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Awareness of federal regulatory mechanisms relevant to community-engaged research: survey of health disparities-oriented NIH-funded investigators

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Abstract

Few studies or investigators involved in community engaged research or community-based participatory research have examined awareness and adoption of federal regulatory mechanisms. We conducted a survey of investigators affiliated with the ten National Institutes of Health (NIH) Centers for Population Health and Health Disparities. A questionnaire designed to capture experience with the conduct and oversight of community engaged research, and awareness of pertinent regulatory mechanisms, including Federalwide Assurances (FWAs), Individual Investigator Agreements (IIAs), and Institutional Review Board Authorization Agreements (IAAs), was completed by 101 respondents (68% response rate). Although most were aware of FWAs, only a minority of those surveyed reported knowledge of IAAs and IIAs and even fewer had used them in their research with community partners. Implications for future training and oversight are discussed.

Keywords

health disparities; community-based participatory research; community-engaged research; IRB oversight; regulation; awareness

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Dr. Smith, an assistant professor at St. Elsewhere University, has just received an NIH grant to test an innovative community-based colon cancer screening program. Her R01 includes a sub-award to the Main Street Community Center (MSCC), which will serve as a site for recruitment, education, and data collection. MSCC leaders serve on a community advisory

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board (CAB), and staff will be involved in recruitment, education, and possibly data collection. The IRB application came back from initial review with few requests for changes, but included this comment from the IRB administrative staff: “MSCC will need to obtain an FWA, and an institutional authorization agreement must be in place before data collection can begin.” Dr. Smith finds out that this process can take several months, which will significantly delay her project timeline.

Community engagement in research is believed to have benefits for both researchers and the affected community (Clinical and Translational Science Awards Consortium, 2011). Community engaged research (CEnR) may help overcome boundaries between researchers and communities, allowing for community input on aspects of study design or implementation (Israel, Schulz, Parker, & Becker, 1998; Ogden, 1999; Schnarch, 2004). In recent years, there has been a strong emphasis on the more intensive community-based participatory research (CBPR), where community members affected by the issue under study participate actively in the design and conduct of the research (for an example, see: http://www.wkkf.org). Both CEnR and more inclusive CBPR approaches aim to empower the community and enable a relationship built on collaboration, reciprocity and shared goals (Guta, Nixon, Gahagan, & Fielden, 2012). Although the value of such approaches is well-recognized, it also is clear that involving community partners or partner entities (e.g., community-based organizations, health clinics, schools, etc.) in CEnR research poses important challenges for regulatory oversight of the research conducted (Flicker, Travers, Guta, McDonald, & Meagher, 2007).

For example, while involvement of community partners may improve trust, it may also pose threats to voluntary informed consent. An individual may have a hard time saying “no” to an invitation to participate in research when the person doing the asking is a friend, neighbor, community leader, or someone from whom they receive health or social services. Involving community partners in the process of research also raises questions about who needs training in human subjects protection and what training is appropriate. For example, what do community partners who promote a study and screen for eligibility but do not obtain informed consent need to know about human subjects protection before they begin their work? What about an individual who collects data from participants who have already provided informed consent? Community partners may also have limited formal education or low literacy that pose barriers to the successful completion of standard human subjects protection training programs (Anderson et al. 2012).

Now consider the case of Dr. Smith. All institutions engaged in research supported by the US Department of Health and Human Services (HHS) must satisfy regulatory requirements related to ensuring compliance and certifying Institutional Review Board (IRB) approval – that is, they must provide written documentation that says they agree to comply with the Common Rule. Determining what constitutes engagement at a level that triggers these requirements can be complicated given the range of activities that community partners participate in and the evolving nature of many CEnR/CBPR studies. However, if federal grant funds are awarded directly or indirectly (e.g., through a subcontract from a university grant recipient to a community agency, as in Dr. Smith’s case), then regulatory obligations are clear.

A number of regulatory mechanisms exist to permit the extension of human subjects oversight to community partners who are not otherwise affiliated with an academic research institution. The broadest of these mechanisms is the Federalwide Assurance, or FWA, which is a statement of principles governing an institution's approach to the protection of human subjects. Any institution receiving funding from HHS to support human subjects research is required to submit an FWA to the Office of Human Research Protections (OHRP); the institution is required to renew the FWA every 5 years (described here: http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html). Submission of an FWA generally entails the adoption of robust internal research review procedures, including in most cases the establishment of an IRB. Such review procedures are often challenging to implement for partner organizations with limited resources and/or research experience.

For this reason, the OHRP has more recently introduced related mechanisms designed to extend the regulatory oversight of assured institutions (i.e. those holding an FWA) to non-assured collaborating individuals and institutions. The Individual Investigator Agreement, or IIA, for example, allows community collaborators not otherwise affiliated with an assured institution to conduct research under the supervision of a principal investigator from an assured institution (see: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html). A related mechanism, the IRB Authorization Agreement or IAA, allows entities that have a FWA to use an IRB at another assured institution for the review of their research. This reduces the burden of establishing an independent IRB and helps streamline review of collaborative research conducted by multiple assured institutions, as would be the case in an academic-community partnership (see: www.hhs.gov/ohrp/assurances/forms/iprotsup.rtf). In both cases, investigators working at the institution with established research oversight mechanisms elect to share those resources with partners who may have little prior experience with research oversight and limited capacity for managing compliance.

Although these regulatory mechanisms were, in many cases, introduced to facilitate the conduct and oversight of broader classes of research including CEnR and CBPR, some have argued that the added burden of the FWA process and related oversight may discourage researchers from conducting important research or partnering with appropriate community-based organizations (Cartwright, Hickman, Bevan, & Shupert, 2004; Newgard & Lewis, 2002). In seeking an FWA, regardless of whether they create their own IRB or designate an outside IRB, an organization must choose a set of ethical principles that the institution will follow in fulfilling its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by that institution. Applicants may choose from the Declaration of Helsinki, the Belmont Report, or a statement of principles formulated by the institutions (subject to approval by OHRP). Additionally, having an FWA means that the Common Rule applies to all the federally sponsored research conducted by that agency (not just the current study in question). Further, if the optional box is selected, then this means that an institution voluntarily elects to apply the Common Rule to all of its (non-exempt) human subjects research regardless of the source of support.

Taking responsibility for these actions requires that an organizational leader understand the responsibilities for human subjects protection, but there is no requirement for any training of the individuals who serve as the primary point of contact for an institution's system for

protecting human subjects (required even if another institution's IRB is designated as the IRB of record and referred to as the Human Protections Administrator) or for the Signatory Official (nor any substantive guidance). Generally this falls to the academic investigators leading the study, who like Dr. Smith, may not have the requisite regulatory expertise. However, there have been no previously published studies of CEnR or CBPR investigators' awareness and adoption of these regulatory mechanisms. Thus we sought to address this issue with a survey aimed at exploring use and awareness of these mechanisms, as well as experience with IRB review more generally, among a group of academic and community investigators affiliated with the NIH-supported Centers for Population Health and Health Disparities (CPHHD). The aim of the CPHHD program (described in detail here: http://www.cancercontrol.cancer.gov/populationhealthcenters/cphhd/index.html) is to "address disparities and inequities in the prevalence and outcomes of several diseases, particularly cancer and heart disease" with community engagement an explicit requirement of all currently funded Centers (RFA-CA-09-001).

Method

Survey development, dissemination, and analysis were spearheaded by a subgroup of representatives from the cross-Center CPHHD Outreach, Ethics, and Dissemination workgroup. The survey of CPHHD academic and community investigators focused on experience with institutional oversight of CEnR and CBPR over the course of one's research career (Tufts IRB approval #10379). CPHHD investigators are leaders in NIH-funded CEnR, making their experiences informative for understanding investigator experiences with relevant regulatory mechanisms. The paper-based survey was distributed at the end of a plenary session of the 2012 annual CPHHD meeting held in Seattle, Washington. One hundred forty-nine investigators (including PIs, research assistants, postdocs, students, and community health workers) from the 10 Centers funded by NHLBI and NCI were registered and the majority were present at the time the survey was distributed. The survey was self-administered and returned immediately upon completion. Individuals were encouraged to complete the survey in an anonymous manner, and only if they were currently working on one of the CPHHD projects (therefore excluding non-CPHHD-affiliated attendees). Written informed consent was waived because no identifying information was collected from respondents.

The survey was designed to capture salient demographic characteristics (including information about training and general research experience), experience with CEnR and/or CBPR, experience with institutional oversight of CEnR and/or CBPR, and finally awareness of specific regulatory mechanisms such as FWAs, IIAs, and IAAs. Demographic information requested included age, gender, race/ethnicity, community vs. university affiliation, job title, years engaged in research, number of NIH grants as principal investigator (PI) or co-Investigator (co-I), highest degree achieved and year of receipt of highest degree.

Experience with CEnR and CBPR was assessed by asking whether respondents had worked on either type of project, how many of each they had worked on, the year they first worked on each type, whether these studies were funded by the NIH, the topical focus of the studies,

and the nature of the population studied. For the purposes of survey completion, CEnR was defined as “meaningful community involvement in the research that falls short of full CBPR”, while CBPR was defined as “full participation of community partners in all aspects of the research, including developing the research question, writing any grants, serving as full members of the scientific leadership of the project and participating in analysis, interpretation of findings and inclusion as co-authors on scientific papers.”

Experience with institutional oversight of CEnR and/or CBPR projects was assessed using mostly close-ended questions, e.g. Yes/No or “Tick all that apply.” Two open-ended questions, which sought to elicit personal experience of managing IRB-related challenges, were left mostly unanswered and those data are not presented here. Experience with IRB challenges were gleaned by asking respondents to indicate which, of 11 types of “main challenges” with respect to working with IRBs, they had experienced over the last 2 years. The type of challenges described included, for example, an IRB not recognizing an ethical concern of relevance to the community, requiring overly burdensome consent procedures, or requiring protocol changes that impacted community partners. A separate question explored whether respondents had any experience seeking approval from community-based IRBs, working with community representatives on IRBs, or submitting to a dedicated IRB panel for CBPR projects.

Finally, respondents were also asked whether they had heard of specific regulatory options relevant to CEnR and/or CBPR, including IAAs, IIAs, and FWAs. If they had heard of any, they were asked whether they had ever used them in general or in a CEnR/CBPR study, including seeking a FWA on behalf of a community partner.

Survey responses were manually entered into a MS Excel spreadsheet and checked for data entry errors. Data were then imported to SPSS (version 20) for statistical analysis, including calculation of descriptive statistics and chi-squared tests of associations between demographic characteristics and awareness of specific regulatory options.

Results

A total of 101 surveys were returned, representing a 68% response rate relative to the total number of registered meeting participants. This may be an underestimate since some registered participants were likely not present at the time the survey was administered.

Sample Demographics

The overall sample had a mean age of 43.6 years and was predominantly female (71.3%), white (75.0%) and non-Hispanic (83.0%) (Table 1). Over 90% of respondents identified as university partners and about half (50.5%) were academic faculty. The mean number of years in research was about 16, number of NIH grants as a PI was 3.5, and number of NIH grants as a co-Investigator was 7.7. A majority of respondents (58.4%) had doctoral degrees and most had received their highest degree 15 or more years prior to completing the survey. In short, respondents were largely NIH investigators and other key personnel on NIH grants, reflective of the nature of those attending the meeting.

Experience with CEnR and/or CBPR

Most respondents reported previous or on-going involvement with CEnR (80.0%) and CBPR (66.3%) projects (Table 2). Respondents reported having conducted an average of 4.1 CEnR projects and 2.2 CBPR projects, with most having started their participation in CEnR prior to 2000 and their CBPR work prior to 2004. About 84% had NIH funding for CEnR- or CBPR-related research. Some reported experience with community-based IRBs (20.7%) or with community representatives on IRBs (27.2%). A few (9.8%) reported they had submitted a research proposal to a dedicated IRB panel for CBPR. These activities may have been enhanced in our sample by those projects working with Native American nations, some of whom have their own IRBs (Brugge & Missaghian, 2006), although we did not inquire about this specifically.

Survey respondents reported involvement in research focused on a broad range of outcomes, including obesity, diet/physical activity, diabetes, smoking, health communication, hypertension, cancer and cardiovascular disease. Target populations engaged in this research included adults, children, racial/ethnic minorities, urban and rural populations, as well as the elderly, low-income populations, and immigrants.

Experience with Institutional Oversight of CEnR and/or CBPR

Eighty-eight of the 101 respondents (87%) reported experiencing at least one major challenge in the preceding two years with IRB review of their CEnR and CBPR projects (Table 3). The most common challenge reported (by 64.8%) was that the consent forms required by the IRB were burdensome, overly long, technical or too complex, a concern which may or may not reflect the community-oriented nature of study protocols. Smaller proportions of those surveyed reported difficulties with the IRB not recognizing an ethical concern specific to the community (9.1%), the IRB raising concerns about community involvement (8%), or the IRB requiring substantial changes to the protocol that affected community involvement (12.5%). When asked whether they were able to resolve the IRB challenges they had experienced, 73.9% replied that they had (Table 2).

Differences in Awareness of Major Regulatory Mechanisms

A majority of respondents were aware of FWAs and almost a third had sought an FWA for a community partner (Table 2). Only 31.7% of respondents, however, reported having heard of IAAs; even fewer (21.8%) had used IAAs, and fewer still (17.8%) had used them in a CEnR/CBPR context. Similarly, only a quarter of respondents had heard of IIAs, 15.8% had used them and only 11.9% had used them in a CEnR/CBPR context.

We compared awareness of IAAs, IIAs, and FWAs among survey respondents, stratified by select demographic characteristics (Table 4). Respondents who reported having many (i.e. 3 or more) CEnR projects were significantly more likely to have reported having heard of IAAs ($\chi^2 = 6.114$, p=0.024) than those with fewer projects. For those reporting many CBPR projects there was a nonsignificant trend toward being more likely to have heard of IAAs ($\chi^2 = 3.382$, p=0.096). No other demographic characteristics, other than gender (women more likely, χ^2=5.608, p=0.019), predicted likelihood of awareness of IAAs.

Similarly, no demographic characteristics other than gender predicted likelihood of awareness of IIAs (women more likely, χ^2=4.204, p=0.043). There was a non-significant trend toward differences in awareness of IIAs based on recency of degree (less recent more likely, χ^2=3.943, p=0.057) and job title (professors more likely, χ^2=4.350, p=0.063).

In contrast, statistically significant differences were observed across all tested demographic comparisons, except for gender, with regard to awareness of FWAs. Specifically, those with many CEnR projects (χ^2=7.932, p=0.006), many CBPR projects (χ^2=7.629, p=0.007), longer-standing experience with CEnR (χ^2=8.013, p=0.007), longer-standing experience with CBPR (χ^2=6.918, p=0.015), or who were older (χ^2=14.518, p=0.000), more experienced (χ^2=8.62, p=0.005), with older degrees (χ^2=8.043, p=0.007), and who were professors (χ^2=8.343, p=0.005) were all more likely to have heard of FWAs.

Small response rates precluded similar statistical assessment of reported *use* of the IAA, IIA, and FWA mechanisms although, interestingly, less experienced investigators appeared slightly more likely to report having used the IIA in their research (data not shown).

Discussion

Oversight of community engaged research (CEnR) and community based participatory research (CBPR) often entails the adoption of supplemental regulatory mechanisms, including the use of Federalwide Assurances (FWAs), Individual Investigator Agreements (IIAs), and/or IRB Authorization Agreements (IAAs) with community partners or partner entities. Yet, as was the case for Dr. Smith in our opening vignette, even reasonably experienced investigators may find themselves caught unprepared when it comes to addressing regulatory expectations relevant to the involvement of community partners in research. The primary finding of our survey of a group of NIH-supported health disparities investigators with extensive experience with CEnR and/or CBPR was that while most were aware of the need for FWAs for those engaged in research, only a third had experience of helping a community partner obtain such an assurance. Furthermore, only a minority of respondents had heard of, or used, either IIAs or IAAs in their research collaborations. These findings suggest a surprising lack of both awareness and use of key regulatory mechanisms designed to facilitate diverse forms of research, including CEnR and CBPR. Such lack of awareness could mean that some NIH-funded studies have not properly extended IRB coverage to their community partners.

A secondary finding was that a majority of respondents experienced challenges in IRB interactions for CEnR/CBPR projects (Table 3). This is consistent with anecdotal reports in the research literature. Flicker et al. (2007) reviewed the content of IRB forms and guidelines and concluded that IRBs “overwhelmingly operate within a biomedical framework that rarely takes into account common CBPR experience.” However, much of what appears in the literature about investigator experience consists of case reports of individual studies (Brown et al., 2010; Malone, Yerger, McGruder, & Froelicher, 2006) and therefore cannot be generalized to all CEnR/CBPR. Our findings provide more evidence that such challenges are ubiquitous, and suggest that more should be done, at both the individual investigator and institutional level, to improve oversight of community engaged research.

There are many other federally funded and non-federally funded community-oriented investigators and we cannot be sure that our sample from CPHHD-affiliated researchers is fully representative. We also had no project-specific information (e.g., how many collaboration institutions per center/project needed to obtain FWA or IAA) and multiple investigators surveyed may have been talking about the same projects. Despite these limitations, there is value in this analysis because there is so little published on the issue and our findings suggest a need for raising awareness and knowledge in this area.

Best Practices

At a minimum, our results suggest that academic institutions with researchers who frequently employ CEnR and/or CBPR approaches in their work should take steps to ensure that their Institutional Review Boards (IRBs) bring to investigators' attention all potentially relevant regulatory mechanisms, including those like the IIA which might allow investigators to collaborate with non-assured community partners and partner entities. In other words, efforts to assist community partners in their capacity building for research must also extend to assistance with research oversight, and this should not wait until the IRB application has been submitted but perhaps should start even before funding has been secured. While individual investigators can certainly do more to make themselves and their students aware of these mechanisms (see Educational Implications below), it is those tasked with responsibility for research approval, i.e. the IRBs, who may be best positioned to identify a need for these mechanisms in specific protocols and provide education and technical assistance to community partners seeking FWAs and trying to understand their obligations for human subjects protection. Some ways IRBs could achieve this include requiring a check off on initial submission forms as to whether there are community partners without an IRB of their own and providing IRB training that covers these mechanisms.

Research Agenda

There are at least two ways in which our findings might be augmented with additional research. As noted above, we obtained survey responses from only a limited number of investigators from a single NIH-supported research network. One straightforward way of testing the generalizability of our findings would be to survey (perhaps electronically) a much wider range of respondents, including investigators with and without funding from the NIH, as well as a larger number of partner entities not normally affiliated with academic research institutions. Although our survey was designed with CPHHD investigators in mind, it could be readily adapted or another survey developed for use with a broader, hopefully nationally representative, sample.

A second way in which the survey findings could be extended would be with a more focused, qualitative, line of inquiry with a subset of investigators active in CEnR and/or CBPR research. It would be possible to explore in greater detail the experiences of investigators who have used pertinent regulatory mechanisms as well as explore barriers to their use as a matter of practice. With qualitative investigation it might also be possible to better glean whether prior challenges with IRB review were idiosyncratic and restricted to just a small number of research protocols or rather represent systemic disagreements with regard to the appropriate role of research oversight as applied to community engaged

research. Interviews with CEnR/CBPR investigators who have been successful as well as IRBs that have implemented institutional-level processes or policies to facilitate CEnR/CBPR could also inform best practices.

More broadly, we do not know how the challenges experienced by CEnR/CBPR researchers differ, if at all, from those of researchers in general (Keith-Spiegel & Tabachnick, 2006; Whitney et al., 2008), and particularly those working outside the clinical research context (Lincoln & Tierney, 2004). Study of IRB challenges should not be confined to CEnR/CBPR as there may be shared barriers across designs and approaches. IRB member and administrator views of, approaches to, and experiences with CEnR/CBPR are complex and also worthy of deeper exploration in order to identify effective solutions (Guta, et al., 2012; Shore, 2007; Wolf, 2010).

Educational Implications

One finding with direct relevance to educational implications was our observation that respondents with more years of experience with CEnR or CBPR were more likely to be aware of FWAs, IIAs, and IAAs. This may suggest that such investigators have "learned by doing" and that lack of awareness could potentially be addressed by making education about regulatory options a more regular part of the training of investigators who plan to involve community directly in their research. Anecdotally we see broad awareness of the need for human subjects training of everyone on a research team, but not so often concern about extending IRB coverage to individuals and institutions not covered by the primary IRB. IRB training and prompts on submission forms, as mentioned above, that are tailored to investigators partnering with community organizations are probably the way to ensure broader awareness. Senior investigators with direct experience of the use of such mechanisms in their research partnerships could also strive to include awareness of regulatory approaches in their mentorship of junior investigators.

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Biographies

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Doug Brugge is Professor of Public Health and Community Medicine at Tufts University School of Medicine. He directs the Tufts Community Research Center and has conducted CEnR and CBPR for almost 20 years, and is director of project 4 of the Puerto Rican Health Disparities Center. He led design of the survey and data collection. He oversaw data management and analysis. He contributed to the interpretation of survey findings, and to the preparation of the manuscript.

Questionnaire on Community Partners and Institutional Review Boards

We are seeking investigators on CPHHD projects to fill out this questionnaire in hopes of learning more about the relationship of community engagement in research and IRB oversight. We ask that you include all of your research experience, not just experience directly related to the P50 on which you work.

Section 1: Demographics

A. What is your age in years? _____

- ☐ Refused

B. What is your gender?

- ☐ Male
- ☐ Female
- ☐ Transgender

☐ Refused

C. What is your race?

☐ White

☐ Black/African American

☐ Asian/Pacific Islander

☐ Native American/American Indian

☐ Other _____

☐ Refused

D. Are you Hispanic/Latino?

☐ Yes

☐ No

☐ Refused

E. Are you (choose the one that best fits)?

☐ Community partner

☐ University partner

☐ Refused

F. What is your current job title (choose the one that best fits)?

☐ Professor

☐ Administrator

☐ Health care provider

☐ Community health worker

☐ Research assistant

☐ Student

☐ Community organizer

☐ Staff at community-based organization

☐ Other _____

☐ Refused

G. About how many years have you spent engaged in research (count years in which you did any research)? _____

☐ Refused

H. In your life, on about how many NIH grants have you been PI (including shared PI and PI of projects within center grants)? _____

☐ Refused

I. In your life, on about how many NIH grants have you been a co-investigator (listed as key personnel)? _____

☐ Refused

J. What is your highest degree?

☐ High school or less

☐ Associate

☐ College

☐ Masters

☐ Doctoral

☐ Other _____

☐ Refused

K. In what year did you receive your highest degree? _____

☐ Refused

Section 2: Experience with CBPR and CEnR

The questions that follow are about your experience with community-based participatory research (CBPR) and community engaged research (CEnR). For the purposes of this survey, please use the following definitions:

CBPR: Full participation of community partners in all aspects of the research, including developing the research question, writing any grants, serving as full members of the scientific leadership of the project and participating in analysis, interpretation of findings and inclusion as co-authors on scientific papers.

CEnR: Meaningful community involvement in the research that falls short of full CBPR.

A) Have you ever worked on a CEnR project?

☐ Yes

☐ No

☐ Refused

B) Have you ever worked on a CBPR project?

☐ Yes

☐ No

☐ Refused

If you answered “no” to both A) and B) skip to Section 3.

If you answered “yes” to either A) or B) above please also answer C) through G):

	CEnR	CBPR
C) On about how many projects of each type have you worked?	____ projects	____ projects
D) In what year did you first work on a project of each type?		
E) Were any of your projects of each type funded by NIH?	☐ Yes ☐ No	☐ Yes ☐ No

F) Have the CEnR/CBPR projects you worked on focused on any of the following topics? (mark all that apply)

Obesity:	☐yes	☐no
Diet/physical activity:	☐yes	☐no
Asthma:	☐yes	☐no
Diabetes:	☐yes	☐no
Smoking/SHS:	☐yes	☐no
Environmental/occupational health:	☐yes	☐no
Mental health:	☐yes	☐no
Health communication/literacy:	☐yes	☐no
Hypertension:	☐yes	☐no
Built environment:	☐yes	☐no
Disabilities:	☐yes	☐no
Cancer:	☐yes	☐no
Cardiovascular disease:	☐yes	☐no
☐Other _____		
☐Refused		

G) Have the CEnR/CBPR projects you worked on focused on any of the following populations? (mark all that apply)

Youth:	☐yes	☐no
Adults	☐yes	☐no
Elderly	☐yes	☐no
Racial/ethnic minorities	☐yes	☐no
Low-income	☐yes	☐no
Urban	☐yes	☐no
Rural	☐yes	☐no
Female	☐yes	☐no

Male	☐yes	☐no
Immigrant	☐yes	☐no
Non-US	☐yes	☐no
☐Other _____		
☐Refused		

Section 3: Ethics of CBPR/CEnR

A. What are the main challenges you have experienced with respect to interactions with IRBs for CEnR/CBPR in the last 2 years? (mark all that apply):

- ☐ IRB did not recognize an ethical concern specific to your community.
- ☐ IRB claimed an ethical concern that you did not think was a problem.
- ☐ Consents were burdensome or overly long, technical or too complex
- ☐ Had problems associated with using a shortened consent form(s)
- ☐ Dealt with issues related to literacy level of consent form(s)
- ☐ IRB was slow processing the application.
- ☐ IRB raised concerns about community involvement.
- ☐ IRB required substantial changes to the protocol that delayed the project.
- ☐ IRB required substantial changes to the protocol that affected the science.
- ☐ IRB required substantive changes to the protocol that affected community involvement.
- ☐ IRB refused to approve the study protocol.
- ☐ Refused

B. Do you have experience with any of the following?

- ☐ seeking approval from a community-based IRB
- ☐ working with community representatives on IRB
- ☐ submitting to a dedicated IRB panel for CBPR projects

C. Were you able to resolve the challenges you encountered with your IRB for CEnR/CBPR?

- ☐ Yes
- ☐ No
- ☐ Some, but not all
- ☐ Refused

D. In a sentence or two, please describe ways that you addressed the challenges noted above.

Section 4: Knowledge of specific regulatory options

A. Have you heard of Institutional Authorization Agreements?

- ☐ Yes
- ☐ No
- ☐ Refused

[Skip A2) and A3) if you answered “no.”]

A2) Have your projects ever used Institutional Authorization Agreements?

- ☐ Yes
- ☐ No
- ☐ Refused

A3) Have your projects ever used an Institutional Authorization Agreements in a CEnR/CBPR study?

- ☐ Yes
- ☐ No
- ☐ Refused

B. Have you heard of of Individual Investigator Agreements?

- ☐ Yes
- ☐ No
- ☐ Refused

[Skip B2) and B3) if you answered “no.”]

B2) Have your projects ever used Individual Investigator Agreements?

- ☐ Yes
- ☐ No
- ☐ Refused

B3) Have your projects ever used an Individual Investigator Agreements in a CEnR/CBPR study?

- ☐ Yes
- ☐ No
- ☐ Refused

C. Are you aware of Federal Wide Assurances?

- ☐ Yes
- ☐ No
- ☐ Refused

[Skip C2) if you answered “no.”]

C2) Have your projects ever sought Federal Wide Assurances for community partners?

- ☐ Yes
- ☐ No
- ☐ Refused

I) Do you have any comments on the effectiveness of Institutional Authorization Agreements, Individual Investigator Agreements or Federal Wide Assurances?

_____
_
_____
_
_____
_
_____
_
_____
_

Table 1

Sample Demographics (N=101). Total N varied slightly between questions.

Category	N	Mean (SD)
Age in Years	92	43.6 (12.5)
Years in Research	99	16.0 (10.7)
Number of NIH Grants as PI	99	3.5 (6.3)
Number of NIH Grants as co-I	92	7.7 (12.9)
Year Received Highest Degree	96	1997.5 (10.0)
Category	**Count**	**(%)**
Gender		
Female	72	71.3
Male	28	27.7
Race		
White	69	75.0
Black/African American	10	10.9
Asian Pacific Islander	4	4.3
Native American/American Indian	4	4.3
Other	5	5.4
Ethnicity		
Hispanic	17	17.0
Non-Hispanic	83	83.0
Research Role		
University Partner	87	90.6
Community Partner	8	8.3
Other	1	1.0
Job Title		
University Faculty	51	50.5
Administrator	11	10.9
Project Staff	17	16.8
Postdoctoral Fellow	7	6.9
Student	5	5.0
Community Partner	5	5.0
Other	4	5.0
Highest Degree		
College	11	10.9
Masters	30	29.7
Doctoral	59	58.4
Other	1	1.0

Table 2

Main Survey Responses (N=101). Total N varied slightly between questions.

Category	N	Mean (SD)
Number of CEnR Projects	80	4.1 (7.4)
Number of CBPR Projects	78	2.2 (2.6)
Year of First CEnR	65	2000.7 (10.0)
Year of First CBPR	58	2004.3 (7.0)
Category	**Count**	**(%)**
CEnR Experience	80	80.0
CBPR Experience	67	66.3
NIH-Funded CEnR	63	84.0
NIH-Funded CBPR	55	83.3
Experience with Community-based IRB	19	20.7
Worked with IRB Community Representative	25	27.2
Submitted to CBPR IRB panel	9	9.8
Resolved IRB challenges	51	73.9
IRB Authorization Agreement (IAA)		
Heard of	32	31.7
Used	22	21.8
Used in CEnR/CBPR	18	17.8
Individual Investigator Agreement (IIA)		
Heard of	25	25.5
Used	16	15.8
Used in CEnR/CBPR	12	11.9
Federalwide Assurance (FWA)		
Aware of	55	54.5
Sought (for Community Partner)	31	30.7

CEnR, Community Engaged Research; CBPR, Community Based Participatory Research.

Table 3

Challenges Experienced in Interactions with IRB for CEnR/CBPR projects in the Preceding Two Years (N=88).

Type of Challenge	Yes (%)
Consents were burdensome or overly long, technical or too complex.	64.8
Dealt with issues related to literacy level of consent form(s).	50.0
IRB was slow processing the application.	50.0
IRB required substantial changes to the protocol that delayed the project.	35.2
IRB claimed an ethical concern that you did not think was a problem.	25.0
IRB required substantial changes to the protocol that affected community involvement.	12.5
IRB required substantial changes to the protocol that affected the science.	10.2
Had problems associated with using a shortened consent form(s).	10.2
IRB did not recognize an ethical concern specific to your community.	9.1
IRB raised concerns about community involvement.	8.0
IRB refused to approve the study protocol.	1.1

Table 4

Awareness of Regulatory Mechanism by Various Demographic Characteristics.

	IAA Count (%)	χ^2 (N)	IIA Count (%)	χ^2 (N)	FWA Count (%)	χ^2 (N)
CEnR Projects						
Few	11 (26)		10 (25)		21 (50)	
Many	16 (55)	**6.114* (71)**	12 (41)	2.077 (69)	24 (83)	**7.932** (71)**
CBPR Projects						
Few	11 (27)		10 (25)		21 (51)	
Many	11 (50)	3.382 (63)	8 (36.4)	0.583 (62)	19 (86)	**7.629** (63)**
CEnR Experience						
Long	16 (43)		14 (40)		28 (76)	
Short	6 (26)	1.798 (60)	7 (30.4)	0.438 (59)	9 (39)	**8.013** (60)**
CBPR Experience						
Long	11 (37)		9 (31)		23 (77)	
Short	6 (21)	1.623 (58)	9 (32)	0.008 (57)	12 (43)	**6.918* (58)**
Age						
Young	14 (29)		10 (20)		17 (35)	
Old	14 (32.6)	0.806 (92)	10 (20)	1.68 (89)	32 (74)	**14.518*** (92)**
Experience						
Less	14 (28)		11 (22)		20 (40)	
More	18 (37)	0.863 (98)	14 (30)	0.885 (96)	34 (69)	**8.62* (99)**
Degree						
New	19 (38)		16 (33)		34 (68)	
Old	10 (22)	3.005 (96)	7 (16)	3.943 (93)	18 (39)	**8.043** (96)**
Occupation						
Faculty	20 (39)		17 (35)		35 (69)	

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	IAA Count (%)	χ^2 (N)	IIA Count (%)	χ^2 (N)	FWA Count (%)	χ^2 (N)
Other	12 (24)	2.701 (101)	8 (16.3)	4.350 (98)	20 (40)	**8.343** ** **(101)**
Gender						
Male	4 (14)		3 (11)		15 (54)	
Female	28 (39)	**5.608** * **(100)**	22 (31)	**4.204** * **(97)**	40 (56)	0.032 (100)

* p<0.05,

** p<0.01,

*** p<0.001