

Community Research Partners Education and Certification Requirements

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Definitions: Human Subjects and Research

Human Subjects:
An individual about whom an investigator conducting research obtains data through **intervention or interaction with individual or identifiable private information**

Research:
A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to **generalizable knowledge**



Ethical Principles for Research

Rule #1:
Respect People

- People should make their own decisions
- Agreement to participate must be freely and voluntarily given

Rule #2:
Do Not Harm

- Avoid known risk of harm to participants
- Minimize potential harms and maximize potential benefits

Rule #3:
Be Fair

- Benefits and burdens should be shared by all people
- Safety and welfare of some groups should not be risked for the benefit of others

Research Regulations

- The federal government has made laws for how research should be done
 - Protecting participants
 - Informing participants
 - Reviewing research before it starts
- Everyone doing research must follow these rules**
- Review boards called "IRBs" enforce these rules at the local level in order to protect the rights and welfare of participants



The Institutional Review Board (IRB)

- **Main Goal: Protect participants from harm!**
- Before a project begins, the IRB weighs risks and benefits:
 - Reviews all forms and procedures
 - Recruitment of participants
 - Informed consent procedures
 - Privacy and confidentiality protection
- Requires changes – big and small.

Research cannot start until approved by the IRB!



Training Requirements

Those engaged in research are required to complete training in the protection of human subjects.

This can be fulfilled by the CITI (Collaborative Institutional Training Initiative) online-training program: <https://www.citiprogram.org/>



"To promote the public's trust in the research enterprise by providing high quality, peer reviewed, web based, research education materials to enhance the integrity and professionalism of investigators and staff conducting research."
CITI Program Mission Statement

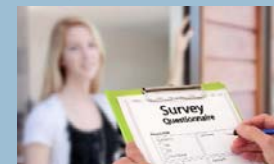
Community Research Partners

- Community-engaged research might include partners from:
 - Community organizations
 - Patients
 - Religious congregations
 - Neighborhoods
- Community research partners may be involved in research by:
 - Participating in a Community Advisory Boards
 - Providing input on recruitment methods
 - Collecting Data
 - Helping to disseminate information



Requirements for Community Research Partners

- In certain circumstances, community partners may be considered investigators who are "engaged" in the research
- The activities that qualify a collaborator as an investigator include:
 - Interacting or intervening with research participants
 - Consenting participants
 - Participating in the collection of or having access to identifiable data



Requirements for Community Research Partners

- If a community collaborator is considered an investigator, than human subjects training is required (CITI Certification)
- More information is available on the Penn IRB website (*IRB Guides – Community Research Partners*)

University of Pennsylvania – Institutional Review Board
Community Research Partners

Recognizing, in an effort to foster community engagement in the research process, partners and other community identifiers are included in certain levels of research design and conduct. In these cases it is important to consider the circumstances when research is conducted on or with the concerned research subjects or individuals, "engaged" in the conduct of research. Each of these cases is addressed below:

Community Collaborators as Research Subjects

There are certain circumstances where community collaborators should be considered research subjects. It occurs when the research team wishes to interact with community partners for the purpose of collecting information that will inform or be a source of research data. The community partner would be considered a human subject and traditional requirements for consent would apply.

A human subject is defined by IRB regulations as follows:

(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains through intervention or interaction with the individual, or

(ii) Identifies private information.

To help consider whether a community collaborator qualifies as research subject please consider the following scenario:

All investigator(s) identify collaborator as partner, which is part of a support group for cancer patients. The investigator wishes to obtain feedback on the topic of questions that should be asked of cancer patients and which ways to understand their responses of those who suffer the health concern.

Scenario 1: The collaborator will be solicited for recruitment 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 for human subjects as no data will be collected from these individuals that will be analyzed as part of the research study.

Scenario 2: After the recruitment is developed the collaborator will be asked to complete the survey, which will be analyzed based on the criteria for recruitment in the study. Data from their survey would be analyzed similarly to all other respondents.

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



- CITI Certification**
 - Required by the University
 - Challenges:** University affiliation needed to access, assumes background knowledge on research
- CIRTI Certification Program**
 - Designed as a substitute to CITI Certification
 - Better suited to the needs of community partners:
 - Addresses ethical issues in plain language
 - Uses real-world examples
 - Focuses on the application of new knowledge
 - Includes participatory activities such as brainstorming, case-based discussions, and role playing
 - Challenges:** Designed to be delivered in-person, workshop takes 3+ hours to complete




Training in Responsible Conduct of Research in the Community

A collaboration between the Community Engagement and Research (CEAR) Core of the UPenn CTSA and the UPenn Office of Regulatory Affairs, Human Research Protections

- The training will feature materials from the CIRTI Certification curriculum (developed at the University of Illinois at Chicago), a human research protection program tailored to meet the unique needs of community research partners.
- It is relevant to the roles and responsibilities of community partners participating in a research project and focuses on skills-building.

Training in Responsible Conduct of Research in the Community



The screenshot shows a web page titled "Community Training" from Penn Medicine. It includes a sub-header "Community Training helps community members and research coordinators work together to train and certify research assistants. Please choose your role below to get started." Below this are two buttons: "Are you an investigator in a research program?" and "Are you a member of the community?".

Questions?



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