
Ethical Issues in CBR: Recommendations for More Relevant Review

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1. Review two studies conducted looking at paradigm of current Research Ethics Board (REB) practices;
2. Present an alternative set of questions for judging community-based research studies that bridge Tri-Council of Canada Principles for Ethics Review and Principles of CBR

Common Problems in Research

- Irrelevance to community
- Poor methodology (waste of resources)
- Research is not giving back
- Communities feel over researched
- Communities feel coerced
- Communities are lied to
- Insensitivity to community concerns or issues
- Benefits to community are minimal

CBR is an approach to research that attempts to address these problems.

Our objectives:

- Is CBR inherently ethical?
- Does it pose unique ethical dilemmas?
- Are they captured in current review processes?
- Are REBs/IRBs using the correct procedures?

- **There are challenges in the current ethical review paradigm as evidenced by two recent studies:**

Study 1 –

- Travers, R., et al., *Proposal for an ethics review board of community-based HIV/AIDS research in Ontario, an OHTN Position Paper*. 2006, OHTN: Toronto, ON.

Study 2 -

- Flicker, S., Travers, R., Guta, A., McDonald, S. & Meagher, A. *Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards*. *Journal of Urban Health*, 2007. **e-pub** (DOI 10.1007/s11524-007-9165-7).

Study 1 –

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Environmental scan – method:

Method....

- Document review
- Review of best practices
- Key informant interviews (15, across Canada)

Environmental scan – results:

- Findings
 - challenges related to access
 - ethics review and power imbalance
 - ownership of projects
 - paradigm fit

Study 2 -

- Flicker, S., Travers, R., Guta, A., McDonald, S. & Meagher, A. *Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards*. *Journal of Urban Health*, 2007. **e-pub** (DOI 10.1007/s11524-007-9165-7).

Method:

- content analysis of REB/IRB forms from select schools of public health in Canada (3) and the US (27)
- convenience sample – US-based Association of Schools of Public Health and select Canadian universities
- scoring tool that sought evidence of CBR principles in action in REB/IRB forms

Our recommendations from these two studies:

- research should continue to identify problems with current ethics review paradigm as well as solutions;
- REB/IRB modes that are supportive of and incorporate the principles of CBR (as ethical guidelines) are needed;
- alternative review guidelines for CBR are needed.

Recommendations:

- in the next few slides, we present some alternative guidelines/questions that could be used by IRBs/REBs.....

Background, Purpose, Objectives

- Provide a description of the background, purpose, objectives and hypothesis for the research.

CBR Alternative

- Is this research *really* justified?
- Who benefits? How?
- How was the community involved or consulted in defining the need?
- Who came up with the objectives and how?
- Are there concrete action outcomes?

Research Methodology

- Describe exactly *how* the research will be carried out.
 - Answer the whos, whats, whens, wheres & whys
 - Procedures to be used in the conduct of the research, (e.g. interviews, questionnaires, chart reviews).
 - State the period during which the procedures will be carried out, how long each will last and be specific about the number and frequency of the procedures.

CBR Alternative - Research Methodology

- How will the community be involved? At what levels? (input, process, outcome)
- What training or capacity building opportunities will you build in?
- Will the methods used be sensitive and appropriate to various communities (consider literacy issues, language barriers, cultural sensitivities, etc)?
- How will you balance scientific rigor and accessibility?

Risks and benefits

- List the anticipated risks and benefits to participants.
- Describe how the risks and benefits are balanced and explain what strategies are in place to minimize/manage any risks.

CBR Alternative - Risks and benefits

- What are the risks for communities? For individuals?
- Be honest about risks – and consider how you will minimize them.
- Are there built in mechanisms for how unflattering results will be dealt with?
- Be clear about who will benefit and how? (How do you distribute the benefits most equitably?)

Informed Consent Process

- Provide a description of the procedures that will be followed to obtain informed consent.
- Include a copy of the information letter(s) and consent form(s).
- Where written informed consent is not being obtained, explain why
- Where minors are to be included as participants, provide a copy of the assent script to be used.

CBR Alternative - Informed Consent Process

- What does this mean for ‘vulnerable’ populations (e.g. children, mentally ill, developmentally challenged)?
- What does it mean to ‘*inform*’?
- What does it mean to ‘*consent*’?
- How do you do this in a culturally sensitive manner?
- Whose permission do you need to talk to whom?
 - Eg consider aboriginal communities...

Privacy and confidentiality

- Provide a description of how privacy and confidentiality will be protected. Include a description of data maintenance, storage, release of information, access to information, use of names or codes, destruction of data at the conclusion of the research; include information on the use of audio- or video-tapes.

CBR Alternative - Privacy and confidentiality

- How do you maintain boundaries between multiple roles (e.g. researcher, counsellor, peer)?
- What processes will you put in place to be inclusive about data analysis and yet maintain privacy of participants?
- Where will you store data? Who will have access to the data? How?
- What rules will you have for working with transcripts or surveys with identifying information?

Compensation

- Describe any reimbursements, remuneration or other compensation that will be provided to the participants, and the terms of this compensation.

CBR Alternative - Compensation

- It is important to reimburse people for their time and honour their efforts – but make sure that honoraria are not ‘coercive’
- Travel, childcare
- Who is managing the budget? Which partners are getting what compensations?
- Who is getting paid? Who is volunteering? How are those decisions being made?
- You cannot link participation to service!!!!

Conflicts of interest

- Provide information relevant to actual or potential conflicts of interest (to allow the Review Committee to assess whether participants require information for informed consent).

CBR Alternative - Conflicts of interest

- what happens when your job depends on the results?
- what happens when you are the researcher and the
 - Friend ,peer, service provider, doctor, nurse, social worker, educator, funder etc

Participants

- Describe who the participants are and why they were selected.
- State the proposed “sample size” ie how many people will be involved.
- Provide relevant inclusion/exclusion criteria.
- Describe any special issues with the proposed population, i.e. incompetent patients or minors.

CBR Alternative - Participants

- Are you really talking to the ‘right’ people to get your questions answered appropriately (e.g. service providers, community members, leaders etc)
- How will you protect vulnerable groups?
- Will the research process include or engage marginalized or disenfranchised folks? How?
- Who speaks for community?
- Is there a reason to exclude some people? Why?

Recruitment

- Describe how and by whom participants will be approached and recruited. Include copies of any recruiting materials (e.g., letters, advertisements, flyers, telephone scripts). State where participants will be recruited from (e.g. hospital, clinic, school)
- Provide a statement of the investigator's relationship, if any, to the participants (e.g., treating physician, teacher).

CBR Alternative - Recruitment

- Need to consider ‘power’ relationships (no coercion!)
- Make sure that ‘service providers’ and ‘researchers’ are different people
- Assure participants that those who do not want to participate will still be assured service
- Who approaches people about the study and how?
- Make sure that you have culturally relevant and appropriate recruitment strategies & materials
- Consider confidentiality...

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