



The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Bioethics Collaborative

Thursday, April 29, 2021 | 1:00PM-4:00PM ET
Virtual Meeting

Ethical Challenges in Community Engagement Meeting Summary

Introduction

Community engagement (CE) may be defined as sponsor, site, institution, or investigator interaction with a community of individuals “affiliated by geographic location, shared interest, or similar circumstances.”¹ For the purposes of this meeting summary, sponsors, sites, institutions, investigators, and others who interact with communities will be referred to as ‘research stakeholders.’

Meeting attendees gained an appreciation for the broad use of the term ‘community engagement’ as it became clear that each attendee used the term to refer to somewhat different activities in research. The first part of the discussion focused on community-based participatory research, a term that may be defined as, “a collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change.”² The discussion on community-based participatory research produced a summary of best practices for community engagement. The second part of the discussion focused on another type of CE, community consultation, and identified areas for further exploration.

Best Practices for Community Engagement

CE should begin with respect and trust; these principles are integral to creating a space in which community members can share their honest opinions with research stakeholders. Research stakeholders demonstrate respect and build trust by interacting with community members before any formal and directed “asks” of the community; they listen to the community, learn about the culture and what is important to its members, and let the community voice their research priorities. Authentic engagement also requires a continued interaction with and investment in a community; engagement cannot be instrumental.

It may be easier for research stakeholders to gain the trust of a community when the individuals engaging a community are community members themselves. In the absence of community ambassadors, individuals working alongside members of the community should understand that they are no longer the ‘experts,’ defer to community members as appropriate, be honest, execute on their promises, and hold themselves accountable for their mistakes.



Trust allows research stakeholders to reciprocate the contributions of community members in a way that feels genuine and not transactional. This can involve participating in shared social events and activities, being attentive to the personal issues of community members, and looking for ways to assist them and meet their needs, regardless of whether those needs are directly related to the research. In some contexts and cultures, payment may be the best way to demonstrate appreciation for the value of an individual's contributions. Attendees suggested that in other cultures, however, community members may feel as though payment undermines the authenticity of their contributions.

Trust is closely related to accountability in CE. Research stakeholders build trust by consistently following through on their commitments. Research stakeholders and communities should strive to set clear expectations about the parameters of their engagement and to make commitments that they can realistically and faithfully fulfill.

Attendees agreed that research and engagement activities are more likely to be successful when CE is built into the infrastructure of a sponsor or a research health care institution. Employing researchers who are also community members and partnering with community health centers (CHCs) both help to embed research in the fabric of the community and provide a route to communication with the sponsor or research site.

Community members who participate in CE want to tell others in their community about why engagement is important, how engagement with researchers can make research more relevant to the community, and what engagement looks like. Thus, CE preferably includes making the products of engagement available to community members. Research stakeholders should consider providing summaries of engagement activities in culturally sensitive and health literate forms. Other mediums, such as public forums and art exhibits, may be alternative ways to share the results of engagement with communities.

CE that is conducted inadequately, paternalistically, or without commitment may harm a community and erode the relationship between a community and research stakeholders, not only for a current research question but for others in the future. Good intentions are insufficient to ensure that CE will be successful; academic researchers often need training to learn how to engage communities in ways that are productive and respectful. However, there is a lack of training curricula and opportunities for CE. Often, a researcher must engage in the community in order to learn to do it successfully, and both sides—researcher and community—should assume that new lessons will be learned, that continuous education will take place, and that each experience will have both new insights and new challenges.

There is a lack of funding for engagement. Funders should allow research stakeholders to budget for CE, specify how they expect research stakeholders to undertake engagement, and the outcomes they anticipate. When funding is available, research stakeholders will benefit from discussion with the community to understand how funds can best be shared and fairly distributed. Establishing a fair market value, for example, for compensating community members for their time and contributions should be done with representatives of the community. It should be noted, however, that in some cases, paying community members may be complicated by



academic administrative policies; it is important for researchers to work with their institution, disclose their intention to pay, and to establish processes so that the promise to pay is able to be fulfilled.

Funding and administrative barriers to paying communities may be tied to the concern that payment will unduly influence community members to participate in engagement and research activities. Attendees rejected this concern, suggesting that concerns of undue influence are overexaggerated and that invoking putatively ethical concerns to limit the provision of goods to a community seems capricious and paternalistic. Funders do not take issue with paying well-resourced research institutions and therefore should not be concerned with paying CHCs. Some federal policies (e.g., Health Resources and Services Administration policies) prevent or obstruct payment to Federally Qualified Health Centers (FQHCs); these policies should be addressed.

There was greater discussion when the attendees considered whether and how to compensate individuals in the community. It seemed that if all people who came to a health center were in need of, or could benefit from, payment, food, or other necessity, then providing such staples to only those individuals who did agree to participate could appear to be undue inducement. Should the researchers give everyone something, and then those who participate “something extra?” If the enrolled participants received “something extra,” should that be done in private, out of view of the other visitors to the health center? If that practice were adopted, then how long would it take for everyone to know, and for the intentional privacy to appear as “deception.” Of course, providing something to all individuals at a site may be infeasible, and that infeasibility should not prevent compensating those who volunteer appropriately. On balance, it was not clear among attendees how significant a risk of undue influence a small gift or provision of a small necessity would be, and that considerations of fair compensation should outweigh the concern.

Throughout the Bioethics Collaborative, the importance of using respectful language during engagement activities was emphasized. While some researchers refer to community members as ‘data providers,’ for instance, a more respectful term is ‘community partners,’ but that term should reflect the ongoing treatment of the community members as true partners. Research stakeholders should also use language intentionally when they define communities. Referring to the ‘Hispanic community,’ for example, disregards important distinctions between members of the Mexican, Puerto Rican, and other communities; glossing over these distinctions is disrespectful and fails to recognize important differences.

Community Consultation and Areas for Further Exploration

The aim of community consultation is to improve a study with a known goal, and not necessarily to address the most important issues of the community. Research stakeholders are listening to community members but not participating in a community; it is important to be clear about the intention and anticipated goals of the relationship. Community consultation, like community-based participatory research, is grounded in trust. Researchers who ask community members for input on their research should explain what will happen to the information they hear (and that, for instance, suggestions will be considered but may not necessarily be implemented) and provide feedback at the end of the process.

Several issues raised during the discussion warrant further attention. One important question is considering when CE should be an ethical imperative, recommended but not required, elective, or even unadvisable. Answering these questions may provide clarity as to how CE should be conducted. What processes should be considered ‘good enough’ for CE was also unclear. It would be a mistake not to engage simply for fear of not being perfect at the task. What is important is honesty, clarity about what is and is not expected by the interaction, follow through on promises made, and respect for the time and contribution.

Potential future work

- Distinguish community consultation for drug development from community-based participatory research:
 - Clarify the goals of community consultation for drug development.
 - Identify the methods that are appropriate for achieving these goals.
 - Clarify the concept of ‘representativeness’ in community consultation for drug development.
 - Identify the dimensions or points to consider when defining ‘representativeness.’
- Further understand barriers to enabling CHCs and FQHCs to engage in research directly, rather than through partnerships with academic health centers. CHCs and FQHCs understand the questions of greatest importance to their communities and building independent capacity for research is necessary.
 - Current limitations to the receipt of overhead dollars is one barrier to address.
 - Methods to hire and retain research staff situated in CHCs and upskilling current staff are necessary. A vibrant research effort would require sufficient research projects for staff to be needed continuously and funding to support it.
- Develop a framework for when CE is an ethical imperative, recommended but not required, elective, or even ill-advised across the various types of CE (e.g., community consultation, community-based participatory research, etc.).
- Develop an approach to payment and funding in CE, including:
 - A framework for paying communities and community members for their contributions.
 - A framework for understanding when payment may be problematic.
 - Solutions for overcoming administrative and funding barriers to CE.
- Develop or find training resources for research stakeholders considering engaging in CE.



References

1. Holzer JK, Ellis L, Merritt MW. Why We Need Community Engagement in Medical Research. *J Investig Med*. 2014;62(6):851-855. doi:10.1097/JIM.0000000000000097
2. Viswanathan M, Ammerman A, Eng E, et al. Community-Based Participatory Research: Assessing the Evidence: Summary. Agency for Healthcare Research and Quality (US); 2004. Accessed May 4, 2021. <https://www.ncbi.nlm.nih.gov/books/NBK11852/>