

IRB/REB Curriculum on Ethical Considerations in Community-Engaged Research

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Background: In 2007, Community-Campus Partnerships for Health (CCPH) and the Tuskegee Bioethics Center co-sponsored an educational conference call series to examine the role of Institutional Review Boards (IRBs) in community-based research. Over 500 researchers, practitioners, and community partners joined the call series, indicating a significant level of interest in the topic. The call series proceedings, “Ensuring Community-Level Research Protections”¹ and subsequent CCPH co-edited theme issue of the Journal of Empirical Research on Human Research Ethics² identified a number of challenges related to research review of community-based research and highlighted conflicts between the protection of individuals participating in research and the protection of communities in which research takes place. In a follow-up survey, call participants indicated that the highest priority for follow-up action should be given to “trainings for IRB members and administrators.” An initial assessment conducted with over 150 American IRB and Canadian Research Ethics Boards (REB) members confirmed their desire and need for a training curriculum on ethical considerations in community-based research made available online and through in-person workshops.

In response, CCPH issued a call for volunteers to develop the curriculum. The response was so overwhelming that two groups were formed: a workgroup to develop the curriculum and an advisory/review committee to review drafts and advise on plans to pilot and disseminate the curriculum. Both groups are comprised of community-based researchers, educators, and IRB and REB members and administrators. Workgroup members are listed on pages 4-5.

Meeting by conference call and email, the workgroup has identified the curriculum’s key components, learning objectives, and intended outcomes. A Canadian subcommittee was also established to ensure that the curriculum is relevant and responsive to the Canadian context. During summer – fall 2009, writing subcommittees are drafting the three core curriculum modules: Definitions and rationale; Ethical Issues; and Ethical Review of CER. The workgroup will be convening in December 2009 to finalize the draft curriculum and confirm the plan for piloting it. With the core modules completed in the first quarter of 2010, additional subcommittees will develop modules to address ethical considerations that arise in specific community populations and contexts including faith-based communities, Tribal and First Nation communities, international settings and community health centers.

Curriculum Audience: The curriculum is intended for administrators and members of IRBs and REBs.

Curriculum Goals, Objectives & Outcomes: The curriculum is intended to bridge the knowledge gap between IRB/REB members and community-based researchers, create a shared understanding of community-engaged research (CER) and the ethical issues that arise in CER, and ensure that ethics review of CER adequately attends to community-level research protections. The curriculum will address the specific ethical issues that arise in the conduct of research in communities, including informed community consent, confidentiality and privacy, community risks and benefits, emergent study designs, data ownership, and dissemination of results.

The draft curriculum will be piloted during winter 2010 with a selected group of IRBs/REBs and feedback incorporated into the final version. The curriculum will be available online and also offered “live” through training workshops at individual IRBs/REBs or at conferences attended by IRBs/REBs (e.g., PRIMR). A selected group of individuals involved in the project (e.g., CCPH staff, curriculum authors, other IRB/REB workgroup members) will be identified and prepared to serve as trainers who can deliver the curriculum at conferences and on-site at IRBs/REBs. (It is important to note, however, that the online curriculum can be

self-administered and is not dependent on having an outside trainer deliver it). The curriculum will also be made available through the CITI platform.

The specific objectives of the curriculum are to:

1. Describe the rationale, principles, methods, risks and benefits of CER
2. Identify ethical considerations that commonly arise in CER in a specific populations and contexts, including faith-based communities, Tribes and First Nations communities, international communities and community health centers
3. Provide tools and case studies that will help reviewers recognize, analyze and address ethical considerations that arise in CER

The intended outcomes of the curriculum are:

1. IRB/REB administrators and members are able to:
 - a. demonstrate an understanding of what CER is and is not
 - b. articulate the ethical issues that arise in the conduct of CER
 - c. conduct informed ethics reviews of CER proposals
2. A diverse group of trainers is able to effectively deliver the curriculum content to IRB/REB administrators and members.

Why “Community-Engaged Research?” We have chosen the term community-engaged research (CER) in order to encompass multiple approaches to research conducted in communities that IRBs and REBs encounter (from “community placed” research to “community-based participatory” research) and to not inadvertently imply the curriculum pertains only to one particular approach. The curriculum will acknowledge that CER currently takes place across a wide spectrum of approaches that engage communities (or not) in different ways and in different phases of the research process. IRB and REB members must be prepared to effectively evaluate the ethics of research protocols that fall all along this spectrum. The curriculum will provide IRBs and REBs with tools and information to examine all research protocols that involve communities and therefore require consideration of community-level ethical issues.

Natural Tensions in the Development of the Curriculum: We recognize that there are inherent tensions that arise in this work. We do not believe that these tensions require an “either/or” approach, but rather that, in most cases, the curriculum can serve dual roles. For example:

- Natural tensions arise in discussing IRBs and REBs because they are not one uniform entity. Across institutions and countries, these boards differ in their operations, approaches, and views of their roles and responsibilities. IRBs and REBs that use the curriculum will take different responses to concepts presented in the curriculum, including whether and how to operationalize them.
- There is a natural tension between working within the conceptual, legal and regulatory frameworks that IRBs/REBs currently operate within and advocating for fundamental changes in these frameworks. This curriculum by its very existence will serve to challenge the status quo of how CER is reviewed by IRBs and REBs. The information and tools provided in the curriculum will help guide these boards to widen their lens from individual-level research protections to also include community-level research protections. The curriculum is not intended to be proscriptive in this regard, but to provide case studies, sample forms and other resources that facilitate the ability of IRBs and REBs to thoroughly review CER protocols.
- There is a natural tension between using the curriculum to raise awareness and understanding of CER, and using the curriculum to advocate for specific outcomes. The curriculum can be used for

both education and advocacy purposes. Some IRBs/REBs may use the curriculum to provide a basic understanding of CER among their members; others may use the curriculum to ignite a much broader discussion and action around the role of IRBs/REBs in ensuring community-level research protections. The curriculum is intended to provide information, pose key questions and foster critical thinking that can guide both education and advocacy efforts.

Curriculum Formatting: Each section contains, as appropriate, the following components. For examples of each, please review the CBPR Curriculum at: <http://www.cbprcurriculum.info/>

- Learning objectives
- Key concepts (main text)
- Example documents that demonstrate key concepts (e.g., sample sections of a research protocol, sample Memorandum of Agreements).
- Case studies and training exercises that illustrate key concepts (e.g., situational scenarios that highlight key ethical concerns), with discussion questions that foster critical thinking
- Citations and recommended resources

Curriculum Evaluation: Outcome #1a and #1b will be measured by administering a multiple choice questionnaire to IRB/REB administrators and members upon completion of the training. The questions will be in response to a set of CER cases where the respondents are asked to apply the curriculum content to the case study questions. Outcome #1c will be measured by asking the participating IRB/REB administrators and members to complete a survey 6 months after the training that assesses whether they have reviewed any CER proposals since the training and if so, the extent to which they have applied what they have learned in their review of the proposals. Versions of these assessments will also be included in the online version of the curriculum.

Outcome #2 will be measured in three ways: (1) trainers will complete a written assessment that will measure their knowledge of the curriculum content prior to and after conducting trainings; (2) IRB/REB administrators and members will be asked to evaluate the effectiveness of the trainer by completing an evaluation form at the conclusion of the training; and (3) the above-mentioned multiple choice questionnaire that assesses whether the immediate outcomes of the training have been achieved.

Evaluation activities will also include gathering feedback from participating IRB/REBs regarding how to strengthen the design and implementation of the curriculum. The participating institutions will be asked to complete a brief feedback survey covering such areas as the challenges encountered in using the curriculum, recommendations for improving the curriculum and suggestions for disseminating the curriculum.

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¹ Grignon J, Wong KA, and Seifer SD. *Ensuring Community-Level Research Protections. Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research.* Seattle, WA: Community-Campus Partnerships for Health, 2008. Available at <http://depts.washington.edu/ccph/irbcalls2.html>

² Shore N, Wong K, Seifer SD, Grignon J, Gamble VN. Advancing the Ethics of Community-Based Participatory Research. *Journal of Empirical Research on Human Research Ethics.* 2008; 3(2), 1-4. Available at http://depts.washington.edu/ccph/pdf_files/JERHRE_intro.pdf