

Research Ethics Reconsidered in the Context of Community-Engaged Research

Background: As community engagement in research is increasingly expected by funding agencies and community organizations, the limitations of federal research ethics regulations and the predominant model of research ethics review are becoming readily apparent.^{1,2} Institution-based Institutional Review Boards (IRBs), designed to protect the rights and welfare of individual study participants, are less equipped to protect the rights and welfare of community members, community partners and communities involved in research. This discordance between the predominant model of research ethics review and community-engaged research (CEnR) has been well documented in the peer-reviewed literature.^{3,4}

The current U.S. system of protection for human research subjects is heavily influenced by the Belmont Report (BR), written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The BR outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, HHS and the Food and Drug Administration revised, and made as compatible as possible under their respective statutory authorities, their human subjects regulations. The Federal Policy for the Protection of Human Subjects also known as the “Common Rule” was published in 1991 and codified in separate regulations by 15 Federal departments and agencies.

The BR principles that guide the IRB process do not cover the scope of ethical issues that arise in CEnR.⁵ With its focus on individual-level ethical considerations, the BR is relatively silent on community and partnership level ethical considerations. For example, missing in the BR are the CEnR ethical principles of community risk, relevance, participation, and benefit. There are instances where the BR speaks to societal considerations of proposed research, yet this is done without much specificity and without explicitly naming the many key considerations and concerns that can arise in CEnR. Consequently, community-engaged researchers question the adequacy of the BR and the federal regulations’ ability to thoroughly and effectively guide assessments of the ethics of CEnR.^{3, 5-10}

The forms that IRBs use for their reviews are also telling. In a content analysis of 30 university-based IRB application forms, community considerations were often missing.¹¹ While all of the forms reviewed inquired about scientific rationale, none queried the community’s perspectives regarding the justification for the study or how barriers to community participation could be minimized. Only 4 forms asked about community or societal level risks and benefits, and only 5 inquired how the findings would be disseminated.

To ensure the ethics and integrity of the research in which they and their communities are engaged, a growing number of community groups have developed their own research review processes that operate independently or in conjunction with institution-based IRBs.^{12, 13} With support from the Greenwall Foundation, in 2009 we completed the first systematic study of community-based processes for research ethics review (referred to herein as CRPs). We identified and described 109 operating and 30 emerging CRPs in the U.S. and found several reasons for their development, including (a) enhancing community protections in research by assuring that community considerations be taken into account, (b) assuring community ownership of the review process, and (c) responding to dissatisfaction with institution-based IRB processes. We also documented the research ethics and integrity issues they consider that institution-based IRBs normally do not, such as culturally appropriate recruitment strategies, opportunities for community training or capacity building, shared power and resources among study partners, and plans to share findings with involved communities.^{6, 7}

Study Aims: The problem we seek to address in our study is that the recommended responses to ensuring a thorough ethical review of CEnR (e.g., IRB education, increasing the number of nonscientific IRB members, creating CRPs), while feasible, cannot solve the underlying issue of the inadequacy of the BR and federal research ethics regulations when applied to CEnR. Just as

Ernest Boyer examined scholarship (at the time defined almost exclusively as scholarship of discovery despite the reality of faculty involvement in other scholarly activities) and articulated a new framework in “Scholarship Reconsidered” (expanding the definition to include scholarship of synthesis, teaching, application and engagement) we aim to reconsider the ethical framework and research ethics review system in light of the realities of CEnR.¹⁴

Our study builds upon our prior Greenwall Foundation-funded study and our recently completed NIH funded National Collaborative Study of Community-Based Processes for Research Ethics Review. With NIH support, we conducted case studies of 5 CRPs (two federally recognized community-based IRBs and three community-based review committees) to better understand the operations, review considerations and impact of CRPs, and a cross-case analysis of cross-cutting themes. For each CRP, we analyzed documents, observed review meetings, conducted reviewer focus groups and interviewed CRP chairs as well as researchers who have had studies reviewed by both a CRP and an institution-based IRB. We found that CRPs view the federal regulations as a “floor” and not a “ceiling” in terms of providing guidance for their reviews by examining both individual and community risks and benefits.¹⁵⁻¹⁸ All of the CRPs consider ethics and integrity issues that go beyond the regulatory requirements to include cultural and community-level considerations.

Our study seeks to analyze the implications of our findings for revised federal research ethics regulations that apply to CEnR and possible scenarios for a system of research ethics review that could effectively implement it. Specifically, we aim to:

1. Articulate a set of ethical principles for CEnR
2. Draft a revised Belmont Report and set of HHS Regulations for the Protection of Human Subjects that encompass the ethical principles for CEnR
3. Develop possible scenarios for a system of research ethics review that could effectively assess the ethics of CEnR

Methods: We will achieve the study aims by performing new analyses of our NIH study data and relevant survey responses from our original Greenwall Foundation-funded study of the 109 CRPs. These will be reviewed and further analyzed through the lens of two overarching questions: what ethical principle does this exemplify and what are the implications for a system of research ethics review? We will pose these same questions of selected peer-reviewed publications on CEnR ethics.³

We will synthesize our analysis into three draft documents:

1. Ethical principles for CEnR
2. A revised Belmont Report and set of HHS Regulations for the Protection of Human Subjects that encompass the ethical principles for CEnR
3. Possible scenarios for a system of research ethics review that could effectively assess the ethics of CEnR

We will seek in-person and online feedback on the drafts from key stakeholder groups, including community-engaged researchers, community research partners, CRP administrators/members, IRB administrators/members, Office of Human Research Protections staff, Secretary’s Advisory Council on Human Research Protections members, and researchers who study research ethics issues. Feedback will be categorized by theme, reviewed and incorporated into final drafts for dissemination as stand-alone documents and as peer-reviewed publications.

Dissemination and Knowledge Mobilization: In addition to disseminating study reports and peer-reviewed publications, we will pursue strategic opportunities to communicate our findings to key stakeholders and mobilize a constituency for change.

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For More Information: Contact study coordinator Alice Park at cbpr@ccph.info and visit our research ethics webpage at <https://ccph.memberclicks.net/research-ethics>

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