Published in final edited form as:
J Empir Res Hum Res Ethics. 2011 June ; 6(2): 23–30. doi:10.1525/jer.2011.6.2.23.

Developing Community Partner Training: Regulations and Relationships

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Abstract

While funders increasingly support research that partners with communities, community partners still must submit to a regulatory oversight structure that does not reflect their unique research ethics challenges and needs. In recognition of the importance of collaborative research endeavors, the authors engaged in a process of reconnaissance and negotiations with local community partners and research ethics boards (REBs) at the University of Michigan to begin to address the mismatch between regulatory demands and community-based research realities. This preliminary process yielded both changes in the REB oversight structure and training required of community partnered research. While the ultimate impact of these changes remains to be seen, the process itself yielded insights and materials of use to both our local REBs, and hopefully those at other institutions as well. This article will present those insights and provide links to those materials.

Keywords

community partners; research ethics education; REB; research ethics boards; training; community-based research

Increasingly, funders, academic institutions, researchers, and community groups are realizing that health research can be more effective and more efficient when it involves collaborations between academic and community sectors. Academic researchers are increasingly entering into partnerships with active members of community organizations to design, implement, and evaluate research aimed at improving health. Community partners often play a pivotal role in the research process, including developing the research project, identifying and recruiting participants, obtaining informed consent, collecting and interpreting data, and ultimately disseminating the findings in appropriate language and venues.

Federal regulations require community partners that engage in these research collaborations to fulfill the same regulatory requirements and trainings for human subjects protections as academic researchers. However, due to their distinct backgrounds and contexts, community partners face daunting challenges in fulfilling these regulations. These include: learning the technical language and requirements of REBs; applying REB requirements in situations vastly different from those for which they were developed; and dealing with ethical challenges for which the regulations are not designed. The only “guidance” community

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partners receive is an online human subjects training course that has been shown to ill-fit their needs.

The authors represent two intermediary roles in this challenging system at one major American research institution. One (Stephanie Solomon) is a scholar in research ethics who focuses on the ethics of REBs and community-engagement in her work. The other (Patricia J. Piechowski) is a research liaison who serves as the go-between for community partners funded by a health institute within the University of Michigan and UM's REBs, a task that often requires obtaining the appropriate materials from community partners for REBs as well as translating REB requirements to community partners. We realized how dependent the REBs and community partners were on a research liaison to develop REB applications for the partners and communicate to the REB the qualifications and realities of the community partners. We heard the REB staff attest numerous times that they trusted the community partners solely because they knew that the liaison was on board with the project. It is problematic for the entire relationship between REBs and community partners to rely on one staff person, no matter how qualified, to serve as liaison. Not all universities have such a position, and there is no guarantee that this position would be as successful in other environments. Furthermore, the existence of this position, while important, only delays the inevitable challenge of fortifying the ever-increasing relationships between REBs and community partners in research.

Together, we have consistently faced the challenges of the gaps in language, culture, and expectations that exist between REBs and community partners, and decided that a response was necessary. We took our starting point from the assumption that an effective solution could only be achieved by a more precise answer to the question, “What are the barriers to community partners in the human subjects protections system?” We set about answering this question through having directed discussions with the players involved: our local REB administrators, our institutional research oversight office, and community partners who have experience partnering with our institution. Through these iterative discussions, we recognized three immediate needs: (1) The communication between REBs and community partners needed facilitation to avoid extensive back-and-forth and miscommunication; (2) our institution needed a consistent and univocal approach to community-partnered research; and (3) a human subjects training was needed that addresses both the needs and learning styles of community partners and the national regulatory and organizational concerns of our academic institution. The remainder of this paper will relate how we came to these conclusions and the process by which we endeavored to address them.

Methods

Consultation with Local REB Administration

Before developing a response, the two investigators recognized the need to be responsive not only to the needs of community partners, but also to the needs of our REBs. They exist within a complex structure of regulations, policies, and laws that restrict the freedom with which they can respond to any given challenge. Consequently, our first step was to approach our local REB managers and administrators, as well as representatives from the Office of the Vice President for Research, to ask the very straightforward question, “What are the challenges you face in reviewing and approving community-engaged research?” We were tactfully trying to better understand, “Why does it take so long?” We realized that this perspective is often missing from accounts of the challenges to community-engaged research, and without their input and buy-in, no effective changes would be possible. We maintained our dialogue with REB representatives throughout our project—from preliminary meetings to identify challenges, to relaying our preliminary solutions, to gaining acceptance for our final products. From this we developed our two-pronged response to the

challenges: develop communication materials to facilitate REB review of community-partnered research and develop a human subjects training acknowledged by our REB administration and relevant to community partners.

Consultation with Community Partners

Patricia J. Piechowski, in her day-to-day work with community partners, observed many instances of research ethics challenges not covered in standard trainings. She was frequently asked by community partners to make sense of REB requests, and heard complaints about the existing online trainings. More troubling, many academic partners perceived their roles as "shielding" their community partners from the burden of REB oversight. Community partners also criticized the REB system as being overly time consuming, burdensome, and even reaching the point of being "not worth it." Community partners were motivated to engage in research to provide more empirical grounding and funding for their practices, and to utilize evidence to justify these services to independent funding sources; however, as the academic burdens increased, some of our community partners were becoming less and less inclined to enter into these partnerships.

After we consulted with the REB administration and developed our two-pronged approach, we began to develop a training that would be accessible, enjoyable, and relevant to our community partners. We therefore shared our preliminary training materials with our community research advocates, who represent community organizations and are experienced in collaborating with academic institutions. With their input, we modified the training, adding more pictures, shortening several sections, and explaining concepts more clearly. We then presented the training to a larger Community Advisory Board (consisting of community and university partners engaged in research in communities). We inquired whether this training was needed, how it could be incorporated into the board's mission to fund community-partnered research, and whether the specific content and approach of the training was acceptable to them. We received positive feedback and some further ideas on improvement, to which we responded.

After the training was complete, we pilot tested it with members of several organizations partnering in research with the University of Michigan throughout the state. This pilot stage involved a pretest, the training, and a posttest. The exercises throughout the training were intended to solicit real-life examples from the participants, which were then used to improve the content and approach of the training. We invite other researchers and community partners who are interested in empirically evaluating this, or a training of their own, to communicate with us so that we can learn from each other.

Results

Results from REB Consultation: Administrative Burdens and Training Burdens

Administrative Burden #1: Multiple REBs for Review of CBPR—At most large universities, review of community-partnered research is distributed among the multiple REBs at the institution, depending on the department of the academic partner; sometimes these academic partners are from the medical school, while others are from the health sciences or social sciences. The corresponding REBs for these schools have differing review styles and foci. We quickly realized that even if a training were recognized by one REB at our institution, there is no guarantee that it would be acceptable to the other REBs. Likewise with any other administrative or procedural changes we would make.

Administrative Burden #2: Obtaining an REB-of-Record—The next step in working with our REB was to determine what hurdles currently existed in the review

process and how we could play a role in removing those hurdles. In answer to the question, "What takes so long?" the answer we received was that it was largely a result of the administration involved in becoming an REB-of-record for an unaffiliated institution (a community-based organization) that is "engaged in research." U.S. Federal Regulation 45 CFR 46.103(a) recognizes as "engaged in human research" any institution whose employees or agents intervene or interact with living individuals for research purposes or to obtain individually identifiable information for research purposes. An institution is also considered to be "engaged in human subjects research" whenever it receives a direct federal award to support this kind of research. As our target audience was community partners who often interacted with living individuals and their information for research purposes *as well as* often received direct awards from the NIH and other federal organizations, they are always "engaged." And "engaged" institutions are federally required to have an REB-of-record.

Our REB consultants informed us that an "engaged" institution can follow federal requirements in two ways. First, it can obtain its own Federal Wide Assurance (FWA), which requires a lengthy and expensive process of developing and registering an institutional REB as well as submitting extensive paperwork. This option is often financially and otherwise impractical for community organizations that usually lack both the money and the human capital to create a standing REB. The other option for a nonacademic institution engaged in research is to request that an existing FWA institution extend its coverage over it by granting an Agreement, either for the organization or for an individual person, and thus provide an REB-of-record for the community partner's institution (or the community partner him/herself). It is this option that is most often chosen when community partners engage in research. We learned that it is this mechanism for extending an academic institution's FWA (and thus REB purview) to cover and take responsibility for community organizations that accounts for much of the lag time until REB approval for community-partnered research. This was surprising to learn, since much criticism of REB review of community-engaged research does not even refer to this administrative burden imposed by the federal government, which is neither a whim of the REBs nor the result of any direct prejudicial stance.

As so much administrative burden was imposed by this process, we inquired into what was required. Our REBs informed us that the U.S. Department of Health and Human Services required Authorization Agreements to be submitted, which list 13 stipulations for the collaborators, as shown in Table 1, and a space for the signatures of the head of the organization and the FWA Institutional Official (who at UM is at the Office for the Vice President for Research).

The University of Michigan employs an altered version of these requirements in three separate forms: (1) an *Individual Investigator Agreement* with a similar 13 requirements; (2) a *Collaborating Institution Agreement* that has an abridged 8 requirements, including putting the rights and welfare of participants above the research, taking a training, not changing the research without REB permission, reporting to the REB any unfavorable or unanticipated problems, obtaining, documenting, and recording informed consent, reporting noncompliance, abiding by all REB determinations, and providing the names of all individuals engaged in research; and (3) an *REB Authorization Agreement* that specifies REB coverage for one specific protocol and testifies that the partnering institution will satisfy relevant federal regulations and the FWA, be solely responsible for compliance, as well as cultivating "a culture of compliance" with the REB and safeguarding human subjects within its local context.

Once signed, the forms are submitted to the REB staff, which ensures they are filled out properly. Then they are passed along to the REB Chair, who then sends them to the FWA

Institutional Official at the University of Michigan. Once signed, the form then is sent back to the REB. This process takes place each time a protocol that partners with a community organization is submitted to the REB. This process is also in addition to the regular protocol review at the REB.

Training Burden—In response to these requirements, the University of Michigan's REBs require that the individuals or institutional leaders designated as the community partners take the online Collaborative Institutional Training Initiative (CITI) program adapted for the University of Michigan, called *Program for Education and Evaluation in Responsible Research and Scholarship* (PEERRS) or "an equivalent training" approved by the REB. In addition, they must read and sign whichever of the above forms is applicable to their circumstances.

The existing training did not address the particular worries voiced by our REB staff members when asked what makes them hesitant to become the REB-of-record for community organizations, nor did it address many of the listed requirements on the three forms. It seemed to the investigators that it was the many signatures and the existence of the Agreement, rather than relevant training to guarantee that the Agreement could be fulfilled, that sealed the deal. We noted that the institution is predictably cautious about taking responsibility for any potential liability that could occur at another institution. We also noted a double standard: REBs assume that because academic researchers are better trained in research skills than community partners, they are therefore more likely to exceed community partners' knowledge and capabilities in research *ethics skills* and implementation of the federal regulations.

Results from Consultation with Community Partners

As we learned from our community partners and as is well reported in the literature, the training required by this process is not tailored to the types of ethics and communication challenges that partners will be facing in community-based research (Boser, 2006; Boser, 2007; Downie & Cottrell, 2001; Flicker et al., 2007; Grossman et al., 2004; Shore, 2007). For example, CITI's discussion of conflicts of interest focuses on financial conflicts of interest, especially as a result of funding from companies with a direct investment in a particular outcome in the research (UM, 2006). However, in the community setting, conflicts of interest more often arise due to personal connections between those implementing the research and those participating in the research. Moreover, the empirical research literature suggests that online courses alone are insufficient ways to teach ethics to researchers, and even more so to the general adult population (Bebeau & Thoma, 1994; DuBois et al., 2008; Kolb, 1984; Macrina, Funk, & Barrett, 2004; Steneck, 2002).

We also learned from our community partners that although many of them were well versed in the history of research atrocities that have been committed, especially the Tuskegee syphilis study, they perceived no connection between these research abuses and the human subjects protection system that they were encountering. They did not express any impression of its importance or significance in protecting research subjects, but merely saw it as another administrative layer involved in interacting with the research community.

We also learned that our community partners wanted as much interaction and actual skill-building as possible in the training. Requests for more role playing and exercises were frequent. Our community partners emphasized that we could not assume any knowledge of acronyms (including *REB*) or even concepts such as *research project*, and that we had to recognize that our audience typically has no experience with such terminology.

Finally, our community partners emphasized that if they were to face another hurdle to research, namely the training we were developing, they wanted concrete returns on their investment of time and energy. This ultimately is the biggest challenge facing our training, because although we have worked closely with our REB to gain recognition of our training and endorsement of it as an alternative to the online version currently required, we could provide no assurance either within our institution or in other institutions that it will have the desired effect of actually facilitating and expediting the approval process. This may prove to be a detriment to any training until the overall regulatory and legal environment becomes more amenable to research in community contexts.

Resulting Products and Responses

Administrative Burden #1: Multiple REBs Reviewing Community-engaged Research—We asked the Office of the Vice President for Research, as well as the managers of the REBs that received these protocols, to agree to allow all community-engaged research that did not include medical procedures to go through one REB, the Health Sciences REB. This allowed us to collaborate on the development of the training and procedural materials with only one set of administrators.

Administrative Burden #2—While acknowledging the regulatory burden and liability risks that major academic institutions take on when becoming an REB-of-record for an unaffiliated institution, we wondered why a community organization needed to go through this extra administrative process each time they submitted a protocol to the REB. Unless staff had changed, the same trainings and assurances that existed at the time of the first Agreement would be in effect, only with more experience, for later protocols. While we were unable to achieve consensus with our REB administration on this issue, we brought it up as a subject of discussion, which they were willing to start negotiations upon. Our REBs admitted that they had allowed this to be the case with certain community partners with which they had a long history of interaction, but they were uncomfortable with allowing merely a training and the forms to carry the Agreements into the future. They were willing to compromise by perhaps allowing the Agreements to be maintained after one or two partnerships between a community organization and the University, which itself would greatly facilitate research, as well as encourage continued collaborations through multiple projects. This negotiation process is still ongoing.

Training Burden—Before developing human subjects training for our community partners, we wanted to ensure that we were not reinventing the wheel. We therefore explored the trainings that already existed in this context. The first two trainings we explored were “Project TRES,” a bilingual human subjects training program for Community Health workers (*promotores*) in Latino communities (Project TRES, 2005), and Family Health International’s “Research Ethics Training Curriculum for Community Representatives” (FHI, 2004). Neither of these trainings specifically targets community *partners*, but rather are aimed at community members *employed* by researchers or research programs. While the issues definitely overlap, the level of responsibility and REB interaction required of community partners is not the same as the roles of community members of research teams. The third training we explored, Susan Goold’s Vulnerable Populations Course at the University of Michigan, is targeted at academic researchers who work with human participants, but unlike most current training, it focuses on capacity building and practice and emphasizes the types of vulnerable groups that researchers may face in communities, not just the ones regulated by the REB (Goold, 2009). As a result of our extensive process of consultations with the REBs, community partners, and the previous relevant trainings, we developed a training course that covers three major sections. The

training is both interactive and activity-centered, with many pictures, diagrams, and concrete cases, and a minimal use of research jargon.

Section 1: Significance of Human Subjects Protections: As a result of our consultations with community partners, we realized that any training must first demonstrate to the audience why the human subjects regulations are important. We therefore begin our training by emphasizing and illustrating the connection between the history of research misconduct and the history of research ethics principles and regulations. We specifically utilize the example of Tuskegee to motivate community partners to recognize that the regulations are not merely hoops to jump through, but institutional attempts to protect human participants in response to atrocities that communities often know very well.

Section 2: Informed Consent: REBs (and existing online trainings) focus on the centrality of the informed consent process for human subjects protections. Our second section breaks down the commonly required components of the informed consent process and the skills needed to competently obtain informed consent from research participants in a community-engaged research context. This section also includes discussions of vulnerable populations and ways to check participant comprehension. All examples and activities involve challenges that arise for obtaining informed consent in community settings.

Section 3: Interaction with the REB: Through our discussions with the REB and with the community partners, we realized how many of the burdens of the process are the result of communication breakdown, as well as skepticism on the REB side regarding the capacity of community partners to communicate necessary information, e.g., adverse events. Our third section provides guidance in how and when to communicate most effectively with the REB; this includes instruction on how to identify adverse events (AEs) and other reportable information or occurrences (ORIOs), when to make amendments, and how to provide sufficient information for the academic institution to complete the Agreement process. This part was specifically designed both to address the requirements in the forms and to respond to the worries voiced by our REBs. In addition, it includes examples of forms that we have developed with our REBs at University of Michigan to provide REBs with appropriate background knowledge of organizations for the REBs, as well as articulating the differing levels and types of roles of community partners so that the process can proceed more smoothly.

We realized that we had to provide a format that was interactive and discussion-based, that was easy to access, and that utilized minimal resources. We developed a model, based largely on Project TRES, involving a set of PowerPoint slides and an accompanying workbook. The PowerPoint slides are best used didactically, and contain numerous activities and case studies for engaging an audience. The workbook contains alternative activities as well as suggestions for adding or deleting particular sections so that the training can be adapted to time constraints. Its purpose is to train a trainer, who would use the PowerPoint slides to provide face-to-face training. Alternatively, if an institution lacked the resources to provide a trainer, the workbook can be used as a stand-alone resource for teaching oneself.

Our ultimate goal with this training was to make it available and adaptable to other institutions throughout the United States. As the research environment becomes more fluid between academic institutions and communities, a nationally recognized training, or at least a nationally recognized skill set, should emerge and affect the way human subject protections are adapted or made consistent with community-partnered research. Consistent REB policies at the federal level as well as between different academic institutions could serve to encourage this type of research in the same way that funders have begun to encourage it. Until the regulatory and legal aspects of human subjects research become

compatible with these types of research, the funding for such research will be undermined by the hurdles this research faces in local institutions.

The training and workbook have been adapted for electronic dissemination and are being tested nationally by a team at the University of Michigan. Once empirical testing is complete, the training will be improved and made available to the general public athttp://www.ibridgenetwork.org.Any questions about the status of this process can be sent to either of the authors.

Best Practices

Reducing the barriers to community-engaged research requires building a bridge between two worlds. The REB world of regulatory requirements, institutional liability worries, and traditional research models needs to be connected to the world of community organizations, with their commitments to practical outcomes, personal connections, community values, and financial limitations. But first, one needs to address the worries that REBs have about becoming the REB-of-record for these partners. REBs need to recognize that training that teaches requirements in a way that is understandable and applicable to community-based research will provide more assurance to the REB-of-record, and build more relevant capacities in the community partners, than existing trainings that have been shown to be inadequate for academic researchers and even more so for those without an academic background. By developing standardized forms that facilitate communication between community partners and the REB (forms that ask questions that make sense to both), one is able to further bridge this gap.

Approaching the REB with the shared goals of making review of community-partnered research more effective and efficient puts everyone on the same team. One should enter the conversation with the REB by asking, “What can we do, from the community-partner side of research, to make your task of reviewing this research easier?”

Community partners vary greatly in their amount of experience with research, type of role in their communities, type of communities, and type and level of their education. It is easiest to work with established communities, that is, groups that “have their own organizational structure and leadership and exist regardless of the research” (Ross et al., 2010, p. 5), and communities that have some experience with research already. In such communities, one can elicit cases of ethical challenges that could be used to adapt the training to relevant community-research contexts. Once a critical mass of case studies is accumulated, the training can serve two further purposes: (1) the generic case studies and examples in the published training can be replaced with cases that are more reflective of the particular context of future trainees, and (2) the training can then be given to those who have no experience with research, and will include practical examples for them to learn from.

Acknowledgments

We thank our two major collaborators: the University of Michigan’s community advocates, partners, and Michigan Institute for Clinical and Health Research's (MICHR) Community Engagement Coordinating Council; and the members of the University of Michigan REB and Office of Vice President for Research. We also acknowledge the financial support of the MICHR and its CTSA grant #UL1RR024986. Finally, we thank our mentors in this project (in alphabetical order): Molly Dwyer-White, Carolyn Sampselle, Nick Steneck, and Marita Titler.

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Science. She was the lead researcher on this project. While the consultations and conversations discussed in this article were jointly attended by both authors, she takes primary responsibility for the content of this article and shares responsibility for the content of the training with Patricia J. Piechowski.

Patricia J. Piechowski is a Clinical Research Liaison with the Community Engagement Program in the Michigan Institute for Clinical and Health Research (MICHR) at the University of Michigan. Her role as Clinical Research Liaison works toward ensuring that investigators address key community issues, and also provides consultation, assistance, and monitoring to research investigators.

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TABLE 1

Authorization Agreement Stipulations for Community Partners.

1	The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1 of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.
2	The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3	The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Agreement.
4	The Investigator will abide by all determinations of the Institutional Review Board (REB) designated under the above FWA and will accept the final authority and decisions of the REB, including but not limited to directives to terminate participation in designated research activities.
5	The Investigator will complete any educational training required by the Institution and/or the REB prior to initiating research covered under this Agreement.
6	The Investigator will report promptly to the REB any proposed changes in the research conducted under this Agreement. The Investigator will not initiate changes in the research without prior REB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7	The Investigator will report immediately to the REB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
8	The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR Part 46 (or any other international or national procedural standards selected on the FWA for the Institution referenced above) and stipulated by the REB.
9	The Investigator acknowledges and agrees to cooperate in the REB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the REB in a timely fashion.
10	The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the REB.
11	Emergency medical care may be delivered without REB review and approval to the extent permitted under applicable federal regulations and state law
12	This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
13	The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research (U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) 2009).