • Conflicts of interest • Case-based discussions about social implications of research for all community members • Ask participants to identify issues that may arise in the study they will be working on
Discuss communication issues and strategies	• How to ask questions when you do not understand • How to speak up when you think something is wrong • Consensus-building • Role plays in which individuals assume the parts of different stakeholders

TABLE 4

Research Agenda for Ethical Issues in CEnR.

Research on Educational Methods

- Evaluate research ethics education programs
- Identify effective instructional methods for different learner groups
- Gather information on research roles played by community partners in order to tailor education to specific levels of engagement

Research on Defining and Resolving Ethical Issues

- Explore how different stakeholders define, approach, and resolve ethical issues
- Test and refine models for facilitating consensus when stakeholders disagree

Research on Participant Views

- Determine actual and potential participants' opinions, preferences, and values regarding (for example)
  - autonomy and informed consent
  - privacy and confidentiality protections
  - barriers to research participation
  - group stigmatization resulting from research participation or findings
  - potential for research to cause distress

Research on Ethical Challenges Unique to CEnR

- Describe the types of financial relationships that exist between academic-community partners
- Examine the potential harms of community partners' dual roles and competing priorities
- Describe real and potential cases of harm to communities and individuals *qua* community membership
- Identify sources of potential stress and distress among community research partners and develop strategies for minimizing stress and distress
- Characterize common problems and describe differences among research designs, populations, and settings
- Recognize and explore areas in need of ethical clarification