



“It’s Like Tuskegee in Reverse”: A Case Study of Ethical Tensions in Institutional Review Board Review of Community-Based Participatory Research

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Community-based participatory research (CBPR) addresses the social justice dimensions of health disparities by engaging marginalized communities, building capacity for action, and encouraging more egalitarian relationships between researchers and communities. CBPR may challenge institutionalized academic practices and the understandings

that inform institutional review board deliberations and, indirectly, prioritize particular kinds of research.

We present our attempt to study, as part of a CBPR partnership, cigarette sales practices in an inner-city community. We use critical and communitarian perspectives to examine the implications of the refusal of the university institutional

review board (in this case, the University of California, San Francisco) to approve the study.

CBPR requires expanding ethical discourse beyond the procedural, principle-based approaches common in biomedical research settings. The current ethics culture of academia may sometimes serve to protect institutional power at the expense of community

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COMMUNITY-BASED

participatory research (CBPR) is a way to identify and address health disparities^{1,2} by engaging marginalized communities, building capacity for action, and ending relationships of dominance in



favor of partnerships working toward health, equality, and parity.³ Public agencies and foundations have developed research funding mechanisms that encourage CBPR,⁴ and multiple obstacles to successful CBPR have been acknowledged.^{5,6} However, little has been written about how CBPR may fundamentally challenge institutionalized academic understandings that shape ethical deliberations, define research and research subjects, and indirectly prioritize clinical trials and other biomedically oriented studies.

For this case study, we drew from communitarian ethics and critical social perspectives to analyze ethical tensions that arose when our CBPR study of single-cigarette sales was denied institutional review board (IRB) approval. We analyzed how an individual-focused, biomedically oriented approach to IRB review of CBPR may have the effect of protecting institutional power structures and perpetuating inequities while precluding research aimed at changing community environments. There is a need for expanded dialogue about the distinctions between individual behaviors and institutional practices, the practical nature of risk calculations, and the potential for institutional conflicts of interest in risk-averse academic environments.

COMMUNITY-BASED PARTICIPATORY RESEARCH

CBPR emphasizes both process and outcome and includes community participation at all

stages.^{5,7-9} CBPR regards the community as a unit of identity; focuses on community strengths rather than needs; envisions research as a collaborative partnership between academic researchers, community members, community organizations and others; integrates knowledge and action to create change; promotes co-learning among all partners to address social inequalities; incorporates cyclical processes; considers health from positive ecological perspectives; and disseminates knowledge to all partners.⁵ CBPR is often conducted in communities where there are social injustices and seeks to make changes in policy and the environment rather than changes in individual behavior. The aim is to enhance community capacity, often through policy-related studies.³ However, such community-level approaches may meet unanticipated obstacles.

CASE STUDY: THE PHAT PROJECT

Background

The Protecting the 'Hood Against Tobacco (PHAT) project is theoretically grounded in the work of educator Paulo Freire,^{10,11} who emphasized dialogue and reciprocity. In this approach, projects belong to the community: *educators* (in this case, academic researchers) are equal *learners* in a respectful partnership. CBPR requires that academics cultivate cultural *humility* by acknowledging that community members are the experts on what it is like to live and work in their neighborhoods.^{12,13}

CBPR demands explicit attention to issues of power and knowledge sharing.^{14,15}

Establishing a Community Partnership

The PHAT project was initiated in 2002 to address tobacco use in 2 geographically contiguous and predominantly African American neighborhoods in San Francisco, Calif. It involved the University of California, San Francisco; the San Francisco African American Tobacco Free Project; and the Bayview and Hunter's Point neighborhoods. A previous community study reported that 48% of Bayview and Hunter's Point households included smokers, and 55% of African Americans surveyed "believe that health and illness are entirely beyond their control" compared with 15% of Whites.^{16(p23)} This suggested that CBPR approaches that emphasized empowerment might be constructive.

The PHAT project was funded by the California Tobacco-Related Disease Research Program. The project began with exploratory focus groups conducted among community members to assess their responses to tobacco industry activities as revealed in internal corporate documents.¹⁷ Residents who were shown documents about the industry's targeting of African Americans felt moved to share them with others and to consider smoking cessation. To build on this work, we established a community partnership to discuss ways to address tobacco-caused harm. Some focus group participants volunteered

to become community research partners.

To learn more about community resources, perspectives, and ideas, we invited focus group volunteers to help design the project. They identified key community leaders and groups with whom we should meet. During a town hall meeting cofacilitated by community research partners, we provided information about tobacco's disproportionate effects on African Americans and we explored attendees' perceptions about resources and community-level obstacles to smoking cessation. We also conducted a community survey. Among the obstacles to cessation mentioned frequently by community members was the availability of single-cigarette sales in the neighborhoods' many convenience and liquor stores.

Single-Cigarette Sales

Single-cigarette sales were viewed as a problem because single cigarettes were readily available and their reduced unit price made it harder for people to sustain cessation. Community members also felt that such sales increased minors' access to cigarettes. Single-cigarette sales, according to community members, were ubiquitous. Most community members who discussed the issue with project staff did not initially realize that state law prohibited sales of single cigarettes. Apprised of this fact, community partners decided to conduct a systematic assessment of the proportion of convenience stores in the community that sold single cigarettes in violation of state law.



Academic and public health partners worked with community members to modify an instrument used in previous studies of store signage. Community members identified the proposed sample by walking the neighborhood and mapping all convenience/liquor stores within community-specified geographic boundaries. IRB approval for an observational study was obtained; this included noting tobacco advertising density, smoking activity, and store sales practices, including single-cigarette sales.

After the protocol was approved, however, the community research partners (all adults) discussed it further with the academic partners and decided that observation alone was inadequate. Some stores were in areas where loitering could be dangerous, and sometimes there was a long time between sales. They argued that it was impractical to wait around to watch for single-cigarette sales. Instead, they wanted to make a single-cigarette purchase attempt and document the result for each store. We returned to the IRB with a modified protocol.

Seeking IRB Approval

Because sales of single cigarettes were illegal, we proposed a procedure to ensure that no individual store, store clerk, or store owner could be identified from the data. This included assigning alphanumeric codes to each store for data collection and keeping the key separate. We promised to report findings only in the aggregate and to not identify individuals or stores by name in any

report. We believed (and still believe) that this procedure was an ethical approach to answering a research question of substantial importance to this community. However, the university IRB did not agree.

The IRB refused to approve our modification for several reasons. First, they did not seem to appreciate the status of our community research partners, who were initially seen as subjects rather than as researchers. This misunderstanding led the IRB to believe that academic researchers were using money to solicit community partners to “commit an illegal act” rather than paying them as research partners. We clarified the relationship with our community research partners in a written response to the IRB.

We also cited relevant sections of the state penal code and pointed out that it is not illegal to *buy* a single cigarette, only to sell them. We noted that, according to our community partners, buying a single cigarette was common neighborhood practice and was an act that any community member could undertake without legal consequences. However, it was illegal for a store to *sell* a single cigarette, although the law virtually was never enforced.

The IRB also argued that trying to buy a single cigarette would constitute “entrapment” of store personnel. In our response, we pointed out that store owners and managers were already responsible for observing state laws as a condition of retail licensure and that store owners would be free to decline and explain that such sales were prohibited.

Referral and Appeal

Upon learning that we wished to appeal, the IRB referred us to the university’s risk management department, which seemed uncertain about its role in the matter and referred us to the university’s legal department. After considerable delay, the legal department informed us that it could not approve any university “involvement in illegal activity,” but it noted that it could find no relevant legal authority or policy that prohibited the research activity we had proposed, because asking to buy a single cigarette was not illegal. After extensive research, the legal department determined that the IRB was the final authority and suggested in its written response to the IRB that the potential danger of violence to our community research partners might be a risk management issue for the university if the researchers were harmed while in the stores. The IRB again denied approval.

PHAT project staff, including academic and community coprincipal investigators and the project director, appealed the decision to the full IRB and made a personal appearance to argue the case. The local district attorney’s office provided—and we submitted—a signed grant of immunity that certified no store owner or clerk would be prosecuted for study-related activities. This, we argued, eliminated potential legal risk for store personnel. We produced documentation from the state tobacco control program, which used (and is mandated under federal law to use) identical procedures

for assessing tobacco sales activities that involved minors. We submitted relevant sections of the California Penal Code that showed buying a single cigarette was not illegal, and we submitted the state attorney general’s written opinion that asking to buy a single cigarette was not considered to be entrapment. We also provided papers published in top peer-reviewed journals that had used the same procedures.^{18–20} Our funder’s project officer wrote a letter on our behalf that supported the project and noted that similar studies had been funded and conducted with IRB approval.

Additionally, we argued that it was important for the university to respect the community’s knowledge and skills in this type of research and that—as community members had forcefully pointed out—it was impractical (and could in fact be even more dangerous) to conduct the study solely with the observational methods that had been originally approved. We produced relevant sections of the federal Code of Regulations that addressed research with human subjects to show the IRB that it did have the latitude to approve such a study. Our primary argument was that store personnel were not research subjects or units of analysis: we were not going to collect data on the *individuals* who did or did not sell cigarettes, we were only going to note whether we were able to purchase a single cigarette at a particular geographic location. However, following vigorous discussion, the



IRB denied for the third and final time our modified research proposal.

IRB Concerns

The IRB wrote that a human subject is “a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual.” While the PHAT team viewed the unit of analysis and research interest as the store, the IRB viewed the clerks as research subjects and argued that we would be prompting them to commit an illegal act without their consent. Furthermore, the IRB did not believe that the anticipated benefits of the study justified what they still saw as a risk to store personnel—however, the precise nature of that remaining risk, given our protection measures, was never specified. IRB members suggested we do a different study and proposed ethnographic observations at a sample of stores, a survey, or a survey of youths who patronized stores, all of which our community partners had already considered and rejected as dangerous or unfeasible.

Community research partners felt betrayed by the IRB’s rejection. In their view, the IRB chose to protect “community predators” over the health of the community itself. This seemed a bitter irony. “It’s like Tuskegee in reverse,” commented one community member, referring to the infamous research in which African American men with syphilis were studied—but not treated—long after a definitive cure for the disease had been discovered.^{21,22}

After extensive discussions about the meaning and implications of the IRB refusal, the community partners decided temporarily to stop working on the PHAT project and do the study independently. As interested citizens, they required no one’s approval before trying to buy a single cigarette in their local stores; thus, there was no practical obstacle to continuing on their own. This decision meant that while community members’ individual knowledge about single-cigarette sales would be enhanced, their findings could not be published or reported as a finding of the PHAT project, which would limit dissemination of this new knowledge and minimize community researchers’ ability to use it to increase community awareness and create change. It also meant that community partners would not be able to benefit from the research expertise of the academic investigators, who were obviously prohibited from assisting with any research disapproved by the IRB. Ironically, this also meant that the university-obtained waiver of prosecution and other safeguards would not apply, potentially exposing stores and clerks to greater legal risk.

ANALYSIS

From a biomedical ethics perspective that is based on principlism and proceduralism, the IRB’s decision appears reasonable, even necessary. From this perspective, store personnel were unambiguously individual autonomous subjects of research;

thus, their consent must be sought. The risk for harm involved not only potential legal implications, but also the consequences of deception. In the IRB’s view, physical risks (e.g., assault) might also have resulted from allowing research partners to engage in what IRB members saw as a questionable—though legal—activity.

Alternatively, this case might be evaluated with a more communitarian and critical approach. Critical community-oriented educators try to “problematize” taken-for-granted assumptions to highlight contradictions and to promote empowerment and positive social change.^{10,23} Such an analysis raises at least 3 questions. Did this proposed study in fact constitute human subjects research? What were the specific risks involved, and for whom were they real risks? Did potential institutional conflicts of interest influence the decisionmaking?

Did This Study Constitute Human Subjects Research?

The US Department of Health and Human Services’ *IRB Guidebook* says that human subjects are “individuals whose physiological or behavioral characteristics and responses are the object of study in a research project.”²⁴ But the object of our study was to assess *institutional practices* within a community, not the responses of individuals within those institutions—a distinction the IRB dismissed as irrelevant but that we believe is worthy of further consideration because of the increasing interest in CBPR and the increasing influence of global

institutions on local communities. By their very nature, institutions have distinct legal and social identities that are something other than a collection of individual legal and social identities, and institutional practices transcend and do not necessarily equate with individual beliefs or behaviors.

Admittedly, the identity of the research subject can be ambiguous in CBPR.²⁵ Because CBPR can be conducted using many different methods, community members may be regarded as researchers or subjects. Still, just as data acquired in any research are open to multiple interpretations, whether or how we construct a research subject is likewise an interpretive decision. Freirean approaches to research seek to break down class and role barriers with community-level inquiry that challenges existing power relationships. The notion of the individual subject may be especially problematic in CBPR informed by Freirean approaches, because its basic assumptions about where inquiry begins are fundamentally different from those of traditional science. From this perspective, which also informs communitarian ethics, the individual subject is not the ultimate focus of ethical thinking. Rather, human beings are deeply and fundamentally situated within a social matrix, and ethical deliberations must first consider that matrix and its meaning.²⁶

What Were the Risks?

Single-cigarette sales are a real concern for inner-city communities coping with multiple



socioeconomic and health disadvantages. Selling single cigarettes encourages relapse among smokers trying to quit, and these cigarettes are more readily available to youths.¹⁹ Single cigarettes are sold without required warnings and at excessive per-stick prices, which further impoverishes low-income smokers.²⁷ African American and Latino youths are more likely to be sold single cigarettes compared with White youths.^{20,28} Single-cigarette sales exemplify an institutionally sustained practice that has disproportionate effects on socioeconomically and racially non-dominant groups.¹⁸

In the IRB's view, our proposal's potential risks included exposing illegal behavior and eliciting feelings of being deceived or fears of entrapment. This appraisal is consistent with traditional biomedical ethics and its focus on individual autonomy, privacy, and agency. However, from a more socially oriented ethical perspective, it can be argued that these risks were negligible compared with the potential benefits to the community of acquiring and acting upon the knowledge the study would generate, especially given the guaranteed immunity from prosecution. Ethicists already consider it reasonable that concern for individuals may become secondary to public health priorities during public health emergencies.²⁹ Although the effects of tobacco on poor communities of color are slow to emerge and thus are not usually regarded as emergencies, the consequences may over time be equally devastating.

Did Institutional Conflicts of Interest Influence Decisionmakers?

The actions and behaviors of individuals and groups are associated with sociohistorical structural and cultural factors that may simultaneously reinforce and obscure oppressive power relationships.^{30–32} Race/ethnicity, class, and gender are part of this configuration, and how individuals and groups act (or do not act) to further their interests or to change oppressive structures is related to their social position. Most academics and legal analysts are socially positioned in advantageous ways that may blind them to the power dynamics embedded in their ethical decisionmaking.³³

An intriguing aspect of this case was the concern with risk management. The early IRB referral to the university's risk management department, whence we were referred to the legal department, suggests that the project was regarded in some way as a legal risk and a financial threat to the university. The subsequent legal analysis—which opined that community research partners might be hurt (and thereby possibly put the university at an economic or legal risk because it would be considered a university project)—supports this interpretation. This raises the question about whether such concerns represent an institutional conflict of interest, because the decision about whether the study was ethical appears to be associated with institutional self-protection.

The suggestion that community partners might be attacked seemed odd, because they live

nearly and visit these stores as part of their daily lives. Why a shopkeeper or bystander would attack someone for asking to buy something that is reportedly sold on a regular basis was unclear, and this concern was unvoiced when the IRB approved the previous observation-only proposal. Would such a fear have been raised if the proposed study was to be conducted in a wealthy White community? This anxiety perhaps reflected deeply embedded assumptions about race/ethnicity and class behaviors in addition to insurance or litigation risks associated with working in poor neighborhoods.⁶ Class and intellectual culture may influence moral analysis more than many academics assume or want to acknowledge.²⁶

The multiple-referral response to our project suggests an institutional avoidance strategy—a fruitless search for clear rules that could be used to deny approval without having to address the complexities of the case. Researchers who serve on IRBs typically have multiple demands on their time. Studies that fit neatly into the biomedical ethics model are perhaps more welcome because they do not require so much additional deliberation.

If ethical decisionmaking is the determination of what is right and good, it is important to consider—from a practical rather than abstract standpoint—whose rights were protected by the IRB's decision and what good was achieved. While the decision ostensibly protected the storekeepers, it actually had the practical effect of rendering them

more vulnerable, because when the community research partners decided to do the study on their own, the waiver of prosecution no longer applied. Although one could argue that it would be better to realize that the study was wrong and should not be conducted at all, community members recognized that they did not require the formal imprimatur of “research” to study their community, a fact known to the IRB.

The IRB also sought to protect community research partners from theorized attacks. However, there was no logical reason—and no evidence was ever offered—as to why this study imposed a serious risk over and above the risks our community partners incurred every day in their neighborhoods.

However, the IRB decision did protect the institutions involved. The decision protected the university from a possible risk management issue, and it protected the stores as entities, whose practices could continue. Ultimately, the decision protected the interests of the tobacco industry and other industries whose representatives wink at illegal cigarette sales.

CONCLUSIONS

IRBs are critically important for evaluating and managing the risks inherent in research and for protecting the human rights of volunteers. However, as this case illustrates, CBPR may require an expansion of ethics dialogues beyond procedural, principle-based approaches that are grounded in individual autonomy. No single voice captures the whole of



bioethics, nor does bioethics capture all that is important for ethical decisionmaking.³⁴ If we are to encourage CBPR, it may be helpful to educate IRBs about other ethical traditions, such as communitarian ethics.³⁵ Including a CBPR expert or ethicist with a communitarian ethics background in CBPR reviews also might be helpful. Finally, we may need to consider how the current ethics culture of academia may have the effect of protecting institutional power at the expense of community empowerment.³⁶ ■

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Contributors

All authors originated ideas, developed the case study, interpreted findings, and reviewed drafts of the article. R.E. Malone completed the critical analyses and wrote the article.

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Human Participant Protection

The initial CBPR project was approved by the University of California, San Francisco committee on human research.

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