

Understanding Community-Based Processes for Research Ethics Review

Co-Sponsored by Community-Campus Partnerships for Health (CCPH) & the University of New England (UNE)
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Background & Significance: Community-based participatory research (CBPR) is increasingly being recognized by national organizations, funding agencies, researchers and communities alike as critical to understanding and addressing our nation's most pressing health concerns. As a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings, CBPR begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change. An underlying assumption of CBPR is that through active and meaningful community involvement, community benefits are maximized and a range of potential harms to individuals and their communities can be prevented. CBPR thus represents a shift from regarding individual community members as *research subjects* to engaging community members and the organizations that represent them as *research partners*. These features of CBPR contribute to ethical considerations that can differ from those encountered in more traditional research approaches.

The Belmont principles that guide Institutional Review Board (IRB) review of human subjects research do not appear to cover the scope of ethical considerations that arise in CBPR, and thus the IRB's application of these principles may not provide a relevant or thorough ethical analysis. IRBs, designed to protect the rights and welfare of *individual* study participants, are neither expected nor equipped to protect the rights and welfare of *communities* involved in research. CBPR considerations are often missing from university-based IRB application forms. A recently published content analysis of 30 IRB forms found that while all of the forms inquired about scientific rationale, none asked about the involved community's perception or input regarding the justification for the study. Only 4 forms asked about community or societal level risks and benefits, and only 5 forms inquired into how the research findings would be disseminated. Studies of CBPR researcher experiences with research ethics review reveal deep concerns about the ethics of partnership processes, social justice, and the need to expand ethical analysis to include community level considerations.

It is increasingly apparent that the IRB system for assuring that research involving human subjects is ethical is insufficient when applied to community-based research. A number of community groups and community-institutional partnerships have established their own community-based processes for research ethics review that operate independently or in parallel with institution-based IRBs. With the exception of federally recognized community IRBs such as those operated by tribes and community health centers, community-based processes for research ethics review are not mandated or regulated. Beyond anecdotal reports, little is known about their prevalence, history, processes, experiences and outcomes. A systematic approach to identifying and studying these processes will increase our understanding of the ethical issues that arise in community-based research and yield promising practices and recommendations for ensuring the protection of communities involved in research. This study is particularly timely as it coincides with substantial National Institutes of Health investments in community-based research (e.g., Clinical and Translational Science Awards, Community-Based Participatory Research Grants) that will only bring these ethical issues further to the fore.

For the purposes of the study, we define "community groups" as entities that include community-based organizations, patient advocacy groups and tribal councils, among others. We define "community-institutional partnerships" as research partnerships between community groups and institutions such as universities and hospitals. We define "community-based processes for research ethics review" as any process implemented by community groups or community-institutional partnerships to assess the ethics of research proposals and determine whether to support, endorse or participate in the research, such as research committees established by community-based organizations, community advisory boards of research centers, and federally regulated IRBs operated by tribes.

Study Aims, Methods & Timeframe:

Aim	Methods	Timeframe
1: Identify and describe community-based processes for research ethics review	Survey	1-10 mos.
2: Assess the similarities and differences between the protocols used by community-based processes for research ethics review and those used by institution-based institutional review boards	Protocol Analysis	3-12 mos.
3: Describe in-depth the history, processes, ethical considerations, experiences and outcomes of community-based processes for research ethics review.	Case Studies	12-24 mos.

Study Products & Outcomes: The study will generate new knowledge about community-based research ethics review that identifies promising practices and recommendations for ensuring the protection of communities involved in research. An intended outcome of the study is the formation of an ongoing collaborative research network among community-based processes for research ethics review. We will determine multiple strategies for disseminating our findings and recommendations to primary audiences, which include communities, community-institutional partnerships, IRB members and administrators, and agencies that fund and regulate research. At a minimum, study products will include:

- Peer-reviewed journal articles that report on methods and findings
- Published case studies of community-based research ethics review processes
- Educational conference calls that feature study findings and recommendations
- An online repository of community-based research ethics review processes and protocols

Study Team: At CCPH: Principal Investigator Sarena D. Seifer, MD, Study Coordinator & Co-Investigator Kristine Wong, MPH, and Graduate Research Assistant Lisa Moy. At UNE: Principal Investigator Nancy Shore, PhD and Kirsten Cyr, Graduate Research Assistant.

Study Advisory Committee: Experts in CBPR and research ethics are serving as study advisors:
Bonnie Duran, DrPH, MPH, Associate Professor of Public Health, University of Washington and Director, Center for Indigenous Health Research, Indigenous Wellness Research Institute, Seattle, WA
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Stephen Sodeke, PhD, Associate Director, Tuskegee University National Center for Bioethics in Research and Health Care and Chair, Tuskegee University Institutional Review Board, Tuskegee, AL,
Eric Wat, MA, Data Manager, Special Services for Groups, Los Angeles, CA

Supporting Organizations: Organizations representing key study stakeholders have written letters of support for the study. We have sought their assistance in reviewing draft study materials, identifying and recruiting survey participants and disseminating study findings.

Association of Asian Pacific Community Health Organizations
National Association of Community Health Centers
National Health Care for the Homeless Council
Public Responsibility in Medicine and Research (PRIM&R)
Tuskegee University National Center for Bioethics in Research and Health Care

IRB Review: The IRBs at the University of Washington and the University of New England reviewed the study and determined that it did not meet the definition of human subjects research and thus did not require IRB review

For More Information: Email the study team at ccphirb@u.washington.edu or cbresearch@une.edu

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