

TRAINING AND ASSURING ADHERENCE OF COMMUNITY MEMBERS IN HUMAN SUBJECTS PROTECTIONS

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BACKGROUND: PRIMARY STUDY RATIONALE

- **Multiple levels of adversity in the lives of sexual minority male youth experiencing homelessness (SMYH).**
- **SMYH exhibit significant health disparities compared to other persons their age in terms of substance use, sexual risk, mental health, and victimization (Cochran, Stewart, Ginzler, & Cauce, 2002; Gattis, 2009).**
- **Many have histories in foster care and criminal justice systems with long-term instability characterizing much of their lives.**
- **Sources of resilience in the lives of SMYH in the face of multiple adversities is not well understood.**

BACKGROUND: CBPR AND RESILIENCE

Community-based participatory research (CBPR) aligns with the study of resilience among marginalized and disenfranchised populations.

CBPR should actively engage communities in the design, implementation, and analysis of research that is relevant to the lives of such communities' members.

- to develop programming that is not deficit-based but *build upon the strengths and resources* present within such communities (Israel, Eng, Schulz, & Parker, 2005; Minkler & Wallerstein, 2008).

BACKGROUND: CBPR PRECEPTS

- **recognizes community as a unit of identity**
- **builds on strengths and resources within the community**
- **facilitates collaborative, equitable partnerships in all research phases**
- **promotes co-learning and capacity building among all partners**

(Israel, et al., 2003)

BACKGROUND: CBPR CONCERNS

- **Barriers to involving community members in data collection and analysis**
 - trust, instability, time/incentives
- **Confidentiality**
- **Safety**
- **Assurance of human subjects protections, ethical standards**

BACKGROUND: PRIMARY STUDY AIMS

- **to better understand how YMSM who experience homelessness respond to adversity in their lives**
- **to produce data that will inform development of programming that will leverage the assets and resources present in the population**
- **to foster the leadership development of homeless and marginally housed YMSM who engage in CBPR design, implementation, and analysis activities.**

COMMUNITY PARTNERSHIP

- **collaboration between the Broadway Youth Center (BYC) and the Department of Health Sciences at DePaul focusing on innovative methods to assess resilience among one of BYC's target populations**
- **research actively involved a cadre of SMYH in design, implementation, and data analysis phases of the study**
- **team of four "Peer Advocates" trained on research methods as part of larger leadership development program for youth at BYC**

RESEARCH PHASES

(1) **formative assessment** of health issues face by homeless and marginally housed YMSM and methods used to assess resilience among this population, involving Community Members and BYC staff in all aspects of the assessment

(2) **training** of DePaul RA and Community Members in research ethics and qualitative methods

(3) in depth **semi-structured interviews** with homeless and/or marginally housed YMSM conducted by a team of DePaul faculty and RA, and community members (Peer Advocates)

(4) **data analysis** conducted by a team of DePaul faculty and students, and community members

TRAINING IN RESEARCH ETHICS

Objectives:

- **Understand roles of community members in research activities**
- **Understand following areas of research ethics**
 - Roles of Researcher, Confidentiality, Vulnerable Populations, Voluntary nature of participation, Human subjects research protections
- **Understand how principles are applied in recruitment, consent processes, data collection**

TRAINING IN RESEARCH ETHICS

Sources:

- FHI, Research Ethics Training Curriculum, 2nd edition

<http://www.fhi360.org/resource/research-ethics-training-curriculum-retc-second-edition>

**Areas: Belmont Principles, Informed Consent,
Confidentiality**

- TCPS 2 CORE – Interactive exercises

**Areas: Respect, Explanation of Risks and Benefits,
Vulnerable Populations, Voluntary Nature of
Participation**

- Adaptations of CITI quiz questions and Canada REB questions

TRAINING OF COMMUNITY MEMBERS (November 2013)

Day 1 Agenda

Discussion of Previous Experience with Research

Why are we Concerned with Protection of Research Participants?

Research Ethics

Qualitative Interviewing

Day 2 Agenda

Research Ethics Review

Research Ethics Quiz

Qualitative Interviewing Review

Discussion of Approach to Research Topic

Review of Draft Instrument

Booster Session in January 2014

CONSIDERATION OF RISKS

What are risks in our Research?



CONSIDERATION OF RISKS

Risks

- Personal nature of asking people about their lives
- Interviews will be conducted by you and recorded
- Potential for violations of confidentiality
- How do we protect against these risks?
- Are there others we should discuss?

ADDRESSING PROTECTIONS

Protections

- Training in *Research Protections* and *Research Ethics*
- Confidentiality maintained throughout
- Transcripts of recordings will be “de-identified”
- Reports of findings will not include participants' personal information
- Others?

GROUNDING IN RESEARCH CONTEXTS

Informed Consent as a Process

- **Informed consent is a communication process**
 - Between the researcher and the participant
 - Starts before the research begins
 - *Continues through the duration of the study*
- *How do you remember informed consent being handled in other research studies you've been a part of?*
- *How well-informed did you feel?*

GROUNDING IN RESEARCH CONTEXTS

Vulnerable Research Participants

- Pregnant women
- Children
- Prisoners
- Mentally ill
- Persons with limited education
- The poor
- Persons with difficult access to health services
- Sex workers

- [How many of the above correspond to persons who go to BYC?]

ASSURANCE: RESEARCH ETHICS

Emphasis on Assessment of Knowledge, Skills, Behavior

1) Research Ethics Quiz

2) Mock Interviews, assessing

- **Explanation of voluntary nature of research, re-consenting**
- **Comfort with asking questions**
- **Facility with question probes**

3) Observance of Interviews

4) Debriefing with Study Participants

ASSURANCE: RESEARCH ETHICS

RELEVANCE OF CITI PROGRAM TO THESE AREAS?

Stage 1. Basic Course	
Module	# of Qs
Students in Research	10
History and Ethical Principles	4
Defining Research w/ Human Subjs	5
The Federal Regulations	5
Assessing Risk	5
Informed Consent	4
Privacy and Confidentiality	3
Research with Prisoners	4
Research with Children	4
Research in Elem/Secondary Schools	4
International Research	3
Internet-Based Research	5
<i>"Coverage"</i>	28%

RCR Course Introduction	
Module	# of Qs
Research Misconduct	5
Data Management	5
Authorship	5
Peer Review	5
Mentoring	6
Conflicts of Interest	6
Collaborative Research	6
Research Involving Human Subjs	11
<i>"Coverage"</i>	21%

ASSURANCE: RESEARCH ETHICS RESOURCES

**Health Canada and the Public Health Agency of
Canada's Research Ethics Board (REB)**

<http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/index-eng.php>

**TCPS 2 (2014)— the latest edition of *Tri-Council Policy
Statement: Ethical Conduct for Research Involving
Humans***

http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf

TCPS 2 Core

<http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

ASSURANCE: RESEARCH ETHICS QUIZ

20 questions

- 12 Multiple Choice
- 8 True-False
- 80% score required to “pass”

Examples:

T F 15. If an interviewer is concerned about the mental health of a participant after completing an interview, revealing the participant’s identity to the head researcher of the team is a violation of the participant’s confidentiality.

8. *Confidentiality* means:

- A. Participants’ responses must not be shared with anyone outside the study
- B. Researchers must be confident in their procedures before ever running a study
- C. The interviewer must not share their research data with others on the research team

ASSURANCE: MOCK INTERVIEWS

- **P.A.s' facility engaging and explaining consent process**
- **P.A.s' comfort with the interview script**
 - Practice, Preparedness, Paraphrasing
- **Opportunities for clarifications**
- **Variation in mastery of the script, process**
 - Multiple mock interviews with some PAs with role playing

ASSURANCE AT RESEARCH SITE

OBSERVANCE OF INTERVIEWS



DEBRIEFING WITH PARTICIPANTS

Assessing:

- Understanding of questions
- Comfort with interview process
- Understanding of how data will be used
- Additional concerns after completion of interview

DATA COLLECTION: FEBRUARY-APRIL 2014

- **20 interviews with SMYH completed**
- **Average length of interview: 50 minutes**
- **Sample: 85% African American, mean age=20.5 years**
- **Interviewers (and interviews):**
 - P.A. #1 (n=6)
 - R.A. (n=6)
 - P.I. (n=4)
 - P.A. #2 (n=3)
 - P.A. #3 (n=1)

CBPR AS LEADERSHIP DEVELOPMENT

I have learned a lot more about the different aspects of conducting a research project...the way and process that a project has to undergo in order to be effective and successful...the aspects of confidentiality and how to make sure you respect the persons you are interviewing. Not only that but I learned a lot more about the resilience of my peers and those who we Peer Advocates are supposed to represent. It showed me that even though we are all currently or were in the same situation that we all have different backgrounds and ways of dealing with our everyday problems.

Peer Advocate, age 21

BARRIERS

➤ **Staff turnover at BYC**

- program director, assistant program director, and drop-in manager present at conceptualization and beginning of project all left the agency prior to data collection phase

➤ **BYC's new location (moved in Autumn 2013)**

- significant degree of community resistance to their current location, including hearings at the City's Zoning Board and meetings with alderman's office and community neighbors associations.
- conflict complicated the delivery of services at its location and the concurrent research activities.

➤ **Space at BYC**

- BYC committed to providing space to conduct confidential interviews, but this necessitated that other programming might not occur at these times
- resulted in a tight schedule of when interviews could be conducted to maximize use of shared space at the agency.

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