Understanding Community-Based Processes for Research Ethics Review

Nancy Shore, University of New England (UNE); Sarena D. Seifer, Community-Campus Partnerships for Health (CCPH); Ruta Bajorunaite, Medical College of Wisconsin (MCW); Kristine Wong, CCPH; Lisa Moy, CCPH; Kirsten Cyr, UNE; Andrea Corage Baden, CCPH

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.

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 (23%) report they have secured a Federal Wide Assurance.

AFFILIATION (n=109)

Community-institutional partnership 36 (33%)  
Community-based organization 26 (24%)  
Community health center 13 (12%)  
Non-profit organization 12 (11%)  
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’s values and beliefs are taken into account 93 (85%)  
- To make sure the community is engaged 82 (75%)  
- To protect community from possible harms 76 (68%)  
- To respond to a growing number of research requests to support/participate in their research 45 (41%)  
- To set own research agenda 18 (17%)

PERCENTAGE OF PROPOSALS ALSO REVIEWED BY AN INSTITUTION-BASED IRB (n=94)

- 1-24% 23 (21%)  
- 25-49% 54 (47%)  
- 50-74% 15 (16%)  
- 75-99% 4 (4%)  
- ALL 34 (36%)  
- Usually do not communicate 31 (34%)  
- Varies 43 (47%)  
- Usually do communicate 20 (22%)

NEXT STEPS

We greatly appreciate the funding provided by the Greenwall Foundation and the guidance of our Study Advisory Committee: Bonnie Dara · Sarah Piker · Bill Freeman · Kelly Fryer-Edwards · Helen McGough · Michele Fraser · Ann-Gel Palermo · Joan Seker · Linda Silva · Stephanie Sodick · Eric Wei

We also thank these organizations for their support:  
- 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 (PRIMR)

For more information, contact the Study Team at cbresearch@une.edu

ACKNOWLEDGEMENTS

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

- Usually communicate if questions arise 20 (22%)
- Usually do not communicate 31 (34%)
- Varies 43 (47%)
- Funders require it 58 (58%)
- Provides an added layer of protection 47 (47%)
- Somewhat positive 30 (33%)
- Somewhat neutral 5 (5%)
- Somewhat negative 3 (3%)
- Extremely negative 2 (2%)

SUBSEQUENT PHASES

· Tuskegee University National Center for Bioethics in Research and Health Care
· National Association of Community Health Centers
· Stephen Sodeke · Eric Wat
· Ann-Gel Palermo · Joan Seker · Linda Silva
· Stephanie Sodick · Eric Wei

For more information, contact the Study Team at cbresearch@une.edu