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From Subject to Participant: Ethics and the Evolving Role of Community in Health Research

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Abstract

Community members play an increasingly important role in public health and health services research. New models of community-engaged research may entail novel ethical priorities. For example, the principles described in the Belmont Report focus on the wellbeing of the research subject, yet community-engaged investigators often eschew the role of subject for that of participant. We conducted semi-structured interviews with 29 community and academic investigators working on 10 community-engaged studies. Interviews elicited perspectives on ethical priorities and ethical challenges. Interviewees drew on the Belmont Report to describe four key principles of ethical community-engaged research (embodying ethical action, respecting participants, generalizing beneficence, and negotiating justice). However, novel aspects of the participant role were the source of most ethical challenges. We advance a theoretical argument that the shift in ethical focus from *subject* to *participant* poses new ethical dilemmas for community-engaged investigators and for other constituents interested in increasing community involvement in health research.

Patients, family members, health advocates, and healthcare agency leaders play substantially different roles in health services and public health research than they did just a few decades ago.¹⁻³ Many major U.S. health research funders today expect community involvement in research design, execution, or dissemination.⁴⁻⁷ For instance, “Engaging communities in research” is a key goal of the National Center for Advancing Translational Science (NCATS) at the National Institutes of Health. The Patient-Centered Outcomes Research Institute (PCORI) prioritizes patient involvement in the development, governance, oversight, and dissemination of research.^{8,p.10} A report commissioned by the Agency for Healthcare Research and Quality (AHRQ) found that “Stakeholder involvement...helps ensure that [AHRQ research] responds to relevant and important issues...develops products that are accessible and user-friendly, and...ultimately reaches its intended audiences.”^{9,p.i}

On the whole, community-engaged research asks community members with lived experience of the health problem under study -- or with responsibility for populations with this lived experience (e.g., community-based agencies, advocates, payers) -- to participate in planning, designing, conducting, interpreting, and/or disseminating research. Community engagement in research can take numerous forms, from limited advisory roles in early stages (e.g., input on research priorities) to key leadership responsibilities at every stage, as in community-based participatory research (CBPR).¹⁰⁻¹³ Consensus-building activities, shared control of data, and long-term partnerships can be key elements of community-engaged projects. These research approaches reflect the growing prominence of patient-advocacy groups and the concept of participatory science.^{1,14,15}

Until the latter decades of the twentieth century, community members primarily participated in research as *subjects*. Indeed, the construction of the role of the research subject is inextricable from the historical development of the human sciences generally and health research specifically.¹⁶⁻¹⁹ Researchers defined the research situation with reference to three aspects of the subject role. First, the role of the subject is context-dependent: an individual becomes a subject by consenting to provide data for a specific study (e.g., in a particular laboratory). Second, the role of the subject is task-focused: it centers on completing activities that generate data, such as giving biological samples or completing tests. Finally, the role of the subject is time-limited: once data collection is complete, the subject role ends, as does, typically, the researcher's relationship with the individual. Once specified, the subject position allowed researchers to elaborate and refine key intellectual assumptions about research rigor, reliability, and validity. Among these were that one can generalize from data on individuals (e.g., those with particular diseases) to larger populations (e.g., others with the same disease); that an individual can be studied in isolation from social context; and that abstract attributes (e.g., intelligence, conscientiousness) can be reliably measured in artificial experimental settings.

The specification of the subject role also structured the concept of research ethics codified in the Belmont Report. The distinction between researcher and subject set the stage for “trust-based obligations” that are the foundation for what we understand as research ethics^{20, p. 542} with the “protection of human subjects” as a core ethical goal.^{21, p. 5} The experimental situation should maximize benefits and reduce risks to subjects as much as possible (the Belmont Report’s “basic ethical principle” of beneficence),²² individuals should participate voluntarily (principle of respect for persons), and risks and benefits to potential research subjects should be fairly distributed (principle of justice). To preserve the voluntarism at the heart of this relationship, both parties should expect the experiment to generate useful knowledge that could not be otherwise obtained²³ and that this knowledge will be free of fabrication and falsehood.²⁴ Institutional Review Boards (IRBs) assess whether subjects are adequately protected and insist upon extra protections for those from vulnerable groups who may experience unusual constraints on voluntary decision-making or who may be less likely to receive the research benefits.²⁵

In contrast, community-engaged investigators enlist individuals in research as *participants*, advocating a transformation “from regarding individual community members as *research subjects* to engaging community members and the organizations that represent them as

research partners."^{10, p.1} Community-engaged investigators prefer the participant role because it "[i]ncreases the possibility of overcoming the understandable distrust of research on the part of communities that have historically been the 'subjects' of such research."^{26, p.181} To community-engaged investigators, words like "subject" and "researcher" can signal exploitation rather than ethical protection because the subject role is seen to require passive acquiescence to others' agendas.^{27,28} Community-engaged investigators also eschew the sharp distinction between subject and researcher and seek to minimize the distance between community and academic participants through the mutual exchange of knowledge and skills.²⁹ Community-engaged research is understood to be "'with' community...rather than 'for' [the] community."^{28, p.321} Community-engaged research participants may include enrolled individuals, research partners, social and constituent groups, funders and payers, study-site staff, and others with some stake in the project.

Many investigators recognize the ethical implications of these new research relationships, but the theory and practice of ethical community-engaged research remain inchoate.³⁰ While community-engaged investigators accept the continued relevance of the three Belmont principles,³¹ they articulate novel ethical priorities³⁰ and encounter new ethical challenges.³²⁻³⁴ Community-engaged investigators have developed innovative approaches to support ethical conduct,³⁵ yet investigators' opinions about ethical priorities can vary.³⁶ While many investigators view community engagement as a means for achieving ethical ends,³⁰ the field lacks objective criteria and shared guidelines for implementing ethical practices in community-engaged research.³⁷ Conceptualizing ethics in community-engaged research is important for developing normative guidelines, educating investigators, and monitoring research conduct.^{38,39}

In this paper, we use interview data from community and academic investigators working on community-engaged projects to describe the ethical priorities and dilemmas in community-engaged research. We compare across projects to outline four principles of ethical community-engaged research and to advance theory that accounts for common ethical challenges. We show that most ethical challenges emerge as a result of the collapse of the subject position. Community-engaged investigators' ethical focus on the participant – a role which is less time-limited, setting-dependent, and task-focused than that of the subject – raises ethical dilemmas that resist resolution through traditional ethical frameworks. By directing attention to this shift from *subject* to *participant*, we characterize sources of ethical challenge, propose strategies that can support ethics in research engaging community members, and raise a set of fundamental questions for further study.

Methods

We used a three-step approach developed in prior studies to select interviewees.⁴⁰ First, we listed all academic investigators (n=17) affiliated with the NIMH Partnered Research Center (PRC), a mental health services research center at the University of California, Los Angeles (UCLA), whose mission is to improve care through academic and community partnerships.⁴¹ Second, we listed current projects of these investigators (n=22) and identified each project's main academic and community partners. Because some Principal

Investigators (PIs) led several projects, we randomly sampled one project per PI to minimize burden. For each sampled project, we invited at least one lead academic and community partner to participate in an individual phone or in-person interview. For projects involving more than two community agencies, we invited at least two academic and two community investigators.

Between January and June 2013, we interviewed 15 academic and 14 community investigators working together on ten sampled projects. We obtained oral consent at the beginning of each interview. We interviewed at least one academic and one community investigator working on all but one sampled project (for which we could not contact a community partner). Typically, two authors conducted each interview. Interviews were audio recorded and professionally transcribed.

A semi-structured interview guide included questions about research ethics and its practice on the project. Using open- and closed-ended questions, we elicited details about ethical priorities and ethical challenges. The project's Advisory Board academic and community members reviewed and commented on the protocol. We tested the protocol with a community and an academic partner, modifying it for clarity and cultural competency. The RAND Human Subjects Protection Committee approved this study.

Three authors analyzed interview data using both content coding and thematic analysis. We first developed a hierarchical codebook based on the interview guide to mark topics (i.e., attributes of ethical research, ethical challenges), which we then counted and categorized. To ensure coding consistency, two experienced qualitative researchers performed coding independently on 20% of the dataset, discussed disagreements until consensus was reached, and then coded the entire dataset. Then, we used thematic coding to identify underlying concepts that linked recurrent and salient statements about ethical priorities and challenges. To refine emergent themes, we used a constant comparative approach, comparing within and across interviewees to delineate connections between concepts.⁴² All authors discussed thematic coding results at several stages. We reviewed examples to reach consensus and then re-coded and refined themes.

Results

Interview Sample Characteristics

Ten sampled projects addressed such topics as community wellbeing and resilience and collaborative care models for the treatment of mental health and substance abuse. Interviewees included 22 women and 7 men; 16 interviewees were white, 5 Hispanic or Latino, 4 African-American, and 4 Asian. Most academic PIs were affiliated with UCLA, RAND, or the University of Southern California. Community PIs came from advocacy agencies, faith-based organizations, school districts, the Veterans Health Administration, county and state departments of health and mental health, or payer agencies.

The Meaning of Ethical Community-Engaged Research

Content-coding categories and counts for responses to the first interview question about attributes of ethical research ("What does it mean to you to say that you are doing ethical

research?”) are shown in Table 1. Ethical challenges mentioned by interviewees are shown in Table 2.

Table 1 shows responses to the first question only, but interviewees elaborated on the meaning of ethical research throughout the interview. One community interviewee captured the viewpoint of many others with her summary of ethical community-engaged research:

The first word that comes to mind is doing the research with integrity. Where I'm respecting my participants. Their needs. I'm being culturally competent. Mainly because I work with African-Americans and Latinos, to be appropriate in how I ask things and how I treat them. And then also making sure that I have integrity with everyone -- with the partners, too, because of the [partnered research] model that we're doing also. Being clear and making sure that I'm following all procedures. Being ethical is respecting their identity 100%. And always putting myself in their shoes. Treat how I want to [be treated] – as a participant, right? And also as a researcher.¹

For this interviewee, ethical community-engaged research meant enacting respect in all interactions. She understood ethical protections to apply to enrolled participants but also aimed to uphold ethical priorities (e.g., cultural competence) with potential participants; the racial, ethnic, and cultural groups of which the participant was a member; and colleagues and co-investigators.

Four themes recurred in interviewees' descriptions of ethical community-engaged research. These themes describe interviewees' overarching approach to conducting ethical research (i.e., embodying ethical action) as well three approaches they used to operationalize it (i.e., respecting all study participants; generalizing benefits while eliminating or mitigating various potential harms; and negotiating with participants – rather than determining *a priori* – what would count as impactful and fair research). As we describe below, in adopting these approaches, interviewees focused ethical action on a new type of object, the participant, and encountered new ethical challenges.

Embodying Ethical Action—Interviewees understood a broad range of activities to have ethical importance. Their approach to conducting ethical community-engaged research involved a heightened attentiveness to the ethical implications of all research activities. We call this approach *embodying ethical action*. For instance, interviewees described ethical community-engaged research as requiring more than compliance with routine protocols. As an academic interviewee said, “[D]oing ethical research means being impeccably in line with the Belmont recommendations and what the federal government wants us to be in line with. That's sort of a minimum standard [for] all projects.” As a community interviewee said, a contract like a Memorandum of Understanding (MOU) is only the scaffolding for an ethical project:

[W]e've had things done in the past where people come and say, oh, this is a contract between [two institutions]. And then they'll say, okay, well, this is all you

¹Interviewee quotes were not edited but essential clarifying information was added in some cases.

need. And it's not all you need. It's just the beginning....[The MOU] just gives you a baseline to say, okay, this is what we agree upon at this level and we'll evolve.

Embodying ethical action entailed meeting the highest ethical standards in each action and interaction through exacting ethical choices and continuous ethical awareness.

Interviewees understood themselves to be moral actors engaged in research as an ethical activity. Many described actuating a new type of ethical practice through mutuality, equity, and shared responsibility. These were valued ends in themselves – not just means to knowledge production. An academic interviewee explained that ethical practice entails not just procedures but a sensibility orienting all activity. This interviewee said that community-engaged investigators had to consider “how do you break through the priors so that the ethics of it can be felt and...are a living, breathing entity?”

Many interviewees framed these expanded priorities as reparative. Academic and community interviewees mentioned instances of historical misconduct as challenges to current research (Table 2). As an academic interviewee said,

in almost every [community] setting that I've been in...they have had negative experiences...with researchers who come and gather information...and then they move on, and they don't necessarily give anything back to the community site. So...there is a lot that has to happen up front to build the relationship...so that they can feel like you're actually there to help them.

These interviewees took ownership for other investigators' past misconduct in an effort to repair relationships with communities on behalf of participants harmed in the past.

Respecting All Study Participants—The Belmont Report defines respect for persons as enacted in the open communication of information relevant to study participation, including risks and benefits, and ensuring voluntary enrollment in the research.⁴³

Interviewees generalized this principle to all participants, aiming to practice respect, truthfulness, and free choice with enrolled and potential participants, research partners, study-site staff, community members, and the community as a whole. As a community interviewee said, “[E]thical research... does not invade one's space, does not disrespect anyone, does not not do benefit [sic] to the community, does not stigmatize.” Respecting participants meant ensuring a careful informed consent process. The study would, as an academic interviewee said, “go that extra mile to make sure that the consent process truly is an informative and collaborative process regardless of who the participant is.” Interviewees also described an obligation to seek consent from the participant's community.

Interviewees described trust and relationship-building on the team and in the community as critical enactments of respect for participants. As a community interviewee says,

Trust is a big piece. There's not, usually not a lot of time and planning to make sure that you give that relationship-building piece that is needed to build that trust for the participant and the community. And then it's often overlooked. So I think that that's the biggest. That relationship-building and the trust area is [sic] a big aspect for ethical research for me.

Interviewees also described the importance of valuing all participants' perspectives. For one community interviewee, respecting participants meant that her research partners valued the mission of her organization: “the academic groups really understanding that what I do and why I do it is not for a commercial purpose.” She added that “sometimes they are really surprised. They say, oh wow, I didn't know you guys did that.” Respecting participants also applied to study-site staff. An academic interviewee cited the need for respectful treatment of staff at community sites such that there is a “pretty immediate, usually within 24 hours... investigation and intervention” that takes place when “a partner feels like a research assistant's been disrespectful.”

Despite the clarity and commonality of this commitment, ensuring respect for participants frequently raised ethical challenges (Table 2). A difficulty in ensuring respect for participants was that participant tasks and involvement varied over time. Participants may function as co-investigators, study advocates, clinical supervisors of study staff, friends of study leaders, or study enrollees. Participants might join, drop out, then re-join the study.²⁸ Inclusiveness was seen to further trust, but interviewees mentioned that personally close relationships among research-team members raised concerns for coercion or unfair treatment. One community interviewee also questioned the validity of study data when relationships between investigators and enrolled participants were close: “sometimes when you interview people that you know, it makes me wonder how accurate their opinion is gonna be...if you're asking, ‘Oh, you have HIV?’ Are they gonna say the truth? Or any other things that might be very personal?”

As one academic explained, “I think the most difficult piece of this has been: ‘Are providers [at the study site] human subjects? And at what point are providers human subjects?’” A community interviewee said that her study team addressed this problem by distinguishing between planning and data collection. Some activities were termed quality improvement efforts not requiring voluntary consent:

[W]e have made this distinction between what's research, because we're initiating it and we're collecting data, and it's totally voluntary to participants; and then what's quality improvement at the clinic [such as]...group planning that we've been doing for six months; and...quality improvement sub-groups that are...testing the interventions. Now, we've had this discussion with [the IRB] about what's research and what's not and who are the participants and subjects...and who aren't, so we decided with [the IRB] that people who are participating in data collection are subjects. That's totally voluntary.

These complex distinctions among research, planning, and quality improvement were needed to set expectations for voluntariness.

Interviewees also said that difficulties protecting confidentiality and privacy could undermine efforts to enact respect for participants.² One community interviewee mentioned that a provider's survey response was inappropriately shared with other stakeholders in an

²The obligation to protect confidentiality is supported by the Belmont principles of respect for persons and beneficence. However, our interviewees described breaches of confidentiality as most concerning because of their potential to undermine trust in the research team, which is most consistent with the theme of respecting all study participants.

effort to facilitate planning activities. Another community interviewee discussed challenges clarifying when patient problems uncovered through research procedures can and cannot be shared with providers:

Research or not, if a provider knows the patient has the problem, no matter what study condition they're in, they're going to help the patient. ...We've had to have, or we're developing it anyway, a kind of a hierarchy of, if it's an emergency, then of course you can't [protect privacy]....And so it sort of [was] determined that patient care comes first and the study comes second.

Finally, a community interviewee described difficulty weighing the responsibility to uphold confidentiality with the need to support one's organization as an employee: "you're in a tricky position because there are pressures for you...to protect the clients and who might have experienced pressures from your organization to do more business." Thus, while practicing respect with all participants was a compelling ethical goal for interviewees, ethical challenges commonly arose from participants' multiple and evolving roles.

Generalizing Benefits While Mitigating Harms—The Belmont Report describes beneficence as maximizing benefits of the research project while minimizing harm to the subject. Benefits could include generating knowledge that will help individuals who share characteristics with the subject. Minimizing harm means ensuring that study procedures are as safe as possible for subjects. Our interviewees agreed that protecting enrolled participants was a key attribute of ethical community-engaged research (Table 1). Yet our interviewees also considered the potential benefit and harm of a variety of study activities and interactions, not just knowledge-production tasks. They also heightened the responsibility of generating benefits to constituents beyond enrolled participants. Interviewees described efforts to generalize benefits to all individuals touched by the study. Almost half stated that ethical community-engaged research must generate community or policy benefit (Table 1). Sound science and compensation for participation did not suffice.

Interviewees mentioned the need to address harm that might result from study procedures (e.g., modifying instruments to improve cultural sensitivity). They further described themselves as responsible for constructively addressing problems identified during the research (e.g., suicidality) even if unrelated to study procedures. A community interviewee said, "I don't feel that it's ethical not to provide services to a student population or school population that we identify as having needs." An academic interviewee added that community-engaged research includes an ethical obligation to address the needs of a community: "[Research] is not causing harm, but you have opportunities to intervene and being socially responsible when there's an opportunity at hand... and it's reasonably within your scope."

The process of generalizing benefits was associated with a number of challenges (Table 2). In particular, interviewees described challenges maximizing benefit and minimizing harm to the research team. Interviewees described participation in the tasks of knowledge-production (e.g., authoring papers) as a way to maximize partner benefit, but they also cited the need to identify substantive research roles for partners as an ethical challenge. Interviewees described the work burden for community partners and difficulties achieving equitable

community compensation as areas of potential harm. Moreover, interviewees said that balancing benefit and harm were complicated by the multiple roles participants played:

They've got their whole job to do and I'm asking them to take part in a research study....[T]hey may be interested in the subject and...want to support what's going on and they certainly want us to come and ask them are you okay with this, or to give them suggestions, but it may be burdensome to them to give them a lot of [research] responsibilities... if they're already stretched to the max just doing the[ir] job.

Another said, “People in partnered sites are busy and stressed...your project is not their priority.”

Some community interviewees elaborated on the burden of research involvement. One described discomfort when asked to make a major decision about study design at a time she was new to leadership in her program and inexperienced in research. A second interviewee found her research responsibilities too challenging and to be insufficiently explained:

Our role is not to be a researcher [but] to provide supportive programs [for patients]. I just don't think maybe it was clearly put...I wasn't sure whether I should take a lead role and say, ‘Okay, let's go on and do this, this and this.’ Or we were kind of waiting for... researchers to say, ‘Okay, here's what we need you guys to do.’

A third summarized the risk/benefit trade-off: “It's really been great [participating in research], even though we're completely overwhelmed with the amount of work there is, but we signed up for that. We actually signed up not knowing how much work [participating in research would require].” In sum, as interviewees concerned themselves with participants of various types with multiple responsibilities, and as they took responsibility for mitigating several types of potential harms, they confronted challenges balancing risks and benefits.

Negotiating What Counts as Impactful and Fair Research—The Belmont Report addresses the balance between the needs of society and research subjects through its principle of *justice*. This requires that research be non-exploitative and fair. Achieving justice involves considering whether the potential societal benefit from research justifies the cost to particular subjects. Moreover, “the selection of research subjects needs to be scrutinized in order to determine whether some classes...are being systematically selected simply because of their easy availability, their compromised position, or their manipulability.”²² The Belmont Report requires researchers to ensure justice through attention to the significance of study aims and through careful choices in study design that generate impactful findings without unduly burdening subjects.

Our interviewees took a different view of the strategies by which investigators could ensure that they generated important findings through non-exploitative procedures. Interviewees emphasized the need to negotiate with participants what would count as impactful and fair research. They described these issues as being determined not ahead of time by researchers alone but in collaboration and over time as participants' perspectives were explored and

understood. For instance, this interviewee expressed concern about *a priori* determinations about research aims and protocols:

A lot of White people come into our community... having already decided what they're going to do, what they're going to talk about, how they're going to talk about us. And we have no way to shut their mouth, close the door, or anything. They come in with the negative ideas and they use them automatically. And that's not ethical.

Another community interviewee, describing a problematic relationship with a researcher, agreed that fair procedures could only be established in discussion with the community:

[T]his investigator is...putting their foot in their mouth constantly. And bypassing anybody else that doesn't agree with what they want to do. I was like, "that ain't how we do things down here." Because they're not taking the time.... They have a clear objective of what they want to do and they're not...trying to see from any other lens.

In community-engaged research, interviewees said, neither the value of the science nor the burden to the participants could be determined without community input.

Interviewees noted that this deliberative approach meant that definitions of scientific validity could not be taken for granted. As a community interviewee said, it is not acceptable for a researcher to say:

"It's just my agenda, what I think I know, and that's all."...It happens a lot with researchers...they feel that the data [are] valid and this is good, and it's evidence-based and, "I saw this and I've done this and that." And it may be true. I'm not saying it is or isn't. But when you come to work in the community, that value system is [different].

Interviewees saw the need for both sides to agree on a study design and on procedures for interpreting data. As an academic interviewee noted,

[Academic researchers] had to kind of try and work with [community members] so that they could understand our language, which is hard for outsiders who...haven't had all of the training in statistical methods and validity and stuff like that. And to kind of teach them and bring them along and get them up to speed and to listen to their opinion even when it goes against the face of everything you've learned in school.

In these ways, interviewees acknowledged that partners might bring differing assumptions about scientific practices to the project.

One academic interviewee remarked on this issue by describing concerns raised in public presentations of findings:

Our community partner wants to talk about some research that we've done, but... oftentimes [we] put caveats on everything, because that's how we've been trained. The community partners haven't been trained that way and will oftentimes say

things that wouldn't come out of our mouths because we would feel us uttering them would be an overstatement.

Another academic interviewee claimed a collaborative approach to science “has the chance of throwing off the scientific validity of your study if you really listen to what they say and do what they say.” Another academic interviewee agreed, seeing collaborative design as a potential threat to objectivity. It may be that “the partners don't like what you're finding and then they want you to somehow change things so that you draw a different conclusion... [S]ome people are more willing to kind of slip more into an advocacy role...I think that's very dangerous.” Without a partner “willing to understand and accept what research is...it does just become advocacy.” As these quotes suggest, academic and community interviewees perceived that some of their core values were at stake in this negotiation.

Interviewees also described a challenge of establishing appropriate study aims and then staying aligned with the study's objectives over time. As an academic interviewee said, “people do have different expectations of what we're supposed to achieve and when we embark on something new, it often is very unwieldy. It takes a lot of time because you have so many different perspectives.” A community interviewee agreed that “we lost sight on a continuing basis of what we were trying to do.” Another described the ongoing, inclusive negotiation of justice: “What I hear [my boss] say [is] we've done so much more for university in research than they've done for us.”

Both academic and community interviewees were concerned about how well they achieved goals of engagement and inclusion because they understood reluctance to participate in research and resultant gaps in inclusiveness as impediments to full resolution of this range of questions about justice. The approach our interviewees described of *negotiating justice* differs substantially from traditional research practices, where researchers share assumptions about the value of science and establish the significance of study aims and the fairness of study procedures in advance of the study implementation.

Discussion

Principles and Practices of Ethics in Community-Engaged Research

Our findings show that community-engaged investigators pursue an overarching aim of embodying ethical action through the practices of respecting all study participants, generalizing benefits while mitigating various potential harms, and negotiating to determine what counts as impactful and fair research. In other words, interviewees' narratives demonstrate that ethical community-engaged research entails four key principles: *embodying ethical action, respecting participants, generalizing beneficence, and negotiating justice*. These principles are related to the principles of ethical research articulated in the Belmont Report. As Shore says, in community-engaged research, “respect for persons could be renamed respect for partnerships.”^{44, p.12} In many instances, interviewees explicitly described Belmont principles as the foundation of their ethical approach or the starting point for an ethical project, and they considered their practices of shared ownership of the research process and bidirectional learning to reflect commitments to autonomy, respect, and justice as described in the Belmont Report.

However, interviewees applied these principles to a new type of ethical object: the participant. Whereas the subject role is time-limited (e.g., spanning data collection), setting-dependent (e.g., in a specific lab), and task-focused (e.g., as required to collect valid data), the participant role has multiple definitions, unfolds in many settings, and is open-ended. Participants may “wear ‘multiple hats’ ... (e.g., investigator, advocate, volunteer, board member, etc.)”^{25, p.40} or shift roles over time. Participants might provide data but also advise, share expertise, advocate for the study, or analyze data. Moreover, participants were understood to speak as individuals but also to represent or bring to the fore the needs of the groups or communities of which they were a part. As a result, interviewees deliberated issues such as respect, beneficence, and justice throughout a broad set of activities, and they often strove to extend respect, mitigation of harm, and just treatment to communities and groups.⁴⁵

By highlighting this shift from subject to participant, we aim to clarify that the Belmont principles and the role of the research subject are intricately intertwined. Many of our interviewees' most common ethical challenges reflected the epistemological and phenomenological differences between the subject and participant roles. Opening roles for participants beyond providing data complicated the protection of confidentiality. Processes that generate benefits for participants (e.g., crafting substantive roles for community members) also carried risks (e.g., work burden). Empowering participants to shape research procedures, a component of many community-engaged studies,^{46,47} sometimes precipitated new ethical challenges. Moreover, the ethical challenges interviewees encountered often resisted resolution through established ethical frameworks (e.g., Belmont principles) and procedures (e.g., IRB review).^{48,49} These procedures did not always help interviewees ensure protections for the varied participants with which they were concerned. In these ways, the participant role may have heightened attention to ethical action but it made the upholding of ethical priorities more complex.

Negotiating justice posed particularly charged ethical dilemmas for our interviewees. Community and academic interviewees suggested some of their most-closely held values were challenged in discussions about study aims, methods, and findings. Some academic interviewees expressed discomfort with blurred lines between advocacy and objectivity. Some community interviewees resented interactions with academic researchers who viewed themselves as arbiters of truth. Interviewees described overt conflicts that ended research collaborations. Some tensions appeared to reflect disagreements about the status of types of knowledge (e.g., experiential *versus* experimental). Their responses imply that community engagement could be difficult for those unwilling to engage in some epistemological debates. In community-engaged research models, not only data ownership^{30,50} but also questions of study design and data interpretation raise fundamental concerns about fairness.

Supporting and Monitoring Ethics in Community-Engaged Research

Some scholars have suggested that augmenting the Belmont Report with relational principles, such as reflexivity, reciprocity, or trust, can help support ethical practice in community-engaged research.^{44,51} We argue that ethical conundrums emerge from redefinitions of the object of ethics rather than from uncertainty about ethical principles. Our

interviewees mitigated ethical challenges by specifying their ethical focus. The community interviewee quoted above weighed the ethical obligations associated with each role a participant played: “Research or not, if a provider knows the patient has the problem, no matter what study condition they're in, they're going to help the patient. [We] have this kind of hierarchy.” In the face of ethical challenges, community-engaged investigators may ask: for which type of participant are we most responsible in this instance? Is it the community as a whole, a community group, the investigator team, or an enrolled participant? Defining the object of ethical concern appeared more practically useful to our interviewees than invoking abstract principles.

Although many practices described as ethically problematic in community-engaged research (e.g., breaches of trust) are difficult to measure and monitor,⁵² the four key principles we describe can be operationalized. Investigators can be asked in funding proposal and community and university IRB applications to clarify potential risks to participants of many types. Investigators can detail plans for respecting participants by clarifying how they will facilitate communication and under what circumstances they may break confidentiality. IRBs can monitor the responsibility to generate benefits while minimizing harm to diverse participants (i.e., the principle of generalizing beneficence) by asking investigators to clarify the potential risks and benefits of participation to research assistants, clinic staff, and community co-investigators, as they would for enrolled subjects. IRBs can request that the study team institute safeguards against potential harms (e.g., work burden). Investigators can outline plans for negotiating justice by describing procedures for communicating study aims and vetting questions about data interpretation. These oversight procedures may not be appropriate for every study. The detail of the safeguarding plan can be benchmarked to participants' vulnerability and the degree of risk they assume, as IRBs do now in moderating protections according to study features.

Future Directions for Building a Community-Engaged Health Research Enterprise

The strategies we outline would extend well-understood ethical safeguards to participants. Yet our findings indicate that building a community-engaged health research enterprise will require comprehensive ethical advances. The refractory ethical challenges described by our interviewees suggest the need for more conceptual and operational clarity about the ethical implications of engaging diverse community stakeholders in health research.⁵³ We highlight three fundamental issues raised by the shift from subject to participant for further investigation.

First, the research community may need to reach consensus on the types of community-engaged research situations that trigger new ethical obligations. Overall, our interviewees agreed about the additional ethical obligations that community engagement entailed. Yet to what extent does our interviewees' consensus about ethical obligations apply to projects using other models of community engagement or addressing other health issues? Does a clinical trial that includes one patient representative on an Advisory Board need to generate direct benefits to her and her community? Do all intervention trials need to include iterative review of aims with study site staff to negotiate fair procedures? Can respect for participants be implemented sufficiently if community stakeholders prefer to help only with some

research procedures, such as dissemination? These are only some of the questions that warrant further exploration.

Second, our findings demonstrate that the epistemological and phenomenological differences between the subject and participant roles may have implications not only for research ethics, but also for scientific knowledge and practice. For example, some strategies used to further ethics in community-engaged research can run counter to scientific norms, such as opening for debate the nature of valid evidence. And community-engaged investigators' attention to the social context of data collection implies a challenge to the assumption that valid data can be collected from an individual removed from her community context. Might investigators produce different knowledge from participants than from subjects? Our data suggest that adopting novel ethical approaches that meet the needs and expectations of academic and community partners may test accepted understandings of objectivity, clinical equipoise, and the superiority of randomized controlled clinical trials.

Finally, the shift from subject to participant may call into question current understandings of consent and autonomy. Family members, advocates, and community members are vital to the research enterprise in part because they are understood to be capable of representing or standing in for others. In this way, the participant is an individual and a collective actor. However, the Belmont Report's principle of respect for persons emphasizes that an individual has the right to make decisions for herself alone. A subject chooses participation regardless of what others endorse, but a participant sometimes chooses for others, such as by deciding which levels of risk are appropriate or which projects will be supported in a community. The strategies for operationalizing ethical research described by our interviewees tend to side-step this difference between individual and collective identities and do not resolve the question of who can decide for whom in research. These and other questions raised by the shift from subject to participant warrant further study if we hope to achieve the promise of participatory research approaches.

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Table 1
Attributes of Ethical Community-Engaged Research*

	Total (n=29)	Community (n=14)	Academic (n=15)
Protection and fair treatment of enrolled participants and their data; enrolled participants not harmed	22	8	14
Study results in community or policy benefit	14	6	8
IRB, HIPAA, Belmont compliant	11	4	7
Appropriate informed consent procedures	8	3	5
Research team practices transparency	6	0	6
Research team practices respect	6	5	1
Research team practice trust or honesty; being personally ethical	5	4	1
Research protocols are sensitive to participants, not stigmatizing, culturally appropriate	5	4	1
Benefits to enrolled participants outweigh risks	4	1	3
Protocols are scientifically rigorous, valid, objective	4	0	4
Adherence to study protocols	4	3	1
Research aim important to community	4	3	1
Study is community partnered or engaged	4	2	2

* responses to interview question one (“What does it mean to you to say that you are doing ethical research?”)

Table 2
Challenges Associated with Upholding Four Key Principles of Ethical Community-Engaged Research*

<i>Embodying Ethical Action</i>
Addressing historical legacy of unethical research
<i>Respecting Participants</i>
Maintaining confidentiality across participants' multiple roles
Being sensitive, responsive to partners' perspectives; culturally appropriate
Pursuing ongoing communication (e.g., deepening understanding, discussing disagreements)
<i>Generalizing Beneficence</i>
Achieving substantive roles for partners in research tasks and decision-making
Managing conflicting priorities that compete with research activities
Obtaining funding for time needed to pursue partnering
Devising alternatives or justifications for randomization or a control arm
Managing work burden of community partners
Modifying survey instruments for cultural appropriateness
Reaching agreement on composition of partnership and compensation
Addressing problems uncovered during research activities
Achieving equitable benefits for all involved participants
<i>Negotiating Justice</i>
Managing reluctance of community stakeholders to engage in research
Staying aligned with study vision over time
Ascertaining the adequacy of success in partnering, trust
Publicly representing research aims and findings such that all partners agree
Maintaining objectivity and scientific equipoise

* each challenge mentioned by at least 3 and less than 12 of 29 interviewees; listed from most to least frequent under each principle

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