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Community Partnered Research Ethics Training in Practice – A Collaborative Approach to Certification

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Abstract

This report describes the development and implementation of a tailored research ethics training that for academic investigators and community research partners (CRP). The Community Partnered Research Ethics Training (CPRET) and Certification is a free and publicly available model and resource created by a university and community partnership to ensure that traditional and non-traditional research partners may study, define and apply principles of human subjects' research. To date, 7 academic and 34 CRP teams have used this highly interactive, engaging, educational and relationship building process to learn human subjects' research and be certified by the University of Pittsburgh IRB. This accessible, flexible and engaging research ethics training process serves as a vehicle to strengthen community and academic partnerships to conduct ethical and culturally sensitive research.

Keywords

Community; research ethics; training; community-based participatory research; CBPR

Federal initiatives and funding opportunities for community engagement in research have burgeoned over the last two decades.(Catalani & Minkler, 2010; Chen, Diaz, Lucas, & Rosenthal, 2010; Viswanathan et al., 2004) Cultivating new methods and tools for facilitating community engagement in research is especially relevant for the translational research enterprise. Respectfully and equitably integrating community members' perspectives in the research process can increase the relevance of research, improve communication during the consent process, protect rights of research participants, and ensure that vulnerable populations are represented in research studies.(Ross et al., 2010a) Community-partnered research raises particular ethical challenges as these studies often involve working together with various leaders and members from underserved, socially disadvantaged, or marginalized communities, communities whose backgrounds often are quite different from those of research investigators.(Ross et al., 2010b, 2010c) Developing relevant and rigorous research ethics certification processes for both community and academic investigators alike is a challenge facing diverse teams of researchers nationally.

Investigators and ethicists have noted how values, guiding principles, and procedures for equitable participation can become entangled with laws, regulations, and policies for protecting human subjects participating in research.(Flicker, Travers, Guta, McDonald, & Meagher, 2007) Investigators and study personnel are required by their university to complete training in the ethical and regulatory aspects of human subjects' research. The currently accepted research ethics training and certification used by universities nationally to meet that requirement is the Collaborative Institutional Training Initiative (CITI Program). Founded in 2000 to focus on human subjects research in biomedicine, the program introduced expanded materials to include social and behavioral researchers in 2004. (Braunschweiler & Hansen, 2000) This commonly used university-required training for research ethics(University of Pittsburgh, 2014) generally was not designed with community research partners in mind, and thus not surprisingly has been critiqued for being cumbersome, inaccessible, and lacking relevant and compelling contemporary examples illustrating research ethics principles that translate to specific community-based studies. (Flicker et al., 2007) Additionally, research ethics trainings often require access to technology and some familiarity with research which, while a reasonable assumption for an audience of investigators, may be an unfair expectation for community partners. Some universities have pursued hybrid-research ethics trainings that are in the form of educational modules for individuals to complete on their own and, as such, do not promote opportunities for bi-directional discussion about ethical concerns that may arise during the course of a study.(Stellefson, Paige, Alber, Barry, & James, 2015)

Current research ethics trainings, traditional and hybrid-models designed to incorporate community partners, have often been limited to a focus on protecting and respecting the rights of autonomous individuals, with comparatively little attention paid to the ethical rights of entire communities.(Stellefson et al., 2015) Respecting individual autonomy through

informed consent is a high priority in community-driven research, but understanding what it means to also consider the interests of communities as a whole is a related challenge, increasingly recognized as an independent and important ethical commitment.(Banks et al., 2013; Mikesell, Bromley, & Khodyakov, 2013; Wallerstein & Duran, 2006; Weijer & Emanuel, 2000) Community-based participatory research (CBPR) approaches and principles focus on bidirectional learning among community and academic partners, although this approach has had less traction in the research ethics certification process, and recognizes, respects and addresses the evidence that “one size does not fit all” when it comes to community-based research ethics training(Anderson et al., 2012; Flicker et al., 2007). Few concrete strategies exist to invite input from community partners in considering the ethical concerns associated with specific research studies including perceptions of risk, trust of the research process, how information will be gathered, interpreted, and shared.

To address this local and national need for flexible and tailored research ethics training and certification, the University of Pittsburgh (Pitt) Clinical Translational Science Institute (CTSI), Institutional Review Board, and Community Research Advisory Board developed a research ethics training for community partners that is adaptable to specific research studies’ needs (<http://www.ctsi.pitt.edu/cpret.shtml>). This training is accessible online, free of charge and supported by the Community Partners Core (CPC) of the CTSI (Grant Number UL1TR000005). With input from community partners, investigators create scenario-based examples of desirable and less desirable situations that could potentially arise during the course of a study that highlight core ethical concerns and principles. This IRB approved tailored research ethics training integrates community partners’ expertise in the study from the start, providing a foundation in human subjects research principles and encouraging communication about anticipated ethical challenges in study implementation at the individual and collective level. The training and certification offers a tool for improving understanding, and collaboration among community members and researchers.

Methods

Description of Materials Development

The University of Pittsburgh’s Community PARTners Core of the Clinical and Translational Science Institute (CTSI) facilitates relationships between community organizations and clinical and translational researchers to enhance collaborative research, foster public trust in clinical and translational research, and increase activities that promote community health. The Community Research Advisory Board (CRAB), which was established in 2001, is an initiative of the Center for Health Equity at the University of Pittsburgh and an interdisciplinary collective of more than 30 individuals who convene monthly to counsel and learn with researchers on how to 1) make their research more relevant to under-represented populations; 2) engage such populations in research; and 3) and to foster collaboration among those populations and researchers interested in addressing health disparities.

To ensure all research ethics components were adhered to, this Community Partnered Research Ethics Training and Certification (CPRET) is structured to include the Collaborative Institutional Training Initiative (CITI) modules. Members of the CRAB reviewed all materials to ensure that the CPRET process and materials (publicly accessible

online at <http://www.ctsi.pitt.edu/cpret.shtml>) were clear, concise, engaging, culturally sensitive, and relevant. To further inform the CPRET process, the CPC sought public input and guidance/feedback through an open round table forum with a diverse range of community members and academic stakeholders. Twenty-three community (e.g., a human service agencies, intimate partners shelter, and community centers) and academic stakeholders (e.g., from medicine, public health, social work, and physical therapy) attended the roundtable meeting, where the evolving CPRET training material and PowerPoint presentation were provided. Attendees engaged in oral and written feedback integrated into CPRET design.

Implementation Process

A brief description and free access to all of the CPRET materials can be found at <http://www.ctsi.pitt.edu/cpret.shtml>. At the University of Pittsburgh, academic researchers either directly request the CPRET training or are encouraged to do so by the University IRB at the time a protocol is being reviewed. Some researchers also seek out description of the training when developing their stakeholder-engaged research proposals. The Principal Investigator/Community Research Partner (PI/CRP) is provided a link to all of the CPRET materials with detailed instructions (Figure 1) for how to tailor the training with project specific research ethics-guided scenarios, implement the program, and submit formal paperwork for the IRB necessary for certifying CRPs to participate in every phase of the research process for their particular study. Feedback provided by community and academic research partners alike indicate that one of the most valuable elements of the CPRET model is the structure for developing scenarios together that are tailored specifically to the study's objectives and which mirror key principles of the human subjects research process. The CPRET program requires that the PI develop specific scenarios, both good and bad examples, of ethical challenges likely to arise during a research study. For example, in a clinic-based study on partner violence taking place on tribal land, the Native research partner sees a study participant at the local market -- how should she respond? This scenario allows for discussions of privacy and confidentiality, and helps to illustrate how easily confidentiality could be breached -- especially in small communities.

Once scenarios are developed, an in-person or webinar version of the complete CPRET training is conducted for all participating academic and community partners who will be part of the core research team. To ensure quality control, production and approval of the scenarios and adherence to the IRB approved CPRET training procedures, the Community Partners Core staff are accessible and involved as requested in the scenario review and approval process and has a CPC member present to observe the community-based implementation of the CPRET training for quality assurance. While the implementation of the CPRET training and filing of completion documents with the IRB is ultimately the responsibility of the study PI, the CPC is available to provide technical assistance throughout the process (Figure 2).

Trainings with Community and Academic Investigators

To date, eight Principal Investigators have used the CPRET model and tools with 7 completed trainings (See Table 1) and a total of 34 community partners, including 8 youth

research advisory board members. Principal Investigators and research staff collected data about the acceptability and feasibility of the program using the feedback forms provided within the CPRET materials.

Results

Among the 18 trainee and 4 instructor feedback forms received to date, participants either agreed or strongly agreed that the training was valuable and that the information about research ethics was presented in an organized, timely and easy to understand manner. Community trainees highlighted that the information they found most important to learn or that was new to them was the overview of the research process, understanding the consent process, and the role of the IRB. Written comments included “The training was a great overview, refresher to my current knowledge base,” “The consent process was such valuable and new information for me,” “how research projects are revised and approved.” Furthermore, trainees also found the research scenarios important stating, “The scenarios were very valuable and made things easier to understand.” under what were most important was the “scenario practice.” Areas that academic and community trainees thought could use improvement focused generally around more time on research scenarios, history of research ethics, and practicing the consent process.

Academic researchers also offered positive feedback about community partners’ responsiveness and engagement as a result of the training. Specifically, one researcher commented that the most valuable aspect was the delivery of this training, “I felt that the training process allowed the community partners to feel like they were an integral part of the research training process, and not just outsiders. By allowing them to discuss and converse about the various topics of research ethics, I think it made them feel more comfortable with the whole research process.” Another investigator reported “It helped open the lines of communication with my community partner. It also helped me find out what the community partner knew and what was ‘new’ information for them.”

Discussion

Development and piloting of this Community Partner Research Ethics training demonstrates that this type of tailored, flexible participatory training is ideal for both academic researchers and community partners. CPRET is intended to increase the capacity of community partners and academic researchers to engage more deeply and equitably together in the research process. A unique aspect of the CPRET training and certification program is the requirement that the lead investigators create study specific scenarios to illustrate key ethical challenges. This process offers an innovative way to involve community stakeholders formally in the research process and to illustrate how broader research ethics principles such as autonomy and beneficence translate into ‘real world’ research studies. Additionally, the CPRET presentation focuses on defining positive research ethics rather than starting with examples of ways in which research has been carried out poorly and unethically in communities. This emphasis on the core principles of research ethics including autonomy, justice and beneficence intentionally creates opportunities to talk about the critical importance of community participation in research and to build trust in the research process. Finally, this

CPRET certification process requires PI and community partner conversation (can be done in person or via webinar based on the distance needed to travel to sites) about the ethics related to a specific research study.

As an exploratory study to assess the acceptability and feasibility of this research ethics training program, this project is not without limitations. The small sample size and the experiences from a single institution preclude generalizability. Initial feedback from this group of early adopters suggests that the academic researchers and community partners benefit from this dynamic, interactive approach. In addition, individuals who may benefit from this training are university employees who have limited to no academic background (e.g., telephone interviewers), for whom the CITI modules are hard to fully understand. Further study is needed to determine to what extent such training results in increased community member involvement and retention in the research process.

Best Practices

To cultivate honest, transparent, equitable and inspiring relationships through research, it is essential to use tools that help develop opportunities for clear and open communication related to the research focus and process. With investigator and community commitment, this CPRET process is designed to provide the resources and structure necessary for cultivating this unique space for learning and action.

Research Agenda & Educational Implications

Development and piloting of this Community Partner Research Ethics training demonstrates that this type of tailored, flexible participatory training is ideal for both academic researchers and community partners. This training may be a valuable tool for Principal Investigators to better engage community members and partners in community based research. More importantly, this process of tailoring research ethics principles to specific studies may help translate research ethics knowledge and practice for the larger community. Community-informed and tailored research ethics trainings such as the one highlighted may facilitate the cultivation of diverse research partnerships, help protect rights and welfare of community participants, and create sustained research partnerships. Further evaluation of the influence and impact of the CPRET process on strengthening and sustaining research partnerships, on recruitment and retention and the quality of community-partnered research studies is warranted. Guided by the knowledge gained from developing and implementing the CPRET process, it is ideal to present and implement the training in a manner that is as participatory and interactive as possible, including community and academic researchers together.

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- Introduction to research & the purpose of research
- Understanding specific case scenarios related to research ethics and conduct when working with human subjects
- Brief history of research & the development of research ethic principles
- Overview of IRB and regulations for research and protection of human subjects
- Definitions and Rules of Research Conduct

The Community-Partnered Research Ethics Training (CPRET) materials are listed below.
Title Page with Table of Contents

- Pledge Statement
- Training Eligibility
- PowerPoint Training Presentation & Guidelines for Tailoring Scenarios
- Confidentiality Agreement
- Feedback & Evaluation
- Community Individual Investigator Agreement
- Glossary
- Certificate of Completion
- Appendices:
- Appendix 1: Training and Certification Description
- Appendix 2: Guidance for Community Partners
- Appendix 3: Guidance for Investigators

Figure 1.
CPRET Training Outline and Detailed Components

OBJECTIVES

Community PARTners Core to provide clear guidance for the community and academic stakeholders utilizing CPRET and certification:

- Provide technical assistance and support to
 - Adapt training materials, specifically the PowerPoint, to be study specific
 - Ensure community partners have a clear understanding of research ethics, especially when covering the importance of Privacy, Autonomy, & Coercion
- Correspond and follow up as needed regarding use and feedback of the training materials

STEP BY STEP SOPs

Step 1: Direct interested community research partners and academics to public access to all CPRET training materials is available at <http://www.ctsi.pitt.edu/partners.shtml>

- Community PARTners Core as needed can be contacted via email at partners@hs.pitt.edu

Step 2: For University of Pittsburgh (Pitt) Academic Researchers **ONLY** can complete CTSI Requests for consultation and technical assistance with IRB approval process via **CTSI Research Requests and Tracking System** at <https://swarm.upmc.com/>

- Community PARTners research coordinator triages the request and corresponds with academic researchers, including principle investigator (PI) and research staff, to schedule in-person consultation

STEP 3: Complete an in-person consultation with academic researchers and Community PARTners members

- Review the contents of the training, specifically the PowerPoint slides with notes and how to tailor scenarios to the PI's study specific needs
 - Cover key points for the PI to create study specific scenarios and emphasize the importance of informed consent and critical intervention elements to the study
 - Answer any follow up questions and concerns
 - Provide Scenario Checklist to guide the adaptation process of the scenarios in PPT

STEP 4: Academic researchers adapt content and study specific scenarios within the PowerPoint presentation

- Researchers uses the scenario checklist as a guideline for adapting the scenarios in the PPT
- Researcher emails study adapted PowerPoint to the Community PARTners for review
 - Community PARTners will follow up as needed regarding revisions or edits
 - Community PARTners and researchers confirm final version of study adapted PowerPoint for the training
- Community PARTners can request to observe training

Figure 2a

STEP 5: Researchers use their adapted version of CPRET to train and complete IRB approval for community partners involved in their

- Researchers have each Community Researcher Partner who completed the training fill out the IRB official documentation “Community Individual Investigator Agreement” (CIIA)
- Researchers email Community PARTners all completed CIIA forms
- Community PARTners will correspond with IRB partners to process CIIA forms with the Office of Research
- Community PARTners will follow up with researchers once signed CIIA forms are obtained from IRB
- All CIIA documentations will be filed under researchers IRB study protocol

STEP 6: Community PARTners Quality Improvement of training materials

- Community PARTners will follow up with researchers regarding feedback and use of training materials
- Community PARTners will discuss any updates or changes with IRB and CRAB collaborative partners as needed

Figure 2b

Figure 2.

Standard Operating Procedures: Community Partnered Research Ethics Training (CPRET)

Table 1

Description of Studies who completed CPRET trainings

Study Title	Study Description	Community Partnerships	Target Population	Target Health Issue	Funding Source
Exploring the Dynamics of Urban Neighborhood Factors on Childhood Asthma Control: A Mixed Methods Approach	In response to persistent and increasing disparities in childhood asthma, this investigation and organizing initiative utilized qualitative and quantitative methods to examine, identifying, understand and addressing neighborhood-level influences perceived to impact asthma care and control.	An interdisciplinary community advisory board of community parents, youth, local organizational representatives, primary care providers and school nurses	Children, families, school nurses and primary care providers affected by asthma or providing care for youth with asthma	Childhood asthma and racial disparities	Grant NIH - 2 KL2 RR024154-06
On the Move in the Community	On the Move is group exercise program based on the biomechanics of walking. The study is examining the feasibility, acceptability, benefits and risks of the On the Move program in community-dwelling older adults in senior housing and community centers	Collaboration with geriatric outreach nurses with senior community centers and facilities along with UPMC Community Provider Services	Older adults and senior communities	Improving elder population walking to promote independence	University of Pittsburgh Aging Institute (Seed Grant)
Partner Violence and Reproductive Coercion Among Native American Women	Interviews will be conducted to focus on NA women living on reservations who are at particularly high risk for unintended pregnancy and where access to services is limited to gain insight about experiences of IPV/SA and the intersection of such violence with their reproductive histories.	Collaboration with Native women's advocates (sexual violence and domestic violence victim service advocates) in multiple sites.	Native American (NA) adolescent and adult women ages 16-50 from various tribal organizations	IPV and sexual assault, reproductive coercion, pregnancy intentions and contraceptive behavior among NA girls and women	National Institutes of Health, National Institute of Child Health and Human Development (NIH/NICHD)
A Comparison of Non-Surgical Treatment Methods for Patients with Lumbar Spinal Stenosis	A comparison of three common approaches to the non-surgical management of patients with lumbar spinal stenosis. Key objective is to produce research evidence relevant to community stakeholders and to inform better decision making about non-surgical treatment options available to LSS patients. The results can help clinicians determine which type of non-surgical treatment is best for which type of patient.	Community stakeholders from Jewish Community Center and the Senior Community Center along with Area Agency on Aging and other community organizations that serve senior citizens.	Community dwelling older adults, 60 and older years of age	Lumbar spinal stenosis with older adults	Patient Centered Outcomes Research Institute (PCORI) funding
University of Pittsburgh Long Term Care Pepper Center Registry	To create a registry with observational, non-experimental database designed to expedite research with in patients managing long term care	Partnership with University of Pittsburgh Claude D. Pepper Older Americans Center and Division of Geriatrics to develop Long Term Care Work Group	Residents in long term care (LTC) over 55 years and older living in nursing facility of UPMC Senior Communities	Improving LTC population access to research being conducted	NIH/National Institute on Aging (NIA)
Trauma Services Intervention to Prevent Violence	To launch a hospital trauma service intervention that will take advantage of a "teachable moment" in the emergency room. All four hospitals will host the program, an evidenced-based effort developed by the National Network of Hospital-based Violence Intervention Programs (NNHVIP) with an adaptation focusing on the social networks of gunshot wound victims, as well as the victims themselves.	The Kingsley Association is the community partner, specifically outreach interventionists	Gunshot victims and social contacts	Emergency department recidivism and violence behaviors	Local foundations including Richard King Mellon Foundation, Hillman Family Foundation and The Pittsburgh Foundation

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Study Title	Study Description	Community Partnerships	Target Population	Target Health Issue	Funding Source
Understanding Delayed Access to HIV Prevention Services among Black MSM	Taking the largest sample of Black men who have sex with men to study the HIV/AIDS treatment cascade	Collaboration with the Center for Black Equity and a number of local community-based organizations that serve the HIV/AIDS prevention needs of Black gay men	Black men who have sex with men	HIV/AIDS	NIH/National Institute of Nursing Research (NINR)