GUIDANCE *for* ETHICAL ENGAGEMENT IN AND WITH COMMUNITIES

By Nicole Rosner

This resource provides guidance on ethics considerations in the design, structure, implementation, and analysis of engagement activities as well as following up after project completion. The information and procedures presented intend to safeguard the rights and well-being of participants and ensure the integrity and validity of the project results. This guidance is not a requirement but rather a resource. Each organization is responsible for establishing and understanding its own ethics protocols.

Institutional Review Boards (IRBs)[1] play a crucial role in ensuring that research involving human subjects is conducted ethically and protects participants' rights and welfare. We have adapted general ethics considerations typically addressed in an IRB review of research with human subjects to be applicable to community engagement projects that use similar methods to gather and analyze social data. Community engagement projects may not aim to develop or contribute to generalizable knowledge (i.e., conduct research) but rather focus primarily on improving local programs and planning. Whether your work requires a formal ethics review process or not, adhering to the ethical standards within research will provide a baseline to ensure that projects are conducted ethically, protect participants' rights and welfare, and their decision-making power is respected and protected throughout the process.

[1] The IRB evaluates research proposals to determine whether they meet ethical guidelines, including considerations such as participant consent, potential risks to participants, and protections for vulnerable populations. Ultimately, the IRB serves to protect the rights and welfare of human subjects involved in research studies.

What Qualifies as Research?

Research is defined by federal regulations at 45 CFR 46.102 (Protection of Human Subjects 2018) as **"a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."** Here, the definitions of "research" and "human subjects" are based on perspectives from the social and behavioral sciences, education, and the humanities. According to the Collaborative Institutional Training Initiative (CITI Program) that provides training and certification in human subjects' research, and how to navigate the IRB process, **"a study that meets the federal regulation's definition of research but does not involve human subjects, does not need IRB review. Similarly, a study may involve human subjects, but not meet the definition of research and would, therefore, not require an IRB review."** (Hicks 2018)

What Does Not Qualify as Research?

Many community engagement projects and activities do not qualify as research based on federal regulations. **Community engagement projects usually involve interacting with people and, at times, collecting data from those participants and publishing those results.** However, community engagement, data collection, and publication of results by themselves do not mean the project qualifies as research. Instead, it is **the project's intent** that clarifies whether the work qualifies as research or not. "Some activities that involve interactions with humans and data gathering may not meet the definition of research because they are designed to accomplish something else, such as program improvement (also called quality improvement activities)" (Hicks 2018). Below are examples of work that does not qualify as research:

- A local government office seeking input from their constituents to inform the design and implementation of a street cleanup program in a specific neighborhood.
- The staff of a university library conducting "a survey of members of an academic unit to find out if the library is meeting the department's need. The project may be a systematic investigation but is not considered research because the intent of the project is to improve the library's service to its patrons, rather than contribute to a body of knowledge (such as, improving all libraries' service methods)." Even if the library staff shared "the results of their program improvement activity at a conference without changing the intent. The project would not become research by virtue of sharing its results." (Hicks 2018)

ETHICS CONSIDERATIONS IN COMMUNITY ENGAGEMENT

Even when a community engagement project does not qualify as "research with human subjects," the following ethics considerations that promote **respect, transparency, continuity, accountability**, and **justice** are important to incorporate into project planning and implementation.

- **Voluntary Participation:** Ensuring that participation in the engagement project or research is voluntary and that participants are free to withdraw at any time without penalty. Verbal or written *(preferred)* informed consent forms are recommended to ensure voluntary participation.

- **Informed Consent:** Fully informing participants about the nature of the engagement or research, including its potential risks and benefits, their rights, purpose, procedures, and alternatives, so they can make an informed decision before agreeing to participate.
A verbal or written informed consent process, such as listening sessions or surveys, can simultaneously inform participants and minimize harm. Key components of informed consent include:

  - **Voluntary:** Participants voluntarily decide whether to participate in the research without coercion or undue influence. All participants remain autonomous with the right to skip questions or withdraw at any time without negative repercussions.
  - **Capacity:** Participants have the capacity to understand the information provided and make an informed decision.
  - **Disclosure:** Researchers or engagement coordinators provide clear and understandable information about the study, project, or activity, including its purpose, procedures, risks, benefits, and alternatives. Ensure participants understand what their data will be used for, who will have access to it, and what the intended outcomes are. If their data could be used to inform future projects or research, inform participants of this possibility.
  - **Understanding:** Present information in a manner that allows participants to comprehend the information and ask questions.
  - **Consent:** Participants provide their explicit voluntary consent to participate in the research, project, or activity, typically by signing a consent form or verbally agreeing to consent.
  - **Templates:** Researchers or engagement coordinators should develop verbal or written *(preferred)* informed consent templates for engagement activities such as listening sessions, community workshops, or interviews.

ETHICS CONSIDERATIONS IN COMMUNITY ENGAGEMENT, Continued

- **Minimization of Harm:** Identifying potential risks to participants, both physical and psychological, and any potential to minimize these risks. Ensure that the potential benefits outweigh these risks.

- **Confidentiality and Privacy:** Protecting the confidentiality of participants' data and ensuring that their privacy is respected throughout the engagement or research process.

  - Privacy involves ensuring that individuals have control over who has access to their personal identifiable information (PII). PII refers to any personal data that can be used to uncover an individual's identity, such as an email address, phone number, or social security number. In research, privacy means identifying what information collected qualifies as PII and taking measures to protect participants' personal data from unauthorized access or disclosure. Researchers must implement procedures to minimize the collection, use, and retention of PII to the extent necessary for the research purpose. This might include using coding systems, de-identifying data, or limiting access to identifiable information only to authorized personnel. These procedures can also be used in engagement processes to help protect the privacy of participants and their PII.

  - Confidentiality refers to the obligation to handle participants' information in a manner that prevents unauthorized access, use, or disclosure. Researchers take steps to maintain the confidentiality of participants' data throughout the research process, including data collection, storage, analysis, and dissemination. This may involve using secure data storage systems, encryption, password protection, and restricted access to research records. Such procedures can also be used in engagement processes to ensure confidential treatment of information.

  - Note: If you are conducting a focus group or listening session, understand that confidentiality cannot be promised in these settings given that organizers cannot guarantee the complete protection of personal information shared with all involved in the group.

- **Fair Selection and Access to Participation:** Ensuring that participants are selected fairly, that vulnerable populations are not exploited or disproportionately included in engagement projects or research studies without justifiable reasons, and providing equitable compensation for participants' time and expertise as well as lowering barriers to participation by providing accessibility accommodations (e.g., translation, location, childcare, food, drink).

- **Balancing Risks and Benefits:** Evaluating whether the potential benefits of the engagement project or research justify any potential risks to participants. This includes respecting participants' time, emotions, and valuing their differences.

- **Conflict of Interest:** Identifying and managing any conflicts of interest among organizers, researchers, or sponsors that could potentially compromise the integrity of the engagement process or research.

- **Data Management and Security:** Ensuring that data collected from participants are stored securely and used only for the purposes outlined in the project scope of work or research protocol.

- **Compliance with Regulations:** Ensuring that the engagement project or research complies with relevant regulations and guidelines. In the case of research, this includes the Belmont Report, the Declaration of Helsinki, and local laws governing research involving human subjects. In the case of engagement activities, this includes ensuring your efforts comply with your organization's ethics regulations.

- **Continuous Monitoring and Following Up:** Monitoring the progress of the engagement process or research to ensure that ethical standards are maintained throughout the duration of the project or study. Following up with participants during and after the conclusion of the project to maintain trust, participant agency, and collaboration, ensure ethical conduct, promote project sustainability, continue partnerships, disseminate knowledge, guarantee, assess and address impact.

- **Protecting Vulnerable Populations:** Designing the project and developing procedures to protect persons or groups of individuals involved in research or engagement that require additional considerations and/or protections to ensure their participation is voluntary. Protections should consider the risk of social (e.g., stigmatization, reputation), financial (e.g., economic burdens), physical (e.g., exposure to physical risks), and psychological (e.g., emotional distress or discomfort) harm. Using an informed consent process helps minimize the increased risks arising from, for example, "limitations in decision-making capacity...or situational circumstances...or because they are especially at risk for exploitation." (NBAC 2001)

These considerations help safeguard the rights and well-being of research participants and ensure the integrity and validity of the research findings.

VULNERABLE POPULATIONS:

Vulnerable populations are groups of individuals who may be at an increased risk of being unduly influenced or exploited in research or engagement settings due to their diminished autonomy, decision-making capacity, or heightened susceptibility to coercion or harm. (Block and Gordan 2019)

Examples of vulnerable populations may include:

1. **Children/minors:** Individuals under the age of 18 who may not have the capacity to fully understand the risks and benefits of participating in research or provide informed consent without parental or guardian involvement.
2. **Pregnant women and human fetuses:** Individuals who may be at risk of harm due to their physiological condition or the potential impact of research interventions on fetal development.
3. **Prisoners:** Individuals who may have limited autonomy and decision-making capacity due to their incarceration status, making them susceptible to coercion or undue influence.
4. **Individuals with cognitive or developmental disabilities:** Individuals who may have impaired decision-making capacity or difficulty understanding complex information, making it challenging for them to provide informed consent.
5. **Economically or educationally disadvantaged individuals:** Individuals who may face barriers to understanding research information or asserting their rights due to limited access to education or resources.
6. **Individuals from underrepresented and/or underserved racial or ethnic groups:** Individuals from disadvantaged communities or populations sharing a particular characteristic, as well as geographic communities, that are shown to have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by communities that have been denied fair, just, and impartial treatment, which may include Black, Latino, Indigenous and Native American persons, Asian Americans and Pacific Islanders, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; persons otherwise adversely affected by persistent poverty or inequality; women; and veterans.

Within a research context, it is essential for researchers and IRBs to recognize and address the specific vulnerabilities of these populations—which are at times intersectional vulnerabilities—to ensure their rights and welfare are respected in research settings.

Within the engagement context, similar safeguards and protections can be implemented to ensure the welfare of all participants, particularly those most vulnerable to potential participation risks. As you develop a strategy for engagement, consider each vulnerable population you might be interacting with. Think about if, when, and/or how to employ the following methods:

- **Use an informed consent process to ensure voluntary participation.**
- **Set up data collection and storage procedures to protect the confidentiality of participants' data and ensure their privacy is respected throughout the engagement process.**
- **Identify potential vulnerable groups who could participate in your engagement process and design the project and procedures to protect those individuals and promote equitable participation.**

These methods help ensure the welfare of all engaged participants.

ETHICS RESOURCES

- The CITI Program provides trainings (at a cost) on how to ethically design, structure, conduct, and analyze research with human subjects. These trainings can be used as ethics guidance in engagement settings that aim to ensure participants are protected and respected through the process*:
- Community-Engaged and Community Based Participatory Research training
- Social-Behavioral-Educational Comprehensive training
- Cornell University provides a template IRB consent form for social and behavioral research projects

** Some institutions such as universities and national laboratories may cover the cost of training.*

REFERENCES

- Jeremy N. Block and Bruce Gordon, “Populations in Research Requiring Additional Considerations and/or Protections” (CITI Program, July 2019), https://www.citiprogram.org/members/index.cfm?pageID=125#view.
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