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

| Elizabeth Bromley, MD, PhD, Lisa Mikesell, PhD, Felica Jones, and Dmitry Khodyakov, PhD

Belmont Report principles focus on the well-being of the research subject, yet community-engaged investigators often eschew the role of subject for that of participant. We conducted semistructured 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 4 key principles of ethical community-engaged research (embodying ethical action, respecting participants, generalizing benefi-cence, and negotiating justice). However, novel aspects of the participant role were the source of most ethical challenges. We theorize that the shift in ethical focus from subject to participant will pose new ethical dilemmas for community-engaged investigators and for other constituents interested in increasing community involvement in health research. (*Am J Public Health.* 2015;105:900–908. doi: 10.2105/AJPH.2014.302403)

Patients, family members, health advocates, and health care 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 US 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 at the National Institutes of Health. The Patient-Centered Outcomes Research Institute prioritizes patient involvement in the development, governance, oversight, and dissemination of research.[8] A report the Agency for Healthcare Research and Quality commissioned found that

> stakeholder involvement . . . helps ensure that [Agency for Healthcare Research and Quality research] responds to relevant and important issues, . . . develops products that are accessible and user-friendly, and . . . ultimately reaches its intended audiences.[9(pi)]

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, 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.[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 20th 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 3 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. Third, 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(p542)] with the "protection of human subjects" as a core ethical goal.[21(p5)] 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 obtained,[23] and they should expect this knowledge to be free of fabrication and falsehood.[24] Institutional review boards (IRBs) assess whether subjects are adequately protected and insist on 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]

By 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(p1)] Community-engaged investigators prefer the participant role because it "increases the possibility of overcoming the understandable distrust of research on the part of communities that have historically been the 'subjects' of such research."[26(p181)]

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' [the] community . . . rather than 'for' [the] community."[28(p321)] 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] Although community-engaged investigators accept the continued relevance of the 3 Belmont principles,[31] they articulate novel ethical priorities[30] 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] Although 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]

We used interview data from community and academic investigators working on community-engaged projects to describe the ethical priorities and dilemmas in community-engaged research. We compared projects to outline 4 principles of ethical

community-engaged research and to advance theory that accounts for common ethical challenges. We have shown 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 that is less time limited, setting dependent, and task focused than is 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 3-step approach developed in previous studies to select interviewees.[40] First, we listed all academic investigators (n = 17) affiliated with the National Institute of Mental Health's Partnered Research Center, a mental health services research center at the University of California, Los Angeles, 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 led several projects, we randomly sampled 1 project per principal investigator to minimize burden. For each sampled project, we invited at least 1 lead academic and 1 community partner to participate in an individual phone or in-person interview. For projects involving more than 2 community agencies, we invited at least 2 academic and 2 community investigators.

Between January and June 2013, we interviewed 15 academic and 14 community investigators working together on 10 sampled projects. We obtained oral informed consent at the beginning of each interview. We interviewed at least 1 academic and 1 community investigator working on all but 1 sampled project (for which we could not contact a community partner). Typically, 2 authors conducted each interview. Interviews were audio recorded and professionally transcribed.

A semistructured 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. Academic and community members of the project's advisory board reviewed and commented on the protocol. We tested the protocol with a community and an academic partner, modifying it for clarity and cultural competency.

Three authors analyzed interview data using both content coding and thematic analysis. We first developed a hierarchical codebook on the basis of the interview guide to mark topics (i.e., attributes of ethical research, ethical challenges), which we then counted and categorized. To ensure coding consistency, 2 experienced qualitative researchers performed coding independently on 20% of the data set, discussed disagreements until consensus was reached, and then coded the entire data set. 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 recoded and refined themes.

RESULTS

Ten sampled projects addressed such topics as community well-being 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 principal investigators were affiliated with the University of California, Los Angeles, RAND, or the University of Southern California.

Community principal investigators 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.

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.

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 coinvestigators.

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 3 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 efficacious and fair research). 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,

> Doing 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 such as a Memorandum of Understanding is only the scaffolding for an ethical project:

> We've had things done in the past where people come and say, oh, this is a contract between [2 institutions]. And then they'll say, okay, well, this is all you need. And it's not all you need. It's just the beginning. . . . [The Memorandum of Understanding] 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 ask, "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

TABLE 1—Attributes of Ethical Community-Engaged Research

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

Note. IRB = institutional review board; HIPAA = Health Insurance Portability and Accountability Act. The table shows the responses to interview question 1: "What does it mean to you to say that you are doing ethical research?"

TABLE 2—Challenges Associated With Upholding 4 Key Principles of Ethical Community-Engaged Research

Principle	Action
Embody ethical action	Address historical legacy of unethical research
Respect participants	Maintain confidentiality across participants' multiple roles
	Be sensitive and responsive to partners' perspectives and be culturally appropriate
	Pursue ongoing communication (e.g., deepen understanding, discuss disagreements)
Generalize beneficence	Achieve substantive roles for partners in research tasks and decision-making
	Manage conflicting priorities that compete with research activities
	Obtain funding for time needed to pursue partnering
	Devise alternatives or justifications for randomization or a control arm
	Manage work burden of community partners
	Modify survey instruments for cultural appropriateness
	Reach agreement on composition of partnership and compensation
	Address problems uncovered during research activities
	Achieve equitable benefits for all involved participants
Negotiate justice	Manage reluctance of community stakeholders to engage in research
	Stay aligned with study vision over time
	Ascertain the adequacy of success in partnering and trust
	Represent research aims and findings so all partners agree
	Maintain objectivity and scientific equipoise

Note. Each challenge was mentioned by at least 3 and fewer than 12 of the 29 interviewees. Challenges are listed from most to least frequent under each principle.

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 held themselves accountable 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, "Ethical research . . . does not invade one's space, does not disrespect anyone, does not not do benefit 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 in the team and in the community as critical enactments of respect for participants. As a community interviewee said,

> 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 a big aspect [of] 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, "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 so 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 coinvestigators, study advocates, clinical supervisors of study staff, friends of study leaders, or study enrollees. Participants might join, drop out, and then rejoin 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:

> We 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 6 months; and . . . quality improvement subgroups 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 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 [you] might have experienced pressures from your organization to do more business." Thus, although 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 numerous challenges (Table 2). In particular, interviewees described challenges with maximizing benefit and minimizing harm to the research team. Interviewees described participation in the tasks of knowledge production (e.g., authoring articles) 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 the 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. . . . They 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 when she was new to leadership in her program and inexperienced in research. A second interviewee found her research responsibilities to be too challenging and 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 Efficacious 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 nonexploitative 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 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 rigorous findings without unduly burdening subjects.

Our interviewees took a different view of the strategies by which investigators could ensure that they generated scientifically important findings through nonexploitative procedures. Interviewees emphasized the need to negotiate with participants what would count as efficacious 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:

This 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, 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. . . . Some 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 quotations 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 [the] university in research than they've done for us."

Both academic and community interviewees were concerned about how well they achieved their 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, in which researchers share assumptions about the value of science and establish the significance of study aims and the fairness of study procedures in advance of study implementation.

DISCUSSION

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 efficacious and fair research. In other words, interviewees' narratives demonstrate that ethical community-engaged research entails 4 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(p12)] In many instances, interviewees explicitly described Belmont principles as the foundation of their ethical approach or the starting point for an ethical project. They considered their practices of shared responsibility in 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(p40)] or shift roles over time. Participants might provide data but also advise, share expertise, advocate 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 have aimed 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 maintaining 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 whom 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 presented particularly charged ethical dilemmas for our interviewees. Community and academic interviewees suggested that 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 vs 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, and trust, can help support ethical practice in community-engaged research.[44,51] We have argued 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.

One community interviewee 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 did 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 4 key principles we have described can be operationalized. Investigators can be asked in funding proposals and in 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 coinvestigators, 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.

Study Limitations

Our study has several limitations. First, our findings are derived from qualitative interviews conducted with a relatively small number of community and academic partners affiliated with a single research center, which limits their generalizability.

Second, the findings may reflect participants' approval bias because some interviewees may have felt compelled to provide socially desirable responses to questions. However, we note that the open-ended, exploratory interview guide did not direct interviewees to give particular responses; participants shared positive, neutral, and negative experiences with conducting community-engaged research; and interviewees showed a high level of agreement on their ethical priorities.

Third, selection bias may limit the findings because a majority of interviewees conducted research related to mental health. Findings may reflect their awareness of the importance of psychosocial concerns and confidentiality or of the potential sensitivity of research inquiry. Although we are aware of the possible impact of these cognitive biases, we note that our interviewees' responses are consistent with the literature on the ethical values practiced in community-engaged research.

Building a Community-Engaged Health Research Enterprise

Even with these limitations, our findings indicate that building a community-engaged

health research enterprise will require comprehensive ethical advances. The refractory ethical challenges our interviewees described suggest the need for more conceptual and operational clarity about the ethical implications of engaging diverse community stakeholders in health research.[53] We highlight 3 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 1 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 a few 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. 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, for example, 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 sidestep 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. ∎

About the Authors

Elizabeth Bromley is with the Semel Institute Center for Health Services and Society, Department of Psychiatry and Biobehavioral Sciences, University of California, Los Angeles and the VA Mental Illness Research, Education and Clinical Center, Greater Los Angeles VA Healthcare System, Los Angeles, CA. Lisa Mikesell is with the Communication Department, School of Communication and Information and the Institute of Health, Health Care Policy, and Aging Research, Rutgers University, New Brunswick, NJ. Felica Jones is with Healthy African American Families II, Los Angeles, CA. Dmitry Khodyakov is with the RAND Corporation, Santa Monica, CA.

Correspondence should be sent to Elizabeth Bromley, UCLA Center for Health Services and Society, 10920 Wilshire Blvd, Suite 300, Los Angeles, CA 90024 (e-mail: ebromley@ ucla.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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Contributors

E. Bromley supervised thematic analyses. E. Bromley and D. Khodyakov conceptualized the study, conducted content coding, and cowrote the article. L. Mikesell conducted content coding and thematic analyses. F. Jones revised interview guides and reviewed thematic analyses. D. Khodyakov supervised content coding. All authors contributed to the overall design of the study, drafting of interview guides, collection of interview data, review of other authors' analyses, and article revision.

Human Participant Protection

The RAND Human Subjects Protection Committee approved this study. Research participants provided informed consent.

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