



## Understanding Community-Based Processes for Research Ethics Review

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### BACKGROUND

It is increasingly apparent that the Institutional Review Board (IRB) system for assuring that research is ethical is insufficient when applied to community-based research. A number of community groups and partnerships have established their own ethics review processes that operate independently or in parallel with institution-based IRBs.

Through studying these processes, we sought to 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 that will only bring these ethical issues further to the fore.

### SPECIFIC AIMS

To identify and describe the types of processes and protocols that community groups and community-institutional partnerships use to assess whether to participate in or support a research study.

To assess the similarities and differences between the protocols used by community-based processes for research ethics review and those used by institution-based IRBs.

### METHODS

To achieve study aim 1, 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 CBPR 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.

To achieve study aim 2, the study team is employing content analysis to examine the documents that guide respondents' ethics review processes. The content of these documents will then be compared to those used by their involved institution-based IRBs. The preliminary findings below focus on the survey results as the content analysis is on going.

*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 community-based process for research ethics review. 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 (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%)

#### REASONS FOR ESTABLISHING REVIEW PROCESS (n=109)

-To make sure the community directly benefits	93 (85%)
-To make sure the community is engaged	82 (75%)
-To protect community from possible risks	74 (68%)
-To respond to a growing number of researcher requests to support/participate in their research	45 (41%)
-To set own research agenda	18 (17%)

#### BENEFITS OF HAVING REVIEW PROCESS

- Ensure that the research conducted is relevant and feasible
- Assure community benefit and minimize risks
- Allow for greater community voice in determining which projects are approved
- Create opportunities for capacity building

Example open-ended comments:

*"Exposes community members to the research process and enterprise to help develop their expertise and knowledge about health issues and disparities in health."*

*"Helps us to focus on research being done the right way, rather than getting steered into projects that seem like a lot of resources, but ultimately ends up hurting the community due to improper research methodology."*

#### REVIEW CONSIDERATIONS

	(MEAN, SD)
-Research methods that are appropriate to the community	2.95 (0.21)
-Good fit with the community's agenda	2.87 (0.34)
-Culturally appropriate recruitment strategies	2.87 (0.41)
-Plans to share findings with communities involved in research	2.87 (0.36)
-Culturally appropriate individual informed consent	2.86 (0.40)
-Community-level risks and benefits	2.85 (0.38)
-Community consent	2.85 (0.38)

Respondents rated 13 considerations on a 3-point scale where 1=Not important, 2=Somewhat important, and 3=Very important. These are the 7 highest rated considerations.

#### PERCENTAGE OF PROPOSALS ALSO REVIEWED BY AN INSTITUTION-BASED IRB (n=109)

None	9 (8%)
1-24%	23 (21%)
25-49%	5 (5%)
50-74%	6 (6%)
75-99%	13 (12%)
ALL	53 (49%)

#### MAIN REASONS FOR SUBMITTING PROPOSALS TO AN INSTITUTION-BASED IRB (n=100)

Involvement of university researchers	82 (82%)
Funders require it	58 (58%)
Provides an added layer of protection	47 (47%)

#### 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%)

#### COMMUNICATION WITH INSTITUTION-BASED IRBS WHEN REVIEWING THE SAME PROPOSAL (n=92)

Usually communicate if questions arise	20 (22%)
Usually communicate after group's review is completed	10 (11%)
Varies	43 (47%)
Usually do not communicate	31 (34%)

### NEXT STEPS

#### SUBSEQUENT PHASES

- Form a collaborative research network with interested survey respondents
- Partner with groups to conduct an in-depth cross-case study analysis of their research ethics review processes

#### PRACTICAL BENEFITS

- Support others engaged in community-based research in developing or strengthening their own review process
- Support institution-based IRBs in their efforts to better respond to community-based research

For more information, contact the Study Team at [cbresearch@une.edu](mailto:cbresearch@une.edu)

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