

## Community Engagement in Human Subjects Research

This guidance establishes additional considerations that apply, on top of the standard criteria for approval of human subjects research, when a study is designed, implemented, or disseminated using community-engaged research methods (ex. Community-Based Participatory Research; Community Advisory Boards; Youth Participatory Action Research, etc.). It is intended to help investigators prepare complete applications and to help the IRB evaluate the unique partnership, consent, risk, and dissemination issues these projects raise.

### Scope

This guidance applies to any human subjects research in which community members, community organizations, or community leaders participate as partners in one or more phases of the research — study conceptualization and design, participant recruitment, data collection, data analysis and interpretation, or dissemination of results — rather than solely as research subjects. It applies regardless of review category (exempt, expedited, or full board) whenever community partnership is a defining feature of the research design.

### Definitions

- **Community-Engaged Research:** This is a broad term that encompasses a wide range of research methods that use active collaboration between academic researchers and community members to address real-world needs. In Community-Engaged Research, community input meaningfully shapes the research beyond just individuals who participate as research subjects. Community involvement in research projects can exist along a continuum, ranging from communities acting as advisors all the way to communities leading research projects.
- **Community Partner:** An individual, organization, advisory board, tribal entity, or governing body that represents the community's interests and participates in the research partnership, which may include serving as a co-investigator.

### Guiding Principles

The following principles apply in addition to, not in place of, the regulatory criteria required for approval of all human subjects research. Investigators conducting community-engaged research are expected to demonstrate how their project reflects these principles, and the IRB will consider the degree to which they are addressed when reviewing the application.

1. The research topic addresses a need, question, or problem defined or affirmed by the community.

2. The research is structured as a genuine partnership, typically led by a team of academic and community co-investigators rather than directed unilaterally by the academic investigator.
3. The community partner's interests, priorities, and concerns about the research are respected throughout the project.
4. Investigators remain open to community insight and lived experience as it informs study design, instruments, and interpretation.
5. Decision-making authority is balanced between researchers and community partners rather than concentrated with the academic team.
6. Mechanisms exist for continuous feedback between partners to strengthen the collaboration and its outcomes over time.
7. Findings are disseminated back to community stakeholders and participants, not solely to academic or scientific audiences.
8. Investigators recognize that partnerships may end, and a plan exists for responsibly closing out the collaboration.

### **IRB Application Considerations**

Investigators should address the following topics in their IRB submission:

- **Description of Community Involvement**  
Explain which phases of the research involve community members and how. Most commonly this includes study design/conceptualization, implementation/conduct, and dissemination of results; depending on the topic, it may also be appropriate to involve community members in data analysis and interpretation and in decisions about how findings will be shared, so that community perspectives are reflected before results are finalized or published.
- **Decision-Making Processes**  
Provide a description of community partner roles and responsibilities, along with a description of how decisions about the research are made.
- **Community Consultation on Risk**  
Describe how community members were or will be consulted to identify risks or issues investigators might not otherwise recognize — for example, literacy or language

barriers, or local cultural beliefs and practices — and how risks were considered at both the individual and community level, including any measures developed with community input to minimize them.

- **Collaborative or Local Ethics Review**

Identify whether the community, tribe, agency, school district, or other entity involved has its own ethical review process. If so, describe the plan to obtain review and approval from that body in addition to (or, where a reliance/collaborative agreement exists, in coordination with) this IRB, and note any institutional or investigator agreements required.

- **Plan for Anticipated Modifications**

Because CBPR procedures and instruments often evolve as a project is implemented, describe anticipated areas of flexibility (e.g., survey wording, recruitment approach) so the IRB can review a protocol that is thorough yet realistic about likely field adjustments, consistent with UM IRB's amendment procedures.

- **Plan for Disclosure of Findings**

Describe how and when findings will be communicated to the community, including consideration of possible group-level implications of disclosure. Many group-level harms in community research arise from how findings are shared rather than from the research itself, so this plan should specifically address how the risk of stigmatizing or otherwise harming the community will be minimized.

- **Plan for Community Benefit**

Describe how the study is designed to produce a benefit to the community involved, and whether the partnership is intended to continue beyond the funded project so that findings can be incorporated into ongoing community programs or services.

- **Letters of Support and Funding**

Include letters of support from the community partner(s) that clearly describe the nature of the partnership.

### **IRB Review Considerations**

In addition to the standard criteria for approval, the UM IRB will consider the following when conducting a review of community-engaged research:

- There is evidence of an equitable partnership between the investigator(s) and the community partner(s).



- The investigators have clearly defined the relevant community or communities for the project and identified the community partner(s) appropriate to that community.
- Community engagement is integral to the research rather than incidental to it.
- Letters of support from the community are clear, specific, and well defined.
- Adequate training opportunities exist for both investigators and community partners engaged in the research.
- The research environment and setting are adequate to support the study, including the likelihood that the community will benefit from the research and that the project can be conducted successfully in that setting.
- The research is designed to contribute to positive change in outcomes for the community.
- The research is likely to foster a long-term relationship between the institution and the community that benefits both parties.

### **Community Member Training**

Community members who are involved in human subjects research may fulfill the University's IRB training requirements by completing **CIRTification**, an online human research protections training program designed specifically for community members and community-engaged research partners. The training is available at [CIRTification](#).

We acknowledge the use of CIRTification training in human research protections from the University of Illinois Chicago Center for Clinical and Translational Science (CCTS), which is supported by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, through Grant Award Number UM1TR005438.