

RELATIONSHIPS BETWEEN COMMUNITY-BASED PROCESSES FOR RESEARCH ETHICS REVIEW AND INSTITUTION-BASED IRBs: A NATIONAL STUDY

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ABSTRACT: COMMUNITY GROUPS ARE IMPLEMENTING research ethics review processes to determine whether and how research is conducted in their communities. We report on a survey of 109 of these community-based review processes about their relationships with institution-based research ethics boards (I-REBs). Ninety-two percent reported that studies they review were also reviewed by an I-REB. Over half characterized their relationship with I-REBs positively. Those with positive relationships were significantly more likely to communicate with the involved I-REBs. Challenges when working with I-REBs included delays, communication problems, and lack of I-REB understanding of community-based participatory research. Strengthening relationships between community-based review processes and I-REBs could ultimately enhance reviews of community-engaged research.

KEY WORDS: research ethics, institutional review board, IRB, research ethics board, REB, community-engaged research, community-based participatory research

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INCREASINGLY, COMMUNITIES ARE PARTNERING with institution-based researchers to understand and address pressing health concerns. The benefits of a partnership approach to research, often referred to as community-engaged research (CEnR), include an increased likelihood of overcoming community distrust of research, employing culturally relevant research strategies, and producing community-level benefits (i.e., National Cancer Institute; 2006; Seifer, Michaels, & Collins, 2010; Schulz, Krieger, & Galea, 2002; Israel et al., 1998).

As McDonald (2009) points out, while the core ethical principles of CEnR are the same as those of biomedical research, “Working with community organizations on collaborative research adds another dimension of ethical issues for researchers to consider. Researchers must be open to understanding communities’ values and priorities when conducting research collaboratively with community organizations.” Thus, CEnR raises ethical considerations that go beyond individual-level protections to include those at the community level. This creates challenges for the institutional review board (IRB) system in the United States, herein referred to as research ethics boards (REBs). REBs, designed to protect the rights and welfare of *individual* study participants, may be less equipped to protect the rights and welfare of *communities* involved in research. Specifically, the principles of human research ethics that guide REBs do not explicitly address the scope of ethical considerations that arise in CEnR. For example, missing in the principles of human research ethics are the guiding principles articulated by Ball and Janyst (2008) that include community relevance, community participation, mutual capacity building, and benefit to indigenous communities. Consequently, REB application of the principles of human research ethics may not provide a thorough ethical analysis (Shore, 2006; Flicker et al., 2007; Ross et al., 2010; Brown et al., 2010). In a review of 30 university-based REB application forms, for example, Flicker et al. found that community considerations were often missing. While the communitarian interpretation of the principles of human research ethics may be growing, many REBs in the United States adhere to the individual view and do not regard community-level protections as under their purview.

A growing number of community groups are implementing their own ethics review processes to determine whether and how research is conducted in their communities. These community-based review processes (CRPs) operate independently, in parallel or in partnership with institution-based REBs (I-REBs), and in some cases are structured as community-based REBs

(i.e., Strauss et al., 2001; Oneha & Beckham, 2004; Quinn, 2004; Travers, 2006; Blumenthal, 2006; Jacklin & Kinoshameg, 2008). In 2009, we completed the first systematic study in the U.S. of CRPs through an online survey of community groups and community-institutional partnerships involved in conducting human subjects research and/or advising on its conduct. We identified potential study participants by reviewing funding and bibliographic databases, posting the study invite to relevant listservs, and asking various organizations to forward the study information to their membership. The study invitation requested that the person(s) most knowledgeable about the community group/partnership's involvement in the review of research complete the survey.

Shore et al. (2010) describe in detail our REB-reviewed study methodology, estimated response rate (31%), and findings from survey questions that asked when and why the CRP was established, its infrastructure, functioning, benefits and challenges. Of the 172 eligible surveys received, we identified 109 groups operating a CRP in 31 states, the District of Columbia, and Puerto Rico, and 30 more in development. Most respondents identified themselves as community-institutional partnerships ($n = 34$; 31%), followed by community-based organizations ($n = 24$; 22%), nonprofit organizations ($n = 13$; 12%), community health centers ($n = 13$; 12%), and tribal organizations ($n = 8$; 7%). The remaining respondents ($n = 17$; 16%) represented various other entities, including K-12 schools and community coalitions. These CRPs routinely consider community-level ethical issues that I-REBs often do not. The three most frequently cited reasons for establishing a CRP were (1) to make sure the community directly benefits, (2) to make sure the community is engaged, and (3) to protect one's community from possible risks (Shore et al., 2010).

Here, we report results from survey questions that asked about how CRPs interface with I-REBs, which included questions pertaining to communication patterns and overall relationship considerations. By examining the interface between CRPs and I-REBs, we aim to inform and improve the ethics review of CEnR.

Method

The survey was developed with the guidance of a study advisory committee (SAC) composed of experts in REBs, CEnR, and the operations of community-based organizations. The survey included multiple-choice questions with an "other" write-in option and open-ended questions. Categories of survey questions

included (1) description of the entity hosting the CRP (herein referred to as "community group/partnership"), (2) types of research reviewed, (3) CRP infrastructure, (4) CRP functioning, (5) CRP benefits and challenges, and (6) relationship of or interaction between the CRP and I-REBs. Our previous paper reports on findings from question categories 1-5 (Shore et al., 2010). This paper reports on the relationship/interaction questions, which included one open-ended question.

We performed descriptive statistical analyses of multiple-choice questions using SAS version 9.2. Additional analyses of the relationship/interaction questions were conducted to determine associations with the quality of relationship with I-REBs. In some instances, participants opted not to answer a particular question, resulting in missing data. The presentation of results indicates the actual number of responses received. The response options included in the tables represent the verbatim multiple-choice options given in the survey. In addition, we performed thematic content analysis of responses to the open-ended question (Strauss & Corbin, 1998). Two research team members independently coded responses and built a codebook for the open-ended question. The codebook was refined through comparison, categorization, and discussion on the interpretation of the codes until an inter-coder reliability rate of 0.99 was achieved (Bakeman & Gottman, 1986). The same two research members independently categorized the "other" responses received in the multiple-choice questions. One hundred percent consensus was reached on the categorization of the "other" responses.

Results

Of the 109 respondents with a CRP, all but 9 ($n = 100$; 92%) reviewed proposals that were also reviewed by an I-REB. Nearly 50% ($n = 53$) reported that all the research proposals they reviewed were also reviewed by an I-REB. Table 1 summarizes the involvement of I-REBs.

TABLE 1. Involvement of I-REBs ($n = 109$).

Percentage of proposals reviewed both by the community group/partnership and by an institution-based IRB	N (%)
100%	53 (49%)
75-99%	13 (12%)
50-74%	6 (6%)
25-49%	5 (5%)
1-24%	23 (21%)
0%	9 (8%)

Below we report results for the 100 survey respondents who reported reviewing proposals that were also reviewed by an I-REB.

Reasons Why an I-REB Is Involved

The most common reasons reported for why the proposals they reviewed were also reviewed by an I-REB were: partners required an REB review (82%), funders required it (58%), and the I-REB provided an additional level of protection for the involved community (47%). Respondents were able to select all applicable reasons.

Process When an I-REB Is Involved

Respondents described what occurs when the same research proposal is reviewed by both their CRP and an I-REB. Table 2 summarizes the responses received.

Thematic analysis of the “other” responses (n = 53) revealed that the four most frequently cited themes were (1) the community group reviews the proposal first (n = 10); (2) the community and institution-based review processes are independent of one another (n = 8); (3) the review practices vary by project (n = 7); and (4) the community group and I-REB review the proposal simultaneously (n = 4).

Communication Patterns between CRPs and I-REBs

We asked respondents to describe communication patterns with I-REBs when they review the same proposals. We received 92 responses, with almost half of the respondents (n = 43; 47%) indicating that communication varies from proposal to proposal. Table 3 summarizes the responses received.

Reasons Why an I-REB Is Not Involved

Of the 94 respondents indicating why an I-REB does not always review proposals submitted to their CRP, nearly half (n = 44, 47%) indicated that the proposals are always reviewed by an I-REB. Table 4 summarizes the responses received regarding the reasons that an I-REB review does not always occur.

Thematic analysis of the “other” responses (n = 29) revealed that the most frequently cited theme was that some of the submitted projects do not require any REB review (n = 13). Other themes included that the respondent’s group/partnership (1) relies mostly on their own REB (n = 4), (2) lacks understanding or knowledge of the REB process (n = 3), and (3) relies on the institution-affiliated partners to complete their own REB requirements (n = 2).

TABLE 2. Reviews Involving Both a CRP and an I-REB (n = 87).*

Response	N (%)
The group/partnership would not review the proposal without documentation that the proposal was <i>submitted</i> to an institution-based IRB.	21 (24%)
The institution-based IRB would not review a proposal unless <i>first approved</i> by the community group/partnership.	16 (18%)
The group/partnership would not review the proposal without documentation that the proposal was <i>approved</i> by an institution-based IRB.	9 (10%)
Other (respondents were provided space to write in their responses)	53 (61%)

*Thirteen of 100 eligible respondents did not respond to this question; respondents were able to check all that applied.

TABLE 3. Communication Patterns When an I-REB Is Involved in Reviewing the Same Proposal (n = 92).*

Response	N (%)
Our communication with the institution-based IRB varies from proposal to proposal.	43 (47%)
We do not usually communicate with the institution-based IRB.	31 (34%)
We usually communicate with the institution-based IRB if we have questions or concerns <i>during the review</i> of the proposal.	20 (22%)
We usually communicate with the institution-based IRB <i>after</i> we have completed the review, and our requirements conflict with their requirements.	10 (11%)

*Eight of 100 eligible respondents did not respond to this question; respondents were able to check all that applied.

TABLE 4. Reasons that an I-REB Does Not Review all Proposals Submitted to the CRP (n = 87).*

Response	N (%)
The group/partnership has its own IRB registered with the U.S. Office for Human Research Protections.	13 (15%)
The group/partnership's review process conducts a thorough review and thus an institution-based IRB review is not required.	9 (10%)
The group/partnership lacks access to an institution-based IRB.	5 (6%)
The cost of an institution-based IRB review	4 (5%)
Lack of satisfaction with the institution-based IRB review	2 (2%)
Other (respondents were provided space to write in their response)	29 (33%)

*Thirteen of 100 eligible respondents did not respond to this question; respondents were able to check all that applied.

TABLE 5. Most Significant Challenges When Working with an I-REB (n = 52).*

Most Significant Challenge with I-REB	N (%)
Time delays	22 (42%)
I-REB's lack of understanding of community-based participatory research	20 (38%)
Communication with I-REB	11 (21%)
No challenges	10 (19%)
Resolution of issues with multiple REBs (i.e., multi-site research)	7 (13%)
No contact with I-REBs	4 (8%)

*Seventy-six of 100 eligible respondents responded to this open-ended question; 14 of those were not usable.

Quality of Relationship between CRPs and I-REBs

Respondents were then asked to describe the quality of their group/partnership's relationship with I-REBs. More than half of the respondents indicated a positive relationship (n = 53; 56%), with 23 (24%) reporting that the relationship was "extremely positive" and 30 (32%) reporting that it was "somewhat positive." Three respondents (3%) described their relationship as "somewhat negative." The remaining 38 respondents (40%) categorized the relationship as "neither positive nor negative."

To gain greater insight into the relationships of the community groups/partnerships and I-REBs, we looked for associations between the reported quality of the relationship and (1) type of entity hosting the community-based review process, (2) communication patterns between the CRP and the I-REB, (3) reasons why proposals are not also reviewed by an I-REB, (4) the process that occurs when the CRP and I-REB both review the same proposal, and (5) percentage of proposals reviewed by the CRP and an I-REB. The only statistically significant association was between the quality of the relationship and communication patterns with the I-REB (reported in Table 3). Respondents who reported they usually communicate with the REB were more likely to characterize their relationship with the I-REB as extremely positive (35% vs. 21%) or "somewhat positive" (55% vs. 22%) than those respondents who do not usually communicate (p = .0036).

Most Significant Challenges Working with I-REBs

We asked respondents the open-ended question, "What is the most significant challenge that your group/partnership has when working with institution-based IRBs [REBs]?" Of the 100 respondents eligible to answer this question, 76 did so. Nine responses could not be coded because of difficulty in interpreting the meaning of the response, and five responses were not applicable to the question. Of the remaining 62 responses that could be coded, most (n = 42; 81%) described challenges that corresponded with one of these themes: (1) time delays, (2) communication problems, (3) lack of understanding of community-based participatory research (CBPR), and (4) difficulty in resolving conflicts with multiple REBs (see Table 5).

TIME DELAYS

The most frequently identified challenge (n = 22) was the length of time it takes to go through the I-REB process, including various iterations and modifications to a given research protocol. Some of the respondents pointed out the significant time investment in completing multiple forms and getting the various documents to be used in the study protocol translated into all the relevant languages. Others identified time delays in working through requirements that conflict with community needs and timeframes. As one respondent stated, "They [REBs] are way too slow. It has gotten

better over time because we now have a relationship with IRB staff at the [University], and it seems they have increased their efforts to expedite applications. However, invariably we sit and wait for approvals and this slows down our timelines.”

COMMUNICATION ISSUES

A related theme to time delays was problematic communication between I-REBs and CRPs ($n = 11$). For example, one respondent stated that one of its biggest challenges was “ensuring that actions subsequent to the initial approval (e.g., re-approvals, amendments) by the IRB are communicated to us in a timely way.” Other respondents pointed out the challenges of poor management and the effects on communication: “They can be very difficult to communicate with, they often lose materials or forget to include projects on the agenda, so the process is often delayed by a few months because of poor management of the group.”

LACK OF UNDERSTANDING OF CBPR

Another frequently identified challenge was I-REBs’ lack of understanding of CBPR and/or, more broadly, community engagement ($n = 20$). Some respondents linked this challenge to the traditional biomedical framework and bench science priorities of the institutions with which they partner, as these verbatim statements from two respondents demonstrate:

Our collaborative shares the goal of human subject protection. However, under the auspices of protecting human subjects, the IRB inadvertently circumvents the very nature and premise of CBPR especially in its initial phase when we are designing the study methodology with community members especially where there is no risk or minimal risk, such as filling out surveys and collecting no identifiable data. IRB is inherently hierarchical and clearly identifies the researcher versus the subject. Whereas in CBPR, the researcher uses a partnership approach that breaks down the barriers between the researcher and the researched and values community partners as equal contributors to research. The community experts are viewed as subjects and not colleagues in almost all cases by university IRBs.

The university IRB is more familiar with controlled research environments and has a difficult time understanding that this research project is based in the community and that all protocols must be culturally appropriate and flexible to deal with a changing environment.

Several respondents stated that standard I-REB procedures, such as an online-only submission process or the use of technical language not understandable by everyone in the community, “do not fit CBPR” and make it difficult to know “what they want from project to project.” Others expressed frustration in identifying the appropriate channels to navigate given the sizeable bureaucracy of most universities.

In addition to challenges faced in terms of different review procedures, one respondent pointed out the significant difference between CRPs and I-REBs regarding how human participant protections are viewed and obtained. As this respondent’s quote reveals, I-REBs often do not consider community-level protections, such as cultural or dignitary harm, and community-level benefits:

They [the IRBs] focus on the individual protections while we focus on both the individual and community protections (tribal groups, etc.). We are interested in the benefits of research in a practical sense while the University is only interested in the use of the available funding and possible potential for new information which may or may not be of any use to anyone.

Two respondents felt that insufficient participation of people who understood their communities on I-REBs could help explain this lack of attention to community-level ethical issues.

Other responses pointed to the challenges of proposing ethnographic and other qualitative methods within a CBPR framework, highlighting the difficulty in “figuring out a model that really focuses on the needs and issues related to qualitative research and non-clinical studies.” As the following statement reveals, an I-REB’s lack of understanding of CBPR and qualitative methods can lead to challenges in understanding the proposed design: “IRB does not understand social research, CBPR, respondent-driven sampling, etc.—they are thoroughly focused upon basic science and clinical trials.”

These methodological conflicts were compounded for two respondents who commented on the disconnection between I-REB requirements for human subjects’ research training and the realities of CBPR. They explain that current ethics training modules, such as the one offered by the Collaborative Institutional Training Initiative (CITI), are designed for academics and not appropriate for community co-researchers. For example, one respondent wrote, “The most significant challenge with the university IRB is the number of CITI modules required for human subjects training. Most modules are not reflective of the practice and CBR [community-based research] we will conduct.” A second respondent pointed out the need for an ethics training course that could be

used easily by community partners who might not be comfortable with the CITI program or similar ethics training programs.

RESOLVING ISSUES WITH MULTIPLE REB

A less frequently reported theme ($n = 4$) emerged concerning problems or conflicts on research projects involving multiple REBs, such as conflicts between CRP and I-REBs, or between the involved I-REBs.

Discussion

A number of research teams, including ours, have questioned the feasibility of expecting I-REBs to fully assess the ethics of CEnR proposals, suggesting that “the protection of communities may be more appropriately situated in review processes developed and managed by the communities involved in research. A system involving community-based and institution-based research ethics review may be the ideal to strive for, despite the inevitable challenges and complexities involved” (Shore et al., 2010). Since CRPs consider community-level ethics issues (Shore et al., 2010), and I-REBs typically do not consider them (Flicker et al., 2007), proposals reviewed by both may benefit from a more thorough ethical analysis. The study findings we present here shed light on the potential for such a system.

Since the vast majority (91%) of community groups/partnerships with CRPs in our study assess research proposals that are also reviewed by REBs (with more than half indicating all proposals they review also undergo REB review), there is potential for these reviews to be coordinated. We are encouraged to see that nearly two-thirds of community groups/partnerships with a CRP communicate at some point with REBs and that over half describe the relationship in positive terms. Although we found a positive association between the extent of communication and the quality of the relationship, we do not know the order of explanation for this observation (e.g., does frequent communication lead to, or result from, positive relationships?) and of course we do not know the perspectives of the involved REBs. Nevertheless, our findings point to the potential for a more thorough and effective ethics review of CEnR if community groups/partnerships with research ethics review processes and REBs routinely communicated.

While our study findings do not point to specific ways to structure a system of community-based and institution-based review of CEnR, there are a number of options that could be considered:

If the CRP is a community REB and there is an academic partner involved in the study, the study could be reviewed by both the community REB and the I-REB simultaneously or sequentially, as would be the case in many

studies involving multiple REBs. If there are conflicts between the reviews provided by each REB, there might be value in having the two REBs meet together with the research team to discuss their concerns and explore a mutually agreeable resolution. If there is no academic partner involved, there is no need for an I-REB review.

If the CRP is not a community REB and there is an academic partner involved in the study, it could be reviewed first by the CRP to ensure that community-level ethical issues are attended to before the I-REB reviews it. A brief description of the CRP, its comments, and research team’s response could be included as part of the application submitted to the I-REB, thereby demonstrating the nature and outcomes of the community review.

If the CRP is not a community REB and there is no academic partner involved in the study, the need for an I-REB review will depend on the specifics of the study. Assuming REB review is required, the research team could submit the study to a for-profit REB or a noninvolved institution-based or community REB willing to serve as the REB of record. An interesting and innovative strategy for REB review of community-led research is being undertaken in Ontario, Canada. Community organizations in the province that are engaged in HIV/AIDS research may submit study proposals to a REB at the University of Toronto specifically designed for this purpose, whether there is U of T involvement in the study or not (information accessible at <http://www.research.utoronto.ca/for-researchers-administrators/ethics/human/boards-committees/hiv-reb/>).

Admittedly, all of these options pose challenges, not the least of which includes the potential for delaying approval of the proposed study. As we elaborate in the Research Agenda below, this area is ripe for further exploration through case studies and demonstration projects.

Some of the challenges expressed by community groups/partnerships in working with I-REBs, such as time delays and communication issues, mirror those identified more generally by researchers and are not unique to CEnR. While all are important and in need of attention, we are especially concerned with CRP perceptions that I-REBs lack understanding of community-based participatory approaches to research. Community-engaged researchers and research partnerships have expressed similar concerns (Shore, 2006; Flicker et al., 2007; Ross et al., 2010; Brown et al., 2010; Grignon, Wong, & Seifer, 2008). Some respondents also raised concerns regarding REB committee composition. Even though the human subjects regulations require nonaffiliated members, this finding indicates how community groups can still feel that REBs do not fully understand their community context and cultural values. As research funding agencies, most notably NIH, increase their support for CEnR, we can only expect REBs to be

reviewing a greater volume of CEnR proposals. Deepening their understanding of foundational principles, practices, and ethics of CEnR is therefore critical.

Many of the questions and issues raised by our study lend themselves well to case studies. Toward that end, we have established a partnership with a diverse group of community groups/partnerships that took part in our survey to conduct a collaborative cross-case study analysis that also includes the I-REBs they work with. This approach will allow us, for example, to gain a more in-depth understanding of how CRPs and I-REBs interact with each other and ways to strengthen relationships. We also intend to “follow” CEnR proposals through both review processes in order to observe how the review entities interface with each other and the research team, to compare the type of feedback the research team receives, and to determine the impact of the feedback on the study design. Whereas case studies will help to understand current practices, demonstration projects could help seed innovations that could then be evaluated.

Best Practices

Strengthening communication and coordination between CRPs and I-REBs may lead to improved understanding of each other’s roles and contexts, stronger working relationships, and ultimately more efficient and thorough reviews of CEnR. The specifics of how this should occur are best determined by these entities themselves. Although the questions in our online survey did not allow us to gather sufficient details about communications and relationships to point to best practices in cases that are working well, a number of innovations have been reported in the literature that might be replicated more widely. These include, for example, sharing some of the same reviewers (Watkins, Shepard, & Corbin-Mark, 2009).

Research Agenda

Further study is needed to fully understand the actual and potential relationships between CRPs and I-REBs. We are especially interested in the outcomes of proposals undergoing both CRP and I-REB reviews. Does review by both, for example, uncover a broader range of ethical issues and lead to CEnR that more thoroughly addresses individual- and community-level risks and benefits? Or, alternatively, do the reviews by both provide redundant feedback, raising the question of how to streamline the review process, particularly for lower-risk proposals? Does it lead to conflicts between the reviews and how, if at all, are they resolved?

Unless a CRP is structured as an actual REB, what power and influence does it actually have in regulating research? Sixteen of the respondents in our study report that I-REBs will not review a proposal unless their CRP has approved it first. For the nine CRPs that will not review a proposal unless the involved I-REB has approved it, it is unclear what weight the REB’s comments and decisions have. Currently there is no model for how to resolve conflicts between two or more review processes. Examining such cases in greater depth could provide useful models for others to follow.

Educational Implications

Ensuring that I-REBs are prepared to conduct ethics review of CEnR should be a priority. The ethics training that IRB members are required to take does not currently include CEnR, but fortunately that is changing with a forthcoming curriculum that will be offered through the CITI platform and also made freely available online (IRB/REB Workgroup on Community-Engaged Research, 2009; K. Hansen, pers. comm., July 13, 2010). Public Responsibility in Medicine and Research and the Association for the Accreditation of Human Research Protection Programs also have increased the CEnR content during their conferences over the past few years. For example, the 2010 annual Public Responsibility in Medicine and Research conference featured a plenary panel and workshops addressing aspects of community engagement (i.e., Barnard et al., 2010; Boateng & Galland, 2010; Seifer, 2010; Seifer & Shore, 2010). In addition to curricula and conference sessions, there are many informal ways for I-REBs to improve their understanding of CEnR. Inviting presentations on CEnR, convening meetings with community-engaged researchers, and discussing journal articles that report on CEnR ethics issues are but a few examples.

Community groups/partnerships with CRPs could benefit from ongoing mechanisms for sharing resources, innovations, and lessons learned. The 23 respondents in our study who reported “very positive” relationships with I-REBs, for example, could have helpful advice to share with other community groups/partnerships that seek to strengthen such relationships. Community-Campus Partnerships for Health has been helping to facilitate these sorts of educational exchanges by sponsoring conference calls and workshops (CCPH, 2007, 2009–2010).

Finally, I-REBs and CRPs could benefit by learning from one another. Having each present to the other on its policies, procedures, successes, and challenges could go a long way toward fostering mutual understanding and respect as well as practical strategies for improving the ethics review of CEnR.

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