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Fulfilling Ethical Responsibility: Moving Beyond the Minimal Standards of Protecting Human Subjects from Research Harm

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Abstract

Problem: Rules for protecting human subjects, in place federally since 1974, have focused primarily on guarding against placing research subjects at social, physical, or psychological risk or violating their privacy and confidentiality. Nevertheless, high-risk communities are routinely subjected to "sins of omission," which limit access to potentially significant research opportunities and result in the absence of studies that could confer high degree of community beneficence.

Purpose of Article: To describe "sins of omission" and provide examples from the Community Networks Program Centers (CNPC) to illustrate how community-based participatory research (CBPR) can prevent them.

Key Points: CBPR is an effective antidote to sins of omission. Activities undertaken by the CNPCs illustrate how adherence to CBPR principles can improve research access and outcomes.

Conclusions: By working with community members as partners, we expand the concept of beneficence to include "community beneficence," thus reducing the probability of "sins of omission."

Keywords

Community-based participatory research, research ethics, institutional review boards, human subjects, community beneficence

In the wake of acknowledged abuses of humans engaged in biomedical experiments, the National Research Act (Public Law 93–348) was signed into law in 1974.[1] This created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, whose purpose was to ensure that research involving human subjects adheres to clear ethical standards. Institutional Review Boards (IRBs) were established to protect human subjects involved in research.[2]

With the development of federal standards for the ethical treatment of human subjects and stringent means for their enforcement through local IRBs, confirmed instances of research harm (including failing to fully inform human subjects or by recklessly exposing them to danger for some presumed higher good) are now relatively rare in biomedical research.[3] IRBs have contributed significantly toward achieving the goal of protecting individuals from harms resulting from involvement in medical research. Rates of actual physical harm are very low and other risks, such as those due to breaches of confidentiality, are rare.[3]

The traditional IRB philosophy and operational perspective grew out of a model of biomedical research that focuses mainly on individual patients enrolled in clinical trials. Over the past 12 to 15 years, the National Cancer Institute (NCI) has moved logically from a nearly exclusive emphasis on an academic institution-inspired model emphasizing clinical trials research toward an interdisciplinary, community partnership model.

The NCI-funded CNPC, through which the authors of this article are funded, represents the latest transition toward CBPR from academically designed and initiated clinical trials research. The CBPR approach emerges from social justice and action research traditions,[4–7] embracing a commitment to work in partnership with disenfranchised, underserved populations to reduce disparities. In the context of the CNPCs, this entails operationalizing its nine principles ranging from recognizing the community as a unit of identity to committing to long-term processes of sustainability.[8,9] In addition to expanding the NCI research agenda and approach, CBPR has important implications for the protection of human subjects and, more important, considering how research can benefit high-risk, underserved members of our society and the communities in which they live.

Our stakeholders from racial, ethnic, and socioeconomic groups that experience disparities have voiced ethical concerns about disease prevention, treatment, racism, medical mistrust, and end-of-life decisions that reflect racial, ethnic, and socioeconomic disparities as well as a variety of social barriers to conducting meaningful research. Similar ethical concerns have been voiced at the researcher–community interface nationally.[10–13] These concerns compel us to address issues from a public health justice perspective; that is, risks and benefits relating to entire high-risk communities rather than only individual study participants. Although the focus on the negative consequences of traditional biomedical research is laudable, it falls far short of what CNPC investigators see as an extended responsibility to our constituencies. This expands the concept of beneficence, one of the pillars of current ethical criteria, to include "community beneficence," which recognizes the rights of communities to engage in active, informed decision making regarding participating in research that may result in reductions of the health disparities they experience.

When we fail to identify and seize opportunities to reduce cancer-related health disparities, including factors that increase the risk of other diseases, we commit "sins of omission," which result in the absence of studies that could confer a high degree of community beneficence, but are rarely done because they are not "required." These "sins" encompass failing to expand understanding of the underlying causes of health inequities, limiting access to research opportunities, failing to intervene meaningfully to reduce community health inequities based on current knowledge, or passively supporting traditional power imbalances between community partners and researchers that inhibit social advances in health equity. Although direct harm to individuals is now rare, "sins of omission" are, in all likelihood, very common. A poorly understood perceptual gap exists among researchers, other stakeholders, and our disparate communities regarding the interpretation and moral balance between these "sins of omission" and the probability of research harm to individuals in biomedical research. This perceptual gap, in turn, may affect participation in research, including intervention trials and the collection of biological specimens from research subjects.

Despite the stated objective that IRBs should take into account the potential benefits of research to address the causes and consequences of health problems, disability, and premature death (in keeping with the norms of "community beneficence"), we believe that their primary objective is to prevent research harm. Although the potential benefits that members of vulnerable populations may derive from CBPR are real, the criteria for evaluating community beneficence are rather abstract and vague. Unlike assessing deleterious effects across studies that receive IRB approval, for which there is both a discernible "numerator" that can be measured (i.e., adverse effects) and a well-defined "denominator" (the total of human subjects recruited into a defined number of protocols) that allow for relatively straightforward computation of "adverse effect" rates, there are no corollary parameters against which we can assess community-level beneficence. It is, therefore, understandable that IRB committees focus on reducing risk, with its straightforward measure of effectiveness, rather than addressing "sins of omission."

Recognition of the problem of "sins of omission" is not new. It was first mentioned in a 1983 article[14] in which it is stated that "research ethics in a 'value-free' science . . . has made researchers value-blind, insufficiently able to foresee possible negative consequences of what they do, but very able to design strategies to agree to structures that protect them;" and by "concentrating so much on top leads to . . . demobilizing the rest, turning them into clients." Hence, "researchers will . . . be tempted into sins of omission – not to pursue constructive knowledge, and not to pursue unpleasant truths, not because they want this, but because the structure leads them in that direction." Our purpose in this article is to examine the ways in which CBPR enhances the assessment of whether the possible risks to human subjects are reasonable in relation to the anticipated benefits.

WEIGHING COMMUNITY BENEFITS IN RELATION TO RISKS

As has been the case for many decades, the primary current focus of IRBs is to protect human subjects by guarding against potential risks associated with their participation in research studies. Researchers are required to identify the potential risks and specify in detail the safeguards to protect subjects from those risks. Safeguards of this kind include medical consultation and individual counseling. Although vigilance in protection of individuals is, of course, very important, there is the danger of not approving research projects that, in fact, may benefit the larger community, including the high-risk communities from which some individual research subjects are drawn. The CNPC-associated communities tend to be both at high risk of disease and generally more likely not to participate in research. A cadre of individuals committed to CBPR is highly likely to propose, design, and implement studies that could benefit the wider community by, for example, reducing cancer-related health disparities related to social inequities and environmental injustices. It is well-documented, however, that CBPR is relatively time consuming and difficult.[15–17] So, in the absence of this commitment to CBPR, these studies would simply never be done. It is important that the IRBs take community beneficence, and the level of deep commitment it implies, into account when making decisions to approve studies

Although the potential benefits to the community may be real, the criteria for evaluating community beneficence are more abstract and vague. Indeed, risk (physical, mental, emotional, and legal) is defined almost exclusively in terms of the individual. There is no comparable detailed consideration of risk to the wider community. Without a more detailed consideration of community beneficence and risk, it is not possible to conduct a sophisticated and balanced assessment of relative benefits and costs to individuals and the wider community.

CBPR PRINCIPLES AND THEIR OPERATIONALIZATION

Although definitions may vary, it is widely agreed that there are nine principles involved in operationalizing of CBPR[8,9]:

1. Recognize the community as a unit of identity.
2. Build on the strengths and resources within the community.
3. Facilitate a collaborative, equitable partnership in all research phases through an empowering and power sharing process that attends to social inequalities.
4. Foster co-learning and capacity building among all partners.
5. Integrate and achieve a balance between data generation and intervention for the mutual benefit of all partners.
6. Focus on the local relevance of public health problems and on ecological perspectives that attend to multiple determinants of health.
7. Involve systems development in a cyclical and iterative process.
8. Disseminate results to all partners and involve them in the wider dissemination of results.
9. Involve a long-term process and commitment to sustainability.

Examples of how these were operationalized in our five CNPC are presented in Table 1.

SUMMARY OF MAJOR POINTS

IRBs need to continue being diligent in protecting research participants from possible harm. Still, we also are obliged to take seriously the ethical implications resulting from not conducting research in disparate communities, namely, "sins of omission." We believe that CBPR can serve as a resource for the development and evaluation of new guidelines for community risk and beneficence. These guidelines, in turn, will contribute to more sophisticated and balanced assessments of the relative benefits and costs to individuals and the wider community in which they live that may be associated with specific research proposals.

Future guidelines should be based on the nine principles of CBPR. Table 1 provides examples illustrating the kinds of things that reviewers might want to consider when evaluating adherence to these principles. When the USC team proposed its first community-guided diet and physical activity intervention trials more than 10 years ago, it was virtually impossible to obtain approval from IRBs accustomed to

Table 1. Examples of Operationalizing CBPR Principles in CNPC Research

Principle	ʻImi Hale—Native Hawaiian Cancer Network	South Carolina Cancer Disparities Community Network	Alameda County Network Program for Reducing Cancer Disparities	WINCART: Weaving an Islander Network for Cancer Awareness, Research and Training	Kansas Community Cancer Disparities Network
Recognize the community as unit of identity	Native Hawaiian and Pacific Islanders have poor cancer survival and limited access to care.[21]	African Americans, as a group, have high cancer incidence and poor survival,[22–26] but very high church attendance.[27]	Alameda County Health Department identified colorectal cancer as an issue in the African-American community.[28,29]	WINCART's Let's Move! program was spearheaded by a nonprofit that serves as the COP lead for the WINCART CNPC.	Rural dwelling Latinos in towns of southwest Kansas and American Indians on reservations in northeast Kansas.
Build on strengths and resources of the community	The cancer patient navigation training and intervention built on Hawaiian value of *kokua* (helping one another) and the Hawaiian tradition of *hoʻokele* (navigating) as a metaphor for navigating the rough waters of the complex and confusing cancer care system.[21,30,31]	This effort tapped into the strength of a rapidly expanding movement that recognizes the connection between spiritual and physical health that, in turn, extends from the deep religious roots of the civil rights era.[27,32–34]	The Church of God in Christ is a spiritual and civic resource. Similarly, Afghan CBOs are a center piece for the Afghan community. Each program builds on spiritual and community resources.[28]	The program targets Pacific Islander churches and social groups that comprise the primary cultural and community resources for Pacific Islanders on the continental United States.	Work with community leaders to identify and train *promotores* (Latinos). Work through tribal councils to begin, pilot test, and tailor projects.
Facilitate collaborative, equitable partnership in all research phases through an empowering and power-sharing process that attends to social inequalities.	Native Hawaiian patients, family supporters, outreach workers, and providers participated in the design, testing, and implementation of a 48-hour navigation curriculum and programs.[21]	This project entailed refining and implementing the diet and physical activity intervention, which was designed by a team of community and academic partners. It culminated in hiring church members to serve as CET members.	Community advisory committees have played a very important role in the development of research, pilot study and outreach projects. The community partners have their own budgets.	Let's Move! was informed by a CBPR study of physical activity and obesity among Pacific Islander young adults.[35]	Work with CABs and engaged community members in both regions to continually adjust research and service activities.
Foster co-learning and capacity building among all partners.	Cancer care providers statewide served as pro bono faculty for the program providing training and expertise. Trainees gained skills in 14 competencies and returned to the program as faculty for future trainings and continuing education sessions. A navigation peer network has been formed.[21,30,31]	Designing the intervention trial required teaching and learning on the part of all partners. CET members obtained valuable skills that are now used in the dissemination phase. Congregants learned about diet and physical activity in relation to stress.[36]	Community members and the research team learned of the high prevalence of family histories of breast and ovarian cancer among Afghan women. Members of the research team also learned that Afghan men, in their traditional role of gatekeepers, can play an important role in facilitating breast cancer screening.	Program champions were identified in each Pacific Islander church/social group, and trained on using Let's Move! to increase physical activity among members.	Train *promotores*. Hire CBPR team members from the American Indian community.

table continues

CAB, community advisory board; CBO, community-based organization; CBPR, community-based participatory research; CET, church education team; CNPC, Community Networks Program Centers.

Table 1. *continued*

Principle	‘Imi Hale—Native Hawaiian Cancer Network	South Carolina Cancer Disparities Community Network	Alameda County Network Program for Reducing Cancer Disparities	WINCART: Weaving an Islander Network for Cancer Awareness, Research and Training	Kansas Community Cancer Disparities Network
Integrate and achieve a balance between data generation and intervention for the mutual benefit of all partners.	Patient satisfaction surveys have provided data for program adjustment and improvement. An annual survey of trainees and working navigators has informed continuing education. Community health centers and hospitals have established cancer patient navigation positions.[30,31]	The dual desire for methodologic rigor and community service helps to ensure community beneficence, and resulted in high rates of participant recruitment and retention to the trial.[37]	Results of the outreach program have led to the refinement of health programs for colorectal cancer in the wider community provided through Alameda Health Services.	Let’s Move! is being used to integrate physical activity into ongoing social activities of Pacific Islander organizations.	Conduct extensive service activities (primarily health fairs and direct care services) alongside research.
Focus on the local relevance of public health problems and on ecological perspectives that attend to multiple determinants of health.	Training has proved relevant to cancer patient navigation in both the clinical and community settings. Navigators address barriers that limit access to timely cancer care. In a randomized controlled trial on Molokai, cancer screening prevalence improved significantly in the navigated group.[30,31,38]	Although the immediate goal was to improve individual health-related behavioral choices, the community always expressed a desire for a broader focus that includes economic development, social justice, environmental pollution, and the role of minor race-specific genetic differences that could increase disease risk.	The Afghan breast cancer program has led to the establishment of an overall health program for Afghan men.	Let’s Move! was evaluated for changes in individual behavior, organizational supports and policies.	Work with local safety net providers and other key stakeholders (local churches, Mexican Consulate, Headstart programs) to address wide ranging needs.
Involve systems development in a cyclical and iterative process.	Training curriculum, methodology, and implementation were developed in response to call to action from providers serving Native Hawaiians and Pacific Islanders, and these providers continue to be involved in navigation research and development.[21]	The Community Advisory Group began the process of study refinement and implementation, a task later assumed by a CAB established solely for the research project. Cross-talk between the CAG and CAB was supported in meetings and web presence.	Community advisory committees have been actively involved in boththe main research and pilot projects as well as our outreach programs.	Intervention included phases for data review, materials development and pretesting, implementation and evaluation before launching webinars for larger scale dissemination.	Iterative work with CABs from each community, interim reports to tribal councils, ongoing work with engaged *promotores*.

table continues

CAB, community advisory board; CBO, community-based organization; CBPR, community-based participatory research; CET, church education team; CNPC, Community Networks Program Centers.

Table 1. *continued*

Principle	'Imi Hale—Native Hawaiian Cancer Network	South Carolina Cancer Disparities Community Network	Alameda County Network Program for Reducing Cancer Disparities	WINCART: Weaving an Islander Network for Cancer Awareness, Research and Training	Kansas Community Cancer Disparities Network
Disseminate results to all partners and involve them in the wider dissemination of results.	Information on the navigation training program, client satisfaction, and patient and system change outcomes has been disseminated through 5 publications[21,30,31,38] and > 50 local and national presentations. Community co-authors were involved in 4 of the 5 publications. The curriculum has been adapted by community colleges in Hawai'i and by programs in the Western United States, and the Pacific.	Comments were solicited as results became available; community members co-presented study findings; and community members were involved as co-authors on scholarly manuscripts.[19,39–41] CAB members were intimately involved in writing a subsequent dissemination and implementation (R01) grant that was funded by the National Institutes of Health. PAR–13–055: Dissemination and Implementation Research in Health.	The Church of God in Christ and Afghan community organizations play an active role in the dissemination of the screening promotion programs. Videos are being developed for Afghan project, which will be disseminated on Afghan television, promising a global audience.	Two webinars disseminated the Let's Move! tool kit to organizational representatives in Utah and Washington.	Community research forums planned and conducted, *Promotores* and tribal health centers involved in dissemination.
Involve a long-term process and commitment to sustainability.	17 formal cancer patient navigation positions have been established in Hawai`i hospitals, and 87% of all graduates report using cancer patient navigation skills in their current jobs as community outreach workers and health care providers. Hawai'i state cancer plan includes 4 specific cancer patient navigation goals to promote equitable access to care.	A 501c(3) CBO was formed that acts as a formal voice for the community, has four paid staff, and functions as a subcontractor to the university for the dissemination and implementation phase of the diet and physical activity intervention.	Colorectal outreach project has involved the fostering of community capacity through Alameda Health Services and Highland Hospital to provide removal of identified polyps. In addition, lay health workers and community health navigators have been trained to serve the Afghan community.	A proposal has been submitted to evaluate Let's Move! using a quasi-experimental community-based design.	New funding obtained through *Ventanillas de Salud* program to support continued health fairs. Agreements in place to support continued health program delivery on reservations.

CAB, community advisory board; CBO, community-based organization; CBPR, community-based participatory research; CET, church education team; CNPC, Community Networks Program Centers.

reviewing clinical trial protocols. Clinic-based IRB members found it difficult to understand the need to accommodate protocol changes, despite the fact that community members expressed their desire to make these trials available and to be allowed the opportunity to modify them as exigencies and new opportunities arose. Difficulties in dealing with hospital-based regulatory impediments provided a major impetus to expand thinking to encompass direct community involvement in designing and conducting research studies. Since that time, we have had extraordinarily positive experiences with the IRBs of record for these CBPR studies. However, IRB members need to be educated continuously on their need to advocate for community beneficence, as well as individual beneficence.

The examples provided in Table 1 illustrate how effective the CNPCs can be with respect to conducting authentic CBPR in communities at very high risk of cancer-related health disparities. As these developments occur, the corollary will be to work with our communities to educate our respective IRBs in considering principles of CBPR in their review of applications to conduct biomedical research. In the process, we will acquire a heightened awareness of the difference between meeting the minimal standards of protecting individual human subjects from harm and the larger imperative to avoid "sins of omission." This also holds the promise of rectifying the pervasive imbalance that has occurred because of well-intentioned attempts on the part of IRBs to limit personal risk and institutional liability.

The CNPCs are committed to serving high-risk populations. The communities we serve expect us to make material differences in improving their situation in general and reducing cancer-related risk factors in particular. Indeed, every grant submitted to the National Institutes of Health requires a section on "public health relevance." We need to be held accountable for delivering on this promise. By being held accountable for our ethical responsibility to partner with communities to reduce cancer-related health disparities, we can reduce "sins of omission." Many practical benefits can ensue, including much higher-than-average rates of study recruitment[18] and biospecimen collections from populations that bear the brunt of health disparities.[19] These populations are often characterized as "hard to reach," but our successes demonstrate that they are rather "hardly reached" because their knowledge and experiences are not generally valued and included in the traditional research process.

Our ability to conduct highly relevant studies with remarkably high rates of recruitment, compliance, and adherence[18] to protocols highlights our ability to address this imbalance through our willingness to engage positively and meaningfully with both the IRBs and our community partners. This is in contrast to working with the primary aim of avoiding risk to individual study participants. We believe that working toward this higher ideal of service to high-risk communities would help to remediate many of the problems that the nation is facing in reducing health disparities.

Results obtained through the use of CBPR practices recognize the unique strengths and perspectives of community partners striving together to achieve social justice and sustainability while decreasing the burden of health-related social disparities. This research allows us to expand the concept of beneficence to include "community beneficence" and to illustrate how avoiding "sins of omission" leads to profoundly better research and health outcomes. In conducting this CBPR, not only have we engaged meaningfully with our community partners, but we also have deepened the understanding between the research team and our IRBs. Our working relationships are now much more conducive to designing and conducting studies that really matter—both to our communities and to advancing the science of health disparities. Clearly, the principles of transdisciplinary and interdisciplinary research being promoted so heavily by the National Institutes of Health are consistent with principles of CBPR.[20] So, while we are serving our communities by being responsive to their stated needs, we also are advancing the science in ways that would be virtually impossible if we were content to ignore them.

With the increased credibility of CBPR to inform and guide study development and implementation,[4,14,20] we may be at a point in history where we will be able to use resources to increase the relevance of research aimed at reducing cancer-related health disparities. In addition to focusing on the broad issues associated with conventional reduction in research risk and the more complicated "sins of omission," it is necessary to review the standard procedures used by IRB committees to monitor research in the field and laboratory. Requested modifications by investigators are viewed as the exception rather than the rule. If there is a deviation, there is, yet again, the potential for increasing individuals' risks from research participation for which the IRB will be on heightened alert. However, in CBPR, the assumption is that researchers and community members will collaborate in the design and execution of a project. Rather than the exception, it is the norm that projects evolve as a result of this collaboration and partnership. As the prevalence of CBPR projects continues to grow, the traditional IRB monitoring procedures may delay and disrupt the partnership, and perhaps undermine the research, thus increasing the possibility of another "sin of omission."

RECOMMENDED GUIDELINES AND SAFEGUARDS FOR COMMUNITY RISK AND BENEFICENCE

Guidelines should include that the project:

1. Addresses an issue that is identified by a diverse and representative mix of community leaders and residents, in collaboration with researchers, as adversely affecting the health and well-being of the community. This can be a documented health disparity, based on disease incidence, stage of disease, and quality and duration of survival. It can also be an issue or circumstance that adversely affects access to primary prevention and quality of life (e.g., access to healthy food outlets and means to engage in physical activity in a safe environment), as well as other screening, diagnostic, treatment, and rehabilitation services. This collaboration between community members and researchers should be based on a consideration by all of the stakeholders of the community's resources and strengths as well as its limitations and challenges.
2. Is based on past and current collaboration with community members.
3. Is monitored and evaluated on a regular basis by members of the community.
4. Includes a plan for sustaining a successful project.

Recommended Safeguards

1. That the NCI convene a national conference representing all of the relevant stakeholders to consider these issues in more detail.
2. Perhaps during, and certainly after, this conference, design and administer a systematic survey to collect information from IRBs, researchers, and community stakeholders on their thoughts and experiences regarding human subject procedures to better understand the causes and consequences of "sins of omission."

It is important to emphasize that we are not recommending that all research approaches be transformed to CBPR. Rather, we contend that CBPR principles and guidelines can lead to a more informed, sophisticated, and balanced consideration by IRBs of whether individual risks are reasonable in relation to anticipated risks and benefits to the wider community.

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