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

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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

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Research Regulations

• The federal government has made laws for how research should be done
  o Protecting participants
  o Informing participants
  o 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:
  o Reviews all forms and procedures
  o Recruitment of participants
  o Informed consent procedures
  o Privacy and confidentiality protection
- Requires changes – big and small.

*Research cannot start
until approved by the IRB!*

Training Requirements

Those <u>engaged in research</u> 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:
  o Community organizations
  o Patients
  o Religious congregations
  o Neighborhoods

- Community research partners may be involved in research by:
  o Participating in a Community Advisory Boards
  o Providing input on recruitment methods
  o Collecting Data
  o Helping to disseminate information

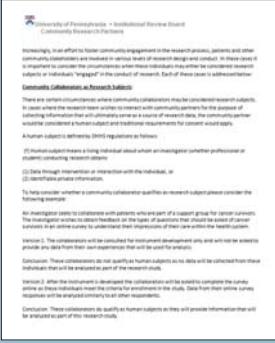### Requirements for Community Research Partners

- In certain circumstances, community partners may be considered <u>investigators</u> who are "engaged" in the research
- The activities that qualify a collaborator as an investigator include:
  o Interacting or intervening with research participants
  o Consenting participants
  o 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)*

- **CITI Certification**
  - o Required by the University
  - o <u>Challenges:</u> University affiliation needed to access, assumes background knowledge on research

- **CIRTification Program**
  - o Designed as a substitute to CITI Certification
  - o 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
  - o <u>Challenges:</u> Designed to be delivered in-person, workshop takes 3+ hours to complete

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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 CIRTIfication 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

Questions?

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