

COMMUNITY ENGAGED RESEARCH IRB BACKGROUND AND TERMS

Background

Human subject research regulations and protections for human subject research participants are well-established. Even with increasing focus on community engagement and new areas of research, the existing regulations are still applicable and can appropriately protect research participants; however, an assumed incompatibility between researchers and regulations can act as an obstacle during the IRB review process. By breaking down the regulations and research protocols into basics and understanding the key components for all parties; researchers and IRBs can work together to create protocols that meet researchers' objectives, meet criteria for approval and result in efficient review by the IRB.

Various terms and phrases are used both by researchers and in publications relating to researchers working together with community members to design and conduct research. Examples of terms used may include community engaged research, community engagement, citizen scientists, volunteer research, advisory boards, and action research, often these are all meant as types of community-based participatory research. The key to all community-based participatory research (CBPR) is that CBPR is a collaborative *approach* to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR is not a research *method*. CBPR relates to the attitudes of the researchers and the context in which the research plan will be applied. CBPR is an approach researchers may use to conduct various methods of research, such as qualitative focus groups, survey methods, social behavioral interventions, or social network analysis. CBPR can appear intimidating when considering it from a regulatory/IRB perspective; but, the underlying research will follow traditional research methods which require standard regulatory review.

Submitting to the IRB

Many researchers are under the misconception that any time they talk or work with "the public" IRB approval is required. The IRB oversees human subject research which is defined by the intent of what the researchers are *doing* with people. If a PI works with their lab staff or other academic researchers to develop a protocol, they design and finalize the protocol and then submit to the IRB for review. However, when researchers work with community members or "non-academic research team members" to develop the protocol, they often submit the IRB application for review prior to beginning that development. Additionally, many researchers struggle with submitting the IRB application at that time because the protocol is not complete, as it has not yet been created. IRBs can only approve a complete protocol with created research materials. At the surface this sounds as though these two objectives are incompatible, but it exemplifies the importance of clearly defining the roles and objectives of the project, the persons involved in the project, and the roles in which they play.

IRB Steps When Reviewing a Submission

1. Define the project (i.e. what is the actual project being submitted, what is the purpose of the data collection, is there a research objective, or a hypothesis driven aim?)
2. Does this project meet the definition of human subject research?
3. Who is engaged in the conduct of human subject research? (i.e., who are the players and what will they do during the conduct of HSR activity)
4. Review the protocol applying applicable regulations (i.e., review the research methods and apply exemptions or appropriate review categories)

Common Terms that may Cause a Disconnect

[Engagement/Engaged](#)

[Research Team/Partners](#)

[Community Advisory Board](#)

[Project/Protocol](#)

[Return/Dissemination of Results](#)

[Compensation](#)

- **Engagement/Engaged**
 - **IRB Meaning** – Engagement in human subjects research or being engaged in human subjects research means that the person/entity “engaged” is subject to all applicable regulations, laws, policies, and requirements, including IRB oversight.
 - **Researcher Meaning** – The act of including stakeholders in activities and communications and allowing them to contribute in a meaningful way.
 - **Notes on “Engaged”** – The CBPR Meaning is a general definition and is not new; however, with the focus on engaging community members with research, it is now appearing more frequently as part of grant applications and overall project descriptions which has filtered to communications with IRBs.
 - **Recommendations** – In order to properly document IRB determinations and considerations, IRBs will need to use the term “engaged”. As the use of the term from the researcher perspective is more descriptive in nature, it is recommended that researchers do not include the use of the word “engaged” or “engagement” in their communications with or submissions to the IRB. Best practices for completing IRB applications generally include clear, concise descriptions of the research including objectives, background, and procedures. Often grant applications and other funding and public communications may be written in a more aspirational manner than is appropriate for the IRB application. Keeping in mind the more factual, procedural, and succinct style needed in IRB applications may assist researchers with preparing IRB documents.

Both researchers and IRB staff need to consider what engagement means to them and each other as they discuss these projects. Any determinations that

Community Engaged Research IRB Background and Terms

need to be made relating to IRB oversight needs and reliance will focus on engagement of both the academic researchers and community members. IRB staff should ensure the researchers understand the details of engagement per DHHS policy and guidance and its importance. Researchers should understand the IRB is not trying to diminish the importance of community members' involvement but is focused on ensuring the appropriate regulations are applied to all individuals.

- **Research Team/Partners**

- **IRB Meaning** – Research team members are people who need to be included on the IRB application. For individuals external to the IRB site, this might be individuals by name, institution, or organization. The IRB considers research team members to be individuals who need some type of IRB oversight.
- **Researcher Meaning** – Research team or research partners are individuals, usually from within a specific community who are working with the researchers. These could be individuals who are assisting with the conduct of research, who are acting in an advisory role, or who are participants in the research. (Academic) Researchers are often trying to develop or strengthen the relationships within the communities and conducting researcher *with* the community rather than *on* the community, so terminology and procedures may be designed to create an equal partnership with community members.
- **Notes on Research Team/Partner** – Institutional IRB policy often defines the “research team” and which individuals must be listed on the IRB application. IRB policies and processes differ with the requirements for the approval and listing of external individuals on IRB applications.
- **Recommendations** – IRB staff should ensure they are clear in any communications or revision request detailing the requirements for research team members according to local policy. Researchers should utilize more specific terminology, for example, organization name, individual name, or specific roles (e.g. United Way employees, community advisory board members) when describing procedures and responsibilities in the IRB application. Avoid using the terms “research team” or “research partners” within the IRB application. IRB staff should ensure consistency throughout the IRB application, as inconsistencies within the application can lead to non-compliance issues in the future. For example, using referring to “research partners” in the IRB application suggests other individuals engaged in the conduct of research. If this is approved, even if it is understood at the time of approval, in the future or in the event of an audit, it would be expected that those research partners have obtained separate IRB approval or are covered via a reliance agreement with the IRB, which may not be necessary based on the actual activities being conducted by these partners.

The IRB is not trying to diminish the role or importance of the community members. The IRB must apply the appropriate regulations to all individuals. The IRB application verbiage is not meant to be utilized for purposes such as grant applications, journal articles, or publicity/communications. The underlying inclusive nature of community-engaged research can increase the regulatory oversight on these studies unnecessarily, if additional language is included that is not required for IRB review purposes.

- **Community Advisory Board**

The term Community Advisory Board or Panel is used frequently and in many contexts. Use of this term or similar terms is insufficient to explain the activities or responsibilities assigned to such a group. The term can be used as a name to describe a group but it should not be used as though the term implies a definition of the group and its activities.

- **Recommendations** – The IRB reviewers and researchers should ensure the following questions are clear in the IRB application:
 1. What exactly will the CAB be doing?
 2. Will they be providing, or advising on, needs to help define intent of the project?
 3. Will they be helping to design tools or interventions?
 4. Will they be participating in the research by completing the tools or interventions?
 5. Are you providing them results or raw data during the study?

The IRB will be trying to assess if the Community Advisory Board is *engaged in the conduct of research*. The application should clearly describe what members of the board will do. Often Community Advisory Boards are an important part of community-engaged research projects to establish relationships and buy-in. These are key factors in being able to conduct the research, but the relationship aspect of the project is not within the purview of the IRB.

- **Other CAB considerations** – Although the activities of the CAB may be considered NHSR, in some cases the researchers want to publish an article *about* the CAB and how it worked. In this case, the CAB *could* be considered participants in a project and not research team members. The IRB application must be very clear on what the intent of this phase is. Determinations about the work of the CAB often are based on the generalizability of this work. The IRB needs to consider if studying the CAB is a systematic investigation designed to contribute to generalizable knowledge. In many cases, an article *about* the process used by the researchers/CAB may result in interesting information and explain a process; however, it may be more of a case report or program evaluation project than human subject research.

- **Community Advisory Board vs. Data Safety Monitoring Board**

A Data and/or Safety Monitoring Board (DSMB) is a group of experts (often independent) that monitor clinical trials to ensure participant safety and data integrity. A Community Advisory Board is not a DSMB and the two should not be conflated. If a project involves a group of people who act as a CAB and as a DSMB, the roles should be clearly defined and described so that the members, researchers, and regulators (IRB, etc.) are clear as to what responsibilities are assigned to each role. A CAB can provide advice and suggestions to researchers related to the data or safety events but do not have the authority to terminate or suspend a study for scientific purposes. A CAB in their role as representatives of a community or leadership in an organization always have the authority to terminate their relationship with the researchers and not permit the researchers access to their community members. For example, a Community Advisory Board may determine they do not approve of the researchers' methods or the ongoing status of the study and thus may no longer allow the researchers access to their member participants or facilities. While this may effectively shut down the research, the CAB authority extends to the relationship and oversight of the participants. Although the IRB may become involved and terminate the research as part of a separate review, technically, the researchers could still conduct the research with a different community. The CAB oversight extends to the individual community, not the researchers themselves. A DSMB however, has authority over the entire project. If the DSMB terminates the research, the researchers must stop all research activities as required by the DSMB and cannot re-open it or start with a different community group without DSMB approval.

- **Project/Protocol**

Large research projects often involve multiple phases. Researchers often think about the research project as a whole. However, IRBs review individual protocols or IRB applications based on the aims/objectives of the project. Many large research projects, particularly those with multiple phases, involve multiple protocols. IRBs will have varying processes; however, in order to approve an application, a complete protocol is needed. Researchers should utilize their IRB's guidance and policies for determining what should be submitted as part of an individual IRB application; however, they should focus on the protocol/phase described within the application. Information about other phases is only needed to assist the IRB with the context and review of the application submitted.

- **Example:** The project works with a community panel to determine needs to be addressed, focus groups with a small group of the community to obtain information to develop an intervention, developing an intervention where groups of participants learn to knit, conducting the intervention groups, and then data will be analyzed and written into an article. This project could be divided into several phases as each phase must be completed prior to the next phase beginning. Additionally, to submit an IRB application at the beginning of the

Community Engaged Research IRB Background and Terms

project for the full project would be incomplete as the IRB would need details on the intervention which have not yet been developed. Instead, the project can be divided into phases based on the individual aims/objectives within the project. The IRB will then have complete information and will make determinations based on the procedures occurring to meet the objectives. Some phases may even be Non-Human Subject Research.

Phase 1: Needs Assessment – Community Panel

Phase 2: Focus Groups

Phase 3: Develop intervention (may not even require an IRB application)

Phase 4: Conduct Intervention

NOTE: Additional documentation or requirements may be required when certifying IRB approval for Federal and/or external funding sources. Funding agencies may require additional notation or documentation in approval letters about the phased approach or timeline for future IRB approvals associated with all phases of the research.

- **Return/Dissemination of Results/Findings**

Research regulations, and thus many IRB applications, refer to the “return of results”. Generally, this concept refers to findings about the individual participant. The original focus on “return of results” related to genetic testing results or incidental findings during medical procedures. IRBs needed to understand if researchers identified that a participant had a certain genetic disorder, were they going to provide that information to the participant. In most cases, this continues to be the intent of IRB requests for information about whether researchers will “return results” to the participants. This terminology comes from regulations and guidance from federal oversight bodies. However, researchers may misinterpret this to mean if results of the overall research project will be given to participants.

One of the key elements of community-engaged research is to work with the community and share information. IRBs, and other human subject research oversight bodies, are very supportive of providing participants with result of the research to participants. However, it is important to ensure that researchers and IRBs are clear on what type of results are being provided to participants.

- **IRB Meaning –**

Return of Results: refers to providing an individual participant specific testing or procedural results from their participation in the study, often this is done during the course of the study (after individual participation but prior to analysis and manuscript preparation).

Dissemination of Results: refers to providing participants as a whole, in certain cases could be individual, with the overall results of the study, this could be done

Community Engaged Research IRB Background and Terms

as part of a published manuscript or could be handled as part of a newsletter, or other communications.

- **Recommendations** – IRBs should ensure the IRB application and related guidance are clear what information they are requesting within the application questions. Additionally, IRB staff should ensure clear and consistent revision requests to the application as necessary. Researchers should be prepared to utilize the IRB definitions and wording within the IRB application as this is based off regulation and the IRB is required to document certain pieces of information in a manner consistent with federal regulations. Researchers are not required to use the IRB terminology within their own research documents or the documents with community partners (for documents not subject to IRB approval). Often, avoiding confusing language and using basic or plain language that clearly states the intent of the researcher can help reduce misunderstandings and additional revision requests.
 - *Notes to IRBs: Should the IRB consider how to evaluate the way in which the community will receive the results as part of the review process?*
 - *Notes to IRBs: Should the deliverables for the dissemination be part of the IRB review and protocol? Should this be considered as part of the PAM process or Final Project Reporting process? Should these deliverables be part of any MOUs or agreements with community organizations?*

- **Compensation**

The IRB must oversee and approve payments made to human subject research participants. However, the IRB does not oversee payments made to research team members. The IRB must review all payments to participants and consider if they are appropriate based on the participation and reducing the risk of coercion to participate in the research. This can be particularly tricky in projects with community involvement as community members may be paid a large amount of money for their expertise and for equality amongst the researchers. However, if those payments were used as compensation for research participants, they may be inappropriate. Determinations must be made by the IRB regarding engagement of individuals in order to separate what payments are being made to an individual in their role as a research participant and in their role as a research team member. This may also require the researchers to follow different payment policies of their institution.

- **Compensation vs. Incentive vs. Reimbursement vs. Gift**

The language used as part of a project is important. Researchers should consider what is important to the community and what they value. The IRB can be more flexible in the terminology that is used that is participant-facing; however, the IRB should document what it considers compensation vs. reimbursement (for example) and how the regulations are being applied. Regardless of the terminology used, IRBs must consider the intent being described and apply the regulations appropriately.
- **Items vs. Money**

Community Engaged Research IRB Background and Terms

Some projects, and some communities, may prefer to compensate participants via items or material goods rather than money. The method of compensation does not necessarily impact how it will be considered but the intent or reason for providing it should be considered. IRBs may have specific policies or may consider types of compensation on a study-by-study basis.

- Not all items provided to participants are considered “compensation”. For example, clinical trials often provide participants marketing materials or “swag” that do not meet the definition of compensation. IRBs have different policies or processes for considering such items and if or how they should be included in an IRB application.

- **Compensating Research Subjects vs. Research Organizations**

Generally, the IRB oversees compensation to research participants, not organizations. However, the IRB may need to consider the role the organization is playing in the research. **Considerations:**

- Is the organization responsible for recruiting participants?
- Does the organization have some type of authority over the potential participants?
- Is the organization engaged in the conduct of research?
- Is supporting the organization creating undue influence or coercing individuals to participate?