

Appendix 3

GUIDANCE FOR INVESTIGATORS HOW TO CONDUCT COMMUNITY PARTNER RESEARCH ETHICS TRAINING

Dear Investigator,

As a growing number of researchers are participating in community-based and community-partnered studies, the Community PARTners (Community Engagement CORE) of the Clinical & Translational Science Institute (CTSI) in collaboration with the Institutional Review Board (IRB) has developed a community partner research ethics training to make sure community partners know how to conduct research that is ethical and safe.

It is important to ask yourself the following questions to better understand whether or not your community partner is ACTIVELY INVOLVED in your research study and needs to complete this training.

* This Community Partner Research Ethics Training and Certification is intended for community partners. We encourage you, Co-Investigators and any other research personnel in your research study to take the training. However, **it is NOT to be a substitute for the standard required IRB research training.**

Will your Community Partner be ACTIVELY INVOLVED in your research study?

- Will your community partner be recruiting and/or consenting human subjects to participate in your research?
- Will your community partner be observing and recording information about human subjects?
- Will your community partner be collecting private information about human subjects?
- Will your community partner be using, studying or analyzing identifiable private information or specimens provided by another institution, yourself or data collected from human subjects for research purposes?

If you answered **YES** to any of these questions above, your community partner is ACTIVELY INVOLVED in research. Therefore, it is IMPORTANT to have your community partner complete the following University of Pittsburgh IRB community partner research ethics training to receive **Community Partners Research Ethics Certification**.

Receiving this IRB-approved certification ensures that your community partner has the basic understanding of the following research topics:

- Introduction to Research & the Purpose of Research
- History of Research & the Development of Research Ethic Principles
- IRB & Federal regulations for Research and Protection of Human Subjects
- Definitions and Rules of Research Conduct
- How to Apply Various Aspects of Research Ethics and Conduct when Working with Human Subjects



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Community PARTners Partnering to Assist Research and Translation

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Before instructing your community partner to complete this community partner research ethics training, it is necessary for you to explain the importance of this training and certification process as an opportunity to protect both themselves and the human subjects participating in the research study. Listed below is the table of contents for the training and indicates where you can include study specific content to tailor YOUR Community Partners Research Ethics Training and Certification materials.

- Pledge Statement
 - A statement completed by the person completing the training to ensure he/she is completing the training and not someone else
- "Who should complete this training?"
 - Series of eligibility questions to ensure appropriate community partners are utilizing the training
- PowerPoint Training presentation *Include content specific to your research study* Provides the educational content for the training
- Confidentiality Agreement
 - o An agreement to maintain confidentiality when it comes to research and human subjects
- Feedback & Evaluation
 - Receive feedback from the participants about the training and its use for enhancing their understanding of research ethics.
- Community Individual Investigator Agreement
 - A sample of the official documentation from our University of Pittsburgh, Institutional Review Board, which is processed and signed by the IRB administrators to complete IRB approval of all participants' who have completed the Community Partners Research Ethics Training.
- Glossary Include acronyms and terms specific to your research study
 - o List of general terms used regarding the research and human subjects
- Certification of Completion
 - Provide personalized certificate of completion to each trainee who completes the training you conducted
 - Once your community partner receives Community Partners Research Ethics Certification, it is GOOD that you and your community partner keep a hard copy of the certification with your research documents. This documentation can be filed and stored with your study protocols.



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Research Study Datasheet

Please provide us feedback about the nature of the research study you are involved in. Thank you!

Name of Principal Investigator or Lead Researcher:

Department:

Email:

Contact:

Name of Research Study:

Brief Description of the Research Study

Describe Your Role in the Research Study

Additional Comments/Feedback:



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