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# Information for NIH Investigators: Points to Consider in Community-Engaged Research (CEnR) and Community-Based Participatory Research (CBPR)

Research using CEnR and CBPR approaches involves unique considerations and opportunities. Use this Points to Consider document when developing CEnR/CBPR protocols.

**NOTE:** As you read the document you will see both bullets and arrows. Items preceded with a bullet apply to CEnR/CBPR protocols more generally. Items called out with an arrow only apply when lay researchers will be conducting the research in the community.

## WHAT IS COMMUNITY ENGAGEMENT AND COMMUNITY-BASED PARTICIPATORY RESEARCH?

Community-Engaged Research (CEnR) and Community-Based Participatory Research (CBPR) are research approaches that can involve community members in the development and conduct of the research. Community engagement research is an approach that respects the values and priorities of the community to be included in the research, (e.g., based on geographic proximity, special interest, or culture). There is a continuum of CEnR methods (e.g., ranging from minimal community consultation - to community consultation/involvement during the design phase of the research - to fully integrated community involvement in the development, design and conduct of the research). The fully integrated model is known as Community Based Participatory Research.

CBPR is a subset of CEnR, which can include involving community members in any or all of the following: the development of the research question, design of the research, recruitment activities, the conduct of the research, as well as analysis and dissemination of the results. When community members assist the study team to conduct the research, we refer to these community members as “lay researchers” in this document.

For more information about CEnR/CBPR we recommend you take the CITI *Community Engaged and Community-based Participatory Research* course that is available via the NIH CITI link on the OHSRP website. We have also provided a selected reading list and a list of authors below.

## PURPOSE

Define the goal of the CEnR/CBPR research (e.g. community health, policies, systems, etc.)

- Is the community of interest clearly defined?
- Is the research question of value to the community?
- Will community partners, participants, or the community potentially benefit from research outcomes?

Define the extent of the community engagement in the research.

- ➢ When lay researchers will be involved in the conduct of the research, define the extent of their involvement.

## COMMUNITY ENGAGEMENT AND COMMUNITY APPROVAL

Depending on the nature of the research, the community involved will vary. Relevant community partners can be from geographical communities, communities of color (Asian, African American, etc.) or culture (Latin, LGBTQ+, American Indian/Alaska Native, Amish, etc.), local health organizations, disease advocacy organizations, or a combination of these groups.

Some communities may require some form of community approval, such as from the governing body of a tribe, a Community Advisory Board (CAB), a school board, or other community based organization. A CAB is an advisory board comprised of members of the community who will advise, or communicate with, the research team.

The purpose of the CAB is to advise the study team about the community in which the proposed research will be conducted (including, e.g., research priorities, culture, language, outreach, study design, or return of results).

- Is Community Approval appropriate? If so, describe how and when will it be sought (concurrently, pre- or post- IRB approval) and how and when it will be documented (MOU, Charter, etc.).
- Will a CAB be established or will the PI work with an established CAB? Describe the CAB's role, function, and processes with enough detail that the IRB can assess its methods.
- Will the community or CAB review research procedures (e.g., recruitment procedures, consent procedures) and the consent documents?
- Will the CAB advise on culturally appropriate consent language or process; or on research procedures or culture?

## COMMUNITY PARTNERS

How will community partners, such as service providers or outreach groups, be identified and mobilized? Does the protocol include periodic assessment of study progress and community feedback to ascertain whether changes are needed? How will community expertise be leveraged to provide interpretations that are only possible from within the community? (See Consent Process below for more information.) If there are disagreements between researchers and the community regarding study conduct, or interpretation of results, how will those differences be addressed or resolved?

- Will community partners or lay researchers be engaged in human subjects research? (i.e., will they obtained informed consent, obtain information through intervention or interaction with participants or analyze identifiable data?) Is there a reliance agreement in place for IRB oversight of those activities?
- Will lay researchers and CAB members be compensated for their efforts? Is the amount appropriate, is it equitable? The PI should work with the IC to establish a mechanism to compensate CAB members and lay researchers for their time and effort (e.g., a contract, or can you work with a scientific collaborator who can facilitate such things as paying for food at meetings?)

## AGREEMENTS

As early as feasible, it is important to understand the specific roles of community members and to determine what agreements are needed to assure FWA coverage and IRB oversight.

- Consider whether an agreement or MOU is needed with the CAB or CAB members.
- ➢ Will lay researchers or community partners obtain consent, conduct research procedures or analyze identifiable research results? If so, the community partner will be engaged in human subjects research. In this case, coverage under a Federalwide Assurance (FWA) and IRB oversight over these activities is required.
- ➢ If the lay researchers or community organization will receive federal funding to support their research activities for the study, they must be covered under an active FWA as required by regulation[1].
- ➢ The FWA will be necessary in order for the community organization to rely upon the NIH IRB, or the IRB of record.
- ➢ Individual lay researchers might be covered under the NIH FWA if OHSRP agrees, and the PI meets the requirements under Policy 109 Coverage Under the NIH FWA.
- ➢ If a reliance agreement or Individual Investigator Agreement is needed, be sure to reach out to IRBO for assistance as early as feasible in order avoid unnecessary delays. (Note: One challenge that could arise is if the community partner does not have a lawyer or other infrastructure needed to facilitate an agreement easily, be sure to inquire with your community partner about this to avoid any surprises.)

## OVERSIGHT

- ➢ If community partners will be involved in the conduct of the research, it is important that that the PI have mechanisms in place to assure proper oversight of these activities. The protocol should describe how the PI will communicate with the lay researchers and oversee their activities.

## TRAINING

### Research Training

- ➢ If lay researchers will carry out research activities (e.g., recruitment, data collection and/or data analysis), the protocol should describe how the lay researchers will be trained to perform those research procedures.

[1] If the IC will establish a business contract with the organization, the HHSAR clause 370.3 requires an active FWA. Otherwise if the community partner will receive federal support (e.g., grant or contract such as from extramural funding), an FWA will also be required.

### Human Subjects Training

Would CAB members benefit from taking human research protections training to help them understand the purpose of research and important issues for community members who participate in the research (e.g., research is not intended to benefit participants)?

- The protocol should describe what human subjects research training will be completed by lay researchers who are engaged in human subjects research, and who will provide that training. If the lay researchers' research activities are overseen by the NIH IRB, they are required to comply with NIH Policy 103 Education Program.

*Note: The NIH cannot provide non-NIH persons access to NIH human research protections training (i.e., CITI training). However, there may be online no-cost sources of training available.*

### RECRUITMENT

The protocol should describe the recruitment plan, including location and methods for community engagement, and any necessary approvals (other than IRB approval). If there are barriers to participation, how are those barriers addressed or mitigated?

- If lay researchers will participate in recruitment, screening, and obtaining consent from participants, this should also be described in detail in the protocol.

### CONFIDENTIALITY

In this context, confidentiality refers to participants protecting from disclosure their personal, sensitive or private information to unauthorized persons. This includes methods used to ensure that information obtained by researchers about their research participants is not improperly divulged. Discuss any confidentiality concerns and their management in the protocol.

- Will data be accessed, stored, accessed or analyzed outside the NIH? How will the data be protected, is appropriate oversight in place, are the correct agreements in place, who will have access, how will errors be corrected and who will address participant concerns about confidentiality?
- How will confidentiality be protected when lay researchers engage in the collection or analysis of identifiable research data?
- Do lay researchers who are conducting the research understand and take participant confidentiality seriously?
- Consider having lay researchers sign a confidentiality agreement or an MOU outlining responsibilities related to privacy and confidentiality.

### PRIVACY

*In this context, privacy refers to subjects and their interest in controlling the access by others to themselves, (e.g., how investigators will ensure that consent and procedures are conducted in a quiet environment, and only include appropriate parties).*

If there are unique privacy concerns or privacy risks, these should be described in the protocol, as well as how those might be managed.

- Could participants be seen entering the research site, could that be stigmatizing?
- Will identifiable (that visibly identify the study title) cards, letters or notices be sent to participants?
- ➢ Are there privacy issues associated with interviews or interview settings? For example, are potential subjects comfortable sharing their personal health information or health history with lay researchers who are their neighbors, could there be a potential for stigma?
- ➢ How will privacy be impacted when lay researchers are responsible for recruiting and obtaining consent from the potential participants, especially when people conducting these activities are known to the participants?

## INFORMED CONSENT DOCUMENT

The informed consent process and consent information should reflect the language and cultural norms of the community. The consent document should minimize or avoid technical language. Consider explaining data ownership in the consent document. Does the consent document make it clear that participation is entirely voluntary?

- ➢ Consider whether translations or interpreters are needed if lay researchers will obtain consent, even if they are bilingual. The purpose of this requirement is to use a neutral interpreter, to reduce the possibility of coercion or undue pressure on the participant to participate in the research.

## CONSENT PROCESS

The informed consent process and consent documentation requirements should reflect the language and cultural norms of the community.

- ➢ If lay researchers will conduct informed consent: Are the right research team members involved in the consent process? For example, are the appropriate research team members explaining the alternatives to participation if there are clinical procedures?
- ➢ The protocol should describe any potential issues arising from using lay researchers for recruitment (e.g., potential stigma, social pressure, bias, or favoritism), and/or how any consent process issues will be mitigated.
- ➢ If lay researchers screen prospective participants or obtain consent, the consent document or consent information should describe additional risks to privacy and confidentiality (e.g., potential for stigma if the subject shares personal information with a lay researcher from their community, how will the subject be assured of confidentiality by a lay researcher who could be their neighbor), and how those risks are mitigated (see the sections on Privacy and Confidentiality above for more information).

## DISSEMINATION OF RESULTS TO THE COMMUNITY

Could the results of the research be stigmatizing or concerning to the community (e.g., culturally) such that the community might object to publication or release of the results of the research? If so, how is this mitigated? The protocol and/or consent document should describe how research results will be shared with the community or with others providing services to the community (e.g. relevant healthcare or government entities).

## RISKS

The protocol should discuss potential risks and benefits (e.g., economic, cultural or infrastructure) inherent in the CEnR/CBPR. Examples include:

- What are the risks to community members as individuals who choose to be part of the study as participants, CAB members or lay researchers?
- Are there risks to individuals who choose not to be participants in the research?
- Could research results cause community harm? How will this be mitigated?
- Consider potential stigma and unequal power dynamics between participants, lay researchers and NIH study staff.
- Describe in the protocol how privacy risks will be mitigated for research procedures that will be conducted in the community (e.g., measurements, history and physicals or surveys), describe for example where there is private place to conduct those procedures. (See Privacy below.)
- Describe in the protocol how confidentiality will be protected if data is to be collected and stored in the community. For example, how will it be stored securely, who will have access to the data, and how will it be transmitted securely to the NIH. (See Confidentiality below.)
- Will compensation lead to tensions within the community (e.g., compensation of CAB members vs compensation of lay researchers, vs compensation of participants)? If so, describe in the protocol plans for how this might be mitigated.

➢ Describe any potential issues arising from using lay researchers for recruitment (e.g., potential stigma, social pressure, bias, or favoritism) and how these issues will be mitigated.

➢ The protocol should describe any potential issues arising from using lay researchers obtaining informed consent: The protocol should describe protections against bias and influence that might reduce autonomy of prospective or actual subjects and/or the community, if applicable.

## OTHER POINTS TO CONSIDER

Although you may be familiar with CEnR/CBPR, you may need to educate your IC colleagues and IC leadership if this is not a research approach that is used in your program. You may need to educate leadership about the need to establish a CAB, to compensate the members, and/or lay researchers.

If you are asked about applicability of Federal Advisory Committee Act (FACA) to the CAB, it is unlikely that the CAB will fall under FACA since the purpose of the CAB is to advise the study team about the protocol being conducted in the community or culture, and not about government policy. To be safe, if you have any questions or need assistance, check with the Office of Federal Advisory Committee Policy.

If you plan to hold events, you can't use federal funds to provide food or drinks. You may need to get creative or work with partners and collaborators to solve problems such as these, but you should not think of them as barriers to conducting ethical community engaged research.

If you are new to this research approach, you may want to consult other NIH researchers who have conducted CEnR/CBPR to learn best practices.

## SELECTED READING LIST

NIH Publication 11-7782, Principles of Community Engagement, Second Edition, https://www.atsdr.cdc.gov/communityengagement/pce_models.html#figure3, Centers for Disease Control and Prevention Atlanta, GA; retrieved 06/10/2021

Community-Based Participatory Research: Ethical Considerations - The Oxford Handbook of Public Health Ethics, March 2019, Buchanan, DR, *et al*, Oxford Press, https://pubmed.ncbi.nlm.nih.gov/20208234/, retrieved 6/16/2021

Research Ethics Education for Community-Engaged Research: A Review and Research Agenda; J Empir Res Hum Res Ethics. 2012 Apr; 7(2): 3–19, Anderson, EA, *et al*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3483026/, retrieved 6/16/2021

Engage for Equity: A Long-Term Study of Community-Based Participatory Research and Community-Engaged Research Practices and Outcomes, Wallerstein, N, *et al,* Health Education & Behavior; 2020, Vol. 47(3) 380–390 https://pubmed.ncbi.nlm.nih.gov/32437293/

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