

**CCPH/Bioethics Center Educational Conference Call Series on IRBs and Ethical  
Issues in Research: Call 6  
"IRB Reform: Changing Policy and Practice to Protect Communities"**

*June 25, 2007*

**Speakers:**

- **Syed Ahmed**, Director of the Center for Healthy Communities (CHC) & Professor of Family and Community Medicine, Medical College of Wisconsin, Milwaukee, WI
- **Sarah Beversdorf**, Rural Health Liaison for the Healthier Wisconsin Partnership Program, Medical College of Wisconsin, Milwaukee, Wisconsin
- **Sarah Flicker**, Assistant Professor, York University, Toronto, Ontario, Canada
- **Robb Travers**, Scientist and Director of Community-Based Research, Ontario HIV Treatment Network, Toronto, Ontario, Canada
- **Nancy Shore**, Assistant Professor at the University of New England School of Social Work, Portland, Maine

[Introduction by Jessica Grignon]

[Introduction by Kristine Wong]

*Nancy Shore:* Thank you, Kristine. I would like to start out by talking about how there is a growing body of literature that exists that describes community-based review mechanisms as well as IRB/CBPR tensions. I was asked to start off by touching upon some of the issues emerging from the literature. Please note that this is not an exhaustive review; the issues to be presented are not necessarily unique to CBPR, other researchers that have a sustained relationship with a community such as ethnographers have also voiced some of the same concerns; and I am not claiming that these views are held by every CBPR researcher for example some researchers report having no challenges with their IRB often attributing this to the fact that they have developed positive working relationships with their IRB.

Some of the issues in the literature in no particular order are IRB risk benefit analysis. Some the questions regarding this issue include whether IRB risk benefit analysis adequately accounts for the community context and whether IRB clearly understand the relevant risks and benefits given the specifics of the CBPR project. Dr. Malone, a previous speaker on the call series, for example reflected upon some of these very issues. As a non-CBPR researcher, Shilders raises some great questions as to whether the IRB process adequately addresses the full range of benefits and whether it operates from a risk avoidant model. In terms of benefits he argues that too often we focus on how a study contributes to our knowledge base rather than consider what the direct benefits are for the involved community. As a result, he developed a matrix to guide researchers and IRB to think more critically about benefits. Both authors also question the regulations frame of reference reflect their biomedical origin and that insufficient knowledge exists regarding the range and severity of risks associated with social sciences. Overall I would argue that a need exists to develop a more critical understanding of what constitutes risk and benefits. A second concern relates to problematic methodological assumptions. Many of these concerns are framed as methodological biases that privilege more traditional

research approaches. Emergent study designs are a common problem as the IRB process operates from the assumption that research study designs are predetermined and fixed. To address this problem Kamu and Peter recommend we shift from seeing the review of emergent designs as occurring all at once to recognizing how certain projects need ongoing review. Others have advocated for research teams to have greater access to the IRB post approval to expedite modifications. Robb and Sarah will provide further insight into these assumptions that are embedded within research ethics application forms. Concerns regarding the degree to which the Belmont principle cover the scope of ethical considerations. I'll be talking more about this as part of my presentation but others have raised this concern. Gilbert for examples talks about the need to introduce additional ethical constructs such as dignity, veracity, sustainability, and justice with an added emphasis on community. A growing body of literature also exists that describes community-based review mechanisms. Two calls sessions focused on this topic. Examples from the literature include Blumenthal's article that describes the community coalition board that governs the Morehouse School of Medicine prevention and research center. Dr. Yancey, a previous presenter on the call series, provided an excellent overview of the process and the different values developed by this coalition board. As a second example Quinn points to community advisory boards as the means to ensure that the respect for communities is actualized. She raises the real concern that by simply adding a new principle there is no guarantee that they will be fully incorporated into the IRB process. And lastly an article by Brown and colleagues talk about the challenges no non university affiliated team members to acquire IRB review. These non-affiliated investigators typically represent community partners that do not have access to their own IRB. So you can see that the topic of ethic review processes and CBPR is being discussed in the literature. You will also find that these issues are a real focus at CBPR conferences, something which Syed will be talking about and relevant issues are also being discussed at other venues such as PRIM&R. Overall the need exists for CBPR and IRB representatives to engage in dialogue and as part of that dialogue we need to flesh out the concerns experienced by CBPR researchers as well as the concerns that IRB reviewers encounter as they assess the ethics of a CBPR project. And from there we can move to the possible solutions that creatively address the challenges experienced by both CBPR and IRB reviewers. I am now going to shift to some of the study findings and at the end of the presentations we hope to hear from you as to what are some of the recommendations you have enact and some of the questions you are wrestling with. So to make a shift, the title of the study that I will be presenting on is "re-conceptualizing the Belmont Principles" and in the interest of time I am actually going to have you all jump to my slide number 7.

So what I will presenting on is an exploratory study which in part focused on trying to understand the similarities and differences between the ethical considerations expressed in the Belmont report and from the CBPR perspective. I approached this project thinking that possibly that these difference were significant contribute factors to the challenges expressed by CBPR researchers with the IRB process. My hope was to understand these differences in order to find creative solutions addressing these tensions. Of note is that I'm reporting on a piece of a larger study and I'm focusing on a piece of the study that

interviewed 10 CBPR researchers. Some of the interview questions are listed on your slide, interviewees were also asked to provide a critique of the Belmont principles.

Next slide. The next set of slides provides an overview of the findings. Given the number of findings, the respect for persons could be renamed “Respect for Partnerships.” Respect entailed acknowledging the skills and experiences within the partnership. Respect also entails empowering practices which includes participatory processes where all partners have a voice in decision making and where there is a commitment to translating findings into actual benefits. As one interviewee commented, if you are bringing someone on as a partner, they are treated as a partner.

Next slide. Respect for persons can have multiple meanings for those involved including the different community partners and the IRB reviewer board. In order to honor the interpretations, one interviewee stated that people should be able to define what respect means to them. Some of the traditional IRB concerns named by the interviews are listed on your slides.

Next slide. Interviewees’ interpretation of beneficence emphasized empowering, subjectivity, and traditional IRB considerations. Discussion of beneficence from an empowerment perspective emphasized research outcomes such as building the power of collective action and strengthening the communities’ ability to solve their concerns. As an example of this perspective one person shared this statement listed on our slide. These outcomes reflect how beneficence goes well beyond the focus of the individual.

Next slide. Beneficence is complicated given that individuals and/or groups have varied interpretations of what constitutes a benefit. And thinking in what is a community benefit researchers need to be self reflective and critically think about the community and research context. Taking a position of good intentions does not necessarily mean sensitively to or awareness of what other may consider an actual benefit. The quote on your slide comes from one interviewee that reflects upon this very issue. Given the complexity of beneficence, one interviewee advocated that the partnership take the discussion of beneficence as a subject of inquiry and discussion point. Engaging in conversations with partners can reduce the likelihood of imposing ones notions of beneficence onto others. In defining beneficence, additional interviews also touch upon the traditional IRB considerations with an added emphasis on benefits.

Next slide. In terms of justice, an equitable research requires an environment where all the stakeholders’ voices are heard and respected throughout the research process. As the quote on your slide indicates, equitable and just process does not occur if people are invited to participate but their participation is relegated to the role of advisor rather to the role of decision maker. The notion of social change reflects the commitment to challenging unjust structural macro level problems. Several interviewees talked about the importance of acknowledging the political nature of CBPR. One interviewee also discussed the issue of sample selection. In this instance, the interviewee talked about the need to justify your sampling considerations more specifically the study should not include vulnerable groups based solely upon convenience.

Next slide. Some people are comfortable with Belmont principles which may be attributed to being schooled in these principles and subsequently unable to think of other ones. Others are comfortable because they think the principles are sufficiently abstract to allow for flexibility in interpretation. Some of the critiques of the principles are listed on the slide. A need exists to clarify the language. Currently the language is perceived as inaccessible and/or confusion. Others call for new principles given community collaboration and cultural considerations there was not consensus as to whether the sense of community collaboration should be applied to all research approaches or just to projects that claim to be community engaged. Several interviewees talked about cultural competence as an ethical consideration which they felt at times was not fully considered by the IRB. For example, IRB application forms tend not to ask about a research team's level of cross-cultural understanding, and instead the IRB review focuses on translating the informed consent form. In terms of group norms, they should evolve within the partnership process and the partnership, rather than the IRB, is in a position to assess whether these norms are upheld. And finally concerns that the principles are culturally bound constructs. Some of the interviewees discussed how the principles or at least the application of these principles by the IRB may overlook how different cultures have different interpretations. As an example, one person discussed how cultural differences are not fully recognized in the actualization of respect for persons.

Next slide. Overall interviewees' responses touched upon the IRB considerations yet pushed the Belmont report framework by introducing the ethics of involvement as well as emphasizing social change in community-level considerations.

Next slide. The next two slides provide a summary comparison between the interviewees' and the Belmont report's conceptualization of the principles. The Belmont report's interpretation of respect for person focuses more on the individual's ability to make an autonomous decision. The researcher-researched relation in the Belmont report is presumably vertical rather than the partnership framework described by the interviewees. As previously discussed, the interviewees' view of respect extends beyond the individual. In terms of beneficence the Belmont report considers individual and societal level benefits. As an example of societal benefits, the report describes research with healthy children who are not the immediate beneficiaries of the study. Interviewees also named beneficence that impacts more than just the individual. Interviewees' conceptualization of beneficence, however, emphasized building collective action and leveraging resources where the community represents an actor in the change process. The Belmont report suggests a framework more consistent with traditional research where the research is more represented of objects that passively contribute to the researchers' understanding and ability to produce individual and/or societal level benefits.

Next slide. In terms of justice, the Belmont report focuses more on the distribution of social goods, risks, and benefits. In terms of social justice, the Belmont report states in part that there needs to be an order of preference in the selection of classes of subjects while recognizing that even with just sampling procedures, "unjust social patterns may

nevertheless appear in the overall distribution of the burden and benefits of research.” The interviewees conceptualization of justice in part considered issues of sample selection but mainly focused on how create a just research process and the value of creating just research outcomes.

Next slide. The relationship paradigm offered by King and her colleagues, represents one way to begin addressing some of these differences. The relationship paradigm was developed in a response to a perceived lack of fit between principles and collaborative research. Benefits of the relationship paradigm include that it helps to foreground the contextual factors such as the historical cultural considerations. It widens the ethical frame of reference as compared to the regulations tendency to focus primarily on the individual human subject. And it challenges assumptions regarding the value and meaning of research. Rather than taking the value of research as a given, the relationship paradigm encourages us to critically reflect upon “what research is, what is it good for, and why researchers do it.”

Next slide. Basically the relationship paradigm prompts research teams to ask IRB reviewers different questions than they might under the principle-ist paradigm. These questions are not intended to replace the questions that derive from the Belmont principles but rather to broaden the scope of ethical considerations. The bolded questions reflect relationship paradigm considerations more than non-bolded items generated by ideas of the interviewees. Ideally these questions will spark conversations resulting in an expanded and refined guide. So for example, what are the relevant relationships specific to this project? Is there a partnership? If so, how was the partnership formed? Who are the partners? How are the different partners involved?

*Kristine Wong:* Nancy, I hate to break in but you have a few more minutes left.

*Nancy Shore:* OK, so this is my last slide.

*Kristine Wong:* Great.

*Nancy Shore:* The slide is what are the potential impacts of this research project? Who benefits? What are the short and long term benefits accounting for the individual and community level? Who determines what constitutes a benefit? And the same line of questions for risks. And finally how will the findings be used? Will findings be used to effect social change? And Robb and Sarah will be sharing other great questions that you might want to consider as well and that is it for my presentation, thank you very much.

*Kristine Wong:* Great, thank you Nancy. Our next presenters are Sarah Flicker and Robb Travers. Sarah Flicker is an assistant professor at York University in the faculty of environmental studies in Toronto. Previously, Sarah was the director for research as the Wellesley Institute from 2004-06. She has a doctorate in social science and health, at the University of Toronto Department of Public Health sciences. Her research interests lie in the area of youth empowerment, health promotion, HIV and community-based participatory research. She hold a MPH, masters of public health, in maternal and child

health and epidemiology at UC Berkley and an honors degrees in anthropology from Brown University. Sarah sits on a number of community boards and believes strongly in community partnerships for research and action. She's an active member of the gendering adolescent AIDS prevention research prevention team and the teenage research group. Her co-presenter will be Robb Travers, scientists and director of the community-based research at the Ontario HIV treatment network in Toronto, Ontario, Canada. Dr. Robb Travers is a scientist and director of community base research at the Ontario HIV Treatment network and an associate research scientist at the center for inner city health at St. Michael's hospital in downtown Toronto. At the OHTN, Dr. Travers is responsible for the development and implementation of a comprehensive program of CBR initiatives as well as facilitating community-academic policy partnerships in HIV research. His passion for community-based research dates back to more than 15 years and is rooted in his experience in community development. Dr. Travers completed a master's degree in community psychology at the Ontario institute for studies in education at the University of Toronto and received his degree in public health sciences from the University of Toronto. Welcome Robb and Sarah.

*Robb Travers:* Thank you Kristine and thank you to both you and Jessica for organizing today. It is a pleasure to be here. What I am going to do is cover the first half of the presentation and then turn it over to Sarah. If you go to slide 2, it says "objectives" and talks a little bit about what we would like to accomplish today. We would like to review two studies that have been conducted here in Canada looking at the paradigm of current research ethic boards or IRBs for those of you in the United States practices and the suitability of those to community-based research. We would like to present an alternative set of questions for judging community-based research studies that bridge Tri-Council Canada principles for ethics review and the principles of CBPR; those are similar to your Belmont principles in the United States, the Tri-Council of Canada.

Next slide. From the literature, what we've gleaned is that the common problems in research that are raised at ethical issues are irrelevant to community. So research is conducted that community members question the relevance of, methodologies are insensitive or poorly thought out and they waste resources, there is a feeling among some community people that research doesn't give back so it is conducted for the sake for knowledge and not for the sake of social action or social change, many communities particularly in Canada, particularly aboriginal communities, feel over-researched, sometimes coerced, and sometimes lied to, and also in the literature is a thread about insensitivity to community concerns on the part of researchers. And finally one of the threads that we pulled from the literature is that benefits to community is often minimal or feeling on the part of communities that this is the case.

Next slide, please. CBR is then is posed as an approach to research to address these problems, or should I say to readdress these problems. So our objectives in our two studies were to really critically think about the questions is CBR inherently ethical? Does it pose unique ethical dilemmas? Are those ethical dilemmas captured in current processes by IRBs? And are they using the correct procedures to assess those unique ethical issues of CBR?

Next slide please, number 5. So we determined that there are challenges in the current ethical review paradigm as evident by two recent studies. Study 1 is done by myself and a group of people that I work with the HIV Treatment Network in Toronto, Canada. It was a feasibility study that was looking at the development of an ethics review board for CBR, community-based research, HIV research, in Ontario. Study 2 was conducted by Sarah Flicker my co-presenter recently published in the journal of urban health that is called ethical dilemma is community-based research recommendations for intuitional review boards and that's the study Sarah will be commenting on in a few slides from now.

Next slide please. Study 1, the Travers et al., study, proposal for an ethic review board for a community-based HIV research review board in Ontario, and OHTN position paper. Next slide. In that study our method was very straightforward. We did a document review or an environmental scan looking at key pieces of literature that have emerged in Canada and the US and other western countries about the issue of ethics review and its suitability for community-based research. We reviewed best practices that we could find in Canada only we limited our scan to Canada for this one. So we reviewed current board that called themselves community-based and the kinds of ways that they operationalize ethics review processes and how that differs from more traditional university or hospital based processes. And we did key information interviews; 15 across Canada. These were people who were well situated to talk about the complexity of ethical issues for CBR both within and without the HIV sector. Challenges, very quickly, or our findings are on the next slide, number 8. We found that there were challenges mainly related to CBR team collaborations who didn't have an academic partner at an institution, so lets say that we are a PhD level research to use as an example working at a particular ethnic-racial community here in downtown Toronto who has designed a very strong and relevant piece of research but because that individual did not have an academic affiliation, they could not access review process at universities or hospitals and thus are limited to their own institutional members. The second key finding had to do with ethics review processes and power imbalances. Many of these projects had to developmental stages where community partners felt a real sense of ownership over their research projects and at the point of time where the university became involved vis-à-vis the ethics review process, community members talked about the back and process with the ethics review board and the research team as a very disempowering type of process that really set up a power imbalance where suddenly the academic partners in the CBR collaborative were in a position of privilege relative to the community partners. This also fit into the issue of ownership of the projects. We heard cases where individual projects had their methodologies redesigned by ethics review boards and they felt that all of a sudden they felt that they were in the position that the ownership of the project were slipping out of their hands and into the hands of the IRB. And finally, and probably most significantly, that led or fits into the next study we are going to talk about is the idea of paradigm fit or more correctly paradigm misfit as we should say, in that people really felt that university research ethics boards and hospital based boards were operating in the paradigm that were much more reflective of biomedical studies and really focused on assessing individuals to risk and didn't attend enough to community sensitivities or issues of community vulnerabilities.

Next slide, number 9. The second study I would like to talk about in terms of our methods and findings is this study led by Sarah Flicker and published in the journal of urban health that is called ethical dilemma is community-based research recommendations for intuitional review boards. Next study. In this study, again a very straight forward method a content analysis of research and IRB forms from select schools of health in Canada and the United States. We chose universities that had forms available online, ethics review forms I should say, and where they were a site of graduate training for public health. We chose these universities because public health departments tend to be very supportive of community-based research and we assumed that they would likely be perhaps be a model that we could count upon to seeing for some change or shift on how IRB or REBs look at community-based research versus more traditional forms of research. We drew upon a convenience sample drawing upon the US Association of Public Health and select Canadian universities, again 27 in the US and 3 in Canada. We developed a scoring tool that sought evidence of community-based principles in action within REB and IRB forms. In other words we looked for the principles of community-based research for example social action or social change and looked at the IRB forms that were being used to see if those kinds of questions were being asked by different institutions.

I am going to talk about our recommendations from the two studies then Sarah will talk about some concrete actions for change. We've identified that research should continue to in deify problems with current review paradigms as well as solutions. That this is an ongoing challenge that requires further research. That IRB and REB modes that are supportive of, or incorporate the principles of CBR and the Tri-County or Belmont principles are needed, and that alternative review guidelines for community-based research protocols are needed for REB and IRBs to use.

Thank you Robb and thank you Nancy for listing some of the questions. So in the next few slides what we would like to do is provide some alternatives guidelines and questions that could be used in IRB or REBs. How we structured our slides is based upon our content analysis. We pulled out the type of questions that was asked at each stage of the research process and have posed some alternative questions that might be asked in CBR studies and you'll see that the principle questions are highlighted a bit differently.

On to slide 13. Many of the IRB forms that we found asked for background, purpose, and objectives. What rarely we saw, and really we never saw, was the question of who benefits from the research and how in terms of a larger community approach. And how the community was consulted in defining the need, who came up with the objectives and how and are they concrete action outcomes. Though again shifting from more an individual risk and benefit to a communal risk and benefit. On slide 14 we list some of the questions we had about research methodology. Describe exactly how the research is carried out, and often forms asked for the who, what, when, where, and why. A very practical approach to a step-by-step approach action plan on what would happen over the course of the research. On slide 15 we list some alternative questions. Once again we ask, how will the community be involved at each step? And at what level? What training

or capacity level building opportunities will be built in? How with the methods be sensitive to various communities considering issues of literacy, language barriers, and cultural sensitivities. And the importance of balancing scientific rigor with community accessibility(?) On slide 15 we list risks and benefits. More often than naught, content analysis of review forms highlighted that IRBs were mainly interested in individualized notions of risk and risk management. Mainly constructed upon a traditional biomedical framework that frames risk in terms of physical or medical risk rather than issues of social or cultural risk to the community. So once again we've identified some red flags. On slide 17 we ask, so what are the risks for communities? How can we think about risk differently? And how can we really be honest about risk because all studies involve some risk. And taking the time to work with a group to really flag the different issues. For instance what are the mechanisms that will be used to handle unflattering results? What happens when you are already working with an already stigmatized community that are written or talked about a lot in very unflattering ways? And how can we use research to counter some those stereotypes perhaps or if the research doesn't come out to counter those stereotypes, how do we contextualize it so that its understood rather than re-stigmatizing an already vulnerable community? And once again thinking about how to redistribute benefits more equitably across the community? On slide 18 we highlight some of the questions that we saw around informed consent. Generally, IRB forms asked for a copy of the letter of informed consent. And really wanted to see that particular types of language was used and mainly the informed consent process mainly operated within a very legal framework in terms of who was liable at various institutions and understanding exactly what would happen for participants. On slide 19, we talk about asking slightly different questions. For instance what does this mean for vulnerable populations— children, people who are mentally ill or developmentally challenged and really what does it mean to both inform and consent? And how can this be done in a culturally sensitive manner in addition to just simply translating into other languages. And whose permission do you need to talk to whom and what does this look like in more traditional communities such as traditional aboriginal or native communities or different stakeholders may be important people to talk to in terms of getting a more communal consent? Issues on Slide 20 around privacy and confidentiality. Many protocol forms asked how data will be managed , stored, release of information, access of information this is a particularly hot topic in Ontario because we have brand new privacy legislation that means all of us here are struggling to figure out how we can adapt our research but we saw this quite commonly across all the forms. This becomes particularly in CBR studies where we involve community members in data collection, data analysis, and perhaps data management. And so what does it look like on slide 21 when you have the same person maintaining multiple boundaries. So perhaps [*unintelligible*] is involved in data collection ,what kind of mechanisms can you put in place to ensure that they are sufficiently trained in issues of confidentiality and what happens when you actually know somebody in the community that you are actually interviewing ? can you actually ensure that the privacy and confidentiality is maintained? What processes can be put in place to be inclusive in the analysis and yet maintain the privacy of participants? How is data stored and who will have access to it and really we're asking this question for a slightly different reason in terms of making sure community members do have access to the data so they can use it and mine it for different sorts of purposes than perhaps academic publications. And what

rules can you put into place for working with transcripts or surveys containing identifying information and how can you protect the privacy and confidentiality of individuals.

*Kristine Wong:* Sarah, you have a few more minutes

*Sarah Flicker:* Terrific. On slide 22 we talk about compensation and remuneration. And we wanted to highlight the importance of putting in and paying attention to issues of travel and child care. But also think about who is managing the budget, and how do those decisions get made, and which partners are compensated for their participation in research and which aren't? So to really flag the interests of equity in terms of compensation. And lastly I want to skip down to slide 26 in terms of recruitment. Often on protocol forms we saw questions asking how and by whom participants will be approached and recruited. And on slide 27 we flag the differences in the type of questions we look for in CBR proposals. And we really need to think about issues of power relationships and no coercion, often even in community-based research. We see service providers doing the recruitment and what does that look like and how we have very clear guidelines and roles for what that will look like in a medical encounter, what does that look like in a community encounter? And how do we make sure that service providers and researchers are different people or perhaps when they are the same people the roles are clearly delineated and understood? And how do we ensure that participants who do not want to participate in research, will still be assured service at their community-based agency? Really thinking through how we approach people, and making sure those strategies are culturally relevant and appropriate. I want to close there. These are just some of the suggestions that we have and they are all laid out in that paper that Robb mentioned being published online. And I want to turn it over to our next speaker.

*Kristine Wong:* Thank you Sarah and Robb. Our final speaker is Syed Ahmed who is the director of the center for healthy communities and professor of community and family medicine at the medical college of Wisconsin in Milwaukee Wisconsin. Syed Ahmed, MD, MPH and Doctor of Public Health, is a professor of family and community medicine and is the director of the center for health communities at the medical school of Wisconsin. He is also a fellow of the American academy of physicians, and a diplomat of the American board of family practice. Through his educational, scholarly and community work Dr. Ahmed has made nationally recognized contributions to community health, to community-academic partnerships, and community-based participatory research, and received numerous local and national rewards. Dr. Ahmed received degrees in medicine and surgery from the medical college of Dacca University in Bangladesh and a masters and a doctorate of public health from the school of public health at the University of Texas in Houston. He completed a residency and a fellowship in family medicine at Baylor College in Houston. Welcome, Dr. Ahmed to the call series.

*Syed Ahmed:* Thank you. Also thank you to CCPH and Tuskegee for presenting this very important series. I would also like to thank Sarah who could not be here in attendance but all the credit goes to Sarah who helped me put this presentation together. This presentation's second slide is titled "story session" we will not get into the story itself but we presented the story at the US conference on CCPH in May 2006. And the story

basically details a challenge we faced at the medical college doing the many programs we do with the communities. That is the basis of discussion and prompted us to share the experience with larger audience and getting their input on how to approach, come up with the strategies so that we have a common voice in address CBPR in medical school. Like number 3 shows the results from a brainstorming session. The whole presentation was based upon that but it also involves the learning involved from the CBPR interest group, literature and our years of experience. The three question that was raised in the conference first one dealt with how academics can work with their IRB, institutional IRB in this case a medical school's IRB to advance the cause of CBPR. Second one was raise, how can we get communities on the same page as it relates to IRB. And third one was what could be the role for a national organization such as CCPH and others. And what next steps we should take to create a national dialogue?

Next slide, number 4. In reference to the article that me, Sarah, and Dr. Beck wrote, this presentation shares a significant part from the article. Next slide number 5. The answer to the first question of what role academics can play to enhance CBPR in their own institution the issues were local in this case what we do. Some of the ideas that came from the attendants and our experience. The very first one from our own experience and attendants was there needs to be a clear level of communication with the IRB. One practical experience in our own medical college, we have developed a very good, I call it a very receptive relationship with our IRB. And that has very helped us when issues arise with the IRB. We met with them from time to time and face to face email telephone, that relationship has helped to clarify from the IRB's end on what does CBPR means. The second idea came out of a member that the IRB staff that the IRB review board should at least be knowledgeable about CBPR. To my knowledge in medical school that is actually not very common. Very few IRB has in their board faculty or staff knowledgeable about CBPR. That is the challenge. Third one. There is definitely a [*unintelligible*] gap from the IRB's part not knowing or understanding the CBPR itself and that creates an issue when proposal goes to the IRB there might not be the right person reviewing that. So again, recently at our institution due to the changes, CBPR projects more partnerships there has been a significant dialogue and that has really helped. That's one thing we've practically found that has been very helpful.

Next slide number 6. It continues with the previous question what can academics do? One thread or suggestion came was to have one IRB for multiple institutions. For example we have many project where we might work with 4 different hospital systems. It can be onerous for us for anyone to go through 4-5 separate IRB. So one idea is to have one IRB and to have other institutions if they agree to list and support that. The second idea that came I call it umbrella protocol. Now this is the one that has really helped us at our medical college. What it means is that as we initially apply for our IRB we present an umbrella protocol which gives an overview of the project itself. As we know CBPR does not come with all the answers first. Even the survey we mentioned we developed after the first year. So when we apply for the IRB we propose future amendments. Our institution has learned that, has agreed to that, and that has really helped getting the IRB initially done review approved and presenting amendments as needed.

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Next slide. I am going to skip all the way to 9 because 7 and 8 Sarah and Robb covered a good bit of it. So I am going to jump to slide number 9. This one question focused on how we can get communities involved with the IRB. Communities could be involved at different levels of understanding, knowledge of IRB. We have worked with very knowledgeable communities depending on the project. Who know the IRB very well. But we have also worked with communities where there is serious lack or misunderstanding of IRB. Other thing which our previous speakers mentioned somewhat is some of the assumptions we see when we work with the communities that [*unintelligible*] even though they know that there is a need for IRB what is the real benefit? What is the research protecting the academics versus the community? And in other way is that the academics actually imposing their bureaucratic rule upon communities. Some of the underlying sense we get as we work with the communities. So the proposal and the comments came from the participants so we need to really need to work with our communities and bi-direction dialogue and understanding on how when we do this research. But we also need to mention not only mention but also explain the potential challenges as we go through the IRB process. We do face IRB challenges in our project and that can hurt the communities who wait to do their project but we have not gone through our IRB as a question. And those challenges has to be brought in as a part of the educational process. And this could be potential challenges but we found out that it would be helpful when we took it upfront.

I am going to suggest to go to slide 11 and some of the comments this slide can be a part of future national dialogue. I would not go through this in detail but this also came from the CCPH on what could be done in the future. So I would like to go back to slide 11 later. But now I am going to jump all the way to slide number 13. The large question to the audience at the CCPH conference in May 2006 is what a national organization like CCPH can do to address this issue of CBPR. One idea was something to do with education. Developing educational materials, tool kit, research, answering the potential questions. And how academics and communities work together in solving these problems? Second suggestions came more on technical assistance. To be a troubleshooter, to be a clearing house. And the last three to build a model of community-based research, develop a framework for a community advisory board, and having a template consent form. Those are the other ideas came from that conference. In conclusion what we need to get into is all the ideas created by today's meeting, all the important 5 other conferences, CCPH and the partner of other organizations. And that should include governmental organizations include NIH CDC and others. And of course for communities to take the lead on national dialogue because CBPR especially in medical schools in the US is relatively a new concept. Many faculty staff and IRB may or may not have an understanding of CBPR and it will keep on creating challenges. Locally we can come up with our own solutions like what we are doing in here. But there has to be a national dialogue and come up with some ideas which can help all the new researchers coming into this field. The questions that need to be answered are many as we start looking into it and the presenters just mentioned that. [51:59] \*\*\* model based on the individual [*unintelligible*]. The other thing is, are we trying to play baseball with the rules of cricket? I bring this up because some people say that baseball evolved from cricket. I play cricket very well but baseball poorly. Or maybe it is better for baseball,

softball. We could think about how it is the same game but it needs to have a community track which is the missing part. In other words is it individual IRB, community IRB or combination of both? Those questions are what we need to explore. We need to create a national guideline for CBPR IRB like a template for consent form but a template for the whole processes itself. And at a minimum especially in medical school, proposing a CBPR track in IRB boards because it becomes difficult when not enough people understand CBPR itself and that create challenge for all of us. And that is the end of my presentation, I kept in time and saving some time for Q&A. Thank you everyone.

*Kristine Wong:* Thank you Dr. Ahmed and all our presenters for your inspirational presentations. I think that one of the main comments to make as an overview of this whole series is that much of the time when we think about policies we think about going to our legislatures or we think about people who are very inaccessible but what all these presenters have send here today is essentially is that the solutions is within our hands. It is within our hands, a diverse group of stakeholders. We have had a variety of folks call in from government from academic researchers to IRB academic administrators, to community folks and I think that all the presenters here have laid out clear recommendations and strategies that we can follow-up on. That the solution is not to rewrite the Tri-Council of Canada principles, or rewrite the Belmont Report, or go to OHRP and ask them to change the regulations. But it is how we take it into our own hands and how we can reinterpret it in a way that creates social justice and creates access to everyone. So with that I would like to open up the call for questions for any of our panelists. We also, as I mentioned before, would like you to feel free to share your overall thoughts about the call series. As well as anywhere we can go next to further... whether it is some of the recommendations that these panelists have talked about today or whether you have some new ideas. The call operator is going to come on momentarily and give you some directions on how to call in and with that I will turn it over to Darcy.

[Directions provided by Operator]

*Kristine Wong:* As with all previous calls we compiled questions from everyone who registered and the first question I would like to throw up there for our presenters to tackle while we're waiting for other calls to come in is as follows: "I am interested in learning how IRBs are changing to accommodate the IRB needs of CBPR."

*Syed Ahmed:* Hi this is Syed. As I mentioned in my presentation, at our institution at least because of many faculty and staff becoming involve in many community projects, that created a significant need that our IRB understands for CBPR. To that end in our staff and IRB boards. They have been quite receptive. They have met with us, dialogue, and they have been receptive when we bring issues up. I cannot say for other medical schools. But my thinking is that as more faculty and medical staff getting into CBPR research and any researching involving communities, there would be some changes. I have no idea at this point what institutions are doing except those institutions who does this type of research. I hear that they have a more receptive boards in terms of CBPR.

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*Kristine Wong:* Thank you very much, Dr. Ahmed. Would any of the other panelists like to respond?

*Sarah Flicker:* Sure, this is Sarah. And I think we seeing things change in Canada from a variety of different pressure points. I think one of the most activists' communities around changing research processes is our aboriginal communities. And they have mandated a whole different set of ethical issues under the rubric of ownership control access and possession. And as a result of their activism their federal funding bodies have asked for different kinds of template agreements around research involving First Nations and aboriginal people in Canada. And as a result our ethic review board are taking a look a little bit differently. So in a way the shifting that is beginning to happen come from the communities to the funding bodies and back to the IRBs and that is a really exciting template that a lot of other communities are taking on.

*Kristine Wong:* Great and we hope to follow your model here on the US. We are working on it.

*Robb Travers:* Kristine, this is Robb and I'm wondering if I could add something to that answer as well. Also in Canada the national ethics in human research which is an umbrella organization that offers policy and guideline directions to its member organizations that are university or hospital based is doing a piece of researching looking at best practices for the assessment of community-based participatory research protocols. They are looking at the existing community-based boards in Canada and some of the challenges faced by those organizations. They have developed models and the goal is to learn from them the best practices and build a capacity-building plan for the other ethics research boards across the country. Hundreds of them that exist to help them become better prepared for community-based protocols that come in. So I would just add that to the excellent examples that Sarah was giving.

*Kristine Wong:* Great, thank you. Operator, do we have any calls waiting for us?

*Operator:* Yes ma'am. The first question comes from ---. Please go ahead, sir.

*Caller:* When I was attending a seminar last year, I picked up the journal of *American Journal of Public Health* and ran across an interesting article, "It is like Tuskegee in Reverse." Do any of the speakers have any experience with that article? Do they have any comments on it?

*Kristine Wong:* Just to answer your question. We had Ruth Malone who you know was the primary author of that article on a previous call on this call series. Would you still like the presenters' comments on that article?

*Caller:* Very much.

*Kristine Wong:* OK, great.

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[pause]

*Sarah Beversdorf:* I am familiar with the article, but tell me perhaps what you think of the article. Where are you going with the question?

*Caller:* Well, when I read it I thought, “Wow. That’s a real case of an IRB going the wrong way.” And then I heard from some of my colleagues from UCSF some of them who are on the IRB had a very different take on all that happened. I kept expecting a letter from them to pop up from them sooner or later in the AJPH but as of yet there has been no response.

*Kristine Wong:* They are preparing a response. Ruth Malone has confirmed that it just hasn’t been published yet.

[pause]

*Kristine Wong:* Well, we like to focus our call on policy change and recommendations so you are welcome to follow-up with any of the presenters offline.

*Caller:* OK. Thank you.

*Kristine Wong:* Thank you very much.

*Operator:* Thank you, Ms. Wong. And the next question comes from ---. Please go ahead.

*Caller:* Thank you. We have been talking about community-based research, community-based participatory research, we are still talking within what I would call a limited paradigm of research. And I would say that it is somewhat being imposed by, in Canada the Tri-Council policy being based on research involving humans. In community-based research in my experience that distinction in research or learning and any other kinds of activity is I would argue somewhat artificial. So I am wondering particularly from a community perspective it may or may not matter whether an activity is research in a formalized university definition or whether it is something else – if it is some kind of learning? Should we start having a conversation about what one could expect in an ethical relationship whether it is research or another activity related to research such as learning?

*Kristine Wong:* Were all the presenters clear on the questions?

*Sarah Flicker:* Well, I have a question. Are you talking in terms of whether this is a conversation that should happen within a partnership or at a level of IRB or REBs?

*Caller:* Yeah, I’m talking particularly about at University of ---. I am actually undertaking a project to take a look at ethical issues that arise in community-based research and learning. And we also just opened a new office and this office is particularly

of the mindset of this bigger term of community-engagement which is research and learning and a whole bunch of other stuff that is somewhat interrelated. So our research ethic board starts to get perhaps a heavier load of research ethics review questions. We are starting to see that we are going outside the very definition of research we are sometimes talking about other activities that may be a prerequisite to research or turn into research and we're starting to wonder do the ethics around community research need to be a bit broader than that very limited definition on what constitutes research. Because in this presentation we are talking about community and the impacts thinking to extend the idea of what do we actually have to be assessing or giving guidance to in terms of ethics. Does it need to be beyond just the definition of research is something that is artificially imposed? And, I am just curious to see if anyone has thought about that. And as the last presenter talked about taking this into our own hands then I think there is a tremendous opportunity for a national organization or national conversation to stop or to take a look at whether that is an artificial distinction. To talk about the relationship between research and learning in a community university partnership.

*Kristine Wong:* I would say that Community-Campus Partnerships for Health has done that in a more informal way just being the organization where they are—working with campuses and communities and making sure people are aware of the principles of community-based participatory research authored by Beth Israel, et al of the University of Michigan-Ann Arbor. I am pretty sure you're familiar with those, but I think those inform the framework that people have been using to educate people that there are different approaches to research such as CBPR that don't follow traditional methods. And that while there may not be anything more formal in place as written up in the Belmont Report, this is a key report that people go to when people ask how do you conduct research in a community ethically.

*Sarah Flicker:* I think there also has been a real interesting national conversation going on recently. Our Tri-Council recently put out a position or a first draft of a position paper changing some of the guidelines on qualitative research in particular. That I think might be more relevant for community research particularly. So all those community meetings you go before you even start a research project, do you need ethical clearance for that? Or when you have a community celebration and you bring your students, is that a form of research or a form of community engagement and participation?

*Syed Ahmed:* This is Syed, I have a couple of comments in this line. One is our institution for any educational project dealing with a community require IRB. And most definitely that is the way it should be and one of the articles that came out in family medicine by Dr. Houston et al in 2006 that developed a consensus statement on improving research. That suggests educational project going through IRB. But one thing we also need to keep in mind is how the community perceives most of the time when we bring IRB issues. And I think communities having more and more IRBs imposed on them is the way to fail, so I think we then need some common sense understanding then too. Having a party with community members does not require IRBs we can go on and on. So that I think we may need to think about how the communities see, is that they get surprised when we say that another IRB process has to happen. And we try to educate them and work with them but I

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think that it is the other issues we need to deal with as we get into CBPR with the very broad understanding of what community engagement means. So that is not completely solved but as far as educational program the community's concern, IRB does look into these projects and what we have and I think they should.

*Kristine Wong:* Perhaps we can open up the line to another caller?

*Operator:* The question comes from ---. Please go ahead.

*Caller:* Good afternoon, my name is ---. Thank you very much. I have a comment and a request. I am impressed that the symptomology and defects in IRB and REB reviews is widely experienced. But I don't find the problem in the Belmont report or the Tri-Council statement, I find the problem in the failures of IRBs and REBs to live up to their responsibility. And it seems to me that this is a matter of persuasion, and more insidious enforcement. And I would like the panels' comments on those assertions.

[pause]

*Caller:* Hello?

*Kristine Wong:* Would anyone like to respond to --- request?

*Robb Travers:* Hi this is Robb. This is a strong statement and a different approach than Sarah and I took in the article and in the study that was published in the journal of urban Health where we talked about the capacity building required for institution review boards. And the problem may very well be that they are unintentionally setting up community-based research teams for unique ethical problems. Now people who have experience sitting on ethical review boards know that on the one hand there are official guidelines and sets of procedures in the form of paper and checklists that guide the work of REBs and then there is the actual discussion that goes on with team members. I think we don't understand enough of that. And that is another avenue of research that could untangle what you are suggesting. And of course you know there are always examples of IRBs and REBs of doing really terrific work when it comes to CBR and of course many examples we have all experienced tremendous amounts of changed. It's a complicated picture that we are facing.

*Kristine Wong:* May we have the next question please?

*Operator:* Thank you Ms. Wong. If there are any additional questions or comments please press 0 then 1 now.

*Kristine Wong:* So, there are no more questions in the queue?

*Operator:* Yes ma'am. At this time there are no more questions from the audience.

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*Kristine Wong:* Great, thank you very much. Well, it is my pleasure and privilege to close out this call series. And to thank you for being a key part in this growing movement in ethics review boards and institutional review boards. And we welcome your comments in the coming months. Before we close we would like you to know that we will be putting a report summarizing the major points and resources mentioned in the call series. We also be convening an advisory group to advise us how we can move forward in a way that makes most sense. I would like to thank Vanessa Northing Gamble of the Tuskegee University National Center for Bioethics in Research and Healthcare for moderating the lion share of the call series, and thank you to today's speakers for today's comments and to everyone who participated in the call series whether as a questioner, speaker, or a listener. And lastly I would like to encourage you to continue this conversation on listservs through your own community, institutions, and workplaces. And with that I would like to turn it over to Jessica Grignon for some closing comments.

*Jessica Grignon:* Thank you Kristine, to our presenters, and for everyone for calling in not only in today's call but all the other calls in the series as well.