HUMAN SUBJECTS PROTECTION TRAINING FOR COMMUNITY HEALTH WORKERS

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Community Health Workers and community-engaged research

- Community Health Workers (CHWs) are increasingly involved in design and implementation of health-related research.
- Growing partnership with CHW and academic researchers.
- CHWs are a bridge between researchers and the community.
Community-engaged research

• *Process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people* (Fawcett et al., 1995).
• Collaborative approach to research that equitably involves all partners in the research process
• Recognizes the unique strengths of all partners
• Produces culturally relevant, reliable, and valid tools
Discussion Question #1:

What are some challenges related to research that you’ve faced when working with community health workers?
CASE STUDY: HUMAN SUBJECTS PROTECTION TRAINING FOR THE SOUTHEAST ASIAN WOMEN’S HEALTH PROJECT
Southeast Asian Women’s Health Project

• Examine barriers and facilitators to cervical cancer screening among Cambodian and Lao women

• Examine how Cambodian and Lao mothers and daughters talk about cervical cancer and screening
Methods

• Hired bilingual and bicultural community health workers
• Conducted focus groups
• In-depth interviews with mother-daughter dyads
• Engaged community advisory board
Community Health Workers

CHALLENGES

- Small pool of candidates/small community
- Little or no research experience
- Extensive training and monitoring
Human Subjects Protection Training

• Obligated to ensure that studies:
  – meet the highest standards of research design
  – Protect human subjects

• Everyone on the research team needs to go through human subjects protection training
IRB Challenges

• CITI Training -
• Developed for academic researchers
• Traditionally focused on biomedical research
• No relevance to community-engaged research
• Lack of cultural relevance
• Academic jargon
• Access to computer, internet
• Modules take a long time to complete
Share your group’s list of challenges
How did we get here…

• Spoke with university’s Institutional Review Board
• Center for Clinical & Translational Science (CCTS)
• Literature review
  – CITI training not translated in Khmer or Lao
  – CHW research ethics training in low-resource countries
    – Only description of modification process

• No alternative human subjects protection training for community health worker
Human Subjects Protection Training

• Adapted CITI training’s Social and Behavioral Research modules
• Developed 7 research ethics modules
  – 6 modules on research ethics
  – 1 module on research protocol
Areas of adaptation

• Access
• Cultural relevance
• Literacy
• Research experience
Areas of adaptation

• **Access**
  – CITI training – need computer and internet
  – Locally focused and in person
Areas of adaptation

• Access

• **Cultural relevance**
  – Situations that can occur in the community
  – Beliefs and knowledge (e.g., research = treated like guinea pigs)
Areas of adaptation

• Access
• Cultural relevance

• **Literacy**
  – In-person presentation
  – Tailor training to the needs of CHWs
  – Answer questions, clarify content
  – Use of plain language
Areas of adaptation

• Access
• Cultural relevance
• Literacy

• Research experience
  – CHWs with little or no experience in research
Module 1: Introduction to Research

- Different types of research (RCT vs qualitative/exploratory)
- Research methods
- Roles and responsibilities of research team members (e.g., Principal Investigator, Co-Investigators, recruiters, interviewers, etc.)
Module 2: Principles of Research Ethics

- Respect
- Beneficence
- Justice
- Belmont Report
- Case studies – e.g., Tuskegee syphilis study
Discussion Question #2

• Risks to individuals/group: Harms to individuals can occur during the research process when a person is labeled and recruited because of membership in a group.

• Think of examples of risks from participating in research that may occur in your own community.
Module 3: Protection of Human Subjects

- Define *human subjects*
- Define vulnerable populations
- Describe voluntary participation
- Describe coercion and ways to avoid it
- Identify how to assess physical and psychological risks
Discussion Question #3

• What are some culturally appropriate strategies that you would use to recruit people into a research study?
Module 4: Informed Consent

- What is informed consent?
- Why is it needed?
- Process to obtain informed consent
- The consent form – what should be included
• Role play exercises
Module 5: Privacy and Confidentiality

- Define privacy and confidentiality
- Describe ways to protect personal health information
- Describe HIPAA
- Define breach of confidentiality
- Identify situations when confidentiality is breached
Discussion case: *Secrets*

- Researchers partner with local communities so that participants can interact with someone who is familiar.
- What are some of the “pluses” and “minuses” of being involved in research in one’s own community?
Module 6: Unanticipated Problems and Reporting Requirements

- Define unanticipated problems and adverse events
- Identify unanticipated problems that need to be reported
- Describe how to report to the IRB
- What to do if you are not sure
• Discussion Case: To tell the truth
Delivery Method

• One full-day training
• Provided project binder with all PowerPoint slides, quizzes, study protocol, and materials
• Presented content in each module
• Quiz at the end of each module (3-5 questions)
• 80% correct to pass
• Time for discussion for concepts that was not clear
What worked

• Locally focused – tailored to CHWs community and knowledge
• In-person – develop relationship with CHWs
• Use of slides and discussion
• Role playing – engage community members to be partners in problem solving
IRB

- Needed approval from OSU’s IRB
- Explanation provided in IRB application
- CHWs were manually approved in the system
Recommendations

• Work with IRB early in the development process
• Anticipate key personnel may potentially have challenges with standardized human subjects protection training (CITI, NIH)
Recommendations

- CHWs may need ongoing support
- Refresher trainings
- Adapting human subjects protection training to meet the needs and preferences of community is feasible and valuable
What’s new...

• 2016 – CITI incorporated new Community-Engaged Research (CEnR) Modules into training

• Collaboration between the CITI Program and the Harvard Catalyst Community Engaged Research Subcommittee
  – Intro to CEnR
  – Intro to CBPR
  – Ethical and Practical Considerations in CEnR
Thank you