Reviewer’s report

Title: IRB Challenges in Community-based Participatory Research on Human Exposure to Environmental Toxins: A Case Study

Version: 1 Date: 16 February 2010

Reviewer: Robert Hood

Reviewer’s report:

The paper is an important contribution to the field. The authors discuss their experience obtaining review of community-based participatory research by a university IRB. There is significant literature devoted to chronicling problems with IRBs; this paper extends this literature to community based participatory research (CBPR). The authors claim that CBRP is essentially different in relevant ways from other kinds of research (biomedical research in particular); that these ethically-relevant differences are largely unknown to IRBs, and that in their attempt to uphold standard ethical principles (respect for persons, beneficence, justice), IRBs actually fail to honor the spirit of these values. The authors claim that CBPR, due to its commitments to the community involved in the research, is actually better at upholding these values than some IRB protections. Finally, authors make suggestions that may improve the process of review for CBPR.

Minor essential revisions:

The author's should exercise caution over the scope of their claims about IRBs. For example, p3 "general unfamiliarity of many IRBs"; see also "most IRBs" (p13). Such claims are vague and appear anecdotal; authors appear to recognize that additional research needs to be done to quantify the issue; I recommend changing this throughout to something like: "unfamiliarity of IRBs in this sample". Notwithstanding the authors' methods for selecting IRBs based on NIEHS's Environmental Justice Program, the study does not involve a more systematic survey of IRBs reviewing CBPR. The current article is important even with out a quantified measure, so I would recommend the authors take care to note the ability to generalize the observations beyond those selected for this case study may have limitations pending a more systematic study.

Discretionary Revisions

A central claim in the paper is that IRB review is often inappropriate to the methods, challenges and objectives of other approaches to research from across the disciplines (p5). I would encourage the authors to clarify whether their claim is that CBPR is different in principle (incompatible with the existing regulations), or whether the problems they encountered are based on encounters with IRBS that lack appropriate qualifications and expertise (IRBs are not competent to review CBPR). It appears the authors' claim is that CBPR is different in principle; perhaps that could be clarified. Regardless of whether CBPR is different in
principle, IRBs need to be sufficiently qualified through education and expertise to review in practice. I believe the IRB behavior the authors describe may not comply with regulation; rather than failing to recognize the different nature of CBPR research, the IRB behavior may reflect what happens when IRBs lack appropriate qualifications and expertise to review research (itself a regulatory violation). The question of whether the regulations are intrinsically flawed, or whether they are implemented incompetently, is also central to other discussions of problems with IRBs, such as those by social scientists, oral historians, and those in public health.

There are reasons to be cautious about the extent of the distinction the authors draw between traditional research, which they characterize as individually-focused, and CBPR which is community-focused (p2 and following). A key difference between clinical care (which is indeed individually-patient focused) and clinical research is precisely between treating a particular person and engaging individuals in research, the benefits of which, if any, may only exist for future populations rather than the particular people in the current research. The involvement of lay persons in research, and reporting results may not be as unique to CBPR research as the authors suggest (p6). Some clinical research makes more explicit considerations of community benefits, and incorporates lay persons in the conduct and design of research. For example, breast cancer research, and HIV research both feature significant community involvement in research, where members of organizations such as ACT-UP were involved in the development of hypotheses and worked with drug companies to design research studies consistent with community needs. The fact that federally-funded HIV research requires a community advisory board to incorporate community attitudes is a lasting contribution of this attention—in biomedical research—to incorporate community attitudes. If nothing else, it suggests that CBPR is not entirely absent even from FDA-regulated studies of new drugs and medical devices.

Whether or not CBPR is different from other kinds of research in morally relevant ways, I think the article could be strengthened by incorporating the specific ways the regulations as written hold IRBs accountable to do a better job of knowing about CBPR, and reviewing it effectively.

The authors should consider whether a standard distinction in the field, that between review by the IRB on the one hand, and the other organizational considerations that are part of the human research protection program broadly (which include things such as ensuring adequately trained investigators, reviewing contracts for human research protections, and so on). In light of this distinction, the authors' complaint about the difficulties they faced in getting their institution to accept jurisdiction over external research (p7) is separate from IRB review per se, and likely represents other considerations such as organizational attitudes toward potential legal risk and media coverage. A similar point is about the organization's choice of method for ensuring researchers are adequately trained (p9). While the CITI course may be longer, otherwise both trainings 1) are focused on biomedical and social behavioral research; 2) are on-line. Authors
should revise this section to reflect that the general problem is that organizations
should be careful when specifying a particular way of ensuring researchers are
appropriately qualified, that it does not have unintended consequences and pose
difficulties when involving researchers who do not have access to computers or
online training. This problem is hardly unique to CBPR though—it would also
apply to international research in developing countries, for example. (This may
be an example where the issue is not something intrinsic to CBPR research, but
is true whenever research involves people who do not have access to online
training)

p10 and following. Regarding confidentiality of research results. In addition to the
ethical arguments made by the authors, I think their point could be strengthened
if they explain that the IRBs appear to have made a regulatory error. The
regulatory requirement is that "When appropriate, there are adequate provisions
to protect the privacy of subjects and to maintain the confidentiality of data" (45
CFR 46.111(a)(7)). The crucial phrase here is "when appropriate". IRBs have
extensive discretion, the exercise of which is essential when (as the authors
demonstrate) it may not be appropriate in CBPR to maintain confidentiality;
participant-researchers may prefer to not maintain confidentiality, and that other
values may override protections of confidentiality. The point here is there is no
requirement to protect confidentiality—only to protect confidentiality when
appropriate. This represents then a problem with IRB practice, instead of a
limitation intrinsic to regulation. Those engaged in CBPR may need to confront
IRBs that make demands beyond or outside of regulatory requirements. This
point could perhaps be inserted, for example, at the end of the paragraph ending
with "From the perspective of CBPR..." (p11).

With one qualification, I concur with the authors' concerns that the worry of IRBs
about psychological harms if participants receive research results fails to
recognize that the participant-researchers in CBPR are in a better position by
virtue of their role in designing and conducting research to understand the
results, and it is paternalistic to "protect" them from disclosure. The qualification
is that if CPBR involves FDA-regulated unapproved lab test kits (considered
medical devices under regulation) regulations require the unapproved test is not
used as a diagnostic procedure without confirmation of the diagnosis by another,
medically established diagnostic product or procedure (21 CFR 812(2)(b)(3)).
Authors should consider clarifying whether the disclosures discussed involved
FDA-regulated tests.

p18 I would consider the authors to consider whether some of the problems they
encountered may have been due to IRBs not taking appropriate care with
regulatory requirements. And perhaps mention that part of what CBPR
researchers may need to do is explain regulations to IRBs (e.g., explain that the
requirement is to protect confidentiality when appropriate). The authors should
consider strengthening the point "If the IRB lacks the familiarity, experience..."
Rather than saying that an expert can be brought in (this sounds as though it is
optional), obtaining a consultant when the IRB lacks qualifications and expertise
is in fact a requirement in regulation. IRBs that do not have expertise in CBPR
actually may not be reviewing research consistent with regulatory requirements. Regulations specify that the IRB shall be sufficiently qualified through the experience and qualifications of its members, including professional qualifications and awareness of community attitudes (45 CFR 46.107(a)). Arguably, if an IRB lacks awareness of community partners and community attitudes, or does not include sufficient professional expertise (e.g., individuals experienced in CBPR when conducting its review) then it is not meeting regulatory requirements. Here is another example where the regulations actually may require more of IRBs than some demonstrate in practice.

I might encourage the authors to add an additional point -- that CBPR researchers and partners can try to help IRBs understand the flexibility in regulation. This arguably should not be a requirement of CBPR researchers, but it may be in their interest to do so. Also, CBPR researchers may want to consider seriously joining IRBs--especially consider inviting CBPR community members to volunteer to serve on IRBs. Perhaps the authors might also consider recommending that IRBs that review CBPR research should add persons with CBPR expertise--and community members with this expertise (see also p23--that is, not just having community representation on IRBs, but having community members with the knowledge and expertise obtained through participating in a CBPR process). I think that IRBs should be interesting in adding this perspective even if they do not review substantial amounts of CBPR research, because of the importance of the perspective. For example, our agency added an IRB member with CBPR expertise to the agency's IRB in recognition of the need for additional expertise, but this person has brought tremendous expertise and strengthened our IRB because of insights based on CBPR experience.

p19 The recommendation that IRBs understand CBPR is just asking that IRBs fulfill their regulatory requirement--that when reviewing research the membership is sufficiently qualified through education and expertise.

p20 re regulating IRB conflicts. I think this point could be made in a stronger way. IRBs are explicitly prohibited from considering policy implications for public health and other implications ("The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility." 45 CFR 46.111(a)(2)). Authors may want to consider whether they think this is really about conflicts of interest (where a researcher has obligations to participants that conflict with obligations to the research) or is rather a significant failure to review research under regulatory requirements.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Declaration of competing interests:
I declare that I have no competing interests