Community-Based Participatory Research (CBPR)
VU Human Research Protections Program Guidance

Community-based participatory research (CBPR) involves an equitable community-engaged approach to collaboratively facilitate positive outcomes for a particular community. Below are some considerations for CBPR when submitting studies to the VU IRB for review.

- Engagement of community collaborators in human research
- Human research ethics training for community collaborators
- Minimizing risks and maximizing benefits for research participants and the community
- Data ownership and disclosing research results
- Funding considerations
- Modifying an IRB approved CBPR study
- International CBPR (conducted outside of the United States)

Engagement of Community Collaborators in Human Research

The VU IRB must have a clear understanding of how community partners and members are engaged in human subjects research (HSR) per federal regulations. Depending on the specific role and responsibilities a community partner or local individual has in the research, they may or may not be engaged in human research. Any individual or organization engaged in human subjects research (HSR) must have proper regulatory oversight.

Researchers are responsible for conveying the responsibilities and roles of community collaborators to the VU HRPP. In some cases, an IRB authorization agreement (IAA) (otherwise known as a reliance agreement) with the organization or an individual investigator's agreement (IIA) with an individual may be necessary (refer to *HRP-103 Investigator Manual Appendix A-9 and A-10* found on the VU HRPP website). If VU HRPP is providing regulatory oversight for community collaborators via a reliance agreement, these collaborators must complete all required training, adhere to institutional policies, and must not have a conflict of interest (refer to *HRP-055 Financial Conflicts of Interest* found on the VU HRPP website).

A community collaborator is considered engaged in human research if they are actively recruiting (answering questions on about the study as part of the research team), consenting, collecting data from research participants, or have access to and/or are

analyzing identifiable data (directly identifiable or coded data with access to the code link file).

Example: An individual at a small community-based organization is partnering with a VU researcher to conduct human research in the U.S. This person is fielding questions about the study from potential research participants and receiving coded research data (with access to the file linking codes to identifiers) for analysis. The duties performed by the community collaborator in this research are not within the scope of what their organization normally offers or implements. The VU HRPP would consider this community collaborator to be acting independently, not on behalf of their organization. The individual community collaborator is considered engaged in human research. There are two considerations researchers can make in this circumstance.

- In this design, the individual community collaborator must either receive ethical oversight/IRB review from their organization (if available) or they may be added as part of research personnel under the regulatory oversight of VU via an agreement called an individual investigator's agreement (IIA). The decision regarding whether an IIA can be executed is made by the VU HRPP.

OR

- The VU researchers can redesign the study so the community collaborator is not engaged in human research. Instead of fielding the questions from potential research participants and receiving access to the code link file, the collaborator can pass a recruitment flyer to the participants so they can contact the VU research team for study questions and only receive de-identified data for analysis. This scenario would not constitute engagement in human research and no regulatory oversight for this individual is required.

A community partner assists with study design aspects such as: consulting the research team on how to approach participants, identifying inclusion and eligibility criteria, determining compensation/incentives, or pointing out unique risks to the community members and how to minimize these risks. In this case they would not be considered engaged in human research.

Example: In a study on health disparities in underserved communities, a Community Advisory Board (CAB) was formed, including local leaders, healthcare providers, educators, and community members, to ensure the research was culturally appropriate and aligned with community needs. The CAB members helped to refine research questions, adapt recruitment materials, and identify barriers such as community mistrust of researchers and additional language considerations. After data collection, the CAB members offered insights to contextualize findings and ensure they reflected community experiences.

In this design, the CAB members play an important role in ensuring an ethical study design and meaningful interpretation of research results. Since the CAB members do not interact with the participants and have no access to identifiable research data, their involvement in the study is not considered research with human participants, and therefore, does not require regulatory oversight from the ethics committee.

Community Advisory Board (CAB)

If a community advisory board (CAB) is incorporated as part of the research, the IRB submission should include a description of the roles and responsibilities of the CAB

members, whether CAB members have access to identifiable data, and whether CAB members will be interacting with research participants at any point during the research life cycle.

Site Permissions / Letters of Support
If applicable, researchers must also indicate in their IRB submission whether site permissions or letters of support are necessary for the research to be conducted with communities involved in the research. Upon receiving them, these should be submitted to the VU IRB in the electronic IRB system.

Human Research Ethics Training for Community Collaborators

Community collaborators who are engaged in human research and covered by the ethical oversight of the VU HRPP will be required to complete human subjects research training. Currently, the VU HRPP offers training through the CITI Program. VU HRPP will consider alternative human research ethics training (e.g., FHI 360) when CITI training cannot be completed. This will be assessed on a case-by-case basis.

To access and complete the CITI Program at no fee to the Principal Investigator or community partner:

- (a) Create an account with your email address;
- (b) Select Vanderbilt University as the institution you are affiliating with; and
- (c) Complete the relevant CITI training module
    - *Human Research - Group 1. Biomedical Research Investigators and Key Personnel* ***OR***
    - *Human Research - Group 2. Social Behavioral Investigators and Key Personnel* training.

Minimizing Risks and Maximizing Benefits for Research Participants and the Community

It is important for researchers to provide a detailed description of foreseeable research-related risks in the IRB submission. The VU HRPP encourages researchers to work with community partners to identify these risks and adequate safeguards to minimize research-related risks for individuals and the community.

Maximizing benefits for both individual research participants and communities involved is an important consideration for researchers. Researchers should convey all research-related benefits in the IRB submission.

Data Ownership and Disclosing Research Results

A clear plan for data ownership and disclosure of research results is one way to minimize risks to the individuals and the communities involved (e.g., group harms, stigmatization). Researchers are encouraged to work with community partners to make shared decisions around data ownership and research results disclosures. This approach creates equitability in the research, builds trust with community members, respects the voices

contributing to the research, and ensures the data is handled with care. Researchers should relay how the results will be disclosed, who has ownership of the data, the confidentiality protections of the data, and who has access to identifiable and/or coded data in the study protocol, as well as the consent form. If agreements are necessary (e.g., data use agreements, etc.), these should also be fully executed.

Funding Considerations

If VU is the prime recipient of federal funds, please contact the VU HRPP to discuss requirements for IRB review and potential reliance agreements.

Modifications to the IRB Approved Study

If you are modifying your research to add non-VU community collaborators (individually or as an organization) after initial IRB approval, please ensure all appropriate regulatory reviews and agreements are executed (e.g., IRB Authorization Agreements (IAA) (also known as reliance agreements), Individual Investigator's Agreement (IIA)). Modifications relating to study documents or procedures must be submitted for review to the VU HRPP.

International CBPR Considerations

For human research conducted outside of the United States, international community collaborators who are engaged in human research must receive ethical oversight. If the research will undergo local ethics committee review and approval (similar to a U.S. IRB review), please submit the approval letter to the VU HRPP in the electronic IRB system. For VU researchers who are partnering with international community collaborators on human research and are unsure about ethical oversight for these collaborators, please contact the VU HRPP.

Questions

Contact the VU HRPP at irb@vanderbilt.edu.