Title

Permalink
https://escholarship.org/uc/item/05p3q662

Journal
IRB, 38(3)

ISSN
0193-7758

Authors
Cargill, SS
DeBruin, D
Eder, M
et al.

Publication Date
2016-05-01

Peer reviewed
Community-Engaged Research Ethics Review: Exploring Flexibility in Federal Regulations

Introduction

Academic researchers, community leaders, and funders increasingly advocate for engaging patients and communities in the research process. The umbrella term “community engaged research” (CEnR) encompasses a spectrum of activities. Here we apply the term to any approach to research that incorporates individuals or organizations from the targeted community as agents in shaping the research.1 This definition presupposes a level of control assigned to community members or representatives beyond that of participant or staff-member-for-hire. CEnR as defined here involves community representatives in consultative roles [e.g., membership on active Community Advisory Boards (CABs)] or leadership roles, (e.g., named co-Investigators on grants). CEnR approaches shape the research process in various ways, including collaborative identification of problems, identifying data collection methods, developing study implementation strategies, and/or providing feedback and consultation regarding interpretation and dissemination of results.2,3 This approach yields an iterative dynamic that is more sensitive to realities “on the ground” as they emerge and more responsive to numerous perspectives on the research design and implementation.

CEnR has numerous goals, some of which are consistent with traditional scientific aims, such as improving the scientific validity and reliability of knowledge gained and incorporating relevant expertise in the research team.4,5 Other goals are consistent with the regulatory aims of IRBs, such as avoiding insensitivity to cultural concerns, use of participants from one community for research that primarily benefits individuals from other communities, exploitation of vulnerable communities, and, in the worst of cases, outright abuse of research subjects.4–6 These goals, along with the incorporation of non-academic members in the research process, provide challenges for IRB review insofar as they diverge from the IRB’s regulatory focus on protection of individual research participants from the mostly physical risks of academic investigator-led, prospectively articulated research. In this divergence, CEnR is just one of a growing number of fields that challenge this traditional model, including--but not limited to--social and behavioral research,7 comparative effectiveness research,8 and quality improvement.9 They make it difficult, if not impossible, to define the expertise of the research team in purely academic terms, articulate the entire protocol prior to the inception of research, define risks and benefits of research in terms of individual risk and general societal benefit, and many other challenges. These challenges, and their accompanying
regulatory requirements, have been repeatedly articulated in public health and research ethics scholarship.

In response, some proponents of CEnR have suggested that the federal regulations need to be fundamentally altered and that IRBs should radically change how they review CEnR by incorporating the broader goals of CEnR into their review. While we must acknowledge inconsistencies between IRB review and CEnR, we should be cautious of prematurely adding new review considerations and regulations. Expanding IRBs’ responsibilities to include the broader scope of priorities in CEnR may negatively affect the timeliness and diffuse the focus of IRB review of CEnR while slowing the translation of research findings into practice. But perhaps more importantly, while CEnR’s advocates articulate important concerns, many of these are best left to the authority and expertise of communities to arbitrate. Increasing IRBs’ authority to evaluate these goals of CEnR, particularly given the extremely limited number of community representatives on most IRBs, continues the practice of discounting community stakeholders’ expertise and authority within the ethical review process.

In contrast, we suggest that the dialogue between CEnR advocates and IRBs should focus on the domains where their goals overlap and their processes are compatible and defer authority over these broader goals to negotiations between the academic and community voices within the CEnR process. Rather than requiring special or additional rules for reviewing CEnR, IRBs should instead recognize the flexibility that exists within current regulations to address these shared domains and decrease the burden on these types of research. The tension between CEnR researchers and IRBs is real. The federal regulations were developed by those immersed in the biomedical model of research. Nonetheless, the actual language of the Code of Federal Regulations and subsequent guidance issued by the Office of Human Research Protections (OHRP) leave quite a bit of latitude for interpretation and application in different contexts. This manuscript explores the ways in which IRBs can utilize the flexibility within the current code of federal regulations and guidance to review CEnR appropriately and where IRBs should recognize and respect the strengths of the CEnR process to address broader ethical issues outside of its domain.

We explore the flexibility in the federal regulations and the utilization of this flexibility for CEnR by focusing on seven major requirements of IRB review that can be seen as in tension with key aspects of the CEnR approach:

1. Determining whether collaborating sites and individuals are engaged in research;
2. Evaluating the competence of CEnR teams;
3. Identifying the appropriate expertise to review CEnR proposals;
4. Ensuring fairness in the selection and recruitment of participants;
5. Ensuring the voluntary informed consent of research participants;
6. Evaluating and minimizing risks; and
7. Managing the review of emergent research design.
Determining Whether Collaborating Sites and Individuals are Engaged in Research

Since community members are agents in CEnR approaches, community organizations can serve as the grant-receiving institution, and community members frequently qualify as research personnel. As such, both community organizations and individuals fall under regulatory purview. IRBs recognize research personnel in terms of their “engagement” (or not) in the research process. The use of the term “engaged” in the regulations refers to a level of involvement in human subject research that incurs regulatory obligations. This use is distinct from its meaning in common parlance and in CEnR. The process of establishing that an individual or organization unaffiliated with an academic institution is “engaged” incurs both time and energy costs for both institutions and research teams. Those involved with CEnR have noted the bureaucratic burden of acquiring administrative recognition for community members of the research team, especially when they are not employees of or affiliated with the academic institution. But IRBs at academic institutions can utilize flexibility within the regulations to minimize barriers and to set up the most appropriate relationship between IRBs and CEnR research team members outside of the institution.

OHRP guidelines recognize either institutions or individuals as “engaged” in research, depending on specific circumstances. Nonacademic institutions are considered engaged in research if: 1) the organization received federal grant funding for human participants research; OR 2) the employees or agents of the organization, for the purposes of a research project, obtain data from participants through intervening or interacting with them, obtain identifiable private information about participants of research, or obtain informed consent from the participants of research. These criteria very often apply to community organizations or their employees in CEnR approaches. If a community organization or its employees are deemed to be officially “engaged” in research, the organization incurs regulatory responsibilities, such as obtaining and maintaining a Federal-Wide Assurance (FWA) and designating an IRB of record. Otherwise, individual collaborators can be considered engaged on their own under the condition that they are “employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research,” or “not acting as an employee of any institution with respect to his or her involvement in the research…”

Community organizations that partner on research or those that employ community members on research teams can be deemed “engaged” under this definition and thus, require an FWA and thus must either develop their own IRB or identify and formally partner with one or more OHRP registered IRBs. While this latter option appears less burdensome that creating and populating their own IRB, it is in fact quite burdensome as well. On the OHRP application one indicates the principles an organization will use as the basis for the ethical oversight of human subjects...
research and provides a list of IRB partners. Every change in the list of IRB partners requires submittal of a revised application. In addition, both the organization with the IRB that is providing oversight and the organization working under an FWA must maintain on file a current “Institutional Review Board Authorization Agreement.” Finally, organizations working under an FWA are required to renew their research misconduct assurance by annually submitting a report to the Office of Research Integrity (ORI) on any misconduct allegations, inquiries or investigations. While completing brief applications and reports may not appear too onerous a task, understanding federal guidance and properly maintaining an FWA requires and consumes dedicated organizational resources. The filings are computer based and require registration of specific individuals and maintenance of passwords. These formal requirements are in addition to the work of obtaining IRB approval for each project, training project personnel and managing project implementations.

IRBs at academic institutions should be cognizant of these responsibilities that accompany designating a community organization as “engaged.” We suggest considering community organizations to be engaged in research only when they receive research grants on a routine basis or are the primary recipient of a federal grant. We also suggest that the IRB Authorization Agreement with a community organization that meets these criteria stipulate that it applies to numerous projects if the community organization is collaborating with the academic institution repeatedly. Otherwise, they should appeal to the second alternative: community members on the research team should be designated as collaborating individual investigators (either independent or institutional), which is less burdensome for both the individuals and their employer organizations.

**Evaluating the Competence of CEnR Research Teams**

While 45 CFR 46 makes no mention of mandatory training in the protection of human subjects, the inclusion of competent research personnel is implicit in the requirement to ensure minimization of risk [45 CFR 46.111(a)1]. More directly, OHRP requires that institutions granted a FWA are responsible for ensuring that investigators “understand and act in accordance with the federal regulations.” Further, “OHRP strongly recommends that institutions and their designated IRBs establish training and oversight mechanisms (appropriate to the nature and volume of their research) . . .”

Existing training programs in human research protections typically do not meet the needs of community members on research teams. Comprehensive training such as that required by most academic institutions [e.g., Collaborative IRB Training Initiative (CITI)], may not be relevant, feasible, adequate, or culturally or contextually appropriate for community partners with narrowly-defined roles. Such training programs also often assume a fairly high level of familiarity with research.

---

1 A sample template is available at [http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf](http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf)
While all individuals involved in research must be trained in the application of general human research participant protections (e.g., protecting confidentiality of data), individual research roles carry specific requirements and qualifications. Standard training programs often do not focus on the necessary skills for day-to-day research activities in a community context (e.g., having an informed consent conversation). There may also be considerations that are specific to the risks of a particular research project (e.g., recognizing when a participant becomes emotionally upset and providing resources for further information or support) or the research- or intervention-related procedures to be performed (e.g., administering a questionnaire or medical assessment).

This variability may require protocol-specific training, education, licensing, or other credentials. It may be appropriate for IRBs to request documentation or other evidence of appropriate skills or training for individuals employed outside of the institution. Community Advisory Boards (CABs), Community Review Boards (CRBs), community consultants, and community team members may be helpful in identifying appropriate training requirements for a particular CEnR project. Given the flexibility of OHRP’s stated requirement, IRBs should accept and increasingly are accepting alternative trainings more appropriate to the roles and challenges faced by CEnR research teams. These alternative trainings are growing in number and available from various sources.\(^{23-25}\)

**Identifying the Appropriate Expertise to Review CEnR Protocols**

“The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.” [45 CFR 46.107]

In order to best protect research participants, the federal regulations call for IRBs to include members who are “sufficiently qualified” to review studies. These qualifications should include expertise about both the methods and the populations of reviewed studies. CEnR is an approach to research rather than a method. Researchers from many different disciplines, including biomedical, social and behavioral specialties, utilize CEnR. At the same time, experience conducting CenR constitutes an important domain of expertise, similar to experience conducting randomized controlled trials or focus groups. IRBs should ensure that board members with experience with community engagement are involved in the review of CEnR protocols.

\(^{ii}\) While CABs and CRBs can and are used to review many types of activities, here we are focusing those that have a designated research review role.
In addition to methodological expertise, the call for experience and expertise in “community attitudes” (i.e., community expertise) recognizes that adequate review requires sufficient knowledge about the participant community in order to assess the risks and benefits, as well as burdens, that would face members of that community should they participate in the study. Likewise, knowledge of communities could assist in evaluating the appropriateness of the recruitment and informed consent process. However, having only one or two individuals as the unaffiliated and/or nonscientist members is unlikely to provide the board with sufficient expertise in community attitudes, since 1) research at any institution is likely to take place within multiple communities and 2) these members are not usually recruited or asked to provide community expertise. The regulations do not prohibit IRBs from having as many unaffiliated and nonscientific members as there are scientists and other affiliated members. While identifying appropriate individuals with the time to devote to un- or undercompensated work is challenging, individuals with specific types of expertise need not be permanent full-time IRB members. The regulations acknowledge the potential limits of adequate expertise among IRB members and have a built-in remedy:

“[I]nvite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.” [45 CFR 46.107(f)].”

IRBs can call in a “consultant” when a protocol raises issues outside their members’ expertise, but this limited practice can be taken much further. Scholars exploring “cultural humility” suggest that the most ethical approach is to assume that no one from outside a specific community is an expert on that community and that professionals should approach the groups they want to study with an attitude of openness and learning. This approach suggests that IRBs should err on the side of caution and seek consultation when reviewing protocols involving communities with which they have limited familiarity, especially in one-off or international contexts.

While availing themselves of their “community” members and consultations, IRBs should also recognize that if CEnR projects consult community representatives throughout the process, as most do, they need not reinvent the wheel in their reviews. IRBs can ensure that research is sensitive to community attitudes indirectly by ensuring that self-identified CEnR protocols attest to incorporating community input. Federal regulations give limited guidance on how IRBs should incorporate other types of review mechanisms, but models for this exist. IRBs can inquire whether a CEnR project has gone through appropriate local/community review by requiring one or more letters of support from community leaders, CABs or CRBs. Investigators should describe in their IRB application how communities were or will be engaged in the development of the research as well as any substantive input that has influenced the protocol (e.g., changes to recruitment or informed consent methods). Many CEnR projects use a group consultation
approach, such as engaging input from CABs or CRBs, and the process of convening and consulting these groups can be described in the IRB protocol. Some IRBs already use this type of procedure in the case of hospitals, prisons, and other institutions where research takes place. Another possible approach is to require community review for IRB approval in the same way that IRBs currently incorporate scientific and data safety monitoring reviews.

**Ensuring Fairness in the Selection and Recruitment of Participants**

IRBs are charged with assuring that “Selection of Subjects is Equitable.” [45 CFR 46.111(a)3] Community members on the research team are often affiliated with (or perhaps even leaders of) community organizations with which they have significant loyalties and/or histories. These relationships may introduce potential biases to the research process as community members, like academic investigators, may be invested in finding certain answers to research questions for political, economic, or practical reasons. Community members in service and research roles may experience conflicts between their obligations to their clients or patients and their obligations to the research. Such dynamics could have a direct impact on human subjects protections, especially in terms of fair recruitment and voluntary informed consent. Community members on the research team may also have close relationships to the people they select and recruit. This may pose risks of coercion or undue inducement in much the same way as it does for clinician-researchers. While Conflicts of Interest Committees and IRBs are well versed in evaluating financial conflicts of interest, such potential nonfinancial conflicts are at risk of either being neglected or overemphasized, if considered in isolation from the dynamics of the community context of the research. Determining whether these concerns are applicable to specific team members in specific communities requires community expertise. Thus, the question of who participates in recruitment processes is an area where review by community experts or CEnR experts on the IRB, as described above, may be helpful or even necessary.

**Ensuring the Voluntary Informed Consent of Research Participants**

The regulations allow flexibility in terms of both the content and the process of informed consent, provided the disclosure serves to minimize risk and enhance participants’ understanding of the research.

“The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.” [45 CFR 46.116]

This flexibility provides latitude in adapting standard required consent language to different community audiences with different literacy levels and cultural norms. The challenges to achieving appropriate language in a consent form are vast and not unique to CEnR approaches. Like with issues of subject selection and recruitment,
IRBs should recognize that CEnR approaches can mitigate many of the concerns regarding appropriateness of informed consent language, content, and process. For example, if community members on the research team suggest that using a long written document could be problematic, a community advisory board could be instrumental in determining other appropriate means for obtaining informed consent. Such input can provide the IRB with more reliable assurance that language, content, and process are appropriate to that community.

Many CEnR studies recruit participants with limited proficiency in English both within the U.S. and in international research, such as in studies on health disparities and barriers experienced by minority communities. If non-English speaking participants are going to be included, IRBs review translated informed consent documents and other study materials. Often though IRBs do not have language expertise and therefore rely on evidence of professional translation services or standardized translation procedures (e.g., back-translation). Community research partners may be fluent in another language and therefore integral not only to the recruitment of participants, data collection, and intervention delivery but may have a key role to play in ensuring adequate translation.

Beyond language, traditional informed consent requirements may pose challenges given the cultural values and preferences of different communities. For example, consent (or “blessing”) from community leaders may be required, the dynamics of authority within familial relationships may require involvement of parents or spouses for adult participants, or cultural norms regarding privacy could implicate where consent conversations should take place. Although these considerations are not unique to CEnR approaches, IRBs should recognize that CEnR teams are in a privileged position to recognize them, since members of the research team have expertise in working with the specific community in question. With cultural humility, IRBs should seriously consider input from community members on the research team or community boards regarding when these adaptations improve the informed consent process and lower risks to participants. For more complex projects, IRBs can utilize local experts to develop workable adaptations to the consent process that satisfy both regulatory requirements and local needs. For example, community experts may have ideas on the logistics of how to achieve both community-level consent and individual consent, or how to obtain individual consent that shows respect for familial and community norms and values.

**Evaluating and Minimizing Risks**

Assessing the risk of a research protocol is an important aspect of IRB review. Many have criticized IRBs for overestimating\(^{12,32}\) as well as underestimating\(^{33}\) the nonphysical risks of research that deviate from the traditional physical risk focus of the biomedical model. The regulations once again provide flexibility on this issue and parameters that can be used more appropriately for CEnR.
“[I]n evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).” [45 CFR 46.111(a)2]

While the reference to “therapies” clearly has clinical standard of care in mind, it more broadly indicates that IRB reviewers should focus only on the risks associated with the protocol that are directly related to the research. Risks associated with the standard of care or services that would be offered anyway should not factor into the risk classification. For example, much CEnR takes place in partnership with community-based organizations (CBOs) that serve high-risk communities, such as the homeless, inner-city youth, etc., on a regular basis. The question for IRBs is not how much risk is there in the context, but how much risk is being added by the research. CEnR protocols often encounter barriers to approval because IRBs see first the risks of the context and do not filter out the risks that would exist even without the research being conducted.12

“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]

The spirit behind this regulation is to prevent IRBs from speculating about risks less directly connected to the research, such as those that occur further into the future and those consequences of the results of the research, rather than the process of participating in the research.34 Concerns about “effects of applying knowledge” may include stigma, discrimination, and/or legal repercussions at both the individual and the community level.

These “excluded” risks are often of central importance to communities engaged in research. Thus, many in CEnR argue for the importance of identifying these risks and some encourage including them in IRB review.14 We recommend that IRBs continue to follow the spirit of this regulation by avoiding speculation, but acknowledging that community expertise may be able to reasonably anticipate harms that IRBs without this expertise cannot. First, IRBs may perceive effects of applying knowledge from the study as long-range and unforeseeable when people with community expertise and experience consider them reasonably foreseeable and expected in the short term. Communities with experience of stigma and discrimination based on scientific data, may rightly anticipate risks of proposed research, making these types of risks just as predictable and harmful (and short-term) as the risks of research participation itself.

Second, recent scholarship has pointed out that there is an important distinction between group-mediated risks that affect individuals (such as discrimination against an individual due to membership in a group) and group-level harms, such as those that directly impact the structure and health of communities.35,36 IRBs are
charged with protecting individual research participants rather than groups, but they should recognize that individual participants can incur research risks by being affiliated with groups and communities, and this constitutes another important category of risks they should consider.

Even though IRBs should stay within their charge of protecting individuals as opposed to groups, this is not to say that group-level harms are not important to consider. But these considerations are best left to the authority and expertise of CRBs, CABs or community leaders to evaluate. Just as an IRB can approve research but another institutional body (e.g. risk management) can disapprove that research, a CAB, CRB, or community organization can and should be able to deny a researcher from conducting IRB-approved research if they believe it is harmful to their community. Properly conducted CEnR, which shares control of the research with members of the community, would need to be answerable to these concerns.

**Managing the Review of Emergent Research Designs**

The current regulatory framework assumes that the research protocol is fully articulated prior to the initiation of a study and that ethical research adheres to this outlined protocol. Research that deviates from research plans requires either prospective approval of amendments or reporting of problematic deviations after the fact. Within the current regulatory framework, unapproved implementation of changes prior to IRB review and authorization constitute “protocol deviations,” “protocol violations,” “protocol variances,” or even “non-compliance.” These labels at best imply exceptions to the rule and at worst unethical behavior deserving of penalties.

In many cases, CEnR protocols are not fully articulated when the research activities begin. Such protocols follow an “emergent design” approach that is intended to be responsive as feedback from the community and experience inform the research plan. Due to this dynamic nature of CEnR, many changes to protocols may need to happen immediately, which may necessitate going to the IRB after the change has occurred rather than prospectively. Emergent design in CEnR presupposes that these alterations will be commonplace and that such changes are good research practice (that is, responsive to community needs and preferences). This is a significant mismatch between the current regulatory framework and CEnR approaches. There are two potential avenues within the current regulations to bring IRB practice and CEnR approaches closer together: expedited review of prospective changes and accepting protocols with built-in flexibility.

“An IRB may use the expedited review procedure to review...minor changes in previously approved research during the period (of one year or less) for which approval is authorized.” [45 CFR 46.110(b)2]
OHRP guidance allows individual institutions to determine when prospective changes are minor or major.\(^{37}\) While institutions with more CEnR experience may consider certain frequently occurring revisions to be “minor” changes, the delays and administrative burdens that follow the requirement for even expedited review of each particular change can significantly disrupt the flow of CEnR in ways that may not be recoverable and that incentivize withholding information. While there currently appears to be no regulatory flexibility beyond expedited review of minor changes, there are signs that the process may change in the future.\(^{iii}\)

Another potential solution is for the IRB to accept flexible research protocols, provided that the potential range of paths forward is comprehensively and accurately outlined. The Secretary’s Advisory Commission on Human Research Protections (SACHRP) recommends writing protocols with built-in flexibility, as long as it does not adversely affect participants’ safety or the quality of the science.\(^{38}\) Variations within that defined scope would not constitute deviations from the protocol. For example, researchers could supply the IRB with and interview guide that includes topics and examples of questions to be used in questionnaires, surveys or focus groups, rather than a specific list. Then, if community feedback during implementation suggests that certain questions or wordings are insensitive, inappropriate, etc., these can be altered without additional IRB review. Accepting a more flexible protocol would not eliminate IRB authorization nor the need for a prospective research plan as required by the regulations; rather, such an approach creates space for emergent designs to evolve and for the responsiveness required of many CEnR projects.

**Conclusion**

Community engagement in research is acclaimed on both methodological and ethical grounds and is increasingly prevalent. Many of the ethical commitments of CEnR overlap with IRBs regulatory considerations, such as improving the real-world

---

\(^{iii}\) For example, the University of Michigan has implemented demonstration projects with non-federally funded research protocols that explore the options afforded to research institutions that do not apply the federal regulations to non-federally funded research, or those who “uncheck the box.” (See Bledsoe CH. Hope in the IRB mire? The Federalwide Assurance box 4(b) option. 2006. [www.medanthro.net/academic/irb.html](http://www.medanthro.net/academic/irb.html). One of these demonstration projects was to allow a specific list of “Permissible Minor Modifications” in non-federally funded protocols to be implemented prior to IRB review and then examining the effects of this change on the risks posed to human subjects. (See Human Research Protection Program. [http://www.hrpp.umich.edu/initiative/demonstrations.html](http://www.hrpp.umich.edu/initiative/demonstrations.html)) Another example comes from the 1996 International Conference for Harmonisation (ICH) Good Clinical Practices report. The ICH attempted to provide reasonable exceptions to the requirement for at least an expedited review for minor changes. The report suggests that exceptions include changes that involve only logistical or administrative aspects of the trial. [See International Conference on Harmonisation (ICH). Good Clinical Practice. [http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html](http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html)] Finally, some have suggested that IRBs establish special review processes for such changes, carried out by an IRB subcommittee or a designated contact person for CEnR projects. (See Shore, 2007.)
benefit of research, increasing sensitivity to cultural concerns, maximizing benefit to
the individuals who participate in research, and preventing the outright abuse of
subjects. Meanwhile, other ethical commitments of CEnR may fall outside IRB
purview, such as considering community-level risks, fair and equal partnerships,
and benefits sharing.

We advocate for a more coordinated approach to ethics in the review and conduct of
CEnR and agree with Ross et al. that the IRB cannot and should not be solely
responsible for assuring the ethics of a given CEnR study in all domains. Individual
investigators, conflict of interest committees, research ethics consultation programs,
research subject advocacy programs, data safety monitoring boards, CABs, and
community review boards all have important roles to play in ensuring the ethical
conduct of CEnR. The federal regulations and their implementation in IRB review
must assure adequate and appropriate adjudication of those regulatory concerns
that are within the IRB’s purview aimed at protecting individual research subjects
from harm. By recognizing the flexibility within the current regulations and
guidance, IRBs can apply federal standards both consistently and appropriately to
CEnR while reducing current burdens. At the same time, IRBs can avoid the mission
creep that would lead to their adjudicating ethical concerns that are outside of their
expertise and purview.

References

1 Anderson, E, Solomon S, Heitman E, Dubois J, Fisher C, Kost R et al. Research
Ethics Education for Community-Engaged Research: A Review and Research

2 Israel BA, Eng E, Schulz AJ, Parker EA. Introduction to methods in community-
based participatory research for health. Methods Community-Based Particip Res

3 Minkler M, Wallerstein N. Community-Based Participatory Research for Health:

4 Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based
research: Assessing partnership approaches to improve public health. Annu Rev

5 Minkler M. Community-based research partnerships: challenges and

6 Shore N. Community-Based Participatory Research and the Ethics Review

7 De Vries R, DeBruin DA, Goodgame A. Ethics Review of Social, Behavioral, and
Economic Research: Where Should We Go From Here? Ethics Behav 2004; 14:
351–368.


32 Childress H. The anthropologist and the crayons: Changing our focus from

33 Shore N. Community-based participatory research and the ethics review

34 Gray BH. Changing Federal Regulation of IRBs, Part III: Social Research and the

35 Hausman DM. Group risks, risks to groups, and group engagement in genetics

protections in community-engaged research: a research ethics framework. *J
Empir Res Hum Res Ethics JERHRE* 2010; 5: 5.


38 Secretary's Advisory Committee on Human Research Protections. SACHRP
Minutes. 2011.

39 Ross LF. 360 degrees of human subjects protections in community-engaged