

Partnership Perspectives



Volume IV, Issue I

Winter 2007

Partnership Perspectives is published by Community-Campus Partnerships for Health (CCPH), a nonprofit membership organization that promotes health (broadly defined) through partnerships between communities and higher educational institutions.

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Correct Citation:

Seifer SD and Sgambelluri AR (editors). *Partnership Perspectives*. 2007; IV:I. Seattle, WA: Community-Campus Partnerships for Health.

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Community-Academic Partnerships and Institutional Review Board Insights

Sarah Beversdorf, Syed M. Ahmed and Barbra Beck

Introduction

Community and academia co-exist on the same planet, but they operate with different systems of accountability, process and communication. With an intersection of community and academia, a collision of cultures occurs. Within the scope of community-academic partnerships, the opportunities for culture clash are numerous. One of those opportunities happens when the academic Institutional Review Board (IRB) is involved.

With oversight for assuring the safety of human research study participants, the IRB is bound by federal guidelines, institutional precedent, and its own cultural understanding of research. The IRB's guiding principals may not be familiar to or seem reasonable to communities or even to individuals working within the same academic institution. This article begins with a story that outlines what happens when an urban-based IRB intersects with a rural community through a community-academic partnership. The remainder of the article discusses three sets of strategies for increasing the understanding of and communication between communities and academic institution IRBs.

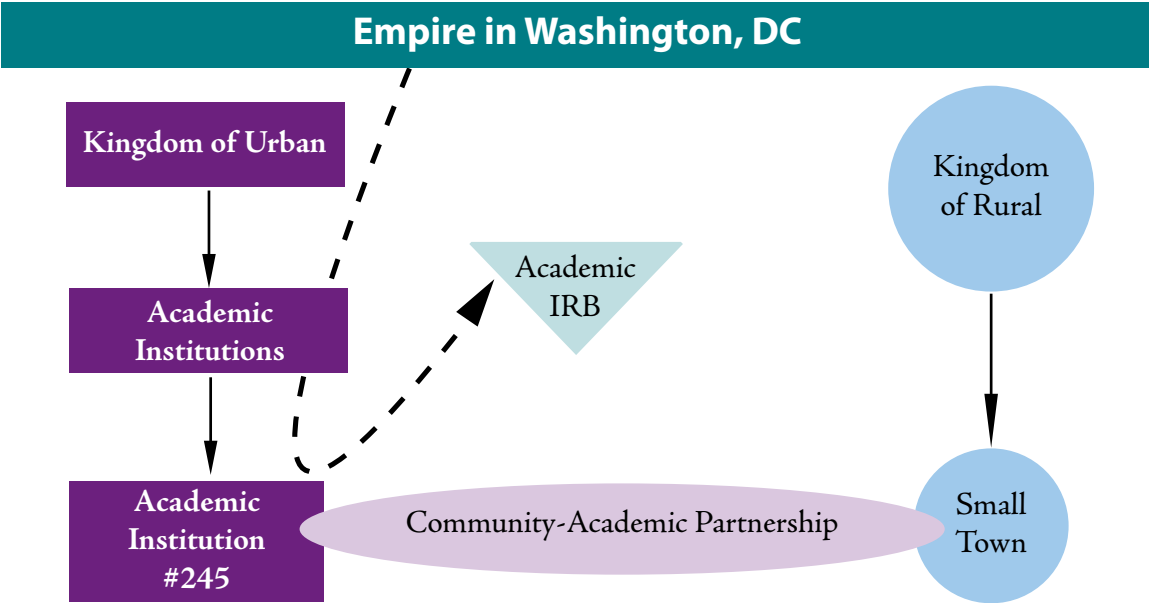
AcaInsti's, Kingdoms, and the Emperor

Our story begins many years after residents of SmallTown in the Kingdom of Rural developed a partnership with employees of Academic Institution #245 (AcaInsti #245) from the Kingdom of Urban [Figure 1].

Eight or 10 years passed – the dates weren't all that important to the partnership – and the relationship grew. Together, they focused on programmatic efforts to reduce substance abuse and support youth. In fact, the partnership seemed to be doing so well that the AcaInsti #245 folks determined that others in the Kingdom of Rural and the Kingdom of Urban needed to know about this good work! They set about planning how they would tell others about the success they had with their partnership (in other words, how they would contribute to generalizable knowledge). However, before they could share the great results with the Kingdoms of Rural and Urban, they needed to get some additional survey information from SmallTown, and they needed to do it in accordance with the rules and laws of AcaInsti #245. The research rules were determined by the Emperor in Washington, DC. The partners thought: "This is going to be an interesting intersection of AcaInsti #245 and SmallTown." No one in AcaInsti #245 had really tried to apply AcaInsti's rules to anyplace outside of AcaInsti, especially anyplace in another Kingdom, like SmallTown. Needless to say, they were a little concerned as to how it would all turn out....

Everyone did what they thought they were supposed to. The AcaInsti #245 employees, who were new to this research concept, participated in the Emperor's training on the importance of how to collect research information. AcaInsti #245 employees submitted a report to their

Figure 1: Relationships between the Community Academic Partnership and the Institutional Review Board



Institutional Review Board (AcaIRB) that indicated how they were going to do the research. Key residents of SmallTown understood that there were rules, and although they weren't exactly clear of the necessity for the rules and the reasoning behind the rules, they were willing to follow them. Everything seemed like it would be just fine, until... A very practical, down-to-earth SmallTown farmer said that if the research was done in the way that was mandated by the AcaIRB, almost no one would participate, and if no one participated then it really wouldn't be reflective of SmallTown, and if it wasn't reflective of SmallTown, then what was the point?

Well, this made a lot of sense to the new-to-research employees at AcaInsti #245, and so they said, "That's okay. We'll just not broadcast our successes; we'll not contribute to generalizable knowledge, and we'll carry on as we had been, doing good work with the community." The partners assumed that if they didn't conduct the survey as research, they could simply adjust their approach and implement the survey in the way that would obtain the most reflective picture of SmallTown. Given that everyone involved was primarily interested in seeing success in the community, this solution was satisfactory to all the partners. What they neglected to do, however, was tell the AcaIRB that they had changed their plans....

AcaInsti #245 employees and the SmallTown residents went ahead with their revised plans and gathered the information through a survey. The information that was collected was reflective of SmallTown, and the results indicated positive health impacts. While the partners shared this information generously in their own community, they were disappointed not to be able to share the information with others in the Kingdoms.

As the AcaInsti #245 employees further explored the distinctions between 'research' and 'evaluation of programs', it became clear that deciding to not do the SmallTown survey research in the manner approved by AcaIRB had many more implications than just a decision on the part of the partnership.

As time passed, inklings of trouble began to appear. As the AcaInsti #245 employees further explored the distinctions between ‘research’ and ‘evaluation of programs,’ it became clear that deciding to not do the SmallTown survey research in the manner approved by AcaIRB had many more implications than just a decision on the part of the partnership. Apparently, there were forms to be filed, protocols to be withdrawn, and a lot of other paperwork. This part of the process had not been in the training from the Emperor. Now the AcaInsti #245 employees had serious problems.

When the AcaIRB found out what had happened, they determined that since the information was intended to be gathered one way and then was gathered differently, the results could not even be used in SmallTown to share with each other. In other words, the information needed to be destroyed. This was very confusing to SmallTown residents, as they didn’t particularly care how the information was collected and they didn’t feel violated; they just cared that it accurately reflected their own situation. Which it was (accurate) and did (reflect their own situation).

Because the AcaIRB had never been to SmallTown or any place remotely like it, and had never experienced a relationship like that between SmallTown and those few AcaInsti #245 employees, they didn’t understand the motivation behind the efforts, and didn’t understand the reasoning behind changing how the information was collected at the last minute. They didn’t understand the power of a partnership, the respect and trust that was built and maintained, and the give and take that is paramount in a partnership. Confusion reigned for quite some time.

After multiple formal and informal conversations, and reviews, the AcaIRB seemed to understand and began to work with AcaInsti #245 employees to address the current situation and move forward. This led to conversations about how SmallTown and AcaInsti #245 could actually DO research (so that information could be shared) AND gather the information in a way that was truly reflective of SmallTown. Eventually, SmallTown-involved AcaInsti #245 employees came up with a solution, a very creative and logistically challenging solution, and worked with SmallTown residents to make it happen. The solution overcame the concerns voiced by the AcaIRB, AND met the needs of SmallTown. The AcaIRB accepted this, and the plan was advanced.

Eventually, SmallTown-involved AcaInsti #245 employees came up with a solution, a very creative and logistically challenging solution, and worked with SmallTown residents to make it happen.

When the day finally came to collect the information (*for the second time*), the systems were in place – or so they thought. It seemed to go like clockwork. After a few hours, the information was gathered and everyone went home. It wasn’t until a few days later that someone realized that there had been a glitch: information was collected from some participants who were not supposed to be in the study!

The first thing the partners did was contact the relevant individuals in SmallTown. An AcaInsti #245 employee, well-known in SmallTown, made the calls. They explained what had happened, apologized, and asked if there was anything they could do. Then they sent a formal

follow-up letter. Another SmallTown-involved AcaInsti #245 employee filed the deviation paperwork with the AcaIRB.

This time, the results of the process were much different. The AcaIRB accepted all the information and made no comments on the reported deviation. In addition, those who weren't supposed to participate in the information collection but did were forgiving of the error and supported the overall efforts of the partnership; this happened only because of the long-standing relationships that had been established. In the end, both the rules and laws of AcaInsti #245 and the SmallTown 'law of common sense' worked well.

Lessons Learned from Community-Academic Partnership IRB Interactions

This story reveals many lessons to be learned and questions that can be raised.

- The AcaIRB at AcaInsti #245 had a very limited understanding of the motivations of the community and the academic partners involved in the project, nor did the AcaIRB understand the context of the project or the partnership. The literature supports this reality. In a July 2006 Ovid/Medline search of "IRB and ethics and code of ethics", only 20 of the 244 articles included "community", and none of them included "partnership". How can IRBs increase their understanding of community-based research? What is their accountability to understand community-based research?
- It is essential that communities increase their understanding of research, research participation and IRBs. However, most community members have limited time (and interest) to attend to these issues. How can academicians increase community understanding while also respecting the time limitations of their community counterparts?
- In the end of the story, the survey was conducted a second time as a result of many conversations, some very creative thinking and a commitment to handle some complicated logistics. The intersection of community-based research and IRB requirements often necessitates such measures, which can cause a number of other challenges. Recent literature indicates some of the IRB-required processes may inhibit even well-educated academic faculty participants from participating in studies (Morahan, 2006). In addition, the time and money commitment needed for IRB protocol revisions, approval and reporting, particularly with multi-institutional collaborative research can be quite high and unexpected (Morahan, 2006) and thus could affect institution's pursuit and funding of future efforts. What are the long-term ramifications of these trends?
- The employees at AcaInsti #245 had completed the required training to conduct the research, but were new to IRB protocols and were not aware of the requirements related to withdrawing the study. Studies indicate that some hospitals do not have investigator human subjects research training requirements (Larson, 2004) and that many faculty are not clear on their own IRB policies related to education (Mavis and Henry, 2005). How can faculty and staff be better trained on the intricacies of their respective IRB process?

As the story demonstrates, communities and academia operate within different paradigms. Many communities conduct business through conversations, meetings and practicality. Many academic institutions conduct business through hierarchies, rules, and reducing liability. These cultural differences can have an impact on joint research ventures.

As academicians increasingly engage communities in research, challenges will continue on multiple levels. The remainder of this article discusses three sets of strategies to increase the communication and understanding between communities and academia around research. Those strategies are: engaging IRBs in community-based research; engaging communities in IRB systems; and the identification of potential Community-Campus Partnerships for Health (CCPH) roles at the national level.

Strategies to Enhance IRB and Community Communication and Understanding

One solution to the gap between communities and academia is communication. Academic institutions must initiate communication with communities, and communities must initiate communication with academic institutions. Both must be willing to listen. Another solution is changing the IRB structures or processes through which community-based research happens. These changes may be at the academic institution or community level.

The strategies below describe how IRBs can increase their understanding of and appreciation for community-based research. Most of these strategies were generated by participants at the 9th Annual CCPH Conference, held May 31-June 3, 2006 in Minneapolis, MN. Article authors and literature have added to the ideas.

Academic researchers skilled in community-based research can develop strong working relationships with one or two IRB staff persons, and thereby increase their understanding of the nature of community-based research.

Engaging IRBs in Community-Based Research

- ✦ Increase the level of communication with the IRB. This can be achieved a number of ways:
 - Academic researchers skilled in community-based research can develop strong working relationships with one or two IRB staff persons, and thereby increase their understanding of the nature of community-based research.
 - Academic researchers skilled in community-based research can volunteer to be a member of the IRB. IRBs are required to have or obtain expertise relevant to any reviewed protocol, and thus may significantly benefit from nonclinical, community-based expertise.
 - Academicians interested in community-based research can hold annual or regular meetings with the IRB members and staff. At least one institution found that a meeting of action researchers and IRB leadership led to future IRB reviews being “thorough, fair-minded, and thoughtful” (Brydon-Miller and Greenwood, 2006). Meeting topic areas may include:
 - ✦ Sharing models, structures, success stories or recommendations of how community-based research can be effective in protecting participants and be sensitive to the context of community (Hueston, 2006; Brydon-Miller and Greenwood, 2006).
 - ✦ Discussing specific examples of how IRB standards (e.g., consent) can actually inhibit some research from occurring. For example, immigrants from some countries may not want to sign their name on anything, for fear of the US or their own government retribution. In this case, the ‘wavier of documentation of consent’ might be an excellent and reasonable approach.

- ♦ Discussing the scope of the IRB. For example, to what extent is the IRB about the protection of human subjects and to what extent is it about the quality of the research protocol itself?
- ♦ When there are multiple institutions participating in the research study, consider what arrangements could be made to have primary and secondary IRBs, or a single IRB, rather than one protocol going through multiple different IRBs (resulting in a delay of approval).
- ♦ When working with communities, academicians may want to create an ‘umbrella protocol’ that outlines the key components of the study, with some ‘to be determined’ items. As the project moves forward, amendments can be made that describe the next steps. This approach provides an overarching framework for the study that gives IRB members and staff a context that they can refer to as the study proceeds.
- ♦ When community-based researchers are on national panels or advisory boards related to research, they can raise the issues surrounding community-based research and IRBs.

Engaging Communities in IRB Systems

- ♦ Create materials that describe aspects of research and research responsibilities/requirements. For instance, materials may describe what it means to be a research subject and/or what is an Institutional Review Board and/or what is the difference between research and programs. The Institute of Medicine has published a list of questions that research participants may want to know about research and participating in research (IOM, 2002).
- ♦ Create materials or hold discussions/workshops on how communities can benefit from IRBs. Examples of benefits include: assuring that the research methods are conducted in a culturally-appropriate manner; increasing the institution’s understanding of community processes and priorities; providing “participants with a sense of the process as a whole and of the possible implications of their participation, allowing for the development of a more genuine informed consent process” (Brydon-Miller and Greenwood, 2006, p. 124); stronger relationships and increased trust between partners, which can lead to additional projects or research.
- ♦ Hold discussions/workshops with communities on research, research protocols and IRBs. Topics might include:
 - o What is the history behind IRBs – make it real (e.g., holocaust, Tuskegee, etc.).
 - o Promotion and tenure in academic institutions – how does it work.
 - o Benefits of research – specific examples of how research from years ago benefits this community today.
 - o Informed consent – what it means, why it is important.
- ♦ Dialogue with community about the community’s history and future with research. Has research ever been done in this community? How has research happened in this community? What would this community like to see done differently in the future with research?
- ♦ Encourage community member representation on IRBs. Every IRB has opportunities for community members to participate. Local, community participation may help increase community members’ comfort and understanding levels with the process, which allow both community and academic partners to share that power more equally.

- ✦ Have a community IRB or another community approval process. While traditional IRBs focus on individual-level protection, a community IRB would focus on community-level protection.

CCPH's Potential Role at a National Level

While many IRB issues can be addressed at the institutional level, IRBs are dictated by federal guidelines, and thus, a national discussion needs to take place. Other authors have also suggested reforms or a national dialogue (Monahan, 2006; Emanuel, 2004; Edgar and Rothman, 1995). Given the community – academic focus of CCPH, it may be able to take a leadership role in this discussion. CCPH may also be able to provide valuable resources to its constituents. Potential roles for CCPH fall into two areas: education and technical assistance.

1) Education

- ✦ Develop educational materials that could be shared with IRBs. The materials might provide information on understanding the context of community-based research, considerations in community-based research, how community-based research is different from clinical research, and some key articles from the literature that demonstrate how IRBs can work with community-based researchers and communities.
- ✦ Develop educational materials or a toolkit that could be shared with researchers and community members. The materials or toolkit could be tailored to meet the needs of individual CCPH members, and might provide information on:
 - What is research?
 - What questions should communities be asking about research?
 - What is the IRB and why are the rules so stringent?
 - How can communities and academia work together to successfully and satisfactorily accomplish research?
 - What other resources are available?

2) Technical Assistance

- ✦ Be a resource for trouble-shooting support. Each community-based research study is unique, and therefore can raise unique questions. CCPH members might find it valuable to have a listserv or expert panel or some other time-sensitive and responsive system to tough IRB questions.
- ✦ Have a clearinghouse or other mechanism to share successful community-based research IRB protocols.
- ✦ Develop a model for a community research board. A template could be created that talks about why a community research board would be created, what the pros and cons might be, what challenges might occur and how to address them, potential structures, etc.
- ✦ Develop a framework and create models for community advisory boards. These might be similar to a research board but have less legal oversight. The framework and model might include:
 - What is the role of an advisory board?
 - What is their intersection with Institutional Review Boards?
 - Simple fact sheets and examples;
 - Tools for community advisory boards to utilize – newspaper articles; pamphlets; etc. These may demystify 'research'.

- ✦ Develop a sample/template consent form that is at the 6th grade reading level. The failure of research consent forms to be at an appropriate reading level for the majority of the US population is well documented (e.g., Paasche-Orlow, 2003; others). CCPH members could tailor the consent to meet the needs of their own IRB, but would be starting with an accessible document.

Next Steps

A number of steps can be taken to move the ideas presented here forward:

- ✦ Create a CCPH advisory group comprised of academic and community IRB experts to discuss recommendations of the article and develop a strategic plan to begin to move forward with specific tasks identified in the article;
- ✦ CCPH can partner with like-minded organizations (e.g., Institute of Medicine, Association of American Medical Colleges, Health Resources and Services Administration, Centers for Disease Control and Prevention) to initiate or facilitate a national IRB dialogue related to community-based research;
- ✦ CCPH, researchers and communities can present at conferences where members of national IRB panels and similar others are attending;
- ✦ CCPH members can choose one or two approaches from this article and advance the approach within their own institution or community.

Conclusion

It is critical that academic institutions and communities protect individuals participating in research. Having information and a dialogue that increases the mutual understanding of the two kingdoms of community and academia are essential precursors to the protection of research participants.

Acknowledgments

The authors would like to gratefully acknowledge the contributions of the CCPH 9th Annual Conference attendees who participated in the “Institutional Review Board Insights” session on June 2, 2006.

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