



Community Based Participatory Research: Challenges and Rewards

Dr. Julie Doherty DM, MSN, RN

Robert E. Rosenthal MD

Conflicts of Interest

- No Conflicts

CBPR: Objectives

- Definition: How does CBPR differ from “standard” research?
- What is a community?
- What are the benefits of CBPR to University researchers? to community partners?
- What are the challenges...to IRB’s...to community-based organizations?
- What are UMB specific policies which should be followed when submitting IRB application?

CBPR:Definition

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- **CBPR** is a collaborative approach to research that involves all **stakeholders** throughout the research process, from establishing the research question, to developing **data** collection tools, to analysis and dissemination of findings. It is a research framework that aims to address the practical concerns of people in a **community** and fundamentally changes the roles of researcher and who is being researched.

CBPR: What is Different?

- ***Standard Research***: PI's ask question, develop research strategy, collect data, present results.
- ***CBPR***: Approach characterized by collaborative partnership development, cooperation & negotiation, & commitment to addressing local health issues
- **Broad spectrum:**
 - Some incorporate few elements of community engagement/minimal collaboration.
 - Others involve community organizations & researchers as equal partners in all aspects of the research.

Community Based Participatory Research: What it is and isn't

- An orientation to research: changes the role of researcher and researched
 - Community placed vs community based
 - Decision makers? Issues, design, finance, etc.
- Not a method or set of methods
- Goal is to influence change in community conditions, norms, systems programs, policies
- Communities may be patients with specific health condition, families/caregivers, health care professionals, racial/ethnic, geographic, identity, etc.

Principles of CBPR

- Builds on strengths & resources within community
- Facilitates collaboration in all phases of research
- Commitment to addressing local health issues
- Brings knowledge gathering & action together for mutual benefit of all partners
- Academics & community learn together –both are empowered
- Disseminates findings to all partners

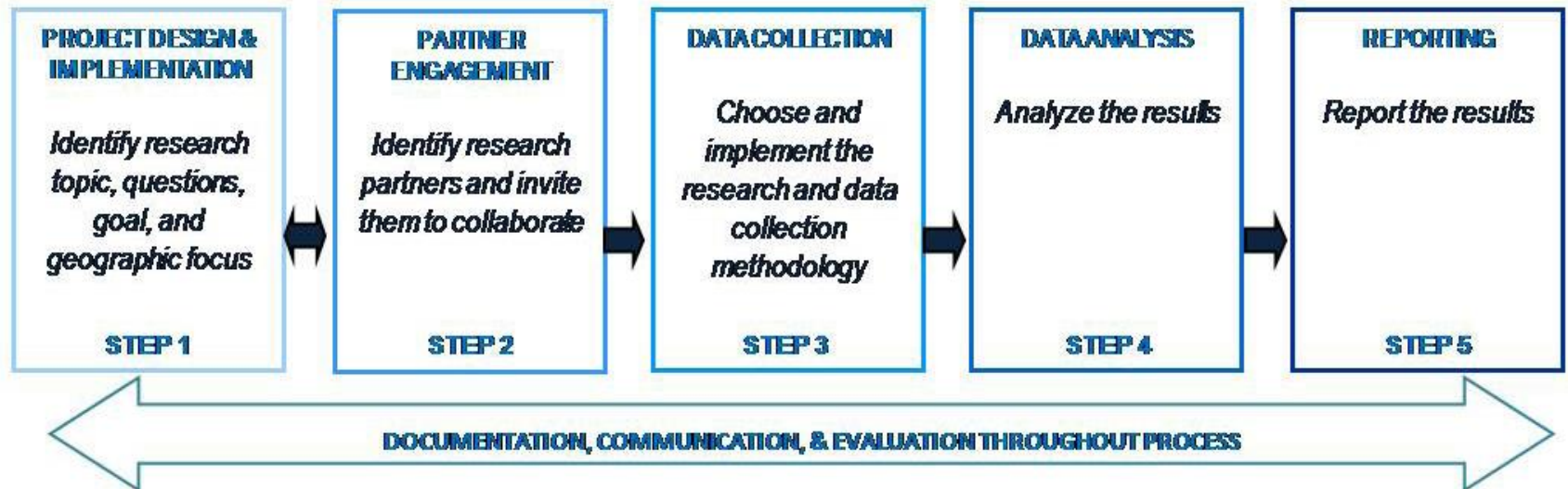
How can communities be engaged in all phases of research?

- Find Partners/Form team
- Form Research Question
- Planning Study
- Conducting Research
- Analyzing data
- Sharing findings
- Taking Action

COMMUNITY BASED PARTICIPATORY RESEARCH PROCESS MODEL

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Community Based Participatory Action Research Project Process Model



What is a Community?

- Place Based: County, City, Neighborhood...
 - Residents have the ultimate knowledge of the issues, strengths and solutions impacting their community
 - Constituents: community members, practitioners, local policy makers and others
- Problem Based: Medical
 - People living with HIV
 - Elderly people with diabetes Sexual and Gender Minorities, People experiencing food insecurity
- Problem Based: Social
 - Sexual and Gender Minorities
 - People experiencing food insecurity

CBPR: Challenges

Hyatt RR et al. Health Policy and Ethics 2009

- How can ethical and participatory research be conducted in a community where leaders do not have strong research base?
- How can University researchers get access to communities which may be suspicious of established research practices?

CBPR: Benefits

Hyatt RR et al. Health Policy and Ethics 2009

- Academic researchers and CBP need each other to address complex social and health issues.
- Community based partners (CBP) enable access to communities with barriers to recruitment and participation.
- Academic collaboration provides CBP with access to university resources.
- Partnership enhances visibility/legitimacy of CBP in the community.
 - Critical to mutual trust/respect: degree of authority over research planning, program execution and reporting of data

Why would communities want to conduct research?

- Describe scope of health priorities/issues in their communities
- Answer questions about their communities or service populations
- Develop/adapt new programs and/or services that are culturally appropriate for their communities
- Conduct evaluation of their programs
- Collect data/stories that help make their case for policy advocacy/funding

Some experiences communities may have had with research

- *It's called 'Helicopter Research.' They flew in, took our personal info, took off. We never got anything back.*
- *The academics got a grant for reducing smoking but what we're really concerned with is gun and gang violence.*
- *Did they need to do that big long study to 'prove' what we already knew?*
- *The professor can't just walk in with the expectation of creating a partnership. It takes time to understand each other and make sure we won't be exploited.*
- *The university implemented and evaluated a really nice program but then the money ended and the program right along with it.*

The Role of IRB in a CBPR Project

Hyatt RR et al. Health Policy and Ethics 2009

- CPBR project aimed at identifying and controlling occupational health and safety risks among immigrant workers in Somerville, MA.
- 3 participating organizations: Tufts U (academic), Immigrant Service Providers Group (community) and Cambridge Health (healthcare)
- Goal: Create participatory environment within CPBR model.
- Design phase: Involve community leaders in preparation and implementation of surveys, analysis plans, interpretation of results.
- Bilingual youths served as teen educators acting under the supervision of experienced adult youth leaders to reach out to immigrant workers in Somerville.
- Resulting survey developed by teen educators, under supervision of occupational health and safety experts and Tufts faculty.

The Role of IRB in a CBPR Project; *Questions from the Community*

Hyatt RR et al. Health Policy and Ethics 2009

- “Why does Tufts require all this bureaucracy? We survey our community all the time and no one worries about this”
- “If they answer the questions then they are giving their consent; if they don’t want to answer, they won’t.”
- “I can identify the people in my organization who will want to do this survey; the consent form will just scare them away.”
- “Why do we need Tufts to approve what we are doing in our community?”

The Role of IRB in a CBPR Project:

Risks to Human Participants

Hyatt RR et al. Health Policy and Ethics 2009

- Worker participation may become known to employers leading to risks of retaliation.
- Employees might reveal that they did not hold a required Mass license to perform residential or business-related services.
- Possible non-compliance with Mass. tax laws
- Employers might not carry required liability insurance.
- Workers/employers might be undocumented immigrants with potential risk of arrest/deportation.
- Teen workers might be identified as acting on behalf of authorities and in opposition to interest of the community.
- Community organizations might be perceived as acting in consort with federal and state agencies in opposition to community interests.

The Role of IRB in a CBPR Project: *Response to Questions from the Community*

Hyatt RR et al. Health Policy and Ethics 2009

- Education
 - Role and operation of IRB
 - History of human participant protections and motivation for IRB existence
 - Examples of IRB helping to identify risks unforeseen by researchers
 - Discussion of Investigators' established research efforts
- Training
 - Research design, informed consent and survey administration
 - Discussion of potential abuses and costs to study participants
- Dialogue
 - Addressed questions within both community and University about each other's capabilities and motives. ***Bidirectional***
 - Direct involvement of IRB administration with CBP to foster understanding among all stakeholder.

The Role of IRB in a CBPR Project:

Recommendations

Hyatt RR et al. Health Policy and Ethics 2009

- Involve community partners with the IRB as early in the research process as possible.
- Meeting with an IRB administrator or representative can lessen the mystique of IRB oversight and help to establish trust on ***both sides***.
- “Face-to-face open discussion of intentions and goals shows all parties that they share the aim of both protecting community members and giving them voice.”
- “...communicate about IRB issues as often and as clearly as possible, with both our community partners and our own IRB, to minimize last minute surprises.”

CBPR: IRB Issues

- IRB's typically do not consider principles of community engagement
 - How well does researcher know community?
 - Has trust been established?
- Following initial approval, no community input for regular reviews
- 19 studies: IRBs generally do not incorporate principles of CBPR into considerations, even when community engaged. (Flicker et al 2007)

Are Research Ethics Committees Prepared for Community-Based Participatory Research?

Tabriz L et al

Journal of Empirical Research on
Human Research Ethics
2015, Vol. 10(5) 488–495
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Table 3. Barriers Reported in Cross-Sectional Studies.

Author	Barriers
Guta et al.	REC forms do not evaluate the following: Community risk Community participation Need for community consent Resources of the CBO Power struggles between CBOs and researchers
Flicker et al.	REC forms do not: Require community consent Document community capacity building Evaluate risk at the communal level Address publication veto by the community
Deeds et al.	Only 17% of the REC concerns with a CBPR project were community related: 35% informed consent 21% minimization of risk 15% design of the project

Note. REC = research ethics committee; CBO = community-based organizations; CBPR = community-based participatory research.

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- Perceived barriers to CBPR success
 - CBPR Researchers
 - Having community partners as part of the research team
 - Reluctance of RECs to approve CBOs outside the university setting.
 - Research Ethic Committees
 - Training difficulties
 - Administrative strain placed on CBO to conduct data collection and capacity building
 - Community Based Organizations
 - RECs slow
 - RECs have difficulty understanding CBPR
 - RECs difficult to engage in communication

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- Do the three Belmont ethical principles can be used to evaluate the ethics of CBPR?
- The authors found that the principles do not provide a comprehensive guide for CBPR (Mikesell et al., 2013).
- The two main principles that do not fit CBPR are autonomy and beneficence, because they both start from the premise of an individual and CBPR focuses on communities.
- RECs are equipped to minimize risk only at the individual level whereas CBPR requires also minimization of a more global or communal risk.


Research Ethics in CPBPR

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- Accessibility of Findings
- Benefits to Participants
- Community Voice
- Credit
- Data Ownership
- Division of Labor
- Justice
- Privacy
- Representation of Local Communities
- Respect
- Rigor of Research and Fidelity To Findings

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- Recommendations:
 - Institutions conducting CBPR need to have CBPR representation in the REC.
 - REC's should re-evaluate their forms to reflect the principles.
 - REC's should hold education sessions on CBPR.
 - Include a CPBR researcher as a member of the REC.
 - CBOs need to assure RECs that the personnel conducting the research is qualified to do so or willing to complete relevant training.
 - Universities and policy makers need to work to adapt regulations to the current research environment.

Engaging IRB's in Developing a Brief, Community-Responsive Human Subjects Training for Community Partners

Calzo JP et al. Prog Community Health Partnersh. 2016;10;471-477

- **Background:** Structure and time constraints of human subjects research training may hinder the training of community partners.
- **Objective:** Engage hospital-based IRB in implementing a brief, community responsive human subjects training session.
- **Methods:** Two-hour, discussion based human subjects training was developed via collaborations among IRB and the community and academic partners
- **Conclusions:** Local IRB's have the potential to assist community partners in building sufficient knowledge of human subjects research protection to engage in specific projects, thereby expediting the progress of vital research to address community needs.

Engaging IRB's in Developing a Brief, Community-Responsive Human Subjects Training for Community Partners

Calzo JP et al. Prog Community Health Partnersh. 2016;10;471-477

Question Addressed	Training Content	Discussion Questions
What is human subjects research?	<ol style="list-style-type: none"> 1) Definitions of human subjects research 2) Review of study design 	<ol style="list-style-type: none"> 1) What is design of current project? 2) How are data being collected?
What do we mean by ethics and ethical conduct?	<ol style="list-style-type: none"> 1) Definitions of ethics and discussion of values (personal, community, etc.) 2) History of how rules were developed 	<ol style="list-style-type: none"> 1) Your experiences with research? 2) Communities' experiences with research? 3) What are common perceptions about research?
What are my ethical responsibilities as a community partner?	<ol style="list-style-type: none"> 1) Belmont report principles 	<ol style="list-style-type: none"> 1) In what ways does the research fit/not fit with your mission? 2) What risks/benefits does the current study pose?

Engaging IRB's in Developing a Brief, Community-Responsive Human Subjects Training for Community Partners

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Question Addressed	Training Content	Discussion Questions
What is an institutional review board?	<ol style="list-style-type: none"> 1) IRB structures, responsibility 2) Definition of vulnerable populations, COI's 3) Components of IRB application 	<ol style="list-style-type: none"> 1) How can you manage potential COI's 2) Are youth in the organization a vulnerable population? 3) What info required for IRB application?
What is informed consent/assent and why is it necessary?	<ol style="list-style-type: none"> 1) 1) Definitions and distinctions between consent and assent 2) Connections between consent/assent and Belmont Report 3) Definition of confidentiality 4) Adverse events and safety plans 	<ol style="list-style-type: none"> 1) What is the minimum information required to sufficiently obtain informed consent or assent for this study? 2) Waiver of parental consent? 3) What unique issues regarding confidentiality may be faced by study participants?




Human Research Protections Guidance

CBPR: Community Engagement

Increasingly, in an effort to foster community engagement in the research process, patients and other community stakeholders are involved in various levels of research design and conduct. In these cases it is important to consider the circumstances when these individuals may either be considered research subjects or individuals “engaged” in the conduct of research.

Community Advisory Board

- Protocol development only
 - Research advice and guidance
 - What is important for the community to learn more about?
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Community Collaborators as Research Subjects

- As defined by DHHS regulations:
 - *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Community Collaborators as Research Subjects

- To help consider whether a community collaborator qualifies as research subject please consider the following example:
 - An investigator seeks to collaborate with patients who are part of a support group for cancer survivors. The investigator wishes to obtain feedback on the types of questions that should be asked of cancer survivors in an online survey to understand their impressions of their care within the health system.

Community Collaborators as Research Subjects

- Version 1: The collaborators will be consulted for instrument development only and will not be asked to provide any data from their own experiences that will be used for analysis.
- Conclusion: These collaborators do not qualify as human subjects as no data will be collected from these individuals that will be analyzed as part of the research study.
 - Non-human subjects research determination

Community Collaborators as Research Subjects

- Version 2: After the instrument is developed the collaborators will be asked to complete the survey online as these individuals meet the criteria for enrollment in the study. Data from their online survey responses will be analyzed similarly to all other respondents.
- Conclusion: These collaborators do qualify as human subjects as they will provide information that will be analyzed as part of this research study.

Community Collaborators as “Investigators” who are “Engaged” in the Research

- There are certain circumstances where community collaborators may be considered investigators who are “engaged” in the research. In these cases, the collaborator’s role in the research must be overseen by an IRB and the researcher would be required to complete appropriate human subjects training prior to initiating any activities related to that engagement.

Community Collaborators as “Investigators” who are “Engaged” in the Research

- Generally “investigators” may include any individual involved in the design, conduct or reporting of research. The types of activities that may qualify a collaborator as an investigator “engaged” in human subjects research may include but are not limited to:
 - Interacting or intervening with research subjects for the purposes of research (e.g. administering a survey, performing a research test, etc.)
 - Consenting subjects for research participation
 - Participating in the collection of or having access to identifiable data from research subjects

Community Collaborators as “Investigators” who are “Engaged” in the Research

To help consider whether a community collaborator qualifies as an investigator engaged in human subjects’ research, please consider the following example:

- A researcher seeks to develop a medication adherence support tool for patients with Alzheimer’s disease and their caregivers. In order to design the tool and the study intervention, the researcher will work with a group of Alzheimer’s patients and caregivers to ensure the ideas of the target population are represented. These individuals will participate in some research team meetings and will be compensated for their time. Their participation will continue throughout the life of the study.

Community Collaborators as “Investigators” who are “Engaged” in the Research

- Version 1: The patients and caregivers will have no interactions with subjects and data presented at research team meetings will be shared in aggregate form only. The patients and caregivers will not have access to individually identifiable subject information.
- Conclusion: These collaborators do not qualify as investigators as they will not interact with subjects nor will they have access to identifiable data from subjects.

Community Collaborators as “Investigators” who are “Engaged” in the Research

- Version 2: The study team believes that the purpose of the research study and the medication adherence tool will be best described to subjects by patients and caregivers. They have asked that their collaborators participate in the consenting process.
- Conclusion: These collaborators do qualify as investigators who are engaged in human subjects’ research. Their involvement in the research must be overseen by an IRB and these individuals must complete applicable human subjects training prior to initiating any activities related to their engagement.

IRB Processes

- Include appropriate details in the protocol
 - Community Involvement
 - Community Consultation
 - Collaborative Review
 - Plan for Modifications
 - Plan for Disclosure of Research Findings
 - Make Benefits Available to Groups

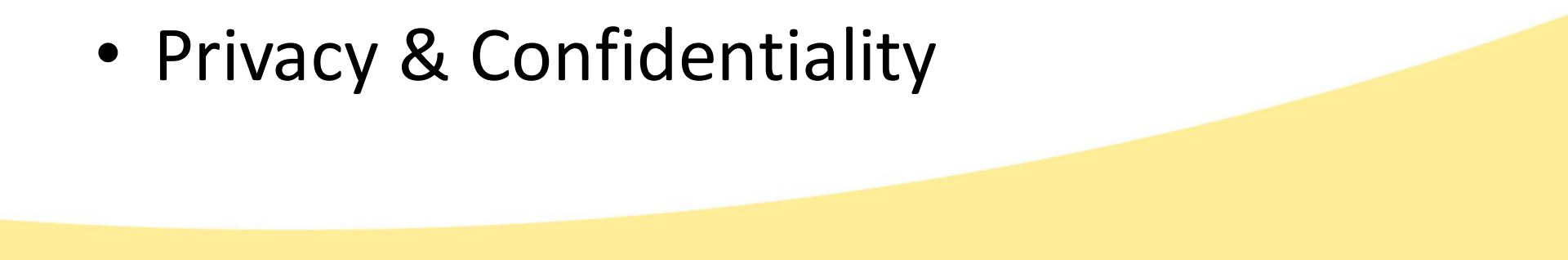
Education and Training

- All research personnel must be provided with appropriate human subjects protection training.
- The community advisory board can help ensure that the training is culturally sensitive and provided in a manner understandable to the community research partners.
- Community partners can meet with IRB representatives to lessen the mystique of IRB oversight, clarify goals and process of the IRB, and further mutual trust.

Guidance

- Consult with HRPO/IRB upon notice of award or prior to protocol development.
- Break down grant into multiple smaller studies/application
 - Coordinate with project officer to facilitate understanding of HRPO processes.
- Roles change over time therefore the applications will also change and mature.
 - NHSR
 - Exempt
 - Minimal Risk/Greater than Minimal Risk

IRB Considerations

- Minimizing risks and Providing Benefits
 - Recruitment Strategies
 - Disseminating Results
 - Informed Consent
 - Distributional Justice
 - Privacy & Confidentiality
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IRB Considerations - COMPENSATION

- Documents required by the state
 - IRB approval letter
 - Comptroller Exception Form
 - “Community Planners” necessary terminology for compensation

IRB Considerations

1. Evidence of an equitable partnership between the investigator and the community partner.
2. The Investigators have defined the relevant community or communities.
3. The community Co-Investigator has identified the appropriate research partner for the project.
4. Community engagement is an integral part of the research.
5. Letters of support (from the community) are clear and well-defined.

IRB Considerations (cont.)

6. There is an appropriate division of funding (if applicable).
7. There are adequate training opportunities for investigators and community members.
8. The research environment is adequate.
 - a. The community benefits from the presence and implementation of the research.
 - b. The research is conducted in an environment that enhances the likelihood of success.
9. The research strives for positive change in the community's outcomes.
10. The research fosters long-term relationships between the University and the community for the benefit of both.

Resources

- Website:

<https://www.unr.edu/research-integrity/human-research/human-research-protection-policy-manual/574-irb-review-of-community-based-participatory-research>

- https://irb.upenn.edu/sites/default/files/irb%20guidance%20document%20on%20community%20research%20partners_0.doc

Resources

- Journal
 - Progress in Community Health Partnerships: Research, Education, and Action
 - Co-Editors-in-Chief : A. Hal Strelnick, MD; Albert Einstein College of Medicine & Ann-Gel Palermo, DrPH, MPH; Icahn School of Medicine at Mount Sinai; Quarterly
- Book
 - Handbook of Community-based Participatory Research
 - Coughlin, S.S., Smith, S.A. & Fernandez (Eds)., Oxford University Press (2017).

Thank You!

UMB HRPO
410-706-5037

hrpo@umaryland.edu

2015 Baltimore City Food Desert and Life Expectancy

 Food Desert

Life Expectancy at Birth (in Years),
Baltimore City, by Community Statistical Area
(Data divided into quintiles)

