



Understanding the Relationships between Community-Based Processes for Research Ethics Review and Institution-based IRBs



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BACKGROUND

Community-engaged research (CEnR) is increasingly recognized by community groups, researchers and funding agencies as critical to addressing our nation's pressing health concerns. With a growth in CEnR, a number of communities and community-institutional partnerships have established ethics review processes that operate independently or in parallel with institution-based IRBs. As a result, institution-based IRBs will need to review more CEnR proposals and potentially interact more with community-based ethics review processes.

Our study sought to systematically describe how these community-based processes for ethics review interface with institution-based IRBs, which included questions pertaining to communication patterns and overall relationship considerations. We refer to these community-based review processes as CRPs, and to institution-based IRBs as IRBs. We acknowledge that some CRPs are federally recognized IRBs.

SPECIFIC AIM

To identify and describe the interactions between CRPs and institution-based IRBs.

METHODS

We conducted an online survey of U.S.-based community groups and community-institutional partnerships involved in research. The selection of survey questions was informed by the CEnR literature and feedback from our Study Advisory Committee. Members of community groups also piloted the survey and provided feedback on its content and the usability of the online format.

We performed descriptive statistical analyses using SAS version 9.2, and thematic content analysis of responses to open-ended questions.

The IRBs at the University of Washington and the University of New England reviewed the study.

RESULTS

Of the 172 respondents, 109 (64%) reported having a CRP. These processes are located in 31 states, the District of Columbia and Puerto Rico, with 6 that serve multiple states and 6 that are national. Forty (37%) report they have secured a Federal Wide Assurance.

AFFILIATION OF SURVEY RESPONDENT (n=109)

-Community-institutional partnership	34 (31%)
-Community-based organization	24 (22%)
-Community health center	13 (12%)
-Non-profit organization	13 (12%)
-Tribal organization	8 (7%)
-Other (e.g., coalition, K-12 school)	17 (16%)

% OF PROPOSALS REVIEWED BY BOTH THE CRP AND AN IRB (n=109)

-100%	53 (49%)
-75-99%	13 (12%)
-50-74%	6 (6%)
-25-49%	5 (5%)
-1-24%	23 (21%)
-0%	9 (8%)

MOST FREQUENTLY CITED REASONS FOR A PROPOSAL BEING REVIEWED BY AN IRB (n=100)

-Partners required an IRB review	82 (82%)
-Funders required it	58 (58%)
-IRB provided additional level of protection for the involved community	47 (47%)

-Respondents were able to select all applicable reasons.

REVIEWS INVOLVING BOTH A CRP AND AN IRB (n=87)

-The CRP would not review the proposal without documentation that the proposal was <i>submitted</i> to an institution-based IRB	21 (24%)
-The IRB would not review a proposal unless <i>first approved</i> by the CRP	58 (58%)
-The CRP would not review the proposal without documentation that the proposal was <i>approved</i> by an IRB	9 (10%)
-Other (respondents were provided space to write-in their responses)	53 (61%)

-Respondents were able to select all applicable reasons.

COMMUNICATION BETWEEN THE CRP AND IRB WHEN BOTH REVIEW THE SAME PROPOSAL (N=92)

-Communication with the institution-based IRB varies from proposal to proposal	43 (47%)
-We usually do not 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 complete the review, and our requirements conflict with their requirements	10 (11%)

-Respondents were able to select all applicable reasons.

RELATIONSHIP WITH INVOLVED INSTITUTION-BASED IRB (n=94)

-Extremely positive	23 (24%)
-Somewhat positive	30 (32%)
-Neither positive or negative	38 (40%)
-Somewhat negative	3 (3%)

MOST SIGNIFICANT CHALLENGE WITH IRBs (n=52)

-Time delays	22 (42%)
-IRB's lack of understanding of CBPR	20 (38%)
-Communication with the IRB	11 (21%)
-No challenges	10 (19%)
-Resolution of issues w/ multiple IRBs	7 (13%)
-No contact with IRBs	4 (8%)

-Categories developed by thematic analysis of open-ended responses.

REASONS AN IRB DOESN'T REVIEW ALL PROPOSALS (N=87)

-The group/partnership has its own IRB registered with OHRP	13 (15%)
-The group/partnership's review process conducts a thorough review and IRB review is not required	9 (10%)
-The group/partnership lacks access to an IRB	5 (6%)
-The cost of an IRB review	4 (5%)
-Lack of satisfaction with the IRB review	2 (2%)
-Other (respondents were provided space to write-in their response)	29 (33%)

-Respondents were able to select all applicable reasons.

DISCUSSION and IMPLICATIONS

Study findings indicate 1) CRPs and IRBs frequently review the same proposals, and 2) the majority of CRPs communicate at some point with the involved IRB. Since CRPs consider community-level ethics issues (Shore et al., In press) and IRBs typically do not (Flicker et al., 2007), presumably proposals reviewed by both have undergone a more thorough ethical analysis. Some of the identified challenges in working with IRBs are not unique to CEnR. While all challenges are important, we were concerned with the perceived lack of IRB understanding of CBPR. As funding agencies increase their support for CEnR, we expect IRBs to be reviewing a greater volume of CEnR proposals. Deepening their understanding of foundational principles, practices and ethics of CEnR is therefore critical. We also believe that strengthening communication and coordination between CRPs and IRBs may lead to stronger working relationships, and ultimately enhanced reviews of CEnR.

-Shore, N., Brazauskas, R., Drew, E., Wong, K., Moy, L., Corage Baden, A., Cyr, K., Ulevic, J., & Seifer, S. (In Press). Understanding community-based processes for research ethics review: A National Study. *American Journal of Public Health*.
-Flicker, S., Travers, R., Guta, A., McDonald, S., Meagher, A. (2007). Ethical dilemmas in community-based participatory research: Recommendations for Institutional Review Boards. *Journal of Urban Health*.

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