



**HUMAN SUBJECTS
PROTECTION TRAINING FOR
COMMUNITY WORKERS
AN EXAMPLE FROM “*FAITH
MOVES MOUNTAINS*”**

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FAITH-BASED COMMUNITY APPR



- Draws on local community assets to promote the use of the Pap test in rural, underserved Appalachian counties.
- This intervention project is a community-based program that involves local women to administer a faith-based LHA intervention.



SPECIFIC AIMS OF THE PROJECT



- To examine the factors (both barriers and assets) that influence the use of Pap smear screenings and follow-up procedures among rural women.
- To administer a faith-based lay health advisor intervention that is community-participatory, theoretically informed, and culturally consistent to increase the use of Pap smears and appropriate follow-up.
- To evaluate the efficacy of the intervention in a group-randomized experimental design.



COMMUNITY WORKERS INVOLVEMENT



- Interviewers who collect data at baseline and posttest follow-up
- LHAs (lay health advisors) who deliver the educational program and a tailored home-based intervention
- Project management staff





PROBLEM

- Standard human subjects protection training protocols have been developed to meet the needs of clinical trials research, laboratory-based behavioral science, or community studies conducted by graduate students and faculty
- Community members may feel reluctant to participate in data collection or other research activities because of the burden of human subjects protection training





PURPOSE

- Develop a human subjects training written in lay terms and containing only information pertinent to the non-key personnel and their role in this project





PROCESS

- Project staff raised very relevant issues of concern about the jargon, lack of access, and questionable relevance of some of the content of the CITI training
- Contacted Office of Research Integrity
- Developed a protocol:
 - included certain key components regarding the process of developing the module, how the education would be administered, and how we would evaluate the efficacy of the training.
 - This protocol is kept on file at the ORI



OBJECTIVES OF TRAINING MODU



- Identify the three fundamental ethical principles that guide the ethical conduct of research involving human participants.
- Define privacy and confidentiality as it applies to protecting human participants and describe how these can be maintained throughout the research process.
- Define informed consent.
- Define conditions under which informed consent may be withdrawn.
- Apply the principles that they learned about during the module to several “real-life” scenarios they were likely to encounter in their daily research practices.





TRAINING MODULE

- Approximately six pages of information
- Overview of the research process and definitions of key important terms, such as “human participant.”
- Addressed key topics:
 - respect for persons
 - beneficence
 - justice
 - informed consent
 - privacy, and confidentiality





EXCERPT FROM OVERVIEW

- In the course of participating in a research study, a person may provide information to you, the interviewer, about other persons such as a spouse, relative, friend, or social acquaintance. The information may be sensitive (e.g., regarding alcohol or drug use, diet, or lifestyle) and personal. Interviewers should treat all information about individuals or other persons they talk to you about as confidential. Identifying information, whether about a human subject or a third party, should be kept secure and protected.





TRAINING

- Presented to the community workers as a part of a day of training.
- Written materials were included in a notebook of information
- Power point presentation





EVALUATION

- Each worker was given a written test to evaluate knowledge of the content presented
- Test administered by the project director and sent to our institution for grading by personnel not involved in this project





TEST

- Specifically developed to cover the content of the educational module
- Written in simple and easy to understand language
- Three sections with matching, true/false, and case study questions
- Community workers were required to successfully answer 80% of the test questions to be considered trained in human subjects' protection and ready to participate in the research project in the specified capacity



CASE STUDIES

- Presented the workers with situations that we felt they might encounter related to human subjects in their particular community and capacity





EXCERPT FROM CASE STUDY

- You have just completed an interview with Ms. B. Her neighbor spots you leaving her home. The neighbor has heard about the Faith Moves Mountains research study at her church and is curious about who is in it and how it works. Later you run into that neighbor in the grocery store and she asks you if Ms. B is part of the Faith Moves Mountain research study.



QUESTION FROM CASE STUDY



- **What would be the most appropriate action to take?**
 - Tell her all about the Faith Moves Mountains study and Ms. B's part in the study.
 - Tell her about the Faith Moves Mountain study and where she can get more information if she is interested in participating, but let her know that the names of people participating is confidential information.
 - Act like you didn't hear what she said and keep shopping.
 - Tell her that you can only share that information with her if she participates in the project.





CONCLUSION

- Received very positive feedback on this training from community workers
- All who have taken it have passed the test
- Community members have expressed satisfaction with the simplicity and utility of both the training content and the test
- Advancement of a grounded, feasible, and rigorous process of protecting human subjects while ensuring CBPR ideals

