IRB Challenges in Multi-Partner Community-Based Participatory Research

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Abstract

IRB Challenges in Multi-Partner Community-based Participatory Research

We report here on the challenges of obtaining institutional review board (IRB) coverage in a multi-partner, community-based participatory research (CBPR) project that entails household air and dust sampling as well as biomonitoring; reporting of aggregate study results through peer-reviewed publications; media outreach and other dissemination strategies; and reporting of individual results to each study participant. Individual-level reporting raises unique challenges for some academic IRBs, many of which are not accustomed to such disclosure. It is also difficult for academic IRBs to approve research projects that involve multiple partners, especially when one or more of the collaborators are community organizations that are principal investigators that do not have their own IRB. We discuss how we have navigated our IRB strategy and show how addressing these IRB issues is becoming increasingly important, as environmental justice and environmental health activists increasingly use individual report-back in their research.

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Research modes, based on community-based participatory research (CBPR), are increasing faster than routine informed consent practices have kept up. Institutional review boards (IRBs) now have to reconsider underlying assumptions informing the ethical review of research, due to several recent trends: (a) increasing community or lay involvement in research, including leadership roles in directing research and data collection; (b) more awareness of the potential for community or collective risks in research; and (c) rising demand for and occurrence of disclosure of individual results to research participants. We report on the challenges of obtaining IRB coverage for a research project that faces each of these issues: multi-partner research, community participation in data collection, a principal investigator based in a community-based organization, and a protocol for reporting individual and aggregate study results. It is difficult for academic IRBs to approve multi-partner research projects, because universities may believe they risk giving up some control and oversight to researchers outside their sphere of authority. When the community group is the principal investigator, the group's leadership of the project may complicate a university's role in human subjects protection oversight and responsibility; concerns may also be heightened when one or more participating organizations lacks its own IRB.

We report here on our specific experience with an ongoing research collaborative while also addressing concerns that may apply to CBPR projects generally. Our research collaborative involves a partnership between three institutions: Brown University, Silent Spring Institute, a non-profit research organization based in Massachusetts that studies links between the environment and women's health, and Communities for a Better Environment (CBE), an environmental justice organization in California that combines organizing, advocacy, litigation,

and research. Our research collaborative seeks to connect environmental justice organizing with research and advocacy on environmental links to breast cancer, and entails environmental sampling of household air and dust, as well as biomonitoring in two study sites-- Cape Cod, Massachusetts and Richmond, California. The project reports aggregate results through peer-reviewed publications, media outreach, and other dissemination strategies. The project also reports individual study results to each study participant, which raises unique challenges for academic IRBs, many of which are not accustomed to such disclosure. While Brown University's IRB presented some initial obstacles to our report-back approach, it was not averse to our protocol and ultimately facilitated an effective human subjects protection oversight strategy for the entire collaborative.

To address our unique challenges, we consulted with other colleagues collaborating on CBPR projects. Our data come from those consultations, our own experiences, and from participants at a workshop we led at the National Institute of Environmental Health Sciences Environmental Justice Program grantees conference in Talkeetna, Alaska, on September 20, 2005. Uncited material stems from our interviews, conversations, and observations.

CBPR projects are often counter-approaches to traditional research strategies that unilaterally study communities without necessarily giving them any resources in the way of capacity-building, training, or data in a form that can be leveraged to support organizing or promote policy change. Also, CBPR projects challenge the notion that research is a value-neutral enterprise, and instead promotes research with immediate application. Further, the community groups that engage in CBPR sometimes seek collective rather than individual rights protection. CBPR projects almost always come with a multi-partner format that includes non-academic and non-medical organizations, and hence differ from the multi-site research common to much

biomedical research, which means that IRBs cannot fall back on routine multi-center approaches. Community-based organizations in CBPR partnerships have different views of research, and also may lack familiarity with IRB processes.

Addressing IRB issues that are specific to CBPR projects is becoming important as environmental justice and health activists are engaging more directly in the scientific enterprise of collecting and analyzing individual-level human data that can inform environmental policy-making (Morello-Frosch et al. 2006; McCormick, Brown, and Zavestoski 2003; Shepard et al. 2002). Many community-academic collaboratives that are addressing environmental health questions now conduct individual report-back similar to our project, which requires a reformulation of informed consent. Yet this report-back strategy poses a unique challenge. While we support ethical research that upholds the rights and self-determination of research participants and their communities, we must also highlight critical short-comings of established research ethics procedures. Our critique suggests an alternative view of informed consent and ethical review that transcends formulaic procedures, and provides a way to empower communities and social change organizations to fully participate in science and human subjects protection.

Background

There are increasing pressures to amplify and extend the three major principles of the Belmont Report: respect for persons (often termed “autonomy”), beneficence, and justice. Three emerging trends in the conduct of research challenge those existing principles and the procedures that have arisen to implement them. First, in terms of respect for persons, there is an increasing awareness of potential for community or collective risks associated with research. This makes it necessary to adjust the principles and procedures of ethical review. Second, in terms of

beneficence, community activists have redefined who gains and loses from research, and hence another shift requires IRBs to alter how they define "research," who is a "researcher," and in what contexts can research take place. Once IRBs open themselves to the possibility of accepting communities as not only sites of research but also as viable researchers, they can alter procedures in order to increase community involvement in human subjects protection. This would include recognizing community groups as principal investigators or as leaders in project management and data collection. Procedural changes may also involve, as with our project, adapting IRB oversight to research collaborations with community-based organizations traditionally outside the university IRB's purview. Third, in terms of justice, activists have redefined notions of justice and fairness. Hence, to appropriately provide IRB oversight of CBPR projects requires a shift in how IRBs oversee relationships between research participants and the data generated from their participation. IRBs need to reassess how they oversee situations in which participants seek access to, and full disclosure of, individual study results, a process that necessitates continued interaction between researchers and participants.

Who Should IRBs Protect – Individuals and/or Communities?

The Belmont Report guides IRBs to ethically protect individuals, and not collectives, beyond ensuring that underrepresented populations be included in study recruitment to the extent feasible (Weijer 1999; Levine 1988). Indeed, the recent requirement for inclusion of underrepresented groups (Food and Drug Administration 1997) is one example of updating that has occurred to the Belmont principles, and is testimony to the need for constant vigilance for updating of principles for human subjects protection. Yet, the focus of most IRBs in their efforts to ensure compliance with the Belmont principles emphasizes the protection of individuals in

biomedical or social science research. While these standardized and stringent review requirements were developed in response to a history of abuses of human subjects in medical and psychological research in the U.S. (e.g. the Tuskeegee syphilis study and more recently, federal radiation experiments), there is mounting concern that informed consent requirements have become too formulaic and inflexible. For example, social scientists have criticized the application of stringent informed consent procedures for very low risk, non-intrusive interview research, such as when interviewees are public officials with a legal mandate to reply to citizens' queries (Bosk and DeVries 2004). Hence, the principle of respect for persons has led to procedures which are often inappropriate impediments to research, while the principle of respect has not been appropriately extended to community-level protections and rights.

Some community advocates argue that research protections are not necessarily designed to protect community interests. IRB approval typically assesses privacy, confidentiality, and individual risks and benefits, but often does not assess whether proposed research is a good idea for the community. Indeed, many communities believe they are over-studied, yet often receive no direct collective benefits. Activists frequently argue that the dissemination of study results from research on their communities can have adverse impacts on a community, even if the rights and confidentiality of individuals are protected. A parallel example can be found in the realm of genetics research. If a particular group is found to have a genetic predisposition to a condition or disease, they may be directly or inadvertently stigmatized in either an individual or collective fashion. There is ample evidence of genetic discrimination by insurers based on genetic predisposition (Draper 1991; Billings et al. 1992; Lapham et al. 1996), and the UK specifically allows that by law (Dickson 2000). Scholars and advocates concerned with genetics and environmental justice fear that entire communities could be stigmatized as a result of group

labeling of genetic variation (Sze and Prakash 2004). This might involve their entire community being passed over for certain programs or benefits, or may simply have to overcome stereotyping that affects the quality of health care they may receive (Weijer 1999).

In more forward-looking approaches to IRB review and human subjects protection, communities convene their own research review boards to collectively assess whether proposed research is justified and whether it benefits the community (Quigley 2006). For example, the Navajo Nation maintains its own IRB to protect its people from research that would not directly help them (Sharpe and Foster 2002). Similarly, the citizens' organization that oversees research on residential exposures from the Fernald, Ohio, nuclear weapons plant will only permit researchers access to its records if there is a concrete benefit for the community, regardless of academic IRB approval (Gerhardstein and Brown 2005). Although an increasing number of communities now consent and oversee research, many communities are less able to do that due to their geographic dispersion, lack of political organization, capacity, or the authority to review research protocols (Weijer 1999). Academic IRBs reviewing research proposals on behalf of such communities need to understand how communities under study are constituted and organized, their communal needs and vulnerabilities, and governance and communication structures for disseminating research (Weijer 1999).

NIH rules were clarified in 1998 to ensure that IRBs have "knowledge of the local research context" and are competent in the review of protocols, and though one member of the IRB must be from outside the institution, there is no requirement for direct community representation (NIH 1998). Community representation on academic IRBs is usually representative of large, well-established organizations rather than grassroots groups, and may not demographically reflect the communities under study (Southeast Community Research Center 2003). While two 2001

reports from the Office of Human Subjects Research of NIH and the National Bioethics Advisory Commission delineate the need for expansion of community involvement in research beyond mere representation on IRBs (Dickert and Sugarman 2005), most pressure for deep community involvement stems from activist groups (Strand et al. 2003).

What is research? Who are researchers? Where does research take place? – Opening up possibilities for community-based research and community researchers

Another important issue for academic IRBs to consider is their definition of "research," who constitutes a "researcher," and in what contexts research can take place. These questions touch on all three Belmont principles: *respect* for persons extends to respect for communities; *beneficence* involves risk or benefit to the community; and *justice* involves a new sense of fairness and equity in who participates in research. Academic IRBs should familiarize themselves with increasingly prevalent CBPR methods (Strand et al. 2003). As federal agencies and foundations support more CBPR projects, they will need to give grantees and academic IRBs more guidance on how to address the unique issues that emerge from academic-community collaborations. Once IRBs accept the possibility of viewing communities as both the sites of research and as viable researchers, they can alter standard procedures for human subjects protection.. Procedural changes may also involve, as in our case, providing oversight to community-based organizations traditionally defined as outside the jurisdiction of the university-based IRB.

University IRBs are reticent to oversee the human subjects protection compliance for academic researchers' partner organizations outside the university. This is likely due to the fact that activist organizations sometimes openly merge research and activism, which is contrary to traditional academic concepts research. Conversely, community groups may resent what they

perceive to be unnecessary scrutiny of formal IRB procedures, since much of their work may involve outreach, organizing and advocacy, which they believe should be under their control. Academic IRBs may also define research differently than community-based organizations (CBOs). For example, CBOs routinely conduct evaluations of conferences they organize, in order to assess whether they are appropriately reaching their constituents. To an academic IRB, this routine practice might look like human subjects research requiring review. CBOs might view involvement in this as an intrusion on a routine process of a CBO seeking feedback from its constituency.

Despite the many real and potential obstacles to collaborative projects, some academic IRBs understand the unique circumstances inherent in CBPR work, and go out of their way to facilitate human subjects protection oversight. Still, in our consultations with other CBPR initiatives, we learned of only one case, other than ours, where the IRB of a major research university agreed to be the IRB of record for a CBO partner and PI in a community-academic research collaborative.

Who owns the data? – Facilitating return of data to study participants

To appropriately provide IRB oversight of CBPR requires a shift in how IRBs oversee the relationship between research participants and the data generated from their participation. This primarily involves the Belmont principles of beneficence and justice – communities want to make sure the research benefits them through the right-to-know process of individual report-back, and activists view this as a form of justice that can challenge existing inequalities of power. At issue here are both the ethics of reporting individual data, and the ethics of report-back given uncertainties about what the data mean.

With respect to the dimension of data ownership, IRBs need to reassess how they oversee situations in which participants desire access to and disclosure of their own study results. In some cases, this necessitates continued interaction between researchers and participants, a process that IRBs may be reluctant to allow and are poorly-designed to manage. If IRBs require review of ongoing communications with study participants, iterative rounds of approval may result in delays that undermine researchers' relationships with participants.

On its face, individual report-back may not seem relevant to community-level rights and confidentiality. Yet, individual report-back is central to addressing community rights in human subjects research, since some of the emerging "lay biomonitoring" studies focus on linking tested individuals to a community of activists or a specific locality. Researchers involved in such studies often recruit study participants based on their willingness to attend meetings and share their experiences of participation (Author 2006). This occurred in the "Body Burden" study, a joint project of Environmental Working Group, Mt. Sinai School of Medicine, and Commonweal (Environmental Working Group 2003). Researchers tested the blood and urine of nine volunteers for 211 possible contaminants — and discovered 167 pollutants, including an average of 56 carcinogens in each person. Aggregate study results appeared in *Public Health Reports* (Thornton et al. 2002). Moreover, study participants voluntarily placed their individual data on the web, with photos and personal biographies to accompany the contaminant data, arrayed to look like the periodic table of the elements (Environmental Working Group 2003). Given the present individualistic framework of human subjects protection, many IRBs may disallow such public disclosure of individual data. Nevertheless, it is becoming increasingly common for study participants to consent to publicly disclosing their individual study results. In the EWG Body Burden Study, scientists spent two years designing the study, gaining approval of the study plan

from Mount Sinai School of Medicine's Institutional Review Board, and recruiting subjects (Baltz et al. 2000). An academic-based physician under IRB supervision actually reported the results to the participants and advised them.

Even if CBPR research projects do not intend for study participants to "go public" in the same way as EWG and other advocacy biomonitoring projects, IRBs may worry that the public disclosure approach will seep into non-advocacy projects. As a result, IRBs tend to take a "one size fits all" approach that allows for aggregate reporting of study results, but restricts the conveyance of individual-level information. For example, some academic IRBs require "passive" individual report-back protocols, which do not allow researchers to proactively contact participants to ask if they want to receive and discuss results. Researchers are limited to mailing a letter that informs study participants how they can contact researchers if they would like to receive individual results. Although concern about confidentiality is warranted, report-back that requires greater initiative on the part of study participants ignores the fact that individuals often do want access to their own data in order to have the capacity to take individual or collective action to reduce their exposures. Participants may also want to be able to share their personal results with other study participants and collectively have the power to disseminate their results through their own networks, communities, and broader public forums. If IRBs put brakes on individual report-back, this can potentially create a situation where confidentiality protections collide with the principle of beneficence. That is why the CBPR challenge leads to reassessing the seemingly contradictory elements of the Belmont principles, and coming up with alternatives that do not involve one principle precluding the other.

Uncertainty in study results is another key issue. As the science and technology for assessing human exposure to pollutants becomes more sophisticated, there has been a proliferation of

biomonitoring studies, including one biannual study conducted by the Centers for Disease Control (Centers for Disease Control and Prevention 2006). Very often, there is little or no information on the human health effects of these pollutants, and this paucity of health data raises ethical issues about how biomonitoring results should be reported and interpreted. Another uncertain and contested issue with reporting individual data is whether reporting of information can induce harm. At the individual level this might occur because the clinical significance of the data is unknown, there may be no valid options to mitigate/address potential health risks revealed by the data, or there is a risk that the participant might be psychologically harmed by knowing the results (Shalowitz et al. 2005).

Problem Areas in Our Research

We now turn to the specific IRB challenges that we encountered in our research collaborative linking environmental justice and breast cancer advocacy through two household exposure studies in California and Massachusetts.

What is the Jurisdiction of IRB Coverage? – University IRB Coverage of Community Partners

One issue many research projects face are IRBs populated by members with little or no familiarity with community-based participatory research. Through personal discussions and email memos, we educated our IRB about the basic nature of CBPR, a research approach with which they were quite unfamiliar. We queried other CBPR projects nationwide to learn how they dealt with university IRB coverage of CBO research partners, and were able to demonstrate useful precedents (We include as an endnote an excerpt from our application letter[1]). We also showed that our community partners were very experienced in scientific research and had extensive familiarity with human subjects protection protocols. Silent Spring Institute has a long track record of state IRB approval for environmental health research funded by state and federal

agencies, and private foundations. While Communities for a Better Environment had no prior experience conducting research that required IRB approval, they are a long-established organization whose research using secondary data, such as oil refinery emissions, was well-known to academic institutions, government agencies, and policy-makers. Moreover, individual CBE staff members had previous experience working for universities and participating in human subjects research. Even with their prior human subjects research experience, staff from both Silent Spring and CBE underwent extensive human subjects protection training through the NIH online certification training and exam. Unfortunately, Brown then decided that the NIH certification exam was insufficient, and required both staff from both organizations to take an additional online course and exam, the (CITI exam). This online training program focuses primarily on issues related to clinical trials and social science research but it does not address the unique human subjects issues in CBPR projects. Thus, CBO staff received training on research scenarios that are not particularly relevant to the projects they are actually working on. This is especially problematic given the time required to complete the training, approximately 5-6 hours. The training module also assumes familiarity with online electronic systems, comfort with multiple-choice test-taking skills, and strong English literacy, raising some significant issues for an environmental justice project.

Because of lack of experience with CBPR projects, the Brown University IRB was initially reluctant to oversee human subjects protection by CBO partner organizations, Silent Spring Institute and Communities for a Better Environment. Despite the household air and dust sampling research being performed 3000 miles away in a California, the IRB's concern was not its lack of proximity to the study site, since this IRB often oversees research conducted in other countries by locally hired researchers. However, our project situation was unique because the PI

on both of our federal grants for this collaborative [the National Institute of Environmental Health Sciences (NIEHS) and the National Science Foundation (NSF)] is the executive director of Silent Spring Institute. This was partly because Silent Spring Institute originated the household exposure research protocol in Cape Cod (Rudel et al. 2003) that we sought to replicate in California. SSI's PI status was also partly due to the fact that NIEHS was encouraging more CBPR project teams to promote leadership by CBO partners. Indeed, at its 2005 annual grantees meeting, the NIEHS staff highlighted those projects that had successfully promoted the administrative and intellectual leadership of community partners in collaboratives. University IRBs will likely see larger numbers of CBOs leading and administering federally funded research projects with academic partners, since many granting agencies are prioritizing research and intervention projects that clearly demonstrate community leadership. Unfortunately, despite NIEHS's key role in promoting the leadership of CBOs in major research grants, the Institute does not offer formal guidance to academic institutional review boards about how to handle the joint-principal investigations across organizations.

All universities that receive federal grant money must operate in accordance with federally prescribed IRB procedures. Academic IRBs directly oversee the research of their faculty members and staff to ensure compliance with federal compliance guidelines. Brown University's IRB was initially concerned about their capacity to directly oversee and hold accountable the research work of our CBO partners since these independent organizations are not legal entities of the university. Of primary concern was the possibility of CBO activities that might violate federal standards and jeopardize the federally-funded research activities and reputation of the university as a whole. Nevertheless, the Department of Health and Human Services Policy for the Protection of Human subjects (available at:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) makes it clear that CBOs can be reprimanded directly by the HHS Office for Human Research Protection (OHRP) for a violation of federal regulations (45 CFR 46.103) for the protection of human subjects. Brown's IRB can contact the OHRP directly if it were to have any concern about a CBO partner's ability to conduct research or to ensure the protection of human subjects in federally funded research. All CBOs conducting research are required to periodically update their OHRP assurance of compliance with human subjects protection guidelines and must report any suspension or termination of research by an IRB

We assured the Brown IRB that there would be strict procedures in place to protect study participants in the interviews, human and household sample collection, and record-keeping activities, and that Brown faculty partners would be responsible for reporting on the collaborative's adherence to approved study protocols. Brown University co-PIs make quarterly visits to Communities for a Better Environment and Silent Spring to check record-keeping and data storage protocols and to ensure that their approved confidentiality procedures are being followed. The IRB initially approved human subjects oversight of our Collaborative for only 18 months of a four year project, but, after continued dialogue and negotiation, the IRB agreed to oversee human subjects compliance for all research partners for the full duration of the project.

After gaining university IRB coverage for CBO research partners, several critical issues remain that must be carefully navigated. University IRBs and community organizations may operate on different timelines, and the intense and lengthy university IRB reporting process can create conflicts. This is particularly the case when the community partner is the PI responsible for ensuring timely progress of the research, but is reliant on a university IRB that has a slow review process. Although many of the initial obstacles have been addressed, the lack of guidance

from federal agencies meant that both researchers and IRB staff members had to work closely to resolve unique and sometimes conflicting institutional concerns. This process resulted in periodic delays during critical phases of the project.

Special Problems with Government IRBs

The intricacies of multi-partner CBPR projects can be heightened when multiple IRBs are involved, especially state government IRBs, as we experienced with the role of the Massachusetts Cancer Registry in a separate human subjects review. In the Cape Cod Household Exposure Study, multiple aspects of the relationship between Silent Spring and the state contributed to a multi-year delay between sampling and the reporting back of individual results to participants. First, the Governor vetoed the state's entire breast cancer research program, eliminating an expected appropriation of approximately $400,000 that would be used, in part, to report to study participants and follow up in homes with worrisome results. The study team did its best to identify other sources of funding and press forward with the project, despite deep staffing cut-backs.

Second, there was a dispute with the Department of Public Health (DPH) about data ownership and access and the stringent and protracted review of all proposed contacts with study participants slowed down report-back, particularly in light of the budget constraints on staff resources. The DPH's Research and Data Access Review (RaDAR) Committee had jurisdiction over the Cape Cod project because many study participants were initially contacted through the Massachusetts Cancer Registry. Therefore, any later stages of work with these participants, such as developing protocols to inform them of their individual household sampling and biomonitoring results, had to be cleared by the RaDAR Committee. Unfortunately, this review

process took many months, and significant difficulties arose in the way the RaDAR Committee and others within the Massachusetts DPH approached our CBPR project.

In one instance, the DPH threatened to require the destruction of environmental and biological samples immediately after the first laboratory chemical analyses were completed. This requirement would have undermined one of the critical goals of the research project – to identify sources of endocrine disrupting compounds in homes. Indeed, study participants had even given informed consent to allow their household air, dust, and tissue data to be analyzed for ten years. This type of informed consent is commonly used because exposure assessment research is a rapidly evolving field as new analytical methods and knowledge about chemicals in consumer products are constantly improving. Therefore, stored samples provide an opportunity to conduct re-analyses as new information and methods become available and more cost-effective. For example, the study team unexpectedly found breakdown products of a banned flame retardant. If the study samples had been destroyed, the researchers would not have been able to retest their study samples to confirm that the parent flame-retardant was indeed the source of the residues. After much negotiation, the RaDAR Committee required the research team to get a new consent from study participants in order to continue storing their samples at the research laboratory.

Another delay occurred when Cape Cod homes with high levels of chemicals were retested to get more detailed measurements that could potentially determine sources of contamination and point to possible remediation strategies. The DPH Bureau of Environmental Health Assessment initially asked to review each letter that went to these households, although after a meeting with Silent Spring Institute and Brown University researchers, approval of prototype letters was finally allowed by Massachusetts DPH.

Again, the principles of beneficence and justice are relevant to the recurring delays that keep study participants from getting their results in a timely fashion and also jeopardize relations between the research team and participants. Women who had provided human tissue and household dust and air samples for the study were understandably disconcerted with the delay in receiving their results, although Silent Spring Institute's respected status in the study area and its skillful handling of the delay issue enabled participants to stay informed on the progress of the research.

Delays in the overall research process also resulted from the RaDAR Committee's unusual level of scrutiny of Silent Spring Institute's manuscripts before submission. Manuscripts are submitted to the RaDAR Committee to ensure compliance with approved study protocols. However, in Silent Spring Institute's case-control study of endocrine disrupting compounds and breast cancer, the RaDAR Committee ruled that the manuscript on breast cancer risk in mothers who had given birth to a boy with hormonally mediated birth defects (hypospadias and cryptorchidism) was not within the approved protocol. The DPH required submission of a new protocol application to conduct this study and a statement by an endocrinologist in support of the research hypothesis. This process resulted in an eight-month delay in submitting the manuscript and cost researchers a substantial amount of time to prepare additional documents. It was unnecessary, since the questions about birth defects were in the original study questionnaire approved by the RaDAR Committee. If the committee did not want research conducted on those health outcomes, it should not have approved the questionnaire in the first place.

The level of conflict regarding human subjects' protection oversight with the Massachusetts RaDAR Committee starkly contrasts with the research team's experience working with Brown University's IRB. This difference may be partly attributable to the different institutional

missions of the State Department of Health and an academic institution. While university-based IRBs are designed to protect study participants within an institutional context aimed at advancing research, state health departments are not fundamentally research organizations. While the DPH is motivated to protect confidentiality and prevent public complaints about the research, it does not necessarily have an interest in promoting research and may be concerned that additional analysis could raise public questions about potential health hazards that the Department may not have the financial resources or the capacity to fully address. These tensions raise potential trade-offs for researchers who use governmental data; some state agencies can severely restrict how data is used in IRB-approved research. Often it appears as though these restrictions have less to do with genuine concerns related to protecting human research subjects and more with controlling the flow of scientific information resulting from previously approved research protocols.

Given these constraints, it is critical for Departments of Public Health to acknowledge their limited capacity to conduct their own environmental health research, while realizing they are critical sources of outstanding data that should be made available to universities and independent researchers with the resources and capacity to analyze and disseminate findings to scientific peers and the public. There are models for this: the CDC is putting the National Health and Nutrition Examination Survey (NHANES) on the web, the California Department of Health Services and other state public health agencies are making their birth data geocoded to census tracts, available to researchers for a nominal cost, and the California Air Resources Board is making much of its air quality data available online.

IRB Issues to Consider for CBPR Researchers

Despite significant obstacles and delays related to IRB review, our collaborative has successfully advanced foward. We moved the Massachusetts RaDAR Committee on several critical issues, through continual pressure by academic partners, Silent Spring Institute, and supporters from the Massachusetts Breast Cancer Coalition, their sister organization, and pressure from state legislators. This kind of broad-based support from community collaborators is critical to ensuring the success of multi-partner CBPR projects. We were fortunate in being able to educate our academic IRB and gain their approval to oversee human subjects' protection. However, it is unclear whether many under-funded and under-staffed CBOs have the time, resources and institutional capacity to overcome such IRB challenges. Further, not all academic researchers are willing to spend so much effort on prolonged negotiations. It also remains to be seen whether or not other academic IRBs are willing and able to grapple with some of the bureaucratic and logistical challenges inherent in the oversight of community-academic collaboratives. Routinizing practices for IRB coverage would greatly increase the viability of CBPR methods. This could occur incrementally as successful projects, such as ours, provide models for others; or through proactive development of guidelines by federal funding agencies.

In certain situations, enlisting the assistance of independent IRBs to oversee the work of CBOs may make more logistical sense for community partners, although this option can be logistically and financially cumbersome. From a practical perspective, using an independent IRB to cover the CBO's participation in a research project may result in added costs and delay if university partners feel they must also seek review for the project from their academic IRB. This process results in duplicative efforts and the potential for conflicting decisions that would have to be negotiated with multiple IRBs. Another logistical issue with independent IRBs is that many

may not meet the federal-wide assurance requirements that "local knowledge" be taken into account. While there is no systematic research on whether such independent IRBs fail to incorporate local knowledge, they may have no impetus to do so without the pressure of community-involved university researchers, and without the pressure from community groups that can appeal to university efforts to build good relations with their surrounding communities. Finally, it remains unclear what kind of sanctioning or disciplinary role independent IRBs actually apply. According to the Association for the Accreditation of Human Research Protection Programs (2006), which provides accreditation for independent IRBs, it remains unclear whether these independent bodies can suspend or terminate research projects, or whether they are limited to merely reporting human subjects protection violations to NIH. The executive director of the Association for the Accreditation of Human Research Protection Programs notes that independent IRBs have the same regulatory authority as IRBs within academic institutions, including the power to suspend or terminate IRB approval. She is unaware of any data on such action, however (Speers 2007). Given the many obstacles, it is possible that CBOs that have not done prior research involving human subjects, may be unlikely to succeed as lead organizations in collaborations. It is also possible that a CBO does not want to be under a university IRB for other reasons – they may want to retain control of the process and not accede to a university's determination of what is best for a community. As one of our community collaborators noted, relationships with academic partners are ephemeral, but an organization's relationship with its constituents remains constant.

Strategies for Navigating the IRB Process for CBPR

Based on our experience, we suggest the following guiding principles for navigating IRB issues to advance multi-partner CBPR projects:

1) *Take the time to educate the IRB*: As mentioned above, we prepared extensive memos to our university IRB that laid out the history and practices of CBPR, and we bolstered this with extensive in-person dialogue and email notes with IRB staff. One of the biggest tasks was to document precedent—i.e., that other researchers at prominent institutions have successfully carried out this kind of work with ethical collaboration, and that another institutional review board had approved such multi-partner collaborative research. Rather than each new applicant having to repeat this process, we think it would be worthwhile to have a routine procedure. One way this could be done is for NIEHS to contract the development of a protocol by a research institution that deal with ongoing community-based participatory research issues (e.g. Campus-Community Partnerships for Health, a nonprofit organization that promotes health through partnerships between communities and higher educational institutions, that now networks over 1,500 communities and campuses to promote health through service-learning, community-based participatory research, broad-based coalitions and other partnership strategies). This could be posted on various relevant websites and also be given as training sessions.

2) *Get to know the members of your IRB before educating them*: One collaborative researcher we consulted suggested researching IRB members in order to assess their familiarity with CBPR. It may be that board members are entirely unfamiliar with the CBPR approach to research and would benefit from some educational presentations on the history of the work, its basic principles, funding agencies supporting this work, scientific and community benefit of CBPR, and the unique ethical considerations it raises. Others have remarked that IRBs need to be educated about CPBR, and hence researchers find themselves in advocacy roles with IRB members. At the University of Denver, one faculty member invited the IRB and human subjects administration to an all-day CBPR workshop to improve overall understanding of the principles

of CBPR and to establish regular communication between researchers and IRBs. Another possible avenue for advocacy work that will address these issues is to communicate with the Applied Research Ethics National Association, an organization that provides resources and information about ethical and procedural issues of campus IRBs (Strand et al. 2003).

3) Make sure academic IRBs know community partners: Academic researchers should make efforts to connect community partners with IRB staff and demonstrate that the community has been involved in the whole research process, and thus their perspective on human subjects protection is essential to the success of the project. This "community consent" can be appended by the research partners to their IRB application. If the IRB lacks familiarity, experience, or the skill set to adequately judge the ethical issues posed by a research project, an outside expert can be brought in to serve and educate the board about the particular ethical and human subjects protection issues raised by CBPR, and to think critically about the particular research proposal at hand (Pritchard 2002).

An Agenda for State and Federal Agencies

The challenges associated with securing effective IRB oversight of community-based participatory research should not be taken as a sign that CBPR is 'too much trouble.' Indeed, funding for CBPR experienced a significant surge from both federal and foundation sources, although recently NIEHS indicated that it may end its well-reputed Environmental Justice program. More recently, NIEHS created the Breast Cancer and Environment Research Centers, which are mandated to have a community-based component. Regardless of the prognosis for short-term funding support for CBPR work, it is critical that funders, particularly federal agencies such as NIH and NSF provide academic institutions more precise guidance on how to

navigate IRB issues unique to academic-community collaboratives. This includes providing additional funding to ensure that all community partners have the resources necessary to work with both academic and independent IRBs to review research and comply with reporting requirements; to encourage academic institutions to provide IRB oversight to both academic and community partners in order to avoid unnecessary delays and expenses in protocol reviews; and to provide access to human subjects training that is specifically relevant to CBPR research. Further, proactively addressing these issues can help all IRB processes, and offer improved protection to individuals and communities. In addition, we believe that these discussions can help in the development of a new paradigm in which government agencies make data more widely available to qualified researchers.

CBPR researchers should press federal agencies to provide guidance to universities on IRB processes, especially in areas of community consent and community partnerships. NIEHS should especially work on this, since it is the primary funder of CBPR projects and therefore should provide academic institutions with guidance to help grantee partners successfully navigate the IRB process.

To begin with, agencies can give clear guidance in the RFAs, where grant opportunities and requirements are spelled out, about the IRB issues that CBPR partners are likely to face. These federal bodies can sensitize universities to the need to support community groups, and show them that most projects may not necessarily entail clinical, high-risk research. Federal agencies can help develop model IRB processes. They can help convince universities that IRB support should come under indirect costs, therefore not forcing community groups to expend their own resources.

Agencies can mandate, or at least promote, consortium-based approval, whereby one institution's IRB is accepted by others in the consortium. Silent Spring Institute has had this experience with Boston University, a partner in other of its projects. Aside from federal mandates on this, university IRBs should voluntarily do it. Further, there is a difference between multi-partner and multi-site collaborations, and this needs to be taken seriously. Indemnification may be one necessary component, so that universities are not responsible for actions of community partners. Federal regulations could also address the problem of conflict of interest by IRBs themselves. If, as in the case of the Massachusetts DPH, IRB members have a vested interest in the outcome of a protocol review because results may have implications for public health action, then it may not be appropriate for the state's IRB to be the authority reviewing human subjects protection for the project. In such cases, an ombuds-type IRB could be created; This policy would resolve the conflicting needs of protecting human subjects and avoiding a conflict of interest that may hinder the progress of a worthy study. Indeed, that IRBs can have their own conflict of interest is a legitimate concern; a recent survey of 893 IRB members at 100 academic institution s found that 36% of IRB members had at least one relationship with industry in the previous year, that only two-thirds of them disclosed such conflicts to the IRB, and of those reporting conflicts, nearly one-third participated in reviews involving firms with which they had such conflict (Campbell et al. 2006). Even the creation of independent IRBs may not completely resolve some of these conflict of interest issues. It has been argued that the three major concerns about independent IRBs are conflict of interest, potential to not properly assess local knowledge due to their distance from the project, and their encouragement of "IRB shopping" in which researchers seek the least stringent reviewing body (Forster 2002).

Conclusion

Research collaborations in the community-based participatory research arena, especially dealing with environmental justice projects, have encountered obstacles from both university and governmental IRBs. In our own project and others, roadblocks have caused costly delays and have led project partners to worry that residents in affected communities might lose faith in the researchers and the scientific enterprise itself. With the aid of colleagues in other partnerships, we were able to amass supportive evidence to make our case for our university IRBto cover all three community and academic partnership our multi-sited research project. Our collaborative's efforts in working with the Massachusetts DPH were ultimately successful, but only after extensive negotiations between Silent Spring Institute and the DPH and the active engagement of the Massachusetts Breast Cancer Coalition, and other constituents on behalf of the research team.

Resolving these IRB challenges is not solely a matter of dealing with pro forma study protocol review requirements. Rather, it is part of a larger process by which CBOs and their academic supporters seek to reframe the whole research enterprise, with a particular focus on empowering community organizations to protect human subjects in scientific research. For this article, we consulted CBPR projects that were funded through the same grant mechanism as our project and that were likely to have similar IRB challenges. A larger survey of how other CBPR projects have handled these issues would significantly advance work in this field. Findings from such work should be disseminated in venues that will reach IRB members, such as this newsletter and conferences that IRB members attend, such as Public Responsibility in Medicine and Research.

One last point should be made about the IRB experience. Despite its challenges, research partners can use this process as way to explore issue of collaboration, privacy and

confidentiality, relations with government agencies, and organizational workloads. As we researched and prepared this paper, we were pleased by the complexities that were uncovered, and by the new networks with which we connected.

References

Association for the Accreditation of Human Research Protection Programs. 2006. “Accreditation Standards.” www.aahrpp.org/www/aspx (accessed December 24, 2006).

Billings, Paul R., Mel Kohn, Margaret deCuevas, Jonathan Beckwith, Joseph S Alper, and Marvin R. Natowicz. 1992. “Discrimination as a Consequence of Genetic Testing”. American Journal of Human Genetics 50: 476-482.

Bosk, Charles and Raymond DeVries. 2004. “Bureaucracies of Mass Deception: Institutional Review Boards and the Ethics of Ethnographic Research.” Annals of the American Academy of Political and Social Science. 595:249-263.

Brown, Phil, Stephen Zavestoski, Sabrina McCormick, Brian Mayer, Rachel Morello-Frosch, and Rebecca J. Gasior. 2004. "Embodied Health Movements: Uncharted Territory in Social Movement Research." Sociology of Health and Illness 26 (1):1-31.

Campbell, Eric G., Joel S. Weissman, Christine Vogeli, Brian R. Clarridge, Melissa Abrahama, Jessica E. Marder, and Greg Koski. 2006. “Financial Relationships Between Institutional Review Boards and Industry.” New England Journal of Medicine 355:2321-9.

Centers for Disease Control and Prevention. 2006. Third national report on human exposure to environmental chemicals. Atlanta: CDC.

Dickert, Neal, and Jeremy Sugarman. 2005. "Ethical Goals of Community Consultation in Research." American Journal of Public Health 95 (7):1123-1127.

Dickson, David. 2000. “UK Insurers Allowed to Use Genetic Tests.” *Nature* 6(11): 1199, November, 2000.

Draper, Elaine. 1991. Risky business : genetic testing and exclusionary practices in the hazardous workplace. Cambridge: Cambridge University Press.

Environmental Working Group. 2003. “Body Burden: The Pollution in People.” http://www.ewg.org/issues/siteindex/issues.php?issueid=5004

Food and Drug Administration. 1997. Food and Drug Administration Moderization Act of 1997. Public Law 105-115, 105th Congress.

Forster, David. 2002. “Independent Institutional Review Boards” Seton Hall Law Review. 32:513-523.

Gerhardstein, Benjamin and Phil Brown. 2005. “The Benefits of Community Medical Monitoring at Nuclear Weapons Production Sites: Lessons from Fernald” Environmental Law Reporter XXXV:10530-10538.

Lapham, E. Virginia, Chahira Kozma, and Joan O. Weiss. 1996 “Genetic Discrimination: Perspectives of Consumers.” Science 274(5287): 621-624, 25 October 1996.

Levine, RJ. 1988. Ethics and Regulation of Clinical Research, 2nd edition. New Haven: Yale University Press.

McCormick, Sabrina, Phil Brown, and Stephen Zavestoski. 2003. "The Personal is Scientific, The Scientific is Political: The Environmental Breast Cancer Movement." Sociological Forum 18:545-576.

Morello-Frosch R, Pastor M, Sadd J, Porras C, Prichard M. “Citizens, Science, and Data Judo: Leveraging Community-based Participatory Research to Build a Regional Collaborative for Environmental Justice in Southern California.” In Methods for Conducting Community-Based Participatory Research in Public Health. Barbara Israel, Eugenia Eng, Amy Shultz, Edith Parker, eds. University of Michigan, Jossey-Bass Press (2005).

Morello-Frosch, Rachel, Stephen Zavestoski, Phil Brown, Rebecca Gasior Altman, Sabrina McCormick, and Brian Mayer. 2006. “Embodied Health Movements: Responses to a

'Scientized' World." In The Political Sociology of Science: Institutions, Networks, and Power, edited by Kelly Moore and Scott Frickel. Madison, WI: University of Wisconsin Press.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research**.** http://ohsr.od.nih.gov/guidelines/belmont.html.

NIH, 1998. "IRB Knowledge of Local Research Context." Division of Human Subjects Protection OPPR. http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm.

Pritchard, Ivor A. 2003 "Travelers and Trolls: Practitioner Research and Institutional Review Boards." Educational Researcher 31(3):3-13.

Quigley, Dianne. 2006. "A Review of Improved Ethical Practices in Environmental and Public Health Research: Case Examples from Native Communities." Health Education and Behavior 33: 130-147.

Shalowitz, David I. and Franklin G. Miller 2005. "Disclosing Individual Results of Clinical Research: Implications of Respect for Participants." Journal of the American Medical Association 294 (6):737-740.

Sharp, Richard R. and Morris W. Foster. 2002. "Community Involvement in the Ethical Review of Genetic Research: Lessons from American Indian and Alaska Native Populations,", National Institute of Environmental Health Sciences, Environmental Health Perspectives Supplements, Volume 110, Number S2 .

Shepard, Peggy M., Mary E. Northridge, Swati Prakash, and Gabriel Stover. 2002. "Preface: Advancing environmental justice through community-based participatory action research." Environmental Health Perspectives 110 (2):139-144.

Southeast Community Research Center. 2003. “Community IRBs: Community Participation on Institutional Review Boards.” Conference Report December 6, 2003. Accessed December 31, 2005. http://www.cbpr.org/index.php?option=com_content&task=view&id=18&Itemid=33

Speers, Marjorie. Personal communication. February 28, 2007.

Strand, Kerry, Nicholas Cutforth, Randy Stoecker, Sam Marullo, and Patrick Donohue. 2003. Community-Based Participatory Research and Higher Education: Principles and PRactices. San Francisco: Jossey-Bass.

Sze Julie and Swati Prakash. 2004. “Human Genetics, Environment, and Communities of Color: Ethical and Social Implications.” Environmental Health Perspectives 112: 740-745.

Weijer, Charles. 1999. "Protecting Communities in Research: Philosophical and Pragmatic Challenges." Cambridge Quarterly of Healthcare Ethics 8:501-513.

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[1] From our letter to the Brown IRB (Rachel Morello-Frosch and Phil Brown, September 29, 2004; revised to remove identifiers to the cited organizations and universities):

“Our request to Brown’s IRB to extend its review to include the data collection and analysis activities both non-academic partners is rooted in the need to ensure IRB coverage for all aspects of this important community-based participatory research collaborative. This year, all academic-community environmental justice grants that were awarded by NIEHS have the community partner as the principal investigator and the academic partners as co-investigators (project descriptions can be viewed on the NIEHS website http://www.niehs.nih.gov/translat/envjust/envjust.htm). The agency’s support of these community-led projects represents an important milestone in the evolution of federal support for community-based participatory research. Many of these projects have successfully undergone IRB review through the academic partner’s institution. For example, one university’s IRB reviewed and approved an asthma program run by a community organization,which involves a study and intervention protocol to decrease asthma severity and incidence in a community school district in a large city. The community partner’s director is the PI on this project and the academic partners are co-PIs.

In addition, we want to note that NIEHS research ethics experts in academia, many community-based organizations, and Native American tribes view the prominent leadership role of CBOs in scientific research as essential to advancing the spirit and intent of informed consent so that study protocols cover the protection of communities as well as individuals. In the process,

university IRBs have played an important role through their certification of the research activities of community-based organizations that are collaborating with academic partners. We have spoken with members of many of these collaboratives in the last few months, and have learned that university IRBs have made important contributions to this process through their coverage of community partners."