

**CCPH/Bioethics Center Educational Conference Call Series on IRBs and Ethical
Issues in Research: Call 4**

**"Beyond the University IRB: Understanding Alternative Models for Human
Protection, Part I: Supplementing the IRB for Community Protection with a
Community Advisory Board"**

May 7, 2007

- Otsehtokon Alex M. McComber (Mohawk), Former Training Coordinator, Kahnawake Schools Diabetes Prevention Project, Kahnawake Mohawk Territory, Quebec, Canada
- Stephen B. Thomas, Professor of Community Health and Social Justice, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA
- Vickie Ybarra, Director of Outreach and Services, Yakima Valley Farmworkers Clinic, Toppenish, WA

Kristine Wong: Hello everybody, my name is Kristine Wong, Program Director at Community-Campus Partnerships for Health. I'd like to welcome all of you to the fourth call of the CCPH Educational Conference Call Series on IRBs and Ethical Issues in Research titled, "Beyond the University IRB: Understanding Alternative Models for Human Protection, Part I: Supplementing the IRB for Community Protection with a Community Advisory Board."

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, speaker biographies, and resource sheets sent out in advance of the call.

The PowerPoint presentations are titled as follows and will be introduced in the following order 1) McComber and 2) Ybarra. 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 handouts, they will be available on the CCPH website shortly.

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 broad-based partnerships. We're a growing network of over 1,300 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 subjects 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. During the first call of the series, we covered the basics of human subjects protections, during the second call in March, we focused on the importance and perspective of community-based IRB members. The third call explored the successes and challenges experienced by community-based participatory research partnerships when maneuvering their proposals through the university IRB review process. You can access the audio files and handouts from these calls on the CCPH homepage at www.ccpb.info.

On today's call and the next call, call number of five, we'll be learning from an array of community members and academics, to talk about why they decided to create further protections for communities through the formation of community advisory boards and independent community IRBs. We will conclude this series with a session that presents recent research on IRBs and discusses the implications of this research for future policy and practice.

Before we begin, I'd like to remind all of you that this conference call is being recorded, including the question and answer period. A digital audio file of the call will be posted on the CCPH web site at www.ccpb.info, so that anyone can freely access the information covered on these calls. If you ask a question during the Q&A period, please remember that you are consenting to having your question be recorded. We are 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.

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-Campbell 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 Campbell: Thank you, Kristine, and welcome out there. As Kristine mentioned, this is call 4 of the series sponsored by the CCPH and the Tuskegee University National Center for Bioethics and Research in Health Care. Today's call is "Beyond the University IRB: Understanding Alternative Models for Human Protection, Part I: Supplementing the IRB for Community Protection with a Community Advisory Board." I'd like to point out that this part 1 of the series we're doing on alternative models for human protection. The second call of this series will be held on May 24. Today we're going to look at the community advisory board model that provides supplemental protections, individual and community, to the university IRB. On the call

on May 24, we will provide examples of independent community IRBs for providing wider community protection.

Now getting back to today's call. Today we will have two speakers. I know that in the original announcement of this series, that Dr. Steven Thomas, Director of the Center for Minority Health at the University of Pittsburgh, was listed as a speaker. But unfortunately, Dr. Thomas will not be able to join us. Participating in this call today are two speakers, and I will introduce both of them in detail before the presentation.

But let me tell you who are two speakers for today are. The first speaker is Otsehtokon Alex M. McComber (Mohawk), the Former Training Coordinator for the Kahnawake Schools Diabetes Prevention Project in Kahnawake Mohawk Territory, Quebec, Canada.

Our second speaker is Vickie Ybarra, who is Director of Outreach and Services of the Yakima Valley Farmworkers Clinic in Yakima, WA. Getting back to Dr. Thomas, for those of you who are interested in the Crab model or the community research advisory board model, which he was going to talk about today, please look at our resource list and articles that Dr. Thomas has written about the topic will be there.

In terms of today's calls, we will cover a number of things. One is to introduce the wide range of human protections options developed by community-based organizations and community-based participatory research partnerships. We also provide examples of community advisory boards that's been created for additional protections for the community but work collaboratively with university IRBs. Why and how these entities were created and how they function and what purposes they serve, and finally how and when to develop a community advisory board.

Now I'd like to turn to our first speaker. As I mentioned, our first speaker is Otsehtokon Alex M. McComber, who is the Former Training Coordinator for the Kahnawake Schools Diabetes Prevention Project of the Kahnawake Mohawk Territory in Quebec, Canada.

Alex is a Mohawk of the Bear clan, from the Kahnawake Territory near Montreal, Quebec, Canada. He was born in Brooklyn, NY. He was part of the original Kahnawake Schools Diabetes Prevention Project team from 1994 until March 2006. He was the interim executive director and training coordinator. He was also a member of the board of directors of the national aboriginal diabetes association from 1999 to 2006, serving as chairperson from 2001 to 2005. he holds a master's in education administration from McGill, which he received in 1996, and is an adjunct professor with the faculty of education. He has also been a substance abuse prevention program coordinator, a high school teacher and principal at the Kahnawake Survival School, baseball coach and former volunteer firefighter. He is presently a freelance consultant in diabetes prevention, health promotion, indigenous education, and strategic planning. Alex is married with three children of the Wolf clan from Kahnawake. Welcome, Alex.

Alex McComber: Hi, Thank you very much and good afternoon, everybody. It's a pleasure to have the opportunity to share the experiences of the people in Kahnawake and

the diabetes Prevention Project. Particularly on community advisory board, our code of research ethics. In my presentation this afternoon, I will look at four pieces. The first is to set the stage, set the foundation of where things come from, because I think it's key for what we did and what we do in Kahnawake. The second will be very brief about the Kahnawake Schools Diabetes Prevention Project or KSDPP. And the creation and development of the community advisory board and its various function. And as the last piece will be around the development of the code of our research ethics, which guides all aspects of the research component of the project.

Before proceeding, I certainly acknowledge this is a team effort from both the community and the researchers, academia, and universities in everything we do with KSDPP in putting this presentation together, that I'm the spokesperson of all those people listed and others as well.

To set the stage, what I want to stress is when we're speaking as [*unintelligible*] Mohawk people, we are coming from a world view from a foundation that is different than what we come to expect and accept in North American society. The Iroquois, or the [*unintelligible*], as we call ourselves, are grounded with the Great Law of Peace [*unintelligible*] which was given to us by peacemaker before, way before the Europeans came in and from the time of first contact with Europeans and all through those 300 some odd years, and through the different histories that have happened, we always maintained a strong, very strong, independent, and nationalistic thinking and acting and not just in a political sense, but also in a social, spiritual, economical context. So that when we, when you meet with Iroquois people, particularly of the six nation Iroquois confederacy, this comes across that we come from this very independent minded foundation.

Coupled with the [*unintelligible*] the Great Law are the stories, the origins of our people, our creation story. Some of the ancient ceremonies and within there reflects key things such as the important of the balance of society between men and women, the equality of all human beings within this society, the emphasis on responsibilities that we have as men and women in not only taking care of today but providing for what we call our....., the faces yet to come, the seven generations ahead. That old thinking is that the things we say and do today, need to be considered because it's going to have an impact down the road.

That foundation then carries us over into Kahnawake, which was established as a community on the St. Lawrence River back in 1680 and in its present location in the early 1700s. as Iroquoian people, as an agricultural people with a strong sense of entrepreneurship, and as we know from the history books, very involved in the conflicts between the English and French in the attempted conquer of North America.

With the creation of Canada in the 1800s, in 1867, then the Indian Act coming into place in 1881 is an attempt by government to turn those old ways around and to as part of that assimilationist ways that they had. Come the turn of the century our men became involved in the iron work industry and traveled to other communities and particularly to the U.S. to work and an interesting note, and it's important and I share it, is that in 1908,

the Quebec bridge collapsed in its construction. There were 34 men from the community were killed because all the men stuck together. What happened is that when they got back to the survivors and the men returned to Kahnawake, the women of the community told the men, if you're going to continue in this iron work industry, you do not go work on the same job anymore, because that's a trauma that is still within the community today. We still experience those pains from those generations ago. I mention that because of the power of people and the power of the work of people as an example.

In the 1950s, the Canadian and U.S. governments put through the St. Lawrence sloughway and effectively cut our territory off the St. Lawrence River. It was a pretty good stab to the heart from the back. It would have been a death knell if the community did not have that independent Iroquoian spirit been so strong. That becomes reflected in the 1960s as the community reasserts itself in politics with the [*unintelligible*] council system and with the reemergence of the long house as traditional government within the community. The education system coming together, parents coming together and taking control of education. People in the community coming together and taking control of how a community and social services, recreation, cultural center and in the last 10 years, very much so the economic spectrum of the community becoming very strong, a very decentralized community.

That all being said. We then come into then talking about the Kahnawake Schools Diabetes Prevention Project. In the mid-1980s, the doctors at our local hospital saw the high rate of diabetes, 12% of adult population having diabetes, and when they brought this information to the community. There were elders who said we have diabetes; we have to live with this. This is our problem. But please do something so they children don't get it. Prevent it in the children. So again there is that seven generation thinking that comes out. From there, the doctors then said well then we need to work this research, move it forward. And that was done by approaching both the education center and the hospital and saying, and as well McGill University and Universite de Montreal, who had the expertise in family medicine and health promotion and get together and say, okay, we need to do something about this, we can get funding through research initiatives, through the national health research and development program at the time in the early '90s.

After several years, there was successful in receiving a funding to set up KSDPP, as we called it. This was going to be something that was going to be different. We go back into our history and we often see that researchers that [*unintelligible*] the slide quotes Dr. Louis T. Montour as saying that "the researchers swoop in, swarm all over the place, get the information and then gone. And nothing ever comes back to the community"...and this needed to be different because it was elders in a community, it was people in the community saying do something about this. So Kahnawake embarked on this community university partnership a particular with the Kahnawake and originally with McGill and the Universite de Montreal. With Kahnawake, the partnership was within education and health. There's always this communicating and working together notion that comes across.

When Rhonda Kirby, my co-worker and I were hired in 1994, we were given this information and okay get something started. There's a big research component on this and we want the community involved. So there was a suggestion within the proposal to have a community advisory board and so we went about contacting all the agencies within the communities, all the services in the community and inviting them to come together and to form an advisory for diabetes prevention. There was a strong public relations campaign about this diabetes crisis, about increasing rates of obesity in the children, what was happening, which we saw in other both in aboriginal communities in Canada, we saw it in Native American communities, we saw it in other aboriginal communities in the world. We knew that we needed to have the people involved in this way, so we proposed to the people who came who gathered and I said that this is a multifunctioning advisory group and the power of this group, the governance of this group comes from the fact that you are representing community, whether it's through the organization or through yourself as an individual community member. The people who came on board, who came together, were in agreement with this very much, because again it goes back to this is more our way of thinking, this is how we do things in our community. The people are going to decide if it will make any kind of difference.

So CAB then came about to monitor the projects intervention activities and also to work with the research team. The research team was comprised of researchers from McGill, researchers from the Universite de Montreal, later on Queens University, of course, the university students that were doing some of the research within, the staff and people from the community as well. CAB always the advisory, the research team or the staff would bring proposals to them, would bring findings to them, and there was discussion about is this, what is the proper way to proceed, there was discussion around these are the findings that we have. From their recommendations, there was recommendations that had come together that were put out to always keep things moving forward within there. As you see in the last page, the decision-making model that we built into KSDPP, reflected mirrored traditional Mohawk decision-making process.

Within a Mohawk council there is what we call the three sides of the house, which are represented by the clans: bear clan, wolf clan, and turtle clan. And in here in the decision-making, how we do things in the long house is that you have what's called the well, and inside the well is where issues are generated and are then put out for discussion, etc. So in our case here, creating the agenda, we agreed that pretty much falls to the responsibility of the staff so researchers, community members, interested potential researcher would contact the staff, contract our office and say, here's some ideas or this a request, this is a research proposal. The staff would do some of the background work and then as we would say in the long house operations, send it across the fire, which then what would go to the researcher. They would have their discussion about that and the two sides, the researchers and the staff, the 90% of whom were from the community would work to an agreement on yes, this is a good research project, this is a good research idea to propose to CAB, to the community advisory board. When both sides had that one mind, it would then go to the community advisory board for confirmation of the decision from there.

So that's the process that was used. Back in 1994/1995, is when the project then embarked on developing a code of research ethics. This code was developed and over a three to four month period, the lead was taken by Dr. Ann Macaulay, who was principal investigator on the first grant and subsequently became scientific director of the project until March 2006. It was the guiding light for the project and it came from a couple of places. It came certainly from the consensual decision-making that is part Mohawk and Iroquoian culture. It also came from the community-based participatory research world which Dr. Macaulay is one of the preeminent participants on that along with Dr. Freeman, who I know is going to be on one of the calls, Sue and Laura Comanda, and people around the world and the original code covered the bases. It gave the project, the community, the researchers, the tools with which to work at building something that had all the parties satisfied but also most importantly had the interest of the community first and foremost in mind.

In the, it was extensively revised in 2003 to 2006 by a team. That's the document that's located on the KSDPP site. Within there, the revision that, it was astounding at how long it took and the team of people who did it, who were about four or five community members, our research coordinator, who was from the community, three to four CAB members and at least two of the senior researchers spent an amazing amount of time going through section by section, and even at times word by word, to build and truly move this document to when I see it, it just blows me away having been involved in the first, at how the principles of both community, Iroquoian culture, and university are respected in here, gives good process on how to proceed with things, and also goes into the relationship with the institutional review boards. And in the experiences that KSDPP has had working with new project proposals coming in, whether it is a masters or a doctoral student coming in, or a post-doc grant that's coming in.

There has been wonderful collaboration between the two, between the tribe of Kahnawake and its CAB and the institutional review board, and there has not been a time when any kind of a (I can't think of a specific example of a problem) where there was a disagreement. I think that things were just so well done within the project in putting process through, and being clear on what was expected that the IRBs at the universities were all in agreement. That yes, both sides have the T's crossed and the I's dotted. So just in conclusion at the last slide, or next to last slide that "The sovereignty of the Kanienkehá:kaof Kahnawa:keto make decisions about research in Kahnawa:keis recognized and respected. The benefits to the community as a whole and to individual community volunteers should be maximized by the researchers. Research should empower the community to support community goals of health and wellness, to promote healthy lifestyle, improve its self-esteem and to fulfill its traditional responsibility of caring for the Seventh Generation." Because as a community, that is our interest in research; the rule that we had laid out and stand by in going forward. That the university and the researcher, yes there are benefits and certainly good things there, but it comes to the full respect of the community and the future of the community. So I thank you very much for your time and for listening to the presentation, I very much look forward to the questions and the discussion. Great thanks to you.

Vanessa Northington Gamble: Thank you very much, Alex. I am sure there will be lots of question for that great presentation.

Our second speaker of the day is Vickie Ybarra, who is the Director of Outreach and Services at the Yakima Valley Farmworkers Clinic in Yakima, WA. And she is, as I said, director of planning and development for the Yakima Valley Farmworkers Clinic, one of the largest community migrant healthcare systems in the country with clinics in Washington and Oregon. She has extensive experience in development, oversight, and evaluation targeting Hispanic and Spanish-speaking populations. She earned her undergraduate degree in nursing from the University of Washington School of Nursing, and in 1996 completed her MPH at the UW. And in her role as a part of the Washington State Board of Health, she has provided leadership for the board's health disparities efforts and in May 2001, co-authored the board's report on health disparities focusing on diversifying the state's healthcare workforce. Ms. Ybarra has been active in efforts to connect local communities to institutions of higher education. She has conducted research related to the presence and service needs of local undocumented women and children. She has also served as a member of the CCPH board of directors from 1997-2000. Ms. Ybarra is active in her community in Hispanic academic achievement. She works with a local group to distribute scholarship dollars and provide community recognition of academic success of local outstanding Hispanic high school student graduates. She has conducted research with the local school district demonstrating the wide gap in college preparedness between Hispanic and non-Hispanic students. Ms. Ybarra has also served, recently elected to the local school board with a focus on achieving the "achievement gap" between Hispanic and non-Hispanic students. Welcome Vickie. And one of the things that I would like to point out is that both you and Alex understand the importance of working with young people in terms of their achievements, since both of you have worked in high schools. I just wanted to point that out, and welcome you to this conference call.

Vickie Ybarra: Thank you, Vanessa. I am very pleased to be here today and to be a part of this series of conference calls. I think this is a terrific mechanism to distribute information and get feedback as well.

As indicated I'm the Program Director for Planning and Development at the Farmworkers Clinic and my hope today is to share with you a bit about our organization, to set the context on how we came about being interested in taking a more proactive stance with universities and researchers interested in studying our community, and then to share with you the process that we have put in place for a local agency research review committee and some of the results from that process.

So to start with, Yakima Farmworkers Clinic is a large community migrant health system with clinics in Washington and Oregon. Our base of operations has always been the Yakima Valley in Central Washington State, but we've grown quite a bit in the last 10-15 years in response to the needs in these 2 states. We served over 115,000 patients last year in primary care, that's primary medical and dental care, and what we know about those patients is about 64% of them are Hispanic and about 39% have been migrant and

seasonal farmworkers as well as family members. And we have special funding to primary care to serve migrant and seasonal farmworkers and their family members. In addition to primary care services medical and dental, we also provide a number of specialty services that have been added onto the organizational profile, over the years again in response to community needs. And those include: a state licensed mental health facility we operate in Yakima County in Washington, a state licensed drug and alcohol treatment program also in Yakima County, a large WIC program (in fact our WICK is the largest in Washington and the largest WIC in Oregon), we have an HIV prevention program in Washington state, and a large community action agency as well in Washington State. And those other services allow us to meet other needs that our patient population presents with.

In terms of the context for research opportunities, we found that as we were growing quite a bit in the 1990's, that we had an increased opportunity for health profession student placement and increased interest on the part of students and faculty who were interested in the unique population we serve. We do have the highest concentration of Hispanic population as well as the highest concentration of migrant, seasonal farmworker population here in Yakima County, in Washington State. And so it became popular for researchers on the other side of the mountains who were interested in studying Hispanic and/or migrant, seasonal, farmworkers, to come over to this side of the state to study and, as Alex has mentioned, that research was often swooping in, gathering data, and then leaving without much benefit left for the community. We saw that in our own organization that often researchers and academics would often work off their individual relationships they had with individual clinicians in our clinics and would find ways to get into the organization that way, in a very informal way. We had no structure or approvals set up so often those projects were set up based upon individual relationships. People would get into the organization, they wouldn't necessarily get access to patient records but could get access to patients themselves or to resources of the organization, staff time, to conduct their research.

We did have some negative experiences with this unorganized process in the 1990's that caused us to rethink how we were interfacing as an organization with researchers. We had a couple projects where resources of the organizations, staff time, were diverted in ways that really weren't acceptable. Clinician time is especially valuable in the clinic where we have more patients trying to access services than we have the ability to provide for, so we need all our clinician resources devoted to patients care. But even non-clinical time is also valuable for us and often researchers were interested in finding bi-lingual interviewers and would use our front-line staff who were bi-lingual to try to interview and collect data for their projects.

We had one or two negative outcomes associated with research. One project in particular involved one of our clinicians and a researcher from outside the community. The community survey. We weren't involved in creating the survey instrument, and the results of the survey reflected poorly upon our organization. And that certainly got the attention of our administrative staff and our Executive Director. And we recognized through that process that we had to take responsibility for the poor internal

communication that was happening. We had not setup structure on how we were going to interface with researchers and we really endeavored to set those up in the mid-1990's.

So the tools that we currently use that we have in place, we developed in the late 1990's. First of all, we have a policy on research involvement and this policy is very simple and straightforward. Basically it says that our primary responsibility is to provide primary care for our patients and we need to ensure that our resources continue to be devoted to that outcome. And that we are interested in partnering with researchers who are interested in issues that are a priority to us. So, for instance we have recognized, as have many communities, that diabetes is a huge issue in our patient population so we are very interested in partnering with researchers who maybe addressing diabetes in a way that ultimately could be beneficial to our patient population. The other thing that the policy on research does is that it sets out a specific expectation that the organization has approval rights over any research that comes to the organization. It doesn't give us any approval rights for anything that is done in the community and there is still quite a bit of research done in the community that doesn't necessarily involve our organization. If a researcher wants to come into our organization and use either patient records or have direct access to patients, or have direct access to staff for research, which we have had interest in, then they must go through this process. We don't necessarily take responsibility for what happens out in the community, outside our organization although we have had interest in the part of community members in what we're doing.

We have an application process. It isn't really a form; we call it the application elements. So these are the items that you need to address if you are a researcher and you want to do research that involves either our patients or our staff or our records. And we have a process for review. The application is no longer than four pages. When we first started this we started getting very long applications. Researchers would basically give us their IRB applications and that wasn't what we were interested in, so we've shortened it.

We also have, we use the principles of community-based research that were developed and signed off on in 1996 in Seattle. And I wasn't involved in creating those, but from what I understand is there was a community group in Seattle who felt overstudied by the University of Washington, particularly health sciences. And they came together in the mid-90's and put together their own principles for community-based research. And I think these are principles that you would find in many code of ethics around the country and that we see in the literature on community-based research. They simply state that community partners should be involved in early stages of the project, helping define the research objective, that community partners should have real influence on project direction, that research process and outcomes should benefit the community, that community members should be involved in analysis and interpretation of data, that productive partnerships should be encouraged to live beyond the life of the project, and that community members should be empowered to initiate their own research projects.

So those principles came to our attention about the same time as when we were putting together our process. And we put those principles into our policy and procedure, and we ask any researcher who is going to do research with us to commit in writing to follow

those principles. And then we established for review a research review committee, which also functions as our HIPAA privacy board. As a provider of primary health care we are bound by HIPAA regulations for privacy and HIPAA does have a mechanism to allow records and patient access for the purpose of research. But they must be reviewed by what HIPAA calls a privacy board. So, we established our research review committee before the HIPAA regulations came into place and once HIPAA was in place and we knew what that meant, we added the responsibilities of the privacy board to our research review committee.

So establishing this process has really helped us. It really changed our orientation with researchers. It caused us to become more proactive as a center so that we're actually looking for researchers who are interested in those issues that affect our patient population. We recognize the responsibility to identify our own needs in terms of research and in terms of protecting our patients and staff and records. It has really created a context in which we assert an equal relationship with researchers, it has introduced negotiation into the process, and I think we have become really adept at negotiating with researchers as well and it sounds like a good idea. But we have a need in this other area of patient care, and what can you do to help us with that? And also it has put us in a position to take risks, sometimes with researchers who might be less well known, less well funded, but whose genuine interest is better aligned with our organization and our patient needs.

So when the research review committee sits down to review applications, which have to be fully supported by what we call a clinic sponsor, a clinician or another person with decision-making authority in the organization who agrees to be the liaison between the researcher and the organization. Once that comes forward to the research review committee we have a number of considerations that we are required by policy to review for before we make a decision about approving a project. We look at the cost and benefits to the organization, so how much in terms of staff time is this going to cost us and how much will we actually get out of it in the end which might actually benefit our patients. We look at alignment with agency priorities, so it has to do with those conditions that are affecting our patients that we're particularly interested in finding answers too. We look at issues surrounding confidentiality. We are not an IRB, and we do not pretend to be an IRB, but we do ask that every research project that comes to us has gone through an IRB. And we require proof of that review and approval by that institutional IRB. We look at sustainability. Is this a project that we might want to sustain beyond the life of the project? If so, does it look likely that we might be able to do that, or has that been addressed in some way? We look at budget distribution. We ask the researcher what their budget is, what their funding source is, and how much does that come to us to participate in this research project? And we're looking for an equitable distribution. We don't have a formula in mind when we go in because what is equitable for each individual research project may be different based upon the expectations for us but we do ask to look at the budget. We do have to consider pressure on key staff. We have a few staff in the organization who end up being clinic sponsor on a lot of these. For example, our dental director, Dr. Mark Cody, works very closely with the University of Washington School of Dentistry and other with other researcher, and has done quite a bit of research with

them over the years. But we can only build Dr. Mark Cody into so many research projects before he is not available for the things we need him for. No matter how many people are willing to pay his salary to have him released for a certain amount of time for a research project we need to consider the other responsibilities that he has and that other key staff has.

And lastly we consider the amount of pressure and buy-in on the clinic sponsor. Sometimes clinic sponsors put their name on projects that they really have not been involved in developing. They have not have time to be as involved as they might have liked. And we need to consider whether that person is really going to have the time to devote to it, to watch for all the protections in our policies, and be a full partner on it. If they are not and they are just putting their name on it that is a consideration that we do take into account when we review the project.

And we also review if the researcher has followed the principles of community-based review which we have adopted at the University of Washington. And those principles, as I said were developed by the community group. The community group was able to get the deans from all the health sciences programs to sign-off on it in 1996. And often we find that we get researchers from those health sciences institutions who have never seen it. Either it was never properly communicated down or they are new and have come after 1996 and so we have an opportunity to educate the on what their own institution is committed to doing in terms of research and working with community. So basically the principles of community-based research that we're looking for with the researcher are: early involvement, real influence on the project direction, process and outcome that should benefit the community that we have a role to play in analysis and interpretation. And this bullet has led to quite a few conversations with researchers, who educate us to the importance of academic integrity and that we may not have the opportunity to make changes in a transcript that is going forward to publication. And we understand and respect that. We still believe that we should have the opportunity to review and provide input on interpretation and analysis, on relationship and empowerment. And that is all the information I have for you. I'll be happy and look forward to answering questions.

Vanessa Northington Gamble: Thank you very much Vickie. And at this time we would like to open up the lines for questions. And the operator will come on the line and tell you the instructions.

[operator instructions]

Operator: Our next question comes from Ann-Gel Palermo, please go ahead.

Ann-Gel Palermo: Hi this is Ann-Gel Palermo from the Harlem Academic and Community Partnership and I wanted to say thank you and thank you to the presenters. And just share a little bit about what we're doing in Harlem in terms of community advisory board and IRB issues. So in Harlem we were a community academic center that was formerly a research center by the CDC, we have been around for 8 years. And we have recently invented ourselves which evolved from doing community-based research

on the social determinants of substance use in Harlem and why it is easier to get drugs than help for drugs. So our roots are in substance abuse and HIV and we have expanded over time to address any pertinent help issue in Harlem using a CBPR approach. And recently the New York Academy of Medicine which is a private institution in East Harlem, not until we showed up did they get that they were in East Harlem, so we take credit for it being a community friendly place, and a neutral zone in the community to talk about health issues, which is probably the biggest compliment the institution could ever get. And so we have a member of our partnership on the IRB at the New York Academy of Medicine. In addition many of the investigators that we work with happen to be in the institution's IRB, who have a history of doing CBPR. And it's basically transformed the way which we've research protocols come across IRBs, looking at being sensitive to community involvement and participation, particularly being sensitive to subjects when it comes to language. Our IRB did not have a translation policy. We, meaning HCAP, initiated the drafting of the policy in the context of doing CBPR and making allowances for which translation can occur both at different points of time in the research process, but also during consent. And I think we developed a very user-friendly translation policy for investigators that tries to consider the different ways translation can happen both formally and informally. So that is very quickly what I wanted to share in terms of a direct interaction with an IRB. We also provide technical assistance to community health coalitions in East Harlem in designing principles of involvement and it's like many of those shared by today by our presenters. That it is our way of protecting ourselves and our way of letting others know the rules of engagement. Whether it is in regards to research, project, program, anything that is requesting our involvement. That there is principles within we follow. So I think this is all that I wanted to share quickly, there is always a lot more to share. I don't want to take up anymore time, so thank you for giving me the opportunity.

Vanessa Northington Gamble: Thank you very much for calling in.

Operator: Thank you. And our next question comes from ---. Please go ahead.

Caller: Hi this is actually ---, I am listening in as well. My question is for Dr. McComber. Do you have any type of educational program for either the CAB, the IRB, or the researchers to introduce them to the principles?

Alex McComber: There is an orientation that takes place when a new researcher comes into the circle. The approach that we took among the staff was kinda along a buddy system. Where one of the staff from the community would take the researcher under their wing and walk them through, and over time of course, through the workings of the project. Particularly the research lines and for sure time spent talking about the Iroquois Mohawk world they have just entered, because there is the Iroquois, Mohawk, and the Kahnawake culture that need to be presented to the researcher to make the workings within a lot smoother. For community advisory board coming into the team there was no formal orientation. Maybe one of the other CAB members taking the person, giving them a quick go-through on what was expected and what was coming down the road. Quite often in our history, it is learning by doing, learning by being thrown into the pool.

Caller: OK. Thank you.

Vanessa Northington Gamble: Vicky, could you also answer that question? What about training in Yakima?

Vickie Ybarra: We have very basic training that we expect our researchers to have gone through, including online IRB training so that they know the principles of human subjects protection. But we have not fully developed a training for our clinic sponsors. We have talked about it, and the need is certainly there because not enough people in the organization really understand how to necessarily engage with researchers in a way that is going to represent the organization and the community in a way that we want too. Those who are most involved in research serve as clinic sponsors, and normally do this very well, but we recognize that as we have an increased number of requests that there are an increased number of people in our organization who are asked to be clinic sponsors, and we're working to develop that now.

Vanessa Northington Gamble: Thank you very much..

Operator: Thank you and our next question comes from ---. Please go ahead.

Caller: I'm calling from the --- and as everyone has said, I am very thankful for everyone's presentations today. And my question is about, because Drs. McComber's work and Ybarra, both spoke about youth involvement. Youth we define as 12 to 30 in my work, and I'm wondering if you were involved in the code of ethics stuff because it does involve them. I'm just wondering if they were involved or educated at all through this processes?

Vickie Ybarra: This is Vickie Ybarra. One of our large research partnerships with the University of Washington School of Public Health involves environmental justice project and we have involved youth extensively in that particular project. We are going on year 4, of a 4-year NIH grant for that. And a group of youth, about 20 youth, are educated about environmental justice, around human subjects project, and our research review process. And those youth go into the community and do surveys in the community about environmental justice issues. So for that cadre of youth, and we pull from our health professional pipeline program, those are youth we hope will come back into the community and be leaders in the health professions and they are educated on the process.

Alex McComber: This is Alex. We did not actively pursue involving youth in the development of the code of ethics or the revision of the code. The reason for that is time considerations and probably not more than that.

Vickie Ybarra: And sometimes it's hard to engage youth with something that seems so dry.

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Alex McComber: Yeah, for sure. And by the way, it is not Dr. McComber. I thank you very much for the compliment, but it's not.

Caller: Alex, I wanted to ask you a little bit more about the youth participation process because in our project we're always trying to involve youth a little bit more. And there are many challenges in doing that, including the turnover of youth from the age of 12 to the age of 15 and how much they change in terms of their interest and them being engaged. I am wondering about your reflections at the school, I am trying to remember if your primary targeted elementary school kids or went straight through to high school? And what the responses are across the developmental stages?

Alex McComber: The focus on the program was elementary school children, primarily grades 1 to grades 6. After the fourth year of the project we had begun outreach projects to the high school children thought it was outside our mandate specifically. But the community advisory board certainly strongly recommended that we made sure that teenagers were receiving some aspects of the project and so a diabetes information health fair, information setup at the high school cafeteria since we do have a high school on reserve, those kind of things were done. Around 2001-02, Dr. Margaret Cargo, was awarded a 2 year grant for involving teenagers in diabetes prevention. And they had a real successful little project that went on. Over a couple of summers, involved 4 youth, and the project coordinator was a young person. She was in her early 20's and they did some poster campaigns, and I think they did a little informational video if memory serves me correctly. But I remember the poster campaigns coming together, and they also surveyed other high school students on the kinds of things they would like to see in regards to diabetes prevention activities for themselves. That type of information was given over to the prevention staff who tried to work a couple of those things into the annual work plans.

Caller: Wow that's awesome. I am going to make one quick comment and then I am going to ditch. And hopefully you will speak to it. I met Amelia at a conference in the beginning of April, telling me about how the Kahnawake are encouraging other aboriginal folks, educating them about developing their own community boards and in fact are touring and helping communities through the process. So I think that's fabulous. Thank you for your time and thank you for letting me ask my question.

Operator: Thank you, and our next question comes from ---. Please go ahead.

Caller: Hi. My question is directed for either speaker and my question concerns what the researchers think about your organizations. And, you know, that researchers often find the IRBs a hurdle to jump over, but having your organizations in place actually expedite the research. Do you get any feedback from them that your organization actually help them get more quickly into their research?

Vickie Ybarra: This is Vickie Ybarra. I think those researchers who have established long term relationships with us or who want to develop long term relationships, they find it's beneficial to have an established relationship to work from. I think it can be off-putting

for those researchers who don't work with us typically, and who come to us in a rush with a project they need to implement right away that they've already written a grant for and we seem to fit somehow. And what we've found is that this new process has been a filter, separating those researchers who wanted to establish a long term research relationship with us from those who aren't. And we think that's worked well.

Alex McComber: This is Alex. Our experiences are similar, echoes what Vickie just explained. The researchers, for sure, being in sync and having an easier process or experience in getting things going. I would talk about the students. The masters, doctorate, and post-doctorate students because that was a significant part of the last grant that KSDPP had. And we were responsible for offering training at academic and community levels and the students who came in with their proposals, etc, found the process...the things that they were to go through were clear, but I can think of a couple of instances of frustration at the detail that was required. Of having to come back to the community advisory board with a proposal, coming back if they had questions about it, and when a project was approved to having to come back and be a part of the reporting. And I think the frustration wasn't a bad thing, it was a part of the learning curve, and it was a frustration that I think quickly became accepted. And at the end of the experience, I know that all of the students felt very comfortable, very satisfied, very accomplished, and certainly made a great number of friends in the community within the CAB by living their research project within the community and through the organization.

Caller: Thank you very much, that was very illuminating.

Operator: Thank you. And our next question comes from ---. Please go ahead

Caller: Hi this is ---. I wasn't sure I was going to be able to successfully make it on the call. I do have a question for the second presenter within reference to the community-based research development group. I am curious to know how you were able to get endorsement by the deans of the various health sciences institutions. I think that is a very novel approach in getting buy-in. I am just wondering on the mechanism for that project.

Vickie Ybarra: This is Vickie Ybarra, and I am sorry if I didn't make it clear. We weren't involved creating that. That document and principles were created by a community group in Seattle. And I am sorry, I don't have the answer to the question. I don't know how they went about getting the deans to sign off on it. We discovered that document through CCPH. They had learned about it and sent it to us. So it might be that CCPH or Sarena might have more information about the group who originally negotiated that with those deans.

Caller: Thank you.

Operator: Thank you. Our next question comes from ---. Please go ahead.

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Caller: Hello. This is a question for Alex. With the upcoming revisions on the Tri-Council policy guidelines. With those new updates, will those update the code of ethics that was recently on the website?

Alex McComber: I can only assume that the research team will take that into consideration looking at the future. I am not involved in the project anymore, directly. But knowing the people on the research team, they would take that into consideration.

Caller: Who is the person involved?

Alex McComber: The scientific director now is Dr. Katherine Gray-Donald. And Dr. Ann Macaulay who was the former scientific director is still a part of the research team. Their information can be accessed at the KSPP website.

Caller: OK. Thank you.

Operator: Thank you. And our next question comes from ---. Please go ahead.

Caller: Hi. This question is for Alex, what an excellent presentation. I have been following the Kahnawake code of ethics since its inception and I'm really pleased to hear about the revision, which I didn't know about. I wanted to ask what Elizabeth asked, whether your policy is feeding into the Tri-Council process, maybe you don't know that?

Alex McComber: I don't

Caller: The other question I had. On the first code of ethics there was an article that was written. It wasn't really on the code of ethics, but on the relationship and the setting up the project, and the code of ethics as a part of that. For those in the academic world, it was really an informative and instructive article and it was a great one to bring to our students, and that kind of thing. And I was wondering if you knew if there would be anything else, if there would be a reporting on the process. It is so valuable for others to get a peek on what went well and what didn't and how you got that amazing document produced. I'm just wondering if you know if there would be any...

Alex McComber: Are you talking about a paper on the revision?

Caller: Yeah.

Alex McComber: I know that back in 2005-06 there was a conversation about doing this and the research coordinator at the time was to have outlined the idea of a paper behind that. I don't think that was done. I do know that KSDPP has in its files are the detailed minutes of every single meeting that they had. And in a lot of cases, verbatim, with the intention that this process would be put together at some point down the road. I hope it would happen.

Caller: Thank you very much.

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Alex McComber: And Dr. Macaulay might be able to shed more light on this too.

Caller: Thank you. I will ask her.

Operator: Thank you. And our next question comes from ---. Please go ahead.

Caller: I wanted to thank the two presenters, they were very good. And I appreciate having the PowerPoint to follow you along. There seems to be many and varied principles. Has there been any talk of reviewing all these different versions and coming up with a national code of ethics for CBPR?

Vickie Ybarra: I am not aware of any discussions in that regard. Alex, are you?

Alex McComber: Same here. I am not aware of any discussions in Canada. For any of the aboriginal groups I would get in touch with the national aboriginal health organization – naho.ca . Somebody there might be able to answer that question for you. I am sorry, I can't.

Operator: Thank you. The next question is comes from ---. Please go ahead.

Caller: Hi. I'm interested in hearing from the presenters or from other people on the call, whether you actually have researchers sign codes of ethics and if so, if you had any challenges in getting signatures.

Vickie Ybarra: Hi this is Vickie Ybarra. It is good to hear from you and it's good to hear from my friends in ---. We have been challenged. We ask researchers to sign a letter where they make a number of commitments including the community-based principles we've identified. And we do have people who do not want to include that in their letter of commitment or statement of commitment. And we don't approve those projects.

Alex McComber: This is Alex. And my experience at KSDPP is that there was no objection from anyone or any challenge from anyone.

Caller: That is interesting.

Caller: But they were all signed?

Alex McComber: Yeah. I am actually looking through the forms that were used. There was a researcher checklist that was done and I think there was the letter of introduction, and things like that and I just wanted to add the comment that the research done at KSPP was specifically related to the diabetes prevention aspects and the data that was collected from elementary school children. In most of the cases in the request for data, it was secondary analysis which made things a bit simpler for people to go along with.

Caller: Yes. Thank you.

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Vanessa Northington Gamble: Vickie, you make it clear though that there is consequence if they do not sign the letter. Don't you?

Vickie Ybarra: Yes. They understand that it is an application and they may or may not be approved for research. So I guess the consequences would be that they don't have the project approved.

Vanessa Northington Gamble: Are there any other questions in the queue?

Operator: Our next question and last question is ---. Please go ahead.

Caller: Hi. Thank you very much. I want to thank you for the presentation and actually the questions have been very good. I have a couple questions that are related: One, where in the institution for instance the university's IRB process, where is the community advisory board fall in that process. Do the researchers work out their proposals and come to the community board for that approval process and then come to the IRB? And the reason I'm asking that is if the IRB makes changes then does the researcher have to come back to the community advisory board? So how does that process work? And then the other question is how when folks are not necessarily a part of staff do you recruit non-professional staff in the community to be a part of the community advisory board?

Vickie Ybarra: This is Vickie Ybarra. I'd be happy to answer at least parts of the first question on how our research review committee interacts with the IRB. The IRB we have most contact with is the University of Washington Institutional Review Board and they do have a requirement that if a researcher is going to work with community that the community submit a letter of cooperation. And we make it clear to the researcher that we don't submit that letter until the research review committee has approved the research project. We also don't allow data collection to begin until we have proof that the IRB has approved it. So, what we have found in most cases is that the project will go through preliminary review with both entities, the IRB and the research review committee. So there's a trading of letters at the last minute so the research can happen.

Caller: OK

Alex McComber: This is Alex. The code of research ethics outlines that the researchers needs to have community board approval before going to the IRB. And in the case there's a change that's made, it needs to come back again. On the second question on recruitment. The process is that the KSDPP office annually sends a letter out to all the organizations within Kahnawake, reminding them about the community advisory board and inviting them to send a representative to participate and that also goes into our community newspaper, that community is welcome to come in. And also there is the process of writing the letter, etc.

Caller: Thank you.

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Vanessa Northington Gamble: I have a question for both of you. You have both spoken a great deal about the researchers coming in and doing the research. I haven't heard you talking about publications, about the researchers signing the agreement. Whether you every had any challenges about how the community was being represented in the final analysis or the final research.

Vickie Ybarra: This is Vickie Ybarra. As part of our expectations in our policy and procedure, it indicates that we expect to review any reports and provide input before it is published. That explicitly includes peer-review publication and we expect opportunity to review and input. We understand that it doesn't necessarily mean that changes what the final publication will in the end look like. But we do reserve the right to have input on how our organization is described in the publication.

Vanessa Northington Gamble: Alex?

Alex McComber: The Community advisory board is very much invited to co-author. Whether it is a journal paper, a community paper, or an abstract for a presentation at a conference, or workshop. The abstract has to go through review through a CAB review and any final document also has to go through CAB review. And I certainly can remember times when the discussion of the wording to make things crystal clear, especially when it came to the protection or description of the community or an entity within the community.

Vanessa Northington Gamble: Thank you. I would like to thank both of you for being a part of this conference call today. And I also would like to thank members of the audience, who called in with questions. Because I think the questions help put these issues into context, but it also made it clear that there's a lot of interest about this area. And as I said earlier, we will be talking about this again on May 24th. And again, Alex and Vickie thank you very much. And at this point I would like to ask Kristine Wong to come back on the line to share more about next month and wrap this up.

[Closing by Kristine Wong]