

## CCPH/Bioethics Center Educational Conference Call Series on IRBs and Ethical Issues in Research: Call 2

### “Highlighting the Importance of the Non-Affiliated (Community) IRB Member”

*March 14, 2007*

#### Speakers:

- **Elda Railey**, Co-Founder, Research Advocacy Network, Arlington Heights, Illinois
- **Mary Lou Smith**, Co-Founder, Research Advocacy Network, Arlington Heights, Illinois
- **Lucille Webb**, Director, Strengthening the Black Family, Raleigh, North Carolina and North Carolina State Department of Public Health IRB Non-Affiliated (Community) Member
- **Gigi McMillan**, Director, We Can Pediatric Brain Tumor Network, Los Angeles, California and University of California – Los Angeles IRB Non-Affiliated (Community) Member

*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 2<sup>nd</sup> call of the educational conference call series on institutional review boards and ethical issues in research titled, “Highlighting the importance of the non-affiliated community IRB member.”

This call series is being cosponsored by Community-Campus Partnership 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 three PowerPoint presentations and biographies and research sheets sent out in advance of the call.

The PowerPoint presentations are titled as follows: 1) Intro slides, 2) Railey Smith and 3) MacMillan. 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. Speaker Lucille Webb will not be using a PowerPoint presentation.

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 1300 communities and campuses across North America and increasingly the world tied together by 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 in the Bioethics Center on IRBs and ethical issues in Community-Campus partnerships.

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During the first call of the series that took place on Feb. 14, 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](http://www.ccpb.info).

This second call will provide insights into the community members' experiences on IRBs and explore the importance of the perspectives in the review process, as well as ways to increase their involvement. On future calls, we'll explore the successes and challenges of CCPH partnership and getting the proposals through the university IRB review process. We'll then learn from an array of community members and academics regarding why they decided to [unintelligible] for the protections of communities through the formation of community advisory boards and independent community IRBs. Lastly we will conclude this series with a session that presents recent research on IRBs and discusses implications of this research for future policy and practice.

Before we begin I'd like to remind you that this conference call is being recorded, including the questions and answer period. A digital audio file of the call will be posted on the CCPH website so that any one can freely access the information covered on these calls.

If you ask a question during the Q&A period, you are consenting to have your question be recorded. We're also planning to use the recordings to develop written products from the call series, such as proceedings. No identifying information about audience members will be included in these written products.

Please remember that if you get disconnected from the call, just dial back into the number 1-800-791-2345, access code, 74133.

Now I'd like to introduce you to today's moderator, Dr. Vanessa Northington Campbell. Dr. Northington Campbell is the director of the Tuskegee University National Center for Bioethics and Research in Health Care. At Tuskegee, Dr. Northington is also a professor of Bioethics in the College of Veterinary Medicine, Nursing and Allied Health. A physician and medical historian, she is an internationally recognized expert on the history of race and racism in American medicine, racial and ethnic disparities in health and health care, cultural competence, diversity and bioethics. And now I'm going to turn it over to Dr. Northington, who will tell us about the focus of today's call, and introduce us to our speakers.

*Vanessa Northington Gamble:* Thank you, Kristine and welcome to all of you who are on this call, as part of our conference call series on institutional review boards and ethical issues in research. And I think that we have planned here a great group of presentations because we are very fortunate to have four effective, passionate pioneering leaders and the importance of the role of non-affiliated community IRB members. So without further ado, I'd like to tell you about today's call. Today as I mentioned, we're going to be highlighting the importance of the non-affiliated or community IRB member.

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Elda Railey and Mary Lou Smith of research advocacy network will discuss both history and role of community non-affiliated, or some people say nonscientific, we can get into that later members of IRBs.

They will provide the results of focus groups of IRB administrators and community members that demonstrate the value of having community members on IRBs, but at the same time as this research, they will also discuss the challenges that community members face in representing the community. Lucille Webb, a director of the Strengthening the Black Family of Raleigh, North Carolina, will demonstrate the benefits from the lay perspective of her perspective, her experiences on being an IRB member with the North Carolina state of North Carolina State Department of Public Health. She will also discuss not just sharing her experiences, but also giving coping strategies in order to be a more effective community IRB member.

Gigi McMillan will discuss her role as a community IRB member at the University of California Los Angeles and she will highlight her efforts to create support systems and ongoing training opportunities that strengthen the role of the community member. And she too will also talk about strategies for recruitment, training and retention of non-affiliated members. And now [unintelligible] she will also talk about the nurturing of what's needed to make sure that people are effective IRB members.

So with that I will [unintelligible] last week, I gave the introduction of everyone in the beginning. I will hold the introductions of everyone before each presentation. So with that, we will begin our first presentation, which will be done by Elda Railey and Mary Lou Smith, who are cofounders of the research advocacy network. And let me begin [unintelligible] Elda. Elda is cofounder of the Research Advocacy network and directory of their advocate institute. She was formerly with the Susan G. Komen Breast Cancer Foundation as Director of Grants.

Elda's interests include education programs to enhance access for people of all backgrounds and socioeconomic status to quality health care. She specializes in collaboration and equipping advocates for more effective integration in research and patient advocacy. She is a member of the Intercultural Cancer Council, the External Advisory Board of the University of California San Francisco Breast Cancer SPORE Specialized Program of Research Excellence, Redes En Accion, EDICT (Eliminating Disparities in Clinical Trials) and has reviewed for Komen, Avon-NCI (National Cancer Institute) Partners in Progress, Centers for Disease Control and Prevention (CDC) and formerly served on the Patient Advocate Committee for ACOSOG (American College of Surgeons Oncology Group).

Mary Lou Smith is also a cofounder of the Research Advocacy Network, which is located in Arlington Heights, Illinois. She is currently serving as the co-chair of the Eastern cooperative oncology Group patient representatives committee and the Radiation Therapy Oncology Group patient advocacy committee. She knows one of their first meetings of the Radiation Therapy Oncology Group did in terms of patients and IRBs was here at Tuskegee. And Mary Lou has also is a community member of the IRB at Rush Medical Center. She serves on the national comprehensive cancer network breast cancer screening and treatment guidelines committee. She has spent over 20 years in health care and before becoming involved in advocacy efforts she managed medical care products for Blue Cross and Blue Shield Association, including the Center for Excellence network for pediatric oncology, a woman's health initiative and clinical trial

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programs. She is also a 20-year breast cancer survivor and has a JD with the health law certification and a master's degree in business administration.

Welcome both of you to this conference. We're looking forward to your presentation.

*Elda Railey:* Thank you, I'd like to start and thank you for you for joining and to CCPH for this opportunity to share with you the perspectives and the work that Research Advocacy Network has done with IRBs in the past few years. This has been done to broaden the scope and in recruitment and education for community members.

While you've been given excellent background in your past call, and what I'll do for you is a few things for you and then go into the topics for your day. Just as a review, we want to talk about how patient rights are protected, and they are protected mainly in 4 ways, with scientific review, institutional review board, [*unintelligible*] safety and monitoring board, and the informed consent process. On slide 2, it doesn't say the word process, but that's a major point that we need to keep reiterating that it is a process and we not just a document.

So if we move on to slide 3, as we said all research involving human subjects is overseen by some form of scientific review. With new drugs, they are subject to FDA approval and review, and approved drugs are subject to the funding agency's review and approval and at almost every point of the development of a protocol there is subject to some sort of scientific peer review.

The informed consent is where we as community members can concentrate alot of our time. Before agreeing to take part, patients as participants have the right to understand all that's involved in a clinical trial. That includes the purpose the procedures and treatment, the possible risk and benefits and the individual rights. Many people think that participants' rights are not always protected in clinical trials and they may remember the past abuses of research that occurred in the infamous Tuskegee Syphilis Study. Today federal regulation help ensure that all government sponsored clinical trials are run in an ethical manner. One of the most important ways that patients are protected is through informed consent, which is required by law. Before someone joins a clinical trial, they must have the trial explained to them, what is being done and what will happen during that trial.

There is also the opportunity for that participant to ask any questions that they have. Participants are also given an informed consent to read. The informed consent form includes written details about the information that was discussed and also describes the confidentiality of the participants' records. If a person decides to join the trial, they are asked to sign the informed consent form. Even after the participant signs the informed consent form, they can still change their minds and stop at any time.

We all have the chance to discuss other treatments or care with the doctor from the trial. The participants [*unintelligible*] to this informed consent process. The research team, which is made up of doctors and nurses, first explain the trial to potential participants in understandable language. And that is something that should be underlined four times and it should be in a language they understand, in their language, and that presents a barrier a lot of times if English is not your first language.

As we discuss in all aspects of the trail with the potential participant to give him or her the consent form, which includes the written details and the confidentiality of the participant's records. Every person agreed to take part in the study, he or she signs the form, and then we must remember that the process doesn't end once the form is signed. If any benefits, risks or side effects are discovered the study, the researchers must inform the study participants. In addition participants are encouraged to ask questions at any time, as to what's happening during this study.

On slide 5, we talk about unaffiliated membership and that is required by the guidelines that are regulations, which read: the IRB must include at least one member whose primary concern are in scientific area and it was one member whose primary are in nonscientific areas. This must also include at least one member who is not otherwise affiliate with the institution and is not part of the immediate family of a person who is affiliated with the institution.

Different IRBs call us by different titles. The regulations require consideration of community attitudes. One member's primary concern must be in a nonscientific area and one member must be non-affiliated with the institution. Community member seems to imply that the individual will represent a specific community or birth of an individuals, most likely the people the hospital serves. This could be a particular ethnic or socioeconomic group. Unaffiliated indicates that the person does not have any formal ties to the institution. The individual would not have any bias toward a particular researcher because of their reputation or the amount of money or prestige they bring to the institution. They will also not have any bias against a particular researcher because they are a student or fellow or might not be as experienced or as well known. This levels the playing field for research ideas. Nonscientific indicates that an individual will represent lay people, so when confronted with a scientific term, the nonscientific acts as a filter for those participants. If a nonscientific member can't understand a scientific concept or term, typically the participant would not be able to understand it either.

In 2001 the National Bioethics Advisory Committee recognized the non-affiliated membership of each IRB be at least 20 percent of its members. I'm sure that over the country that's not true in every situation that's' the hope that we can have 20% representation for the community.

What is the role of the non-affiliated member? They provide the voice of the participant to the research process. That participant may be a healthy volunteer, or a person with a disease or the condition being studied. The non-affiliated member provides a balance and excitement over a new treatment and the reality of an unproven regimen. That balance including balancing benefits versus risks and taking into consideration quality and quantity of life.

Slide 7, we talk about what does a community member bring. A very unique viewpoint, concerns of the participants who are trying to balance their lives with the requirements of the research protocol. We look at the cost in terms of actual expenditure, what will their insurance cover and what will the sponsor of the research pay for? Should it be any cost for transportation, child care or lost time from work? What is the inconvenience factor? How much time will take out of the participant's life? They need to schedule time for tests and questionnaires; will they need to have someone to drive them to and from appointments? What

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will be the emotional cost of participating? Will there be added anxiety because of randomization and the uncertainty of trying an unknown therapy? Are there any concerns about including confidentiality and the use of medical information?

Will pictures be taken, and if so, how will they be used? Are the recruitment materials over promising or not understandable? Are there other ways you think we bring unique viewpoints to the discussions at the table?

Non-affiliated means that we're not biased by the employment that we have. Non-scientific means we're not biased toward the interesting scientific questions. A community representative will represent the neighborhood, the patient's and potential participants, the public and the society at large. And we represent the practical real-world concerns. That's a pretty big bill to fill for one person.

A community brings, never brings on Friday. Most community members center their comments on the informed consent document and patient protections. We look at what people want and need to know to make an informed decision. How much detail and information has the scientist provided? Is it enough? Why do the researchers think this will work? Are the words and concepts explained so lay people can understand it?

We look to the risk/benefit ratio and to the question, do the benefits outweigh the risks, especially in the patient population being studied. There's a fair understanding that the patient may be willing to tolerate high risk if they are dealing with life-threatening conditions, such as metastatic cancer or heart transplant.

We also consider what are the side effects and how toxic is the treatment being studied. Are there adequate ways to monitor the patient's response? Or measures to reduce or minimize the risk? We also want to answer the big picture questions, the scientific questions. Will this research result in better treatments and quality of life for patients?

What are some of the barriers to community participation, I know a lot of the questions that were submitted before our call had to do with this. Some of the things that we defined was that there's not always a clear definition of the role of the community member. The time required to participate as a community member or non-affiliated, nonscientific is also a big factor. The complexity and amount of information to be reviewed by a lay person is often overwhelming. And often there is a lack of public recognition of the work.

Recruitment is also a big issue and how to find willing candidates especially from disadvantaged and socioeconomically disadvantaged populations. Training potential members is also an issue, and lots of times the IRB administrator doesn't know what the nonscientists needs to know.

I'd like to turn it over to Mary Lou Smith, who will discuss the focus group results of a study that the Research Advocacy Network did a couple of years ago. Mary Lou?

*Mary Lou Smith:* Thank you, Elda. With that background, I'd like to share with you our focus group results. As Vanessa said earlier, I have been a community member of the Rush University Medical Center for over 8 years, so it was very exciting for me to be part of these two focus groups and find out how IRB administrator recruited, trained and retained community members

and most of all how other community members felt about the work they did for the IRBs. I'd actually not ever been in the same room as 8 other community members before and that alone was a great experience. So next slide: our organization, the Research Advocacy Network, conducted two focus groups; one for IRB administrators and one for community IRB members. They were hosted at Rush University Medical Center, in Chicago. We wanted to better understand IRB administrators and community members' perspectives about the value and challenges of having IRB community members. These focus groups were led by market researchers with 20 plus years of experience conducting this type of qualitative research.

Next slide: we began by asking each of the focus group what they thought was the value community members brought to the institutional review board. IRB administrators felt community members brought unique and practical perspectives, often a reality check and a healthy skepticism and an intuitive reaction to the trail and the research and so this they felt was a great enhancement to the discussion.

This stated, the community members are not trying to advance the financial or scientific mission of the institution and therefore helps to ensure the integrity of the research. They also felt that we exhibited selflessness in our work on the IRB and that that made us really good role models for the scientists. The community members saw their value as being a counterbalance to the science, another voice. That we consider the human cost, so it's not all about the research or the trial. And the community member felt a special dedication to protect these vulnerable people. Both focus groups saw drawbacks as time-related. If the community member didn't show up and they were needed for quorums, everyone's time and preparation could be lost and obviously most community members are not on-site while the other members of the IRB are. Community members recognize that some of their questions about the science might take time to explain.

Next slide: next we discuss the challenges that each group experienced. The IRB administrator felt that the lack of role definition, some of what Elda was talking about, was one of the biggest challenges, and expecting just one person to fill just too many roles. The community members stated they were doing important work, but had no idea whether they were meeting the needs of the IRB. And many of us have served on IRBs for 5 years, were definitely willing to continue without this particular validation.

Next slide: other challenges that administrators were concerned about was the amount of time it took to read through all the materials. If you have ever seen the packets, they can go over a foot high in protocols. They felt that the complexity of the materials could be a barrier to participation. They stated that the chair was key in making the community member feel comfortable providing input. Community members found the time commitment a barrier to participation. They felt that the IRB meeting could be intimidating. Here you are a nonscientist, for the most part, sitting with a group of scientists discussing the science. They also felt that the chair made a major difference in whether community members felt accepted and valued.

Next slide: the next topic we discuss is training. IRB administrators train community members by discussing regulations that govern IRBs and the institutional policies that their particular academic medical center has, including policies governing vulnerable populations. They discuss the Bellmar report and its findings as a foundation to our current patient protections. Community

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members on the other hand found that observing a meeting very helpful. Others appreciated the opportunity to have a mock review of a protocol. Community members are interested in how do I do this work well. Many have taken online course, and others found newsletters specific to IRB issues and questions helpful.

Next slide: the community members wanted training that discussed the history of patient protections, they wanted skill-building in reviewing protocols and informed consent document, they wanted to better understand the clinical trial process and key scientific principles. Many wanted a scientific mentor they could call with questions. Others thought a glossary of terms and acronyms could be a valuable tool. The Research Advocacy Network used this information to design a preconference program for community IRB members. We presented at the PRIM&R Annual conference in 2005 and 2006. PRIMER stands for Public Responsibility in Research and Medicine. They do most of the training for IRB members and chairs. We also used this information to design a workshop for cancer advocates interested in serving on an IRB.

Next slide: Recognition is a good way to retain members, saying thank you. IRBs recognize the efforts of community members by having events. Some have dinners, others have lunches, so they were an appreciation of the event. Others sent letter to the president of an institution, thanking the community members for their contribution. Some IRBs pay their community members for each meeting. Others try to lessen the cost to the community members by having them attend by conference call.

Community members felt that the best form of appreciation was to get feedback. They liked any token of appreciation: gift certificates, thank you notes or stipends. One of the most interesting ways of recognizing their contribution was to provide them with free education programs at the academic institution that sponsored the IRB.

Next slide: so the bottom line was IRB administrators wanted more community members. They needed that representation and felt that they could use better recruitment tools. They believe that once a community member was engaged, retention was not an issue. Community members found the work intellectually stimulating and very worthwhile. Their one request was an evaluation process so they could be sure they were meeting the expectation of the IRB administrators and chair.

Now I'll turn it over to Vanessa.

*Vanessa Northington Gamble:* Thank you, Mary Lou and Elda, for that great presentation. And next we're going to go to Lucille Webb, how as I mentioned earlier is director of Strengthening the Black Family in Raleigh, North Carolina. And she is going to share some of her experiences about being an IRB community member. She's been an IRB community member for the North Carolina State Department of Public Health and as I mentioned, she was a founding member of Strengthening the Black Family and president of its board of directors. She has spent the past 20 years as a community health advocate and volunteer. Through her work with Strengthening the Black Family, which she founded in 1981, she focuses on developing programs and partnerships that lead to greater economic, health, employment and educational opportunities for all families. Her vision for this nonprofit coalition came out of a conference, and she brought 8 community

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organizations together to collaborate about ways to help African American families optimally utilize existing communities. Given everything she's done, on her bio, she says that she's retired, but she's still out there working for social justice. She's a retired social studies worker and personnel administrator for the Way Count public school system and currently chairs the executive committee of Project DIRECT, which stands for Diabetic Intervention Reaching and Educating Communities Together, a CDC-funded diabetes research development project.

Lucille, welcome to this conference call.

*Lucille Webb:* Thank you very much, Vanessa. I'm currently serving on the North Carolina Division of Public Health Institutional Review Board for the health and safety of human subjects. As a community layperson, that's a term we use here in North Carolina for the division public health. Having been appointed in 2001 as one of the first members of this newly created board, I'm beginning my third three-year term as a member and this term will expire in 2010.

The North Carolina Division of Public Health is the human services agency for the state of North Carolina. Its mission is to serve the people of North Carolina by enabling individuals, families and communities to be health and secure and to achieve social and economic well-being. And of course, as part of this mission, it's appropriate and necessary for the institution to carry out systematic, scientific investigation. However, in carrying out these investigations, it is vital that the trust of the public is maintained and that human subjects who may be involved be provided with all reasonable protection of their rights. Because the recipients of health and human services are often the most vulnerable members of society, it is particularly important that a formal mechanism to ensure these protections is in place. Thus the creating of the North Carolina Division of Public Health Institutional Review Board for the health and safety of human subjects.

This board was created to review the research that is carried on by the division of public health. The appointment is for a three-year term and no member shall be required to serve more than three consecutive terms. And the director of the division selects the chair and I would agree with the previous speaker. The chair is most important in terms of how the whole board will operate, so if a chair is fair and accepts that community member as a member like the rest of them, then I think things will work quite well.

On the division of public health, we say that we should have at least 9 members and at least 5 of these members shall be selected from the division of public health. You should not have more than 2 from the same section. And you should have one individual with expertise in research methods, maybe epidemiology or biostatistics. And then one member who is not otherwise affiliated and then one member should have expertise in clinical social work or public health and at least one member of the IRB must be an individual who is a community person. And that's why I consider myself, that community person.

One of the things that I found most supportive for me was the training and the resources provided when this board was created. We were all new, so we all spent several weeks being trained in how to be good IRB board members and this training was conducted by the IRB chairman from the University of North Carolina at Chapel Hill. So this was very important

because I felt like I got in at the ground floor with the rest of the members in finding out what the role of each member was and what my role was. I did not feel that I was any different. I knew who I was, I was a community member, but I thought that I brought something very important to the table. I thought that each person on that board had something unique to offer and we were there because of that uniqueness and what you could bring. While the scientist could bring his expertise, I could also bring my expertise as that community member who had worked in the community who had predicated in community-based participatory research. So I did not feel intimidated because I participated in the same kind of training they did. I felt like I could ask questions, and what I didn't know I could ask. I also believed that the chairman also played a very important role and North Carolina itself was very much interested in being sure that we had a diverse population on the board and that all members were respected for that.

I also felt very comfortable being in that role because I had for maybe the last 14 years, been working with the UNC School of Public Health in community-based participatory research with the project begun with a community-based public health initiative funded by the W.K. Kellogg Foundation. So we had been working with how to deal with communities, how to deal with the academic institutions, and therefore how to deal with the IRB. I also came from a background of having served for 9 years on our local board of health, where I was also that community person. And I knew what that meant and I knew I needed to bring that voice and help them to see their role through my eyes and what that might be.

I also think that as the community member, I have that voice helping the IRB members to understand how the community views this issue when maybe the researcher would view it in a different. I think learning should take place on both sides, I call it shared learning, because there is much to be learned from each member, and there is much to be learned from the community member that maybe the researcher does not know. But I always came to that board feeling that I was a very important member and that I had something important to say and I had an important contribution to make. But I do think that it requires, as the previous speaker indicated, it requires a great deal of time. it requires a great deal of work, because, in order to be an effective member, you need to understand the information there, in addition to the protocols, as she said can sometimes be overwhelming.

The procedure that we use in our IRB is that the chair will distribute the protocols to each member and then each person will have the responsibility to maybe for reviewing that and making the presentation to all of the IRB members and everyone has the opportunity to participate in that. I have also served in that capacity in serving also in making the presentation. I have felt that I have been a member that had been enabled to do my work, so although I represent that community's voice, I did not see myself as something set aside that I just worked on consent forms or anything else. I looked at the protocols. I reviewed those just like they did. And if I had questions, I knew to raise those. And they were answered. Many times if there are issues that maybe the board needs to have an additional resource, then we call a person in to share their expertise on the research in question, although that person would not have a vote on the IRB board.

I do think that if we are going to assure the community's voice, there has to be a commitment on the part of the community to get involved. It is time-consuming. What we have done here in

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Raleigh, North Carolina, also with our participatory research, we have trained our lay health advisors in the basic principles of the IRB. We've had that done through the University of North Carolina and the principal investigator, Eugenia Ng, who was certified by the UNC to conduct them. So all the people who have been involved in this particular research project, they've been certified through the UNC through Eugenia Ng. That has been very helpful because it also helps the community to understand the IRB. If we understand it, we might be in a better position to talk about it and see how we can bring about changes in the process that would have an impact on the kind of work you do with communities [*unintelligible*].

I do think that it takes dedication but it's also a work in progress. And I'll stop there.

*Vanessa Northington Gamble:* Thank you very much. You did, we feel as we did, as did Elda and Mary Lou, reminding us that community members do bring they're specific and much needed expertise.

Our final speaker for today is Gigi Macmillan, she is executive director of We Can Pediatric Brain Tumor Network in Los Angeles and she is on the UCLA IRB and as I mentioned she is cofounder and executive director of We Can Pediatric Brain Tumor Network. We Can offers information and support to families whose children have brain tumors. Programs include support group meetings, parent education nights, teen groups, sibling workshops, family camps and one-on-one mentoring by trained volunteers.

She sits on the sub part A for the subcommittee for the U.S. Department of Health and Human Services, Secretary of the Advisory Committee on Human Research Protection, and she wants us to know that she is the mother of four lovely children, one of whom is a brain tumor survivor. Welcome, Gigi.

*Gigi McMillan:* Thank you very much. I guess like a lot of moms, I wear a lot of hats. Like any woman. It's interesting, the hats that I wear these days, two of them, I'm on two different IRBs—one as a community member and one as a subject representative for the cognitively impaired. And I also sit on a national IRB for the Pediatric, for the NCI, for the pediatric central IRB that we reviews children's cancer studies. In the past 6 years, that I've been doing this, I've had the chance to travel around the country for speaking engagements and conferences and committee meetings and everywhere I go, I scoop up community members and ask them questions. And the reason I do that is because after 2 years on the UCLA IRB, two years of sitting through committee meetings, I find I'm finally starting to feel like I might be doing a good job. And while I understand the complexity of the IRB review process, two years seemed to me to be too long for me to feel comfortable doing this very important work. So in the past 2 years, I've been asking other community members, other non-scientific members how they feel about what they do, what goes on at their institutions, how they feel about their participation, their job product, what would they change if they could, and I began to see the big picture. I realized that people like myself, lay members of the IRB, were not being properly utilized during the committee process. It wasn't because the administrators or IRB chair or other IRB members did not like us or appreciate us, but more like they did not know what to do with us.

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We heard from Elda about federal regulations that require a non-scientific member in the review process but nobody has ever explained to my satisfaction how that translates to an IRB committee table. And it's this lack of boundary, this lack of clear identity or purpose that poses a problem. I'm a pretty straightforward person and I tend to think in bullet lists, I cut to the bottom line as quickly as possible. I want to know what's expected of me, how to do that job and then I want someone to tell me if I actually met those goals and parameters of the project. So if we go to slide 2, what I did was I used the skills that I use with my families at We Can. There are almost 600 families in the We Can family that work in California and what we do is we teach these families how to be empowered, how to take care of their own situation, how to become part of the process that they are doing, as they manage their children through treatment. So I came up with sort of a little list for myself of how I could approach being a non-affiliated IRB member and maybe help myself feel more comfortable about that process.

So on slide 2, you see I needed to ask other committee members for their opinion. I needed to get this input. And Mary Lou talked about her focus group results. I'm going to tell you in the next three minutes, I'm going to confirm everything that she said.

She did it a very officially with focus groups, and I did it in little coffee room chats all over the country but I ask other committee members, I asked myself IRB administrator for help. I went to her and said, hey, you know what, I've been around for two years now, and here's what I'm hearing and this is what I feel about my committee. What do you think we can do about it? I asked for information that I could use to educate myself. I said, are there any conferences I can go to? Are there any extra training? So I can maybe take that online course that all the investigators have to take? So I had to ask. But more than just asking, I had to take responsibility for the problem. I needed to be persistent. I needed to make specific and reasonable requests. And I had to take the initiative. So when I thought I came up with a good idea, I had to be willing to do some of the work to make it come to task. In other words, I had to make it easy for my administrator to do this thing that I wanted. I had to make it easy for her to help me. Some people will say, that's not my job. I would disagree. If I'm the one with the problem and there's a need out there, and nobody is addressing, yet, I have identified it, I believe that it is my responsibility, my responsibility is to take the initiative to solve the problem.

As a follow-up after any progress was made, so in other words if we did do something that I thought would be good, I needed to follow up on that and make sure it wasn't just a one-time deal. Then you have to document the changes and the successes so that you learn from it and so other people can learn from it.

These are the skills that we can teach as parents and they generalize right over to what I was doing with as I wanted to feel better about my participation as a non-scientific member on the committee. So what was the thing, the very first, what was the very first resolution or solution, I came up with? I asked my local IRB administrator to host a community member lunch. We invited, there are 5 committees that are large institutions, and we invited all 15 community members, nonscientific members, to this lunch, and more than half came and while we were there, we got to meet each other for the first time. And we had sandwiches and we talked and very specifically came up with three things that, if they could have any three things that they wanted from the IRB administrator and the program at UCLA, what would they want. They all

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wanted a mentor. They said when you are a new member on the committee, they need someone to help them through the first few review processes, or they needed someone to call when they had a question about how to review a protocol. Mary Lou mentioned this and Mary Lou said they wanted a scientific member. Actually at UCLA, they said they would like to have another community member mentor. They wanted to know how another lay person managed to feel good about the process of review. They wanted very specific training. Teach me what page one means. What do these numbers mean? How do I read this form? What page do I look for this XYZ item of informed consent? They wanted specific training. The last thing was, I didn't expect it, but I should have, but they wanted a way to network with each other. They wanted to develop a sense of community.

I thought this was ground-breaking and it turns out people had been thinking these particular ideas for a while but Mary Lou and I had a chance to do a workshop at a PRIM&R conference two years ago. This would be, if you look at slide 3, again 60 people in our audience came up with a master list of what they thought the challenges and benefits were of being a community member and also very specifically they wanted from their institutions, so they could do a good job and they had their own set of emotional concerns. They were wondering what was expected of them. So really my casual conversations, my experience at my institution and then a more formal process I went through with Mary Lou and also the focus groups, they come up with what I think are the basics, the five basic things on slide 3, was that community members want training, mentoring, they want respect, they want feedback and they want a sense of community.

So if we examine these for a moment, training is as far as I'm concerned, because I'm a history teacher in my old life, includes a struggle to why we're doing what we're doing. Training includes general technical information and specific skills when reviewing a protocol. It also includes instruction on how to then comment during a meeting, and hardly anybody talks about this. I'm talking about speaking skills. Lay people are not necessarily comfortable talking to a room full of people, especially if it is not their area of expertise. They need nuts and bolts speaking skills. Have your notes prepared. Take a breath. How can I help myself to not be nervous? They needed to learn how to present their comments during the meeting, and they needed to understand how their IRB committee works. What's the hierarchy, who's in charge, what do I do if such and such happens, who do I ask if I have a question?

So that would be the training component that has come back to my attention repeatedly.

Slide 5, I mentioned already. They want mentoring. They want to be assigned to a veteran who will assist them during their first few reviews, someone they can talk to. I think two mentors would be great, Mary Lou, a scientific mentor and a lay mentor

Slide 6: They want respect. New members are often unsure if they have anything valuable to say. One of the hardest things they need to learn, and I'm not shy and have no problem speaking in front of a room full of people, but the hardest thing for me to learn as a layperson was what do I have to say to these scientists who are sitting around the table. And what I learned was anytime my red flag went up, that meant I should speak. That is what I bring to the table. My lay person says, oh, we better talk about something.

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Feedback. Slide 7, the community members want feedback. They don't know if they are doing a good job and someone needs to tell them. And slide 8, a sense of community. The scientists, the doctors, they have this built-in peer system, because they work with each other, they are the doctors, they see each other around the hospital, they've all gone to medical school. They have a sense of belonging. The community members, the non-scientific people, are teachers or maybe lawyers or housewives or survivors themselves. But they don't have that sense of community when they come into a committee meeting. They want to be able to email and phone each other. They want that to be OK, they would like to have regular meetings together, maybe twice a year lunch. They want the opportunity to network with other community members at other institutions.

My next step after dealing with the UCLA and getting assistance from PRIM&R, was what kind of product can I create that might meet these needs. Lucky for me, PRIM&R listened and I designed a community member tract during their 2006 conference. It had slide 9, you can see the 6 things that we applied, the workshops we had over a 3-day period. The history of human subject protection, exactly the issues that I was just talking about, what does the layperson bring, what's the psychology of a meeting, how to review protocol, a chance to grill an actual IRB chair, let me tell you the members of the audience loved that one. And also sort of a support group meeting where we could sit around and talk about our feelings.

At the end of this conference, every community member who attended four of the six workshops, received a certificate of competency that had their name on it, signed by PRIM&R, saying that they had done this. And not only that, a letter was sent to their IRB chair informing the chair that their community member had taken these steps to further educate themselves. This was hugely popular not only that there were administrators in the workshops who wanted the certificates, this letter for themselves. So that was, I consider that to be a success.

I learned something from that and I learned we needed to get even more specific. I learned that a national conference was wonderful, but how can I bring some of those things back to my very own institution? So I came back to my administrator, I said everything was great, we need to send more community members to these conferences but we need to do something a little more specific for our people. So she and her assistant designed a step by step how to review a protocol from a layperson's perspective; an hour and a half workshop where community members can come and with a hypothetical protocol. The administrator goes through it herself page by page and teaches the kinds of things that lay people should be looking and then as a group, they review a second hypothetical protocol together and they practice their skills. I think that's going to be another successful component of the next PRIM&R conference.

What I want to say with regard to recruiting training and retaining community members, my experience for 10 years, I've been working with families whose children have brain tumors. I would generalize that any survivor or family member of a survivor has a vested interest in giving back to the medical community and to the research world. They are passionate, they will take the time, they are knowledgeable civilians and they should be put to good use and I do not think frankly that institutions mine that particular population for as many volunteers as they should. They have a personal desire to be involved, and they should be asked.

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I talked about the kind of training I think they should get. I think you can retain them by offering respect and acknowledgment and the acknowledgment is key, and it doesn't have to be fancy but it needs to be consistent and fair. Just like our children get report cards or you get a pat on the back, we all have a human need to be acknowledged.

And slide 11, I would say the last thing is nurture their passion and the way you nurture their passion is number 1, to get them involved and number 2, teach them what to do and number 3, to tell them when they do a good job.

Thank you.

*Vanessa Northington Gamble:* Thank you very, very much, Gigi. It's clear you feel very passionate as do all of our speakers today on this particular issue. At this point, I'd like the operator Heather to come on and tell us how we're going to open this conference call for questions.

One of the things that all of you did was you really gave a picture of what it means to represent the community and what the expectations are in terms of being a community member. And all of you talked about retention, and nurturing of a community IRB members. I was wondering if any of you would tackle the question, how did you first hear about being an IRB member and how did you get to be on an IRB?

*Gigi McMillan:* Clearly because I was working with hospital officials and doctors as I was forming my programs for my families, I just became known as a reasonable parent and a knowledgeable parent. So because they wanted that kind of consumer perspective on the committee that dealt with their cancer trials, I was invited because of that. Since then, four We Can families, four We Can parents from different families, sit on IRBs or data monitor safety reports.

*Lucille Webb:* I just happened to have, I'll read you this little note: Dear Ms. Webb, I'm pleased to appoint you to serve as one of the first members of our newly established, North Carolina division of public health institutional review board, the Health and Safety of Human Subject. Thank you for your willingness to serve. I'm deeply grateful for people like you who are willing to give their time and talent to make the division of public health all that is must be.

*Vanessa Northington Gamble:* Did you have an idea what an IRB was?

*Lucille Webb:* Yes, I did.

*Vanessa Northington Gamble:* What about Elda or Mary Lou?

*Mary Lou Smith:* I actually had helped a consultant who was working with Rush University Medical Center. They had to have their research stopped for by the office of human research detection for some problems they had had in documentation, so they were actually looking for new members, so the consultant came to me and talk to me about how advocates could be involved, and asked if I would be a community member.

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*Elda Railey:* Actually I'd like to tell you about a program that we had done with the St. Louis [unintelligible] affiliate where they had actually identified vacancies and needs within their community of IRBs that need community members and then we did a workshop and helped connect those people with the IRBs that were needing new members. That's another model of recruiting.

*Vanessa Northington Gamble:* Heather, are there any questions.

*Operator:* No.

*Lucille Webb:* I'd like to add one thing. You asked if I knew about IRBs. You had indicated I was working with Project Direct, which is Diabetes Intervention and Reaching and Educating Communities Together, which is the CDC-funded piece. Our protocol had been stopped several times because our IRB had not been approved by CDC and that's one of the reasons why this IRB board was established by the division of public health. Because of problems at the time with our IRB, our protocol reviewed maybe by North Carolina State University or some other institution, so that was the creation of this because the program was to the State of North Carolina division of public health, the CDC program.

*Kristine Wong:* This is Kristine Wong with the CCPH and I have a question I'd like to pose to the speakers today. What if someone is a community member sitting out there listening to this call and they'd like to become a non-affiliated member but no one has invited them? How would they go about navigating the process of trying to find out more about how to apply to be a non-affiliated member?

*Gigi McMillan:* If they identify themselves to the Offices of Human Research Detection or the Office for Protection of Research Subject. Every institution calls it something different and if they called and said they were interested, I'm fairly certain they would get a call back. If they leave their name, their contact information and maybe a brief description of their background and why they are interested, I think they would get a response. Because I know that there is actually always a need for more non-scientific members.

*Lucille Webb:* I would agree, and we could suggest names, names of persons who might serve on an IRB board to the director of public health. In fact, our non-affiliated member is from the school of nursing in UNC Chapel Hill. But she also one of the other pieces was she also speaks Spanish fluently so we needed that also.

*Vanessa Northington Gamble:* One of the things I found interesting, all of you mentioned the role of the chair. And the importance of the chair in terms of a community member feeling as if he or she is welcome to be on the committee. If you had to develop a training program for chairs, what would you include in a training program for chairs to better help the community member on an IRB?

*Lucille Webb:* One thing the chair and all of the members on the IRB board has to do is to respect that community member and what that community member has to say. And how do you get that

chair to create that kind of environment in the meeting that would make a person feel that there are no wrong questions to ask.

*Gigi McMillan:* That is really interesting too, because you said it before, it's a trickle down from the chair. If they are disdainful of the community member, then everyone else is going to be in short order. I had the most amazing experience as a community member when I reviewed protocols I do not like it when there are two or three pages of side effects that are written in paragraph form. It's very difficult for my layperson brain to really absorb the information in that form. So often, I would say almost every time I review a protocol, I say, "the PI needs to put these side effects in a chart that makes it very clear, which ones are most likely, which are least likely, which ones are severe, which ones are mild, so it's easy to understand." And finally one of the doctors said to me, "are you going to say that every single time?" in really a not very nice tone of voice. And my chair was all over that. My chair said, "yes, she is, if that's the way she feels, and that is why she is here." And that was like being a parent. He had to put his foot down, and I felt supported because I was embarrassed to be spoken to in that tone of voice, but the fact is that's why I'm there, to tell them what I think.

*Operator:* We have two callers on the line now with questions. First caller.

*Caller:* I have two questions. My first question is when you are a community board person, how difficult is it if you feel at all that you have to represent a large group of people? For example, because you have knowledge of a particular part of the community but you don't necessarily have knowledge of all the community that you are representing. My second question is what do you think the role of the IRB is in terms of changing the protocol because of some thoughts that some, from the IRB's point of view, one or two members on the board think that there could be somebody compromised when the researcher, him or herself, has a very good knowledge of the community and does not see the same dreadful effect that is going to happen.

*Gigi McMillan:* I would say the first thing about representing a community. I'm really glad you brought that up. This conversation comes up a lot. Who exactly do I represent on this board? Do I represent ex-high school teachers, mothers of four, mothers of a child with a brain tumor? I speak Spanish but do I represent native speakers. What part of my community do I represent? And actually in several venues now the group has come to consensus that we don't, we cannot possibly represent for all different categories of our community but what we bring to the table is a layperson's knowledge and experience. And part of that experience tells us as a committee that maybe we need to bring in somebody else, if there is a special issue before us. You just do the best you can with what's in front of you and frankly, the doctors at the table also represent part of the community. So you use a collective consciousness to make those decisions.

*Mary Lou Smith:* I usually look at it that I'm representing the patient perspective. I don't really, I'm thoroughly clear with folks when I came on who I represented. So I didn't necessarily represent the neighborhood that Rush University Medical Center was in. that's helpful to me to know I've been clear with them about who I thought I was representing. When we have a protocol that perhaps represents a vulnerable population, such as prisoners, we have a prisoner advocate who comes for that particular protocol to give us a perspective of that vulnerable population. I found that very helpful.

*Operator:* Our next question comes from ---.

*Caller:* I have to first off say hello to Ms. Webb as we are neighbors, I'm calling from ---. My question is for Gigi and Lucille. You both mentioned two points that we addressed here in working with community advisory boards. Lucille, you mentioned shared learning in speaking about the education the researchers need in understanding the background of the community and the community needs training and understanding the background of the nature of the researcher. We call it research literacy for the community and community literacy for the researcher. For you my question is, is there a formal training that you've seen available to assist both the researchers and the community representatives in their improved learning or understanding? And then for Gigi, do you, on slide 9, one of your bullet points is mention of a training or part of the conference titled exactly how do you review a protocol. I wanted to know if there is an actual training, or training materials to support that?

*Lucille Webb:* I don't know about actual formal training, certainly when we have come to the table, I have always expressed that there is learning that goes on both sides. Shared learning, because if you come to the table at an IRB and if we don't go away with having learned anything about how to look at the issues from the standpoint of the community as well as the standpoint of the researcher. That's why I'm saying it has to be shared learning. The researchers learn something about my environment. I may learn something about the IRB board. If you look at the community's perception, it's "that's the IRB over there. They won't let us do anything"—is wrong. Then you need to understand why the IRB and how it works and how you can move to make changes, to be a better participant or more informed participant.

*Gigi McMillan:* I have some good news for you. In my role on the SAC HEART Committee, the subcommittee for the Secretary's Advisory Committee, and we are actually looking at all the federal regulations that govern human subject protections. They are more than 20 years old, and need some rewriting or reinterpreting. We have been working for two years and we've got another two years to go. One of the latest things at one of our last meetings is that in the future there is going to be some OHRP guidance regarding IRB member training. It's going to be a strong recommendation and we're going to strongly recommend it to the secretary that there be some official guidelines what kind of training all IRB members need to go through. Things like state and local laws, relevant ethical applicable principles like the Belmont Report or the Nuremberg Code. However local institutions want to design it, but there are going to be recommendations for training. On a personal level, I came back pretty excited from that PRIM&R conference with those certificates and letters to IRB chairs but what I learned from it is we did not get specific enough. So UCLA has developed this workshop where there are those two protocols I told you about and you learn how to do it with one and then practice on the second. That's going to probably be incorporated into the next PRIM&R conference community member tract, but we haven't printed or published it or put it into any workable, sharable format for now.

*Mary Lou Smith:* I think Elda alluded to it, but we do a training for people who are interested in being IRB members.

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*Operator:* Our next question comes from ---.

*Caller:* I was actually coming back to have my second question raised. Was anybody, members of this panel, or of the group that is listening. My question, if you have a research project that is proposed by a researcher who is a member of a community, how do people from the community handle the situation when the scientific members on a committee of the IRB bring up extraneous objections to some of the research, saying that it cannot be done, or has to be drastically changed?

*Gigi McMillan:* Clearly if you disagree, then you should speak up. But you cannot lead the meeting and that is the job of the chair to identify those kinds of issues. You can share your opinion. I don't think that's a very helpful answer but I think in some situations, I remember, saying we actually have three committee members on each of my committees and there was something being discussed and I was squirming in my seat and I looked over at the other community members were uncomfortable also. And we literally raised our hands and said, "Stop this conversation. We are not happy with this. We need to talk some more." And the conversation went into a much more helpful, efficient path for us. But we had to speak up, or nothing is going to change.

*Kristine Wong:* I would like to recommend that you subscribe to the very next call on April 18, when we will be focusing on how to move community-based participatory research proposals through traditional university IRBs. There will be several speakers and panelists on that call who will be able to answer that question in more depth.

*Operator:* Next caller.

*Caller:* This is --- calling from the ---. I am calling because it seems like, I have a concern, a number of us have a concern. We have spoken among ourselves. How do you even get an institution to acknowledge the need for and the ethics behind having a community members on IRBs? We are a three institutional partnership, so we have three IRBs. The Jackson State is responsible for the community part of the study but there are also issues that come up, I imagine, at the medical center that would require a community person also. What we find is that the community people are really retired professors or somebody that knew somebody. I don't even know how to get them to acknowledge the need to get somebody from the community on the IRB.

*Gigi McMillan:* If you go back to my second slide, it says how do you make changes on your own committee? If you get the opinions of other committee members, I don't mean just lay people, but there are probably some ethical scientists there too who will agree with you. If you ask your IRB administrator for help, if you are persistent and you make a specific request, exactly what do you want. Figure out, do you want a nonprofessional? Define what community member means to you and why you think a different person needs to be on the board than what it is. Take the initiative that means write the letter. Or you can do all of those in nonconfrontational ways, very calmly and professionally present your concerns. Say, "There are several of us who are signing this letter. This is not a petition we just want to bring this to your attention." You have to take the initiative.

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*Caller:* Okay, taking the initiative is not the issue. I think we are dealing with some cultural and attitudinal issues from the leadership and the scientific leadership.

*Lucille:* Do they publish the names of the IRB members?

*Caller:* They are very hard to get.

*Gigi McMillan:* That's tough. I don't know what to do about that one.

*Caller:* All right. Then we'll try the letters and the signatures and that kind of thing again. It's tough to even get questions answered.

*Vanessa Northington Gamble:* That has to be our last call for today. As the Director of the Bioethics Center here at Tuskegee, I was listening to your comments, was busy writing down ideas for continued work in this area. I want to thank you for your creativity and your commitment to this particular area. It's clear from your comments [*unintelligible*]. One of the things that came from your comments is that it's clear that there's work to be done. And that one of the things that has come out of this partnership with CCPH are ways to make sure that community members are respected and nurtured and trained. As part of that Sarena Seifer, who is executive director of CCPH has some comments.

[Closing thank you and other comments from Kristine Wong]