

CCPH/Bioethics Center Educational Conference Call Series on IRBs and Ethical Issues in Research: Call 3

"Community-Based Participatory Research (CBPR) Proposals and the Human Subjects Review Process: Methods for Working with University IRBs"

April 18, 2007

Speakers:

- **Sherril Gelmon**, Professor of Public Health, Mark O. Hatfield School of Government, Portland State University, Portland, Oregon
- **Ruth Malone**, Professor, School of Nursing, University of California – San Francisco, San Francisco, California
- **Elleen Yancey**, Director, Morehouse University School of Medicine Prevention Research Center, Atlanta, Georgia

Kristine Wong: Good afternoon. My name is Kristine Wong, Program Director at Community-Campus Partnerships for Health. I'd like to welcome all of you to the 3rd call of the educational conference call series on institutional review boards and ethical issues in research titled, "Community-Based Participatory Research (CBPR) Proposals and the Human Subjects Review Process: Methods for Working with University IRBs."

This call series is being cosponsored by Community-Campus Partnerships for Health and the Tuskegee University National Center for Bioethics and Research in Health Care, also known as the Bioethics Center. Before I go any further, please make sure you have in front of you the PowerPoint presentations and biographies and research sheets sent out in advance of the call.

The PowerPoint presentations are titled as follows and will be introduced in the following order: 1) Gelmon, 2) Malone and 3) Yancey. These slides have been developed as a visual aid for you to follow during each speaker's presentation. For some reason if you did not receive the slides, they can be access from the CCPH website in the near future.

Founded in 1996, Community-Campus Partnerships for Health, also known as CCPH, is a nonprofit organization that promotes health through partnerships between communities and higher educational institutions. Our focus includes service learning, community-based participatory research and board-based partnerships. We're a growing network of over 1400 communities and campuses across North America and increasingly the world; tied together by a commitment to social justice and our passion for the power of partnerships to transform communities and academe.

The call series is intended to increase understanding of the role of IRBs and other mechanisms for assuring that human subject research is ethical and appropriate, both at individual and community levels. The aim of the series is to provide a comprehensive understanding of the options and tools necessary for communities to determine the approach that is best for them. The series will also inform the development of future initiatives undertaken by CCPH and the Bioethics Center on IRBs and ethical issues in community campus partnerships.

During the first call of the series that took place in February, we covered the basics of human subject protections. You can access an audio file from the call on the CCPH home page at www.ccpb.info. During the second call in March, we focused on the importance and perspectives of community-based IRB members. You can access the audio files and handouts from these calls on the CCPH homepage at www.ccpb.info.

On today's call, we'll explore the successes and challenges experienced by community-based participatory research partnerships when maneuvering their proposals through the university IRB process. On calls 4 and 5, we'll learn from an array of community members and academics regarding why they decided to create further protections for the community through the formation of community advisory boards and independent community IRBs. Lastly we will conclude the series with a session that present recent research on IRBs and discuss the implications of this research for future policy and practice.

[information about being recorded]

Now I'd like to introduce you to today's moderator, Dr. Vanessa Northington Gamble. Dr. Northington Gamble.

Vanessa Northington Gamble: Thank you, Kristine and welcome to all of you from Tuskegee University. And before I introduce the topic and today's speakers, I'd like to say a word of what we're doing here at Tuskegee today. We are preparing for our annual commemoration to honor the men who were part of the Syphilis Study. Because when we talk about IRBs, we also have to remember that because of the sacrifices of the men in the syphilis study that this lead to the strengthening of federal guidelines and research. Even though we have challenges in terms of IRBs, it's important for us to remember how they came about. So we are embarking on a series we're calling 75/35/10 because 2007 is the 75th anniversary of the beginning of the Syphilis Study, the 35th anniversary of the end of the Syphilis Study, and the 10th anniversary of the apology. We also are talking about transformation. One of the things we are doing in this call series is talking about transformation, in terms of how to transform the health care system and the research system to protect people who are involved in this research better.

So with that I would just like to introduce the topic of today's call series, as Kristine mentioned, [*unintelligible*] call series for today is community-based participatory research proposals and the human subject review process, methods for working with university IRBs.

We have three speakers who are going to be looking at this topic from their perspectives. We have Sherril Gelmon, who will be talking about the perspective of the IRB committee, Then we're moving on to Ruth Malone, who will give us a case study on the PHAT Project, which talks about the challenges of CPBR research, and finally, we're going to hear from Elleen Yancey, who will talk about perspectives of intervention, research center at a medical school.

I will introduce each of the speakers right before they give their presentations. As I said, we're going to begin with Sherril Gelmon who is Professor of Public Health at the Mark O. Hatfield School of Government at Portland State University in Portland, Oregon. She is the professor, as I mentioned at the School of Public Health there and chairs the two IRBs at the university. She is

also a 16-year consultant with CCPH. Her primary research responsibilities are in the masters of public health and the masters of public administration program. She's also on the faculty of public administration and policy doctoral program. She currently leads several community-based research projects, addressing the nursing workforce, workforce technology and community health centers, [unintelligible] recognition for community engaged research, of excuse me, community engaged scholarship and community-based learning strategies. She is also the founding chair of the new international association for research of service learning and community engagement. Welcome to the call, Sherril.

Sherril Gelmon: Thank you. I just need to say I'm at a school of government, not a school of public health. I'm delighted to be on the call today and to be able to start by presenting the view from the IRB committee. The institutional review board community which has a mandated responsibility in universities, primarily the perspective I'm going to give but IRBs that are located in community organizations also have similar mandates.

What I propose to do and if you look at my second slide that is titled multiple perspectives, is to talk about the multiple perspectives on the IRB. Then hopefully this will address some of the questions that people raised in advance of the call and may then also help facilitate our discussion.

As I prepared these slides, I realized I was speaking on behalf of the IRB. I was not speaking specifically to community-based participatory research, because the IRB has responsibility for all research and all protection of human subjects. So you'll see that my slides may not be as specific about CBPR as some of you may expect, but hopefully by thinking generically about the IRB we can then consider these specifics around CBPR and in particular the two presentations that follow mine will help explore some of those areas. So you can see on the multiple perspective slide, that I'm going to walk through 6 different perspectives briefly and hopefully everyone on the call will be able to relate to one of these.

My primary message is that the challenge of presenting to an IRB and hoping to be successful and get approval for one's research in particular in using community-based research methods is that we must be attentive to all these different people who are going to review the proposals and you have a responsibility and some concerns and present a coherent proposal. My experience is that any kind of research, the biggest challenge with an IRB is writing a very clear proposal.

Let me walk through all the different perspectives. Let's go to the next slide, which gives a review of the mandate of the IRB. I know this has been covered in past calls, but in case some of you haven't been on the calls, I just wanted to go over this, and why we have IRBs.

Over everything their responsibility is to ensure the protection of the rights and the welfare of human subjects who are involved in any kind of research. The IRB is mandated to be sure that protections are in place to assure the rights and welfare of the human subjects and then that gives the researchers the authority to conduct the research and potentially disseminate the findings.

IRBs carry this responsibility. Their charge is not to redesign your methods or to redesign the data collection instruments or strategies you are going to use except those that have implications for the rights and welfare of human subjects.

As a member of an IRB, I frequently want to rewrite an individual survey, because I think I could make it better and clearer for them, but that's not my job on the IRB. The focus is on protecting the rights and welfare of the human subjects.

IRBs require standardize documentation and now in the era of everything being on websites that documentation is readily available and that documentation facilitates how we conduct human subjects reviews.

Most universities that have any kind of research activities will manage an IRB and they will also conduct reviews for community-based nonprofit organizations that may not have their own reviews. Certainly there is usually a fee and sometimes one wants to shop around and find the organization that has the IRB that is most receptive. But the party obligation as a university IRB is to make that service available. Then again if you are from a community-based nonprofit in search of an IRB, you can certainly scan to find which university or other organization might be suitable for you. There are also IRBs in other kinds of organizations, in teaching hospitals, in health systems, many community research organizations that have active research enterprises run an IRB. Indian health boards and other groups, in the end I will give you a resource that has a list of federally approved IRBs and there are other ways to find your way to others.

So that's what the IRB. Go to the next slide, just again to verify the categories of review and this is federal language in terms of how your application might go through an IRB, whether you are using CPBR or any other method. What we all hope for is waived review, which means we submit our application but we are quickly certified by a member of the IRB and it goes through fairly quickly. The explanations on waived review in brief are when you are primarily conducting surveys, interviews or planning to publish observations that involve almost no risk. Those can be certified by a member of the IRB and they go through quite quickly.

Where there are concerns about some risk because of human subjects, your proposal may be classified as expedited review. These are activities that involved no more than minimal risk or there will be minimal involvement of human subjects. Expedited review moves more quickly, the time varies depending on the IRB, but again it's a fairly expeditious review that gives you the approvals that are necessary.

A full review is what we hear about the most in terms of people getting either stopped by an IRB or the IRB taking a long time and researchers feel this may compromise their research activities because they have to wait for the IRB. Any proposal for research that is funded from the federal authorities, whether funded directly from a government agency or with pass-through must undergo full review. This is one of the requirements of federal funding and it doesn't matter what type of study, so if you are doing anything with federal funding, you need to anticipate in your research process the time necessary not only to prepare your proposal but for the IRB to conduct review. Again, there is no definite time line. Many IRBs post on their websites how long you should anticipate, it can take anywhere from 4 weeks to several months, depending on the IRB,

the nature of your study and other factors. There is no simple answer for what category you will fall into or how long it will take, and this is a place where I would encourage you to check with your local IRB and get some advice from them on how they anticipate your proposals will be reviewed and how long it will take.

If data will not be published or otherwise disseminated, no review is required. Many institutions, universities require for example the graduate students, even if they are not going to be publishing or otherwise disseminating, that they submit and that they are authorized that no review is required if they are doing some community-based project, simply to ensure that the IRB is aware of the activity. That's one where you want to check with your local IRB.

That's the IRB 101 refresher for those of who haven't had it before, for those of you who want to be reminded of this.

Let's go to the next slide, which talks about the institutional authorities. This is the first perspective. The institution, and again, I'm speaking primarily of universities but this could also apply to research conducted through other institutions. The institution assumes the legal responsibility for all research that is conducted or sponsored by it. Even now as researchers we may feel quite independent, when we submit a proposal for funding that will be managed through our institution, our institution must sign off on it. They are taking the legal responsibility and serving as the legal grantee for the funds, so they are assuming the risk and the responsibility. They are concerned about a number of issues for compliance. You can see there that at many institutions there are at least 4 different kinds of compliance committees: human subjects, which we are talking about today, but there are also comparable committees that are looking at research proposals around animal care and use, biosafety, radiation [*unintelligible*] safety and other areas. Human subjects are not the only one, but that's what we will be talking about today.

The institution ensures through that committee structure and those responsibility within the administration of the institution that there are independent determinations separate from the researchers on methods, risks and benefits and rights. Most institutions comprise their IRBs to be interdisciplinary and represent a wide variety of perspectives. So through those committees they review and approve all relevant projects conducted by both faculty and students and the rules are that you are not to begin that research until you have that approval from the IRB. The reality is many of us leave it to the last minute, many of us are in a hurry, we have an opportunity in the community, we want to get something started, but nonetheless from a legal and ethical perspective, we must wait to work through the IRB, before engaging in data collection, in particular with human subjects.

This is so important when we're working in community-based settings with community residents and participants who are determiners of our research but also our subjects.

Let's look at our next slide. I think the staff that supports the IRB are one of the most overlooked resources that exist for us, and I've only come to appreciate this as co-chair at one of the IRBs at my institution. The staff's job is to ensure the smooth and effective functions of the committee and they play a gatekeeping role for proposals, as proposals come in determining the level of

review required, advising the chair of the committee or the vice provost for research or whatever the title might be at your institution and helping truly manage the process. They also have [unintelligible] provide consultation services to researchers and in many institutions have a responsibility to organize training for researchers and IRB members on procedures and protocols. Different institutions have different amounts of this training but the staff is just amazing. They know the guidelines in and out, they know where to find the resources, they themselves have usually gone through extensive training and they are really a wonderful resource that more of us should take advantage of to better learn how to prepare for [unintelligible] submitting our work to the IRB. This is very important when we are doing community-based participatory research and we may have an IRB that we perceive is going to be less than friendly or less than receptive to methods they may not be as familiar with. The staff can really be our advocates and help us through the process.

They manage the entire review process, including all the follow-up and continuing reviews. They can be very helpful in reminding us when we as researchers are supposed to submit those kinds of reviews. Finally another wonderful thing about our staff is that they facilitate access to role model proposals and forms. I don't know about the institutions where those of you on the call come from, but I know that at our institution we are adding more and more sample proposals and forms to the website that supports the IRB so the individual researchers can look and find samples of approved documentation of proposals of surveys, of informed consent guidelines and protocols and really encourage researchers, not to necessarily copy, but to role model from things that have been successful.

For those of us in CPBR, this is particularly important because we can then see what will be passed by the IRB or what has been acceptable and see if we can create our own work to see that we get through some of the hurdles we may be able to anticipate.

The next slide speaks to the role of the faculty chair of the IRB. At most institutions, it is my understanding that it is a faculty member. Sometimes it's an administrator who also holds a faculty employment. This chair of the IRB has responsibility like any other committee chair. They coordinate the process in consultation with the staff but they have public responsibilities for representation of IRB decisions. They usually sign all the letters and therefore assuming some of the institutional representation and authority on behalf of the IRB. When I was approached to take on this role, I talked with our vice provost of research and said "you'll be signing all these letters won't you?" and he said, "no, no, no, that's your responsibility once you are the chair of the IRB."

So the chair has a very public persona and therefore takes the responsibility and the accountability quite seriously. They also may have a role in terms of recruiting new IRB members, so if you are a faculty member at an institution or at any other institution with an IRB and you'd like to get involved in the IRB in particular to represent CPBR, I would encourage you to find out who the chair is and chat them up and let them know of your interest. As a member of the IRB, you can help to influence how IRBs look at CPBR.

Chairs may also assist in training and information sessions, but primarily their responsibility is managing the process.

The next slide speaks to the individuals that serve on the IRBs, which at universities are heavily comprised of faculty members from a variety of disciplines. These faculty members have a very big role to play because they are reviewing all the different levels of proposals. They participate in the IRB meetings which usually occur at least monthly, depending on the size of the institution and the number of proposals and the number of IRBs they have and they engage in the decision-making on the proposals. Part of the decision making is developing advice and guidance for researchers and we often find in the IRB I work with that we are following the protocols but also providing friendly advice to our colleagues to help them in their research. We're not redoing their research but from our mandate of thinking about human subjects, we want to be collegial and hopefully helpful peer advice.

We also independently conduct expedited reviews that do not have to go to the full committee and they provide additional reviews to support staff for presubmission proposals, continuing reviews or proposals that require additional consultation. I know as a faculty member serving on the IRB has been one of the most rewarding of all university committee and one of the few I will happily continue on because I learn so much about what other faculty are doing, what's going on in my institution and in particular in the context of community-based research, I see kinds of research I don't engage in and I learn a lot about new methods that I may be able to apply. I think it is a wonderful thing to do and the faculty take it seriously. It's a lot of work. Our committee meets once a month and we each probably have anywhere from 3-10 hours of work to prepare for that monthly meeting and may have another 4-8 hours per month of reviews that we are doing independently. It's not one of those easy committees to be on, but it's a rewarding committee.

The next slide speaks to community research participants. This really varies depending on the institution and its orientation to the IRB. Community research participants may or may not have an actual role on the IRB depending on local practice. Most IRBs have a community representative and they are particularly valued and respected for their review for proposals that focus on community-based research.

In particular community representative may play an important role to certain vulnerable populations such as children, or prisoners or historically disadvantaged or disenfranchised populations. And the community member often is the gold standard for the committee if others turn into too academic types to remind people of the protection of individual community members and to speak to individual protections as well as collective community protections. It is rare that a community research participant can just come to the IRB because the IRB is a committee structure, but their voice is certainly an important voice that is heard through their collaboration with the faculty researcher as well as to that community representative who isn't the only person thinking of the community but usually plays that role. I know in particular on my committee we have a community member who has done a lot of work in the justice system. So whenever we are looking at a proposal that looks at incarcerated individuals that person's expertise and knowledge of the system is very, very valuable; similarly, those who work with children who can bring those perspectives to us.

The next slide speaks to the researcher who is using CPBR which hit closest to home to many of you on the call. I'd say many of the same things apply to the faculty researcher and to the community researcher. Recognizing they may have different roles, but as we will see in our next two presentations in particular the importance of the collaboration between faculty and community researchers in negotiating the IRB. The researchers prepare the proposal that is going to be reviewed by the IRB and the rules are the same whether it's CPBR or any other research. It's vital for researchers to carefully understand what the IRB is looking for, the rules, the procedures, the issues that get IRBs concerned. And then document all concerns and issues regarding protections of human subjects. This becomes so important in community-based research where we don't have the ability to control in the same way as we might in the laboratory; and where we have certain unique and challenging aspects. So I would ask you as researchers to think very carefully about how you present. In presenting CPBR, I don't think we are presenting a lesser method, or a different method by any means but we may be presenting a method that our colleagues on the IRB are not as familiar with. So it's very important that our proposals be well prepared. Make a clear case that speaks to all of those risks and concerns and explain any unfamiliar methods and translate terminology into terminology that may respond to the different interests or different expertise of those on the IRB.

Let's go to the next slide and sum this up with the challenging situations. The biggest challenge is the IRB member who does not understand CPBR. And I hear a lot of this in particular with IRBs that are located in academic health centers where people are used to a biomedical model and a heavy emphasis on quantitative research methods. We also may have some issues if staff are not familiar with the various protections and strategies for CBPR. That's another challenge. The challenge I think I stated a few times, but I'll keep beating on this one, are the researchers who do not prepare a coherent and well-substantiated description of the proposals. What I find particularly distressing are graduate students who submit proposals for their thesis or their dissertation and have clearly not had sufficient mentoring from the faculty in terms of proposal preparation.

Finally we also may have challenges with community members who don't understand the responsibilities of the IRBs and the value they can offer. We need to respond to all of those challenges. So if you go to the next slide, my advice to you then would be to think about all of these perspectives and present coherent proposals. What that means is learning the rules and regulations in advance of submitting a proposal and finding out in particular about ways and methods to negotiate the IRB when you are doing community-based research, but frankly for all of your research. But in particular if you have heard rumor or gossip that your IRB has a history of not being responsive to CBPR, I really encourage you to consult with IRB staff to answer questions and review samples of exemplary proposals. Use informed consent protocols like those on IRB websites that will speak to the most common issues. If your IRB does not have those sorts of things publicly available, ask your staff for them or ask your faculty chair or your IRB or whoever are the administrative authorities to please provide those and I think for CBPR that's an important thing to ask for and recognize that we need those models.

Finally there's sort of a behavioral comment and that is the IRB does hold an authority position, so it's good to be respectful of the people on the IRB, certainly to ask them questions but to respond quickly to move your research forward.

My last slide is a resources slide. I would encourage you to look to these resources. In particular at the federal level, the office for human research protections, which allows you to search for IRBs in your community that are federally approved but gives you a range of information on local IRBs as well as anything you'd want to know about compliance, regulations, policy, research participation, etc. The actual language for the protection of human subjects is codified in a federal regulation and the website is there for you. And then check the guidelines and procedures at your university or health system or your community IRB website. I would encourage you to consult with the IRB staff on procedures.

I think CBPR should be treated the same way as other research but we have unique issues related to the role of human subjects and protection and with careful thought as you are going to hopefully get through the next two presentations in particular, I think you should be able to negotiate the IRB for CBPR just as you would for any other research.

Thank you very much.

Kristine Wong: This is Kristine Wong, we just heard in the last minute that there's an emergency fire drill at Tuskegee and I'll be stepping in for Dr. Northington Gamble, and introducing the next speaker. The next speaker is Dr. Ruth Malone who is a Professor at the School of Nursing at the University of California in San Francisco. Dr. Malone is a professor of nursing and health policy as well as the vice chair of the department of social and behavioral sciences. Dr. Malone is nationally and internationally known for her tobacco industry documents research which focuses broadly on the public relations aspect of public health with an emphasis on marginalized populations. She leads a multidisciplinary team of researchers working on projects funded by the National Cancer Institute and the California Tobacco Related Disease Research program. In addition to her tobacco industry document studies, she is academic principal investigator on protecting the hood against tobacco, also known as PHAT project, a community participatory research project working with African Americans of San Francisco. She's also published studies examining the tobacco industry's targeting of African Americans, gays and lesbians, and the homeless and mentally ill. She has received several awards for community service work, commitment to diversity and advocacy efforts using tobacco industry documents, including the America Legacy Foundation Civil Jacob's Award.

She is a cofounders of the Nightingales, a nursing activist group focused on exposing and challenging the activities of the tobacco industry. Dr. Malone is an elected fellow in the American Academy of Nursing. Dr. Malone will be presenting a case study that will illustrate some of the key tensions that can arise between a traditional biomedical research institution and community-based participatory research projects.

Ruth Malone: Thank you. I am very honored to be here with this group and I will move fairly quickly through my slides but I did want to acknowledge my coauthors. This presentation is based on a paper we published in the American Journal of Public Health, and it's available there. I wanted to acknowledge my coauthors, whose names are listed on my first slide.

So we can go to the second slide. I should also say in advance that we've gone back and forth a bit about formatting and there are a few formatting glitches that we'll get to down the line that I

noticed from slide 11 on. So please forgive those, they are entirely my own fault. The PHAT project was a community participatory project in San Francisco in the Bayview Hunters Point community of San Francisco, focusing primarily on African Americans, who as many of you know are disproportionately affected by tobacco-related disease. In this community, 55% of the African American residents, felt that health and wellness were really beyond their control compared to 15% of the white residents. So we felt that a community participatory approach emphasizing empowerment would be useful for approaching the issue of tobacco in this community.

Next slide. I'm not going to go into a lot of detail on community participatory research. I thought we were going to have a little more of that, but I'm assuming most of you are already doing that, and are already familiar with the assumptions of this sort of research. But in brief, our community research partners participated in all phases of the research, including designing that study and asking questions. We identified community leaders and groups who worked with us. Our partners conducted a community survey. They were particularly interested in cessation so they conducted a survey on cessation.

Next slide. And they found that looseys or single cigarette sales were identified as an obstacle to cessation. Now why did this make it harder for people? Partly if they were trying to quit smoking and they could buy just one more cigarette, it was cheaper than buying a pack, they were readily available at most convenience and liquor stores in the community. Of course, there are no warnings on single cigarettes. And in fact, single cigarettes are not legal in the state of California or in most states. Our community partners did not realize that those were illegal sales, so we set out to study this issue as a major obstacle for people who were trying to quit smoking.

The community research partners decided they wanted to look at the issue of single cigarette sales. So they started by mapping all convenience and liquor stores in the community and we were going to take a look at this issue there. As many of you know, the IRB requires that if you are changing your protocol, you have to go back to them and of course with this sort of research, that's one of the difficulties is that your protocol is being developed on the fly as you go. So we put in modifications saying that we wanted to do an observational study of the stores looking at their advertising density and smoking activity and store sales practices including single cigarette sales. Next slide. However, after we got approval for that and went back and were discussing it with our research partners, they said this is not going to work, we don't just want to observe. We actually want to try to buy a cigarette. One of the problems was that you can't just hang around these stores. No loitering is allowed, and it could even be dangerous to just hang around watching. It could be quite a while between sales. Next slide. So the long waiting times were impractical. The partners wanted one purchase attempt at each store. So we revised our protocol and returned to the IRB with this modified protocol.

We said, we knew the IRB might have some issues about us asking to buy a single cigarette, so we assured them we would never identify any individual store, clerk or owner in our data, click through now through the subsequent parts of this slide and continue clicking, two clicks. There were no identifying reports of any individuals by name. We were going to report the findings only in the aggregate. Next slide. The IRB refused our modification, they did not understand first of all that our research partners were paid researchers on the team, that they were actually part of

our team. Click again, they said that we would be soliciting them to commit an illegal act. And click once more, and they said that trying to buy a single cigarette would constitute entrapment of store personnel. Next slide.

So they set us off on, we decided to appeal their denial of our study and they set us off on a sort of circular route. Click once. The IRB, and click again, said why didn't we speak to risk management of the university about this study? We went to risk management, they handle things like insurance contracts and lawsuits and they were very puzzled about why we would be coming to them with an appeal of an IRB application. So click again. They referred us to the university's legal department. The legal department after a great lengthy time, after we kept asking them if they had more information or what was going to happen, referred us ,finally they said they could find no relevant authority that would preclude us from doing this because actually it was not illegal to ask to buy a single cigarette. It was only illegal to sell them. They referred us back to the IRB and said the IRB did have the authority to approve our study.

The IRB, click once more, denied our appeal. Now going on to slide 11, after you click to slide 11, give two more clicks, actually three more clicks because of our formatting glitch. We went to the IRB and appealed again, and we went back with a district attorney's signed grant of immunity saying that no one would be prosecuted as a result of participating in this study or being part of this study, that they would not go after any store owners or managers, we showed them the part's of the California penal code, that buying a single cigarette was not in fact illegal. We had a written opinion from the state attorney general that our practices were not entrapment. We showed them literature where this had been done before in other studies and approved by other university IRBs. Click once more. We also had another letter of support from our funders, a state tobacco research program. Next slide. We also argued that it was important for the university to respect the community's knowledge and skills, that that was part of the nature of this study. The unit of analysis was the store, we were not interested in any data about the individuals working in the store. We weren't going to say they were old, young, white, black, what they did, who they were. We cared not at all who they were. We only wanted to know in the store, could we buy a cigarette?

Next slide. The IRB made its final decision, and it was no. So we spent a lot of time subsequently trying to figure out how to make lemonade out of our lemons that they had given us. Click the next study. We realized that first of all we went back and we had gone and appealed to the IRB in person. They said in their letter in response to us that they anticipated benefits of the study did not justify the risks although they were never completely clear on what those risks were. They suggested we do a different type of study, like a survey or talk to the kids hanging out outside the stores. Our community partners really didn't feel this was feasible. Click again. Now here on this slide #15, please click three times. Our community partners responded to the IRB decision by feeling that it was a betrayal. They felt that we were protected community predators by this university decision. The CRPs (community research partners) actually broke off from our project to carry out the study independently because of course as interested citizens not working with the university, they did not need IRB approval to go and ask people if they could buy a cigarette. They gained knowledge about single cigarette sales, but it could not be published or reported as a finding of the PHAT project. We could not help them disseminate this knowledge.

Next slide click three times. From a biomedical ethics perspective that we believe the university IRB was choosing this makes sense. They focus on individuals as subjects, the store personnel as subject. They must provide consent, they take a principled based approach and they accused us of basically of ignoring the unethical consequences of deception and putting the community members at risk, although that risk was also very ill-specified. Next slide. From a critical or communitarian ethics perspective, and here we are drawing on some of Dan Callahan's work, human beings are viewed as social not isolated individual. Click through three times. Social, it takes a social ecological perspective on the risks and benefits and finally clicking again, a critical and communitarian perspective looks at problematizing our assumptions about human beings and sees them much more collectively in groups.

Click to slide 18. So we analyzed our failure in this case with three questions. Did it actually constitute human subjects research. What were the risks and who was at risk? And did institutional conflicts of interest influence the decision-making?

Did it constitute human subjects research? Well, we said human subjects are clicking once more human subjects are individuals whose physiologic or behavioral characteristics and responses are the object of study. Click again. Our study was to assess institutional practices within a community, not the individuals. We think this is a very important distinction that has been understudied, in the human subjects literature. Click to slide #20, and do 2 clicks. From the biomedical perspective, the risks were for the store clerks, exposing their behavior, of feeling deceived, of feeling lured into acting illegally. From a communitarian view, the risks were for the stores. They could potentially be accused of engaging in illegal activity, but given the protections we felt then and still feel that our , that there was very negligible risk for them. And it would be incredibly important for the community to know. Click to slide #21.

Did institutional conflicts of interest influence the decision-making? Click three times. There was this sort of hot potato referral, which was odd, because it's very strange to be referred to risk management for a research proposal review. We felt that indicated some concern that we might be getting the university into a sticky legal situation or a place where they might be vulnerable to lawsuits. We really question whether they were protecting the university or the subjects given the protections that we had said we would use. They raised some other issues that I don't have time to talk about here, in terms of violence in the community and we really had to question whether they saw certain risks as more inherent in lower income communities, even given the fact that our partners lived in these communities and knew how to negotiate them.

So just to conclude we do think IRBs are critically important for evaluating and managing risks. We certainly don't deny that and the lessons of Tuskegee hold true here, but we also want to call attention to power dynamics embedded in all ethical decision-making. And to say clicking again for a third time, if we are going to encourage community-based participatory research, IRB may need to expand their ethical horizons beyond just the typical biomedical perspectives to take into account some of these communitarian perspectives. Click once more. And we also think that IRBs need to be sensitized to the issues around protecting institutional power versus community empowerment. And I'd be happy to take some questions when we have time. Thank you.

Vanessa Northington Gamble: Thank you for that provocative presentation. Our final presentation today is going to be from Elleen Yancey, who is Director of the Morehouse University School of Medicine Prevention Research Center in Atlanta, Georgia. Elleen is Assistant Clinical Professor at Morehouse School of Medicine, the Department of Community Health and Preventive Medicine. She is also director of the Morehouse School of Medicine Prevention Research Center. She is the principal investigator on HIV grants and other health promotion and disease prevention research. Her work includes work on stroke prevention, faculty development for health services for professional cultural competence in health care and program evaluation for community-based organizations. She's also a consultant and lecturer regionally and nationally through community-based prevents in research, cultural competence and also HIV risk reduction. Before she went to Morehouse, she was the director of the Fulton County Department of Mental Health, Mental Retardation and Substance Abuse, and for many years served on the Georgia Governor's mental health advisory committee. Welcome to this conference call series

Elleen Yancey: Thank you, Vanessa. I'm pleased to be a part of this presentation. Morehouse School of Medicine has long-standing collaborative relationship with CPH and for the presentation I'll just very briefly discuss some of the practices of our prevention research center that have helped us move our CBPR proposals through Morehouse School of Medicine's IRB. It's not pain free nor is it necessarily speedy in all cases, but through collaboration and ongoing communications those of us who submit CBPR proposals to the IRB and working with the IRB, the IRB has a learned generally the concept and the processes that go forth in CBPR proposal and has been supportive in our efforts to move our research forward. As sort of a background and our approach in terms of our prevention research center submitting CBPR research on the next slide, we talk about our theme. Our theme is risk reduction and early detection in African American and other minority communities. And important there is the emphasis on a coalition for prevention research, the coalition including most multiple community partners as well as academic and agency research partners.

Now this translates to a focus on identifying and disseminating effective health promotion and again the emphasis is on effective health promotion to individuals, families and communities as we move to our next slide, talking about healthy bodies, healthy minds, healthy families, this is our prevention research center approach to implementing the goals of our activities. And the focus is on identified health needs and priorities for the coalition partners and the coalition community partners drive this focus. We make sure that at least annually and sometimes more often, we have assessments within the community in terms of getting specific handle on what the health priorities needs are in the health perspectives. The community residents identify these needs both through surveys, through focus groups and through individual interviews and communication with our prevention research center staff and faculty. The PRC is governed by a community coalition board that is a majority of community residents, members, and this is important in that it has a governing body and policy-making which is different from many of the prevention research centers and other areas in other academic areas of community-based research.

If it ever came to a vote, which fortunately it hasn't, the community representatives on our coalition board, and these are neighborhood representatives of organizations, they would have

the final word and potentially the majority votes in terms of whether a proposal is accepted and that's a step that I'll go into further detail about. CBPR from our community's perspective as well as our institution's perspective must be culturally sensitive and designed to effectively translate into applicable methods of health promotion and disease prevention. This information must go beyond general publications directly into the communities. One of the questions that is always asked for, asked of researchers seeking approval of our coalition board to go forth with community-based research is how will the community benefit. And often their focus is not on the journal publications, but how this translates to potential decrease in health disparities and increase in health promotion directly into the community. It's important to convey these concepts to the members of the IRBs and to talk about how we do CBPR. So we in our PRC actively participate university-wide in grand rounds talking about community-based prevention research. Our individuals grant proposals, our coalition, we provide campus-wide workshops, face-to-face interactions and have research collaborations not only with researchers in our department where we are based, which is community health and preventive medicine department but also with the basic scientists and with the clinicians.

We market our approach, that's a major area for us here in the institution. And it's ongoing each year.

Move to the next slide. We talk about community-based participatory research, and I'm sure all of you have your definition that you use, but for our purposes I'll just briefly talk about what works for us. It's a collaborative process of research involving the researcher and community representatives and it engages community members. We also employ the local knowledge of the understanding of the health problems and the design and the interventions that are invested in community members' interest. Community members are involved in the process and the products of our research as well. Part of that is that prior to submission for publication on any of our research findings, a draft goes to our community board and there is an ad-hoc committee on the community board that reviews the publication, gives input and then we go forth with submitting to journals.

In addition to this, the community members are invested in the dissemination and the use of the research findings so ultimately their goal is a reduction in health disparities and when I say dissemination that includes community newsletters, town hall meetings, other things that are invested and held directly in communities. We move to the next slide, our Morehouse PRC community team coalition board developed three primary priorities that guide the direction of our PRC research and this was done back in 1998 when the PRC was first funded and it is revisited annually to make sure that the priorities continue to represent the interests of the community. The first and they are not listed in a value sense, but number one, the projects must focus on reducing identified health disparities and because number two, the health status of African American men in our communities is alarming in many of the health areas, the projects, they don't require that all projects address health status of African American men but they encourage that as many health focus research is for African American men, research projects be proposed and funding sought to go forth in that area. Thirdly that the projects must focus on the reduction of social, economic and environmental injustice, and this often is not necessarily the first priority especially for basic science researcher, so that is an area of focus that we represent and communicate with all of our departments in terms of how their research from bench to

bedside to the community can have value. As well we function as liaison communications for the understanding of the more technical critical research to the community members.

Our community coalition board has an established community IRB that review all four research proposals using these priorities as guidelines so if there's a thumbs up or thumbs down, that directs our process and there's only been a very limited number of challenges since the inception of the board and of the PRC and as education has facilitated on both sides, we've had changes that have had to be made, but they have been for the betterment of the research project and have facilitated getting it through the intuitional IRB. As we move forward, in terms of community values in the next slide, the coalition board also established a set of community values. There are nine of them and they are used to determine whether the proposed PRC research is appropriate to and addresses our partner communities. And all of our proposed research must have prior approval by our community IRB. So once we've gone through the challenges of our community IRB, it makes it less difficult for approval with the institutional IRB. There have been recommendations for revisions prior to submission and ongoing review and these principles are listed on the slide, the first one being the policies and programs must be based on mutual respect and justice.

The second is a right to self-determination. In other words, the participants of the research process, and these are all involving human subject, for the most part, have a right to determine their involvement and withdraw and other things that are specific to their participation. The third is that communities are at an equal partner at every level of the research and that enforced principles of informed consent must be carefully addressed.

Number five, socially and culturally and environmentally sensitive research is necessary. As you go to the next slide, number six, addresses research processes and outcomes that must benefit the community. That's a common question that comes forth and every proposal that comes to our PRC. The bottom line for the community members is what will the community benefit from participating in the research, how does this translate to better health practices and better health outcomes? Seven is community partners are involved in the analysis and interpretation of the data and the dissemination of the results. I talked just abit about the dissemination process and one of the things I get asked frequently and in our presentation and conferences, is that what role can communities play in the interpretation of the data, and generally our response is that the residents who live in the community and we are not talking about individual participants, we're talking about group responses, we can get interpretation of statistical data in terms of what this means from those who are in the community.

We are not contaminating the result in that we are not talking about specific individuals but sometimes there are issues that are important to get feedback from those who generally within the community have provided the information. We are required to give periodic reviews and updates on the status of our research as the projects continue and this has to be done at our board meetings which are held every two months.

Number eight. The partnerships must last beyond the funded research so the focus as well is on making sure as best we can that there's training for grant writing, that we facilitate partnerships with the health agencies and other entities that can help the growth of focusing on health

promotion beyond the ending of the grants that we have. The ninth, and one of the most important for the communities as well as the academic institution is that the community is empowered to initiate community-based research on their own. So we provide training on how that can be done from a community perspective as well.

Moving to the next slide, research evaluation criteria. The coalition board also developed these criteria. The project should not violate the community values or standards. Projects should have the potential to benefit community through a health promotion intervention. The project should be subject to evaluation and that's a key area. We must be able to document that we are able to do what the proposal is and if we have not been able to, then we are also learning by identifying the challenges that may arise and projects, if effective, must be replicable.

Next slide, the IRB requirements including training for our staff are very traditional. Initially we are required to complete the CITI course and protection of human research subjects. In addition to that the principle investigators are also required to complete the basic sciences section in addition to the behavioral sciences section. That generally includes history and ethical principles, basic IRB regulations, informed consent, research with protected populations, FDA-regulated research, HIPAA and human subjects research, conflicts of interest involving human subjects.

Next slide, the Morehouse IRB, basic our protocols include basic demographic information. We have to make sure we respond to such questions such as will the participants in this study be asked to consider in participation in other studies conducted by the PI or other research at Morehouse school of medicine, and if so, explain, we also have to have a very clearly identified timeline or Gantt chart. The general study information in our application includes recruitment, screening procedures, very carefully and very clearly documented as to how participants will be recruited and screened. Funding sources and description of the recruitment location and then in the area of research conduct and progress, in other words how we will address informed consent and one of the things we said is very closely scrutinized by our IRB is the reading level and the reading accessibility and readability. So it's generally required that our consent form, our protocol have reading level no higher than 9th grade. As you know when you are putting legal information in that's a challenge. However our IRB has been quite helpful in providing training and workshops university-wide for samples in that.

For the other requirements on the next slide, we address areas of human subject information. Now not very often are there community-based participatory research subjects that involved blood or tissue storage. However because we are asked to collaborate with a number of other clinical department at the school of medicine, there have been research proposals that included stroke prevention and cardiovascular disease that did involve sample tissues collection. So those protocols were very, very closely scrutinized.

In the next committee, next slide, behavior research subcommittee, our IRB committee has a subcommittee that's composed primarily of CBPR researchers. Preventive medicine physicians, behavioral scientists, PhD of psychology, doctor of social work faculty. And their focus is when the review CBPR applications are highly focused on the protocol, recruitment, intended intervention, informed consent, because we do have research that involves adolescents and multiple detailed questions recommendations on areas that address these [*unintelligible*]

Sometimes we feel it's not unlike a dissertation defense. But the subcommittee is quite supportive, will meet with us as a committee with their questions that are best addressed face to face. We have some questions often not unlike like 'how will the individuals be secluded.' In the application it is noted that and then they will identify specific lines in the protocol that they are recommending changes. What's the intended intervention? And very, very specific kinds of questions and suggestions in one of our applications it said please be, you need to consider modification of your assurance of confidentiality and the survey stated that the survey was confidential. The committee recommended that wording be changed that will be worded such as will be kept confidential to the extent allowed by law. So that's just a very brief overview of our PRC and our IRB process. Last slide, I invite you to visit our website to learn more about our research and our community focus activities and I'm available for questions.

Vanessa Northington Gamble: Thank you very much, we've had three great presentations. It's been interesting about the presentations is that they all dealt with training and training in lots of different respects, in terms of training of the researchers, the community and the IRB. Being a historian, one of the things that has come up this week and in previous [*unintelligible*] is the whole issue of how we deal with an IRB system that was developed to deal with clinical research and how do you now work with that system in terms of not just community-based participatory research but historians and social science research. The other thing that the presentation brought up is the importance of priorities and sometimes how these priorities can conflict and given the quality and the richness of these three presentations, I'm sure there are lots of questions out there. Let's open up the call for questions and procedures.

Operator: Our first question comes from ---.

Caller: I have a question for Dr. Malone and I enjoyed all the presentations very much. She highlighted the schism between biomedical and participatory research and as I heard about the stone wall that her project encountered, I guess it was another way to view it. I wanted to say it and collect her reaction. If the object of this project was to show that some or all of the store that you targeted are selling single cigarettes, I suppose and this [*unintelligible*] in a different way, I suppose it's possible to say there are different ways to demonstrate that, different methods to skin a cat. It may well be that there are better ways to demonstrate what they are doing than using actors and deception and certainly using actors and deception are necessary to demonstrate what you want d to demonstrate. So from that point of view, it's harder to see that this is a biomedical social science schism and perhaps just a different way of viewing how the IRB saw the purpose of the study?

Ruth Malone: I'm not entirely sure I understand your question. But that was, we discussed more of these issues in more detail in our paper, which I would suggest you might want to look at. This is a very short-hand version of what we went through. I think the issue is that yes, if you believe that the unit of analysis is the individual clerk and that what we are studying is whether individuals sell us cigarettes, then it makes sense to say this is a biomedical ethics view, this is an act of deception. However we were wanting to basically measure the prevalence of this practice within institutions within the community. We actually went through lots of discussion about alternative ways to measure that prevalence, none of which according to our research partners after discussion at great length, seemed to think it feasible or realistic. We proposed to use a

procedure that the state of California actually uses to assess minor purchases. We do not believe that it is deceptive and unethical. I hope that that helps. I'm not sure if that answers the question or not in terms of other way to answer that question.

Caller: Thank you.

Operator: Our next question comes from ---.

Caller: Hi, this is---. I wanted to first point out one thing. Dr. Gelmon talked about the three levels of review. I believe what she presented was the policy, the local policies of Portland State University. There are three level of review that are spelled out in the federal regulations, but they use them slightly from what she had spelled out. So there will be differences with different IRBs at different institutions. The question I have though is actually for Dr. Yancey. I'm wondering, I think it's great that we all have a community IRB for the PRC and I'm wondering if it's, if that is an IRB that is actually registered with OHRP, because if it is an IRB that is registered with OHRP, it might be that the IRB at Morehouse School of Medicine could defer to that IRB rather than be PRC going through two different IRB reviews, one at the community IRB level and one again at the institutional level. Is that something that you have looked at?

Elleen Yancey: No we have not looked at that, and our community coalition board identifies this committee as the community IRB but in terms of the required regulations for an IRB, I'm not sure that the committee could withstand the requirements there. So their role primarily is to review proposed research based on the coalition board's values and priorities and to provide suggestions for protocol revision if necessary or if they see it making for their purposes the research more effective as it translates to the community. Morehouse IRB is aware and understands and has had communications with our coalition board community IRB, however, Morehouse still maintains the legal and the final oversight responsibility and quite often what has been recommended by the community stands in good stead in terms of what is then presented to the Morehouse IRB. So it's a little more time-consuming but it then helps to facilitate an increased trust involved and collaboration with communities so we have very little difficulty in participant recruitment because the communities have been involved with us right from the very start as well as retention.

Caller: That's great. I love your model. I think it's really wonderful and I'm glad to hear that you have that kind of input. I thought there might be a way to streamline your system a little bit more even. Thank you.

Elleen Yancey: That's a good thought. We'll pursue that. Thank you for the recommendation.

Operator: Our next question comes from ---.

Caller: My question is for Dr. Yancey. I'm wondering first of all how did you recruit your coalition members? And secondly, did they have to go through any training?

Elleen Yancey: In terms of the recruitment, Morehouse School of Medicine has been in existence for about 27 years and the focus and the philosophy has been to train healthcare professionals to

serve the underserved. So from the inception of the development of the institution there was a focus on partnership and communication with communities. In terms of the Prevention Research Center, we were funded in 1998, but with the Community Health and Preventive Medicine Department, there were partnerships with identified communities across metropolitan Atlanta, prior to our being as a PRC. So for the communities that were identified as the core communities for our coalition board, there was already pre-existing relationships. Those communities primarily in Southeast Atlanta which has a high population because of the density of the population so that compares to many multiple rural areas and these communities have high identified areas of health disparities so when the initial PRC application was submitted, partners that were already in existence signed on. Since 1998, we had additional communities request to become part of the coalition board as they are aware of research. So part of how the board is composed at this point is that any communities that are involved with PRC research which now goes beyond the core community partners can participate on the board but will not have voting privileges. The academic institutions that are part of the coalition board are, of course, Morehouse School of Medicine and Georgia State University and Emory University and there are community agencies such as the Atlanta Housing Authority, Board of Education, Fulton County Health Department, etc., so it came about initially as a volunteer group that was formalized with by-laws and membership and the values and the evaluation criteria I talked briefly about.

Caller: And do voting members have to go through any training?

Elleen Yancey: All members as they come on board are provided coalition board training. That's a one-day workshop where we provide training on community-based participatory research, general research practices, community partnerships, education on the role and function of board members, providing information to them specific to PRC/Morehouse School of Medicine, primary funding sources and an overview of all our current research. We also have a curriculum for grant writing and are in the process of designing a curriculum for community-based participatory research to be conducted in communities.

Operator: Our next question comes from ---.

Caller: We're enjoying the conference and at our IRB, we're exposed to a social behavior protocol, so we're very used to this type of thing, but we have a question which is when does recruitment start or is it just a concept that is not applicable in this instance. When does the research actually start? We were hoping this would tell us exactly what community-based research is and point addressing issues of how do you get around as a standard IRB would be, what is your recruiting process. You guys talk about engaging the community at every level. We're wondering in standard IRB terms how do you deal with things like recruitment and data collection starting and so forth.

Ruth Malone: This is Ruth, I can respond about our process. Our recruitment for our research partners started out of a focus group study we did to try to assess how community members felt about tobacco issues and particularly we exposed them to some of our tobacco industry documents related to the industry's targeting of African Americans. And in our approval process for that focus group study, we also included something about, and I don't have it verbatim to

forward but we also included something about asking them if they would be willing to be recontacted for other studies or other work on this topic. So those who indicated they would be, we contacted them to ask them if they would be interested in developing a study with us. Now at that point and I think we did an initial IRB application saying that we were working with partners who we had identified through these earlier focus groups. I believe that is how we did it, and then when we actually went to do other work, they didn't, we didn't. I'm trying to remember was our community survey, what we did about that. We just did a fairly pro forma thing on that, but you know this is one of the very interesting issues that this sort of work does raise. There is, there are these blurry boundaries around a lot of different aspects of the work because you really are blurring the boundaries between researchers and researched. You're blurring the boundaries between the beginning of a project and the end of a project. These are still areas where we haven't necessarily worked it all out, nor do I think we necessarily will work it all out.

Elleen Yancey: To add to what was just said, probably for us recruitment may have a number of different levels. In terms of the more traditional perspective and definition of participant recruitment, we do not start recruiting persons to participate in identified research until the IRB the Morehouse School of Medicine IRB approval. Prior to that, there is ongoing communication and collaboration with communities in terms of their needs. We provide training, resources, technical assistance to community neighborhood organizations. So as we talk about what the overall focus on the direction of the PRC research and there are persons who are identified and they come to us when you have research that addresses this areas, we are interested in working with you on it, but then we don't do official signing up participant risk and following protocol perspectives until such research is funded and approved by the coalition board and our institutional IRB.

Vanessa Northington Gamble: Sherril, do you have anything to add?

Sherril Gelmon: Yes, I would just echo what was said and the one thing I would encourage people to make sure they are careful of is to not use language like "how to get around the IRB." We just had a very active discussion at CCPH conference about this. The point is not to get around the IRB. The point is to learn what the IRB expects and then to make your case very clearly and in terms of recruitment, you really shouldn't be actively recruiting until you have permission to do the study, which is what the IRB gives you. But the reality is you must start recruitment early. There needs to be this very clear communication and careful negotiation between the community members, the community researchers and the IRB to ensure that everybody knows what everybody is doing in a transparent approach that is clear and open to everyone.

[Vanessa Northington Gamble closing comments]

[Kristine Wong closing comments]

