Penn University of Pennsylvania | Human Research Protections Program

Community-Based Participatory Research (CBPR)

Community-based participatory research (CBPR) is a form of community-engaged research, involving a collaborative approach for participation, shared decision-making, and mutual ownership in all aspects of the research process by communities affected.

Additional IRB Considerations for CBPR

Studies that involve community collaboration or engagement may require special considerations to both protect participants and facilitate conduct of the research.

Researchers should consider the following when designing their protocol:

- Plans for initial and ongoing relationship and trust building with the community and community organizations;
    - This could include but is not limited to plans for dissemination of research results to community organization(s) and/or the research participants involved;
- Any special conditions or vulnerabilities of the targeted population or community, and measures to protect these participants / community;
    - How will the conduct and results of this study impact the community?
- Potential benefits from the research to the community, partner organizations, and individuals and how these may be distributed;
- Plans for seeking input or feedback from the community or partner organizations;
    - What input or feedback will be sought in the research design?
    - Will input be at the onset or throughout the conduct of the study?
    - How will incorporation, or lack thereof, be communicated back?
- Plans for assistance/ collaboration from the community or partner organizations, if applicable;
    - Will assistance with recruitment, enrollment, consent, or conducting procedures be needed?
- The potential need for incentives to the community, partner organizations, and individuals;

The IRB strongly recommends the use of the Community Based Research form to work through the areas above, identify additional IRB requirements, and to facilitate IRB review.

Community Collaborators Considerations

In CBPR, it is important to consider the circumstances when community stakeholders may either be considered research participants or individuals "engaged" in the conduct of research. Both of these cases are addressed below.

Community Collaborators as Research Participants

There are certain circumstances where community collaborators may be considered research participants. In cases where the research team wishes to interact with community partners for the purpose of collecting information that will ultimately serve as a source of research data, the community partner would be considered a human participant and traditional requirements for consent would apply.

A human participant is defined by DHHS regulations as follows:
(f) *Human participant* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

To help consider whether a community collaborator qualifies as research participant please consider the following example:

An investigator seeks to collaborate with patients who are part of a support group for cancer survivors. The investigator wishes to obtain feedback on the types of questions that should be asked of cancer survivors in an online survey to understand their impressions of their care within the health system.

Version 1: The collaborators will be consulted for instrument development only and will not be asked to provide any data from their own experiences that will be used for analysis.

Conclusion: These collaborators do not qualify as human participants as no data will be collected from these individuals that will be analyzed as part of the research study.

Version 2: After the instrument is developed the collaborators will be asked to complete the survey online as these individuals meet the criteria for enrollment in the study. Data from their online survey responses will be analyzed similarly to all other respondents.

Conclusion: These collaborators do qualify as human participants as they will provide information that will be analyzed as part of this research study.

Community Collaborators as “Investigators” who are “Engaged” in the Research

There are certain circumstances where community collaborators may be considered investigators who are “engaged” in the research. In these cases, the collaborator’s role in the research must be overseen by an IRB and the researcher would be required to complete appropriate human participants training prior to initiating any activities related to that engagement.

Generally, “investigators” may include any individual involved in the design, conduct or reporting of research. The types of activities that may qualify a collaborator as an investigator “engaged” in human participants research may include but are not limited to:

1. Interacting or Intervening with research participants for the purposes of research (e.g. administering a survey, performing a research test, etc.).
2. Consenting participants for research participation
3. Participating in the collection of or having access to identifiable data from research participants

To help consider whether a community collaborator qualifies as an investigator engaged in human participants’ research, please consider the following example:

A researcher seeks to develop a medication adherence support tool for patients with Alzheimer’s disease and their caregivers. In order to design the tool and the study intervention, the researcher will work with a group of Alzheimer’s patients and caregivers to ensure the ideas of the target population are represented. These individuals will participate in some research team meetings and will be compensated for their time. Their participation will continue throughout the life of the study.

Version 1: The patients and caregivers will have no interactions with participants and data presented at research team meetings will be shared in aggregate form only. The patients and caregivers will not have access to individually identifiable participant information.

Conclusion: These collaborators do not qualify as investigators as they will not interact with participants nor will they have access to identifiable data from participants.

Version 2: The study team believes that the purpose of the research study and the medication adherence tool will be best described to participants by patients and caregivers. They have asked that their collaborators participate in the consenting process.

Conclusion: These collaborators do qualify as investigators who are engaged in human participants’ research. Their involvement in the research must be overseen by an IRB and these individuals must complete applicable human participants training prior to initiating any activities related to their engagement.
Please Note: In the event that you have a community collaborator who you feel may qualify as an investigator, please contact the IRB staff to discuss options for IRB review including the potential requirement for execution of an individual investigator agreement.