

Conference Call Series on Institutional Review Boards and Ethical Issues in Research

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Ethical review processes and CBPR

- Risk/benefit analysis
- Methodological assumptions
- Scope of the Belmont Principles
- Descriptions of community-based review mechanisms
- Community partners and IRB review coverage

Re-conceptualizing the Belmont Principles

Belmont Report: Respect for Persons

- “Agents should be treated as autonomous agents, and...persons with diminished autonomy are entitled to protection” (Basic Ethical Principles, ¶ 3)
- “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them” (Applications, ¶ 2)

Belmont Report: Beneficence

- “Do no harm” and “maximize possible benefits and minimize harm” (Basic Ethical Principles, ¶ 7)
- Actualized through a risk-benefit assessment

Belmont Report: Justice

- “Who ought to receive the benefits of research and bear its burdens?” (Basic Ethical Principles, ¶ 11)
- The researcher “should not offer potentially beneficial research only to some patients who are in their favor or select only ‘undesirable’ persons for risky research” (Applications, ¶ 20).
- “Requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens on already burdened persons” (Applications, ¶ 20).

Methodology

- Exploratory study
- Sample: 10 CBPR researchers
- Interviews
 - What does respect for persons mean to you?
 - What does beneficence mean to you?
 - What does justice mean to you?

Respect for Persons

- Respect for Partnerships
 - Valuing different skills and experiences
 - Adhering to empowering practices
 - Inclusive decision-making
 - Translating findings into actual community benefits

“If you are bringing someone on as a partner, they are treated as a partner”

Respect for Persons

- Multiple meanings
 - Respect for persons “varies from project to project and from community to community”
 - Respect entails “respecting differences among participants”
- Traditional IRB considerations
 - Sufficient information to make informed decisions
 - Participation is voluntary

Beneficence

- Empowerment

- Emphasis on research outcomes

- “If our research does not help the community organizations that we’re working with improve their condition that brought them to us, then we haven’t done our jobs. ...I am saying that we have to be able to provide some product that will help them think more critically about what they do everyday, or leverage resources or solve a problem.”

Beneficence

- Varied interpretations of what constitutes a benefit
 - “Out of good faith, myself and other members of our team were doing things we genuinely believed were in the best interest of the community and its residents, but the community had a very different interpretation of the potential impact of our research”
- Traditional IRB considerations
 - Risk/benefit analysis
 - “I would just twist it and say it’s not do no harm, it’s actually you better do some good”

Justice

- Equitable research processes

“Justice means that people have equal access to decision-making. And you can have community members participate all you want, and if all they're doing is sharing information and not feeling like they're influencing policy and decision-making, then that's a very unjust and very unequal level of participation.”

- Social change

“Justice really isn't about helping people; it's about changing the social conditions that cause them to need help to begin with. And ideally this form of research shouldn't be just about working again at an individual level of analysis. Ideally at some point it moves to collective action at a structural target, whether that target is racism, sexism, or classism or whatever.”

- Sample selection

Critiques of the Belmont Principles

- Clarification of the language
 - “[The language] is sort of old school...very academic, and obviously were written for people who are doing more traditional research”
- Call for additional principles
 - Community collaboration
 - Cultural considerations
- Call for CBPR guidelines- “norms for the group”
 - All the partners being upfront with each other
 - Fair distribution of resources
 - Active participation
- Principles as culturally bound constructs

Overall

- Expanded upon the Belmont Report framework
 - Ethics of involvement
 - Emphasis on social change
 - Greater attention to community-level considerations

Discussion

■ CBPR

- Respect for Persons:
 - Focus on the individual, community, and the partnership itself
- Beneficence:
 - Collective action, leveraging resources
 - Community as an actor in the change process

■ Belmont Report

- Respect for Persons:
 - Greater focus on the individual
- Beneficence:
 - Individual and societal level considerations
 - Language used suggests researched as more representative of objects that passively contribute to production of benefits

Discussion

■ CBPR

■ Justice

- Equitable processes
- Social change
- Sample selection

■ Belmont Report

■ Justice:

- Focus on fair sample selection processes
- Recognition of broader social injustices

Recommendations

- Relationship paradigm (King, Stein, Henderson, 1999)
 - Expands ethical analysis
 - Challenges assumptions regarding the value and meaning of research
 - Prompts us to ask different questions as part of our ethical analysis

Questions

- **What are the relevant relationships specific to this project?**
 - Is there a partnership? And if so, 1) how was the partnership formed, 2) who are the different partners, and 3) how are the different partners involved?

Questions

- **What are the potential impacts of this research project?**
 - Who benefits, and what are the short & long term benefits (accounting for both individual and community level)? Who determines what constitutes a “benefit”?
 - What are the short & long term risks (accounting for both individual and community level)? What steps are taken to minimize these risks? Who determines what constitutes a “risk”?
 - How will the findings be used? Will findings be used to effect social change?

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