

**CCPH/Bioethics Center Educational Conference Call Series on IRBs and Ethical
Issues in Research: Call 5**

**"Beyond the University IRB: Understanding Alternative Models for Human
Protections, Part II: Creating an Independent Community IRB - When is it Right
for You?"**

May 24, 2007

Speakers

- **Sheila Beckham**, Preventive Health Services Director, Waianae Coast Comprehensive Health Center, Waianae, Hawaii
- **Bill Freeman**, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College, Bellingham, Washington
- **Jacqueline Tran**, Program Manager, Orange County Asian and Pacific Islander Community Alliance, Garden Grove, California
- **Eric Wat**, Data Manager, Special Services for Groups, Los Angeles, California

[Operator instructions]

[CCPH background by Kristine Wong]

Vanessa Northington Gamble: Thank you, Kristine, and hello to our participants and our speakers. As Kristine said, this is the second in our series of calls looking at alternative models for human protections. And what I would like to do, Kristine has mentioned the topic, but I would like to go into more detail on the five goals for this particular call and then introduce you to our speakers. The first goal of this call is to review the wide range of human protection options developed by community-based organizations and CBPR partnerships, from community advisory boards that supplement university IRBs, to independent community review boards. We are also going to hear descriptions of independent community IRBs and to learn more about why they were created and how they were created. The other thing we are going to do today is to learn how these entities function and what purposes they serve. And I know many of you are interested on how and when one should develop an independent community review board. One of the topics that have been an ongoing topic as we have been going through this call series is the ownership of data and the benefits of research. And once again, we are going to talk about that and how it differs in community IRBs and university IRBs in terms of independent community IRBs. We will have 4 speakers today and, as I said, I will introduce each of the speakers in turn.

The first speaker we have is Sheila Beckham, Preventive Health Services Director of the Waianae Coast Comprehensive Health Center. And what she is going to do is discuss the research committee IRB at the Waianae Coast Comprehensive Health Center. And at the health center Sheila oversees chronic health management, traditional Hawaiian health, lifestyle enhancement, preventive health nutrition, and a primary health clinic. She chairs the Center's research committee and the IRB, she has been at the health center for 24 years, and she has been active both locally and nationally in various professional organization boards, and has numerous publications related to her work in health disparities. She received her Bachelor of Science at Whittier College, her Masters and

postgraduate work at the University of Hawaii, and is a registered dietician. Welcome Sheila.

Sheila Beckham: Thank you Vanessa. To set the stage, the Waianae Coast Comprehensive Health Center is a federally qualified community health center located on the rural, leeward coast of Oahu. The Waianae Coast, home to the 4th largest group of native Hawaiians in Hawaii, has long been of interest to researchers desiring to study native Hawaiians. It has been a place where researchers come, deliver services, collect data, and leave when their funding ends; taking their program, and their data—never to return.

Slide 2. In 1990, the Waianae Coast Comprehensive Health Center entered into a joint partnership with the University of Hawaii's Cancer Research Center to implement the Waianae Cancer Research Project. Through much negotiation, growth, and "out of comfort zone" experience, the Waianae community established and published their protocols on the principles and guidelines of research in 1992. And the protocol for publication and dissemination of project data in 1995 that would guide future community-based research on the coast. Waianae Coast Comprehensive Health Center multidisciplinary research committee, and we have two different bodies that review research, was established about this time to assume responsibility for reviewing any research that might involve our patients, staff, or community residents. And to protect the community from negative research experience.

Slide 3. Ten years later, the committee reviewed and expanded its research review guidelines from the early community driven protocols. To view the board approved policy and procedures as they now stand, they now are available on our website. The research committee's primary purpose is to ensure that all proposals approved by the committee are sensitive to the ethnic community culture on the coast. And the second purpose is to ensure the research is relevant to the needs of the community.

Slide 4. An important distinction between the research committee and a traditional IRB is that the research committee reviews a potential proposal before it is submitted for funding and before providing the valued letter of support. The proposals are evaluated not only on scientific merit, but also involvement of community on all phases of development and implementation and whether meaningful data has been produced.

Slide 5. All too often researchers are one day away from completing a proposal and plan on implementing the research on the Waianae community. All too often, because the researcher perceives that the project will be of value. Agencies and participants are expected to provide support.

Slide 6. The research committee therefore considers a number of things. We look at benefit and cost to the community. Resources that are provided, but also resources that are required for successful implementation. Also the degree of collaboration, congruence with the mission of the agency, utilization of community-based strategies, and the issue of data ownership.

Slide 7. The review process requires that the request to conduct research form be completed with all of the elements on this slide. And I wasn't able to put the exact form on there, so it looks a bit busy. But we do ask at a minimum that we receive an abstract and preferably, we receive the entire proposal 2 weeks before we review the entire proposal.

Slide 8. If funded, the proposal will then come to our formal IRB which was established to protect the special features of our community and to ensure the community has a voice. Waianae felt it was necessary to establish its own IRB in 2005 after sharing the unique features of our research review process with various research institutions, and noting that many researchers continued to bypass the non-binding process of our research committee in hopes of obtaining expedited approval for a proposal.

Slide 9. Many researchers have also questioned the need to obtain approval from our IRB when they have already received approval from what they consider to be a gold-standard, a university or medical center based IRB.

Slide 10. The major difference between our community IRB and various institution IRB is the extent which the community will go to ensure that the participants as well as the researcher fully understand all aspects of the research—its purpose, its benefit, its risk. That means that the consenting process may require a person from the community, who is known and sensitive to the needs of the community to actually do the consenting process. And it will probably take much longer than if it was done by someone outside the community. Another difference is the understanding that the process of recruitment, implementation, and analysis, are issues impacted by ethnicity and culture. And need to be given special consideration. Our community-based IRB has intimate knowledge of our community. And is in a position to determine successful elements related to community-based research. And it is also in a good position to foresee potential pitfalls if proposals are not community sensitive.

Slide 11. Board composition is multidisciplinary, and involves collaborative partners from university schools that have signed research MOUs with our health center. The committee also includes traditional healers, community, representatives from medicine, behavioral health, nursing, social sciences, nutrition, academic, administration, and education. We have established a community advisory committee, which is truly representative of the community

Slide 12. This gives you an overview of the review process. I am not going to go through it, but you can see that we prefer to a proposal to come to us at its inception to go through the research review committee. It is not that we won't accept proposals that come to us which haven't gone through research review committee, but it helps us to be better able to support the proposal.

Slide 13. I have listed our website, the website of our health center. And we have all of our research and all of our IRB policy and procedures placed on our website and we also have a publication related to our research experiences.

Vanessa Northington Gamble: Thank you very much. I hope we have time at the end for questions. So we can hear more about getting people “out of their comfort zones” and what was the impetus behind that. But right now, let's move on to our next presentation. I made an error when I said we have three speakers. We have three presentations, but we have 4 different speakers today. The next presentation is going to be from Jacqueline Tran who is the Program Manager at the Orange County Asian and Pacific Islander Community Alliance, and also Eric Wat who is the Data Manager at the Special Services for Groups. And what they are going to do is give an overview of the purpose of community IRBs, how to maintain them, and the community benefits. Before they go into their presentation, let me tell you a bit more about Jacqueline and Eric. Jacqueline, as I mentioned, is the Program Manager of the Orange County Asian and Pacific Islander Community Alliance, which is in Garden Grove, CA. She is also the Program Manager of the National Cancer Institute funded WINCART. And WINCART means Weaving an Islander Network for Cancer Awareness, Research, and Training, a project at Cal-State Fullerton. WINCART is a multiyear project focusing on reducing disparities in cancer among Pacific Islander communities with a focus on Southern California. The project focuses on community-based participatory action research as a mechanism to address cancer disparities. And as I mentioned, she is also the program manager at the Orange County Asian and Pacific Islander Community Alliance. And this is a non-profit community organization serving the Asian and Pacific Islander Communities regarding health, policy, youth, capacity development, and education needs. Jacqueline's work has focused on community advocacy for quality linguistic and culturally appropriate healthcare especially among underrepresented Asian and Pacific Islander subgroups. She received her undergraduate degree in biology and Asian-American studies, and Masters in Public Health in the department of health services at the University of California at Los Angeles and is currently pursuing a doctoral degree in health services. Our second presenter in this portion of our program is Eric Wat who is the Data Manager at the Special Services for Groups which is in Los Angeles. He has managed the census data and the geographic information services since 2002, which is the research and evaluation unit of the Special Services for Groups. SSG's mission is to help identify the needs of their community and develop local and grass roots solutions to their problems. At SSG, Eric participates in program develop, program evaluation plans, administers an IRB, and provides technical assistance to community-based organizations and public agencies on data mining use and mapping. Since 2005 Eric has been the chair of the Asian Pacific American Community Research Roundtable which aims to promote equitable and effective research partnerships between academic researchers and community-based organizations. Welcome to both of you.

Jacqueline: Thank you very much, Vanessa. Good afternoon and thank you for allowing Eric and I to share our community institutional review board with you. We will be presenting information as a team and I will be providing some background information

and then Eric will share some information on the operation and maintenance of our IRB.
Next Slide.

I'd like to start by sharing some background information on our organizations. Special Services for Groups was established in 1952. It is a nonprofit organization dedicated to finding community-based solutions to the social and economic issues facing those in greatest need. SSG has evolved into a model organization which is designed to provide services to diverse groups with maximum efficiency and impact. This is achieved by managing and developing programs that serve our many communities by encouraging their involvement and self-sufficiency. SSG believes that the needs of groups and individuals cross traditional, ethnic, and racial boundaries. SSG serves as the bridge for those people with common needs to pool resources for the greatest good for all. SSG is based in downtown Los Angeles in California, and has over 23 programs with 3 affiliate organizations in Los Angeles, Orange County, and San Francisco. The Orange County Asian and Pacific Islander Community Alliance or OCAPICA is SSG's affiliate in Orange County. It was established in 1997 and the mission is to build a healthier and stronger community by enhancing the wellbeing of Asian and Pacific Islanders through inclusive partnerships in the areas of service, education, advocacy, organizing and research. OCAPICA conducts various programs in the areas of health, education, youth, and policy.

Next slide. Why was the community IRB started? The primary reason for OCAPICA and SSG to establish a community IRB was that the work we were conducting in the community in terms of underserved and underrepresented communities. A lot of the communities that we worked with were not represented on university IRBs and we felt that it was important that this voice was a part of this process. Initially the project stemmed out of an effort of nationally funded centers for disease control projects that addressed disparities in breast and cervical cancers among Southeast Asian and Pacific Islander communities. And as stated, there was a history of research projects with SSG and OCAPICA and a growing trend in the community for community-based participatory research. And we felt that it was important that an equitable partnership between community and academics; that the process was also represented in the IRB process. The reasons also for starting the IRB was to provide education for our community, to engage individuals in the community on the IRB process, and to look at the issues of data and resources.

Next Slide. How is the community IRB started? As noted, it was started by the CDC REACH 2010 path for women project and it seemed a natural and appropriate progression from that project because of our CBPR process. And having equitable and shared participation, in our minds, included the IRB process. We presented this idea to both our program staff and partners and had the support of leadership at both organizations and throughout the community. As a result of that, we dedicated a staff person and intern for over a year to conduct research and development to review multiple IRBs, to assess what was out there, and how they worked, and whether they met the needs of the communities we served. By consensus it appeared that we needed to develop this community IRB to ensure that our communities were being represented and under

research ethics the needs of the community were being addressed. Following models through universities we had worked with, we formed our community IRB and developed policy and procedures. This includes application forms, meeting protocol, review guidelines and training tools both for IRB members and our partner organizations. Our policy and procedures included documents and procedures which included: Why do we need an IRB? What does an IRB do? What are ethical principles and guidelines? What entails membership roles? What is the IRB authority? IRB submission processes, IRB meetings, IRB review processes and criteria, and also how to appeal on IRB actions. We also provide templates and examples for client forms such as informed consent.

Next slide. When did the community IRB start? As stated, it took about a year to develop research on the processes and to develop the protocol and procedures for the actual IRB. In 2004, we received approval from the Department of Human and Health Services and received our official IRB number. Once we were approved, it actually took about another 6 months to get up and running, to recruit organization and community leaders to be IRB members, and then have them complete training in order to be a part of this IRB process. And since then we've completed and reviewed multiple applications, and actually have a renewal for our community IRB.

Next slide. What is the purpose of the community IRB? In essence, to empower our community, to provide guidance on human subject protections, to engage and educate community programs and partners on the importance of IRB, to empower community partners and partners to be equal research partners, and to give a voice to underrepresented communities regarding research, especially regarding human subjects, and importantly to build capacity within our communities. The purpose was not to burden programs with more work and creating other opportunities for submitting IRBs, but really to give parity to our community members and partners to not only negotiate with academic partners but also with funders regarding issues such as data ownership and to raise their legitimacy as an equal research funder.

Now I would like to switch the discussion over to Eric who will speak about the operations and maintenance of the IRB.

Eric Wat: Thank you Jackie and good afternoon to everyone. When I started at SSG as a data manager and IRB administrator, a lot of the ground work and research had already been done and a lot of this had been done by Jackie. I am going to focus on the (next slide) small day-to-day operations of the SSG IRB. We accept IRB applications on a quarterly basis for review. And what happens, usually, someone contacts us and we talk about whether or not the project needs to be reviewed first of all, and whether the IRB is the right match for them. And if we decide that this is a good match, then we will send them the application and forms so they can fill it out. We also determine a timeline. I usually like to give 4 to 6 weeks for the committee to review a proposal and we also decide if any technical assistance they might need in filling out the IRB. I will also share some concerns that IRB members usually have with community-based research to help them fill out the application. Then we do have an internal review board for usually SSG programs and affiliated organizations, as well as community partners. Once the project

has been approved, by the end of the year they will have to fill out a report. Also, if it is a multiyear project then we also review renewal requests.

Next slide. How is the community IRB maintained? I listed some roles and responsibilities for the IRB, most of this is done by the IRB administrator. To maintain records of all applications, to document all processes of the IRB, so this includes the filing of minutes, to coordinate application review requests, so working with applicants and also with the board to make sure the application goes through in a timely manner. To communicate with the IRB contact person, for review materials and review process. Most of the time, actually all of the time, we don't approve proposals right away. We usually ask for more materials after the meeting. So a lot of this is communicating that to the contact person so we can get the appropriate material to finish the review process. And occasionally provide workshops and technical assistance on research design methodology and research human subjects project for community-based researchers. The structure of the IRB is basically, a staff person (namely me) who coordinates all requests this is support of SSG but we also have in-kind support in terms of meeting costs and also volunteer participation by the IRB members. All members of the IRB have agreed to participate on a voluntary basis. And they have stated multiple times that this IRB is so important and it is a benefit and opportunity to be a part of this IRB and to bring awareness and resources to community projects and members.

Next slide. This is a continuation on how the IRB is maintained. On average, we receive three applications per year not including renewals. As I said earlier, we meet about quarterly so we are not maximizing our potential yet. So we are looking to expanding the IRB so we can review requests from external organizations—organizations that are not a part of SSG or our community partners. With IRB renewal for those multi-year projects, we want to make sure it is not burdensome to applicants. We understand that applicants might have more than one IRB approval and they have funders that they have to respond to every year so we want to make sure that whatever information that we ask is something that is also being asked by other people as well so they don't have to go through different processes in fulfilling that request. So we are asking that if they have reports that are due to the funder, so maybe to the IRB just submit them so we can keep them on file and if there are additional questions we can do it on a case-by-base basis.

In terms of recruitment of IRB members, our members are originally recruited from organizations and affiliate community members from the SSG family, and we want to make sure that the members are diverse not in terms of just race and gender, but also educational background. So we do have someone with a PhD, but we also do have folks who are very very experienced in community-based research but have no more than a high school diploma. We haven't decided on terms. In terms of people 3 years ago, they are more likely to stay on. So in terms of terms we create new members instead. We actually have about 10 IRB members which can be a challenge to maintain communications sometimes.

Next Slide. The benefits to the community. It is very important to us and to the IRB members that the community owns the data. SSG does not have any ownership but we

are very concerned about how the data will be disseminated back to the community. So I will talk a little about that. SSG also serves as a conduit of oversight for human subject protection. So any individual who has been approved can list us in the informed consent form and person can contact us if they think human subjects has been compromised. Community and organization IRB members become more aware of the IRB process. What we do a bit differently is once someone sends an application to us, it doesn't just go to the IRB board for review, we actually ask them to come in and meet with the IRB board so they actually have a conversation. So, the process creates a lot more transparency and people know what's going on and if a modification is being asked, they know what it's being asked. And I know from experience, sometimes dealing with other IRBs—if we were asked to modify something, we are not quite sure what the IRB is asking, it's a lot of second guessing when we try to submit something back for approval. So you see we eliminated that process. And in so doing, we hope to empower communities in the IRB process.

Next slide. We also see the meeting as a way to share best practices, research methods that might have worked in other communities, tools that have proven to be community friendly, and also solutions to common challenges. We created a learning forum. When applicants meet with the committee they discuss the functions and challenges of the IRB and brainstorm solutions together. So instead of question and answer a lot of times it is discussion in these meetings between the IRB board meetings and the applicants. And also it is the condition where every committee is a bit different and what worked in one may not work well in another. I also tell applicants that the committee might ask very tough questions, and it is not because they don't believe in your project but probably because they have also dealt with similar challenges and they want to know how you are going to deal with these challenges so they can learn from that as well. So in terms of transparency, we find that it to be a little more constructive and reduces defensiveness on the part of the applicant. And I think for a lot of community researchers, especially those who are not university affiliated, this might be the only forum to network with community-based researchers. And also benefits from the research process beyond the research findings. I know from some of the discussion we have in these meetings, not only have to do with findings, you'll get the really great data and we'll talk about that, we also talk about how this could actually benefit or increase the capacity of your organization, increase networking and cooperation in the community. And also improve the outreach education in the community.

The last benefit that I want to talk about is conflict resolution. We have developed a conflict resolution policy. We actually haven't had to use it yet, but it was a suggestion from one of the applicants. And this is a role that we can take on as well if any conflict should arise with committee members about the direction of the research or sometimes between the community and university partners. So we have developed a mediation process that people can use if that comes up. And fortunately it hasn't been used yet.

For the next slide, I'm going to talk about the projects that have been approved by the community IRB. And the next 2 slides are a list of the 8 projects that have been approved. Our first project was an assessment of Southeast Asian family who support

young children to measure their school readiness. We also have a project on impact of refugees and torture victims on their homeland and the application of a child-abuse prevention program in the Cambodian and Korean communities, identification and sustainable outcomes for minority adolescent clients, occupational therapy program. The next slide continued, the Asian and Pacific Islander communities to reduce cancer disparities, adaptation of evidence based programs for individuals reentry back into their communities, one of our recent approved studies is a community assessment of the bisexual, gay, and transgender Asian community and their health needs—and also an exploration of Southeast Asian women and breast health services. So as you can see a lot of these research projects are dealing populations that are very vulnerable and very unique and small in comparison to other types of research projects.

On the next slide I will discuss the common issues addressed or raised by our community IRB. First and foremost is the informed consent process. Our community members want to make sure the consent process is completely voluntary. That the subjects, a lot of times the researchers are also providers, that we want to make sure the subject can still receive services even if they don't participate. And also sometimes, based upon the population I just talked about in the previous slides, there might be sensitive topics that researchers may need to be aware of that might be raised during the process—subjects such as HIV/AIDS and criminal activities. We want to make sure that the informed consent form has contact person and information just in case the subjects have any questions or concern about their participation in the process. Members are also concerned about the length and form of the consent process. A lot of times people come in with a very traditional way of presenting the informed consent form; it looks like a contract which can intimidate a lot of the subjects in these communities. So we have sample forms that might be more friendly to the community. The IRB members are also very concerned about data use and dissemination. Just because an applicant is a community-based organization, it doesn't mean sometimes that the data gets back to the community, so we have a lot of questions on how the data will be disseminated. Also a lot of concern about language, that it should be conversational not scientific. In some cases definitely translated and interpretation should be provided. There is also question of verbal consent for those subjects who may not be able to read or write.

And in the next slide we talk about subject recruitment and selection. We do have research projects that use experimental design. We want to make sure the control groups still receive some services; we also want to make sure that subject recruitment does not expose subjects to harm. So for example with the LGBT South Asian project, they were going out to community events to possibly identify subjects for their research. So we want to make sure that the way they do their research does not really expose their subjects as LGBT in a community that may not be very tolerant of them. Subject selection—we want to make sure it is not used as reward and punishment. This is applicable to the one about reentry individuals since the services begin while the individual is still in prison. We want to make sure that participation in the program is not used as reward for some and not for others. Other concerns are the role of conflict for the researcher. As I stated earlier, a lot of the researchers are also providers so they have a different type of relationship with the community or individual already. So there's an

issue of mandated reporting. So if someone expresses an intent to harm self or others, or express any type of abuse being perpetrated on them or by them, then they need to report it to the appropriate authorities. And just because you are a researcher does not exempt you from that role. And then also clients, since they are also talking to someone who is a provider, who might want more than just answering surveys they might actually want to get some counseling or services from the researchers; so, how to avoid on the spot counseling, how to refer them to the appropriate resources. These are some of the issues that the IRB are concerned with. I am going to hand it back over to Jackie to finish up the final slides of the presentation. Thank you.

Jacqueline Tran: Alright. Some of the other questions that pertain to creating an IRB is how and when to start an IRB. And I don't have a specific formula for anybody, but really what we did was to review resources and to really get a sense of what was available in the community if it was effective and if it was meeting the needs of the community that we worked with. And for some reason that you feel there is a gap in services and importantly if there is a means to support this effort then that might be a reason and impetus to start the IRB. I think what is also important is to work with existing resources, see if you can help with a change process within those resources, and if that doesn't work to start the IRB. In reality, it is a lot a work and it requires a long term commitment. It is not a short term project where you develop something and then you walk away. So it is an investment and all need to be aware of what this type of investment means. But I think the rewards we've found in terms of developing an IRB have been very rich, not only in terms of providing a voice for our community members but also a lot for our community researchers to feel very convicted on the strength of this resource and that it really does to help elevate the equity community and community researchers in community research in partnering in collaboration with universities.

Next slide. We provide a couple of resources that we utilized to develop our policy and procedures as well as provide trainings for our community members and IRB members on IRB processes.

Next slide. We wanted to thank everyone for giving us an opportunity to share the work that we've done. And we've provided contact information for both of us if you should have any questions or concerns that don't get answered later in the call. Thank you very much .

Vanessa Northington Gamble: Thank you Jackie and Eric. I am always amazed when persons do dual presentations and do it flawlessly and I just wanted to thank you for that great presentation.

Our final speaker is Bill Freeman. For those of you who have been participants in this call series will remember that Bill was a speaker in our first call substituting for Francine Romero, so we welcome Bill once again to the conference call. And Bill is the director of the Tribal Community Health Program at Northwest Indian College. Northwest Indian College is a two-year community college chartered by the Lummi Nation in Western Washington State. Bill retired from the Indian Health Service in January 2002 after 25

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years. In his first 13 years at IHS he was a family physician in a health clinic in the Lummi Nation, Bill is also the human protections administrator at Northwest Indian College and a member of its institutional board. And his presentation today, he is going to discuss to give us a background on the key motivators for an independent IRB and also give some practical challenges and solutions for forming and maintain community IRBs. Welcome once again Bill.

Bill Freeman: Thank you Vanessa and good afternoon everyone. The first slide contains my contact information. “Creating a Community IRB: when is it right for you?” Hopefully it’ll be of some help to you.

Second slide. As we say in the Lummi language [*unintelligible*], thank you to my teachers and mentors and also my respected wife, Carolyn Robbins.

Next slide, number three. Why do communities develop their own IRB? This is from the previous presentations. I am just trying to summarize what we’ve heard today. It’s a going trend, we want to make sure the community has a voice, it may be required or encouraged by the funder, to protect special features of the community, there is sometimes a little or no representation of the community on the university IRB, to ensure informed consent by community members in the community.

Slide Four. Two frequent motivators that I’ve seen and we’ve also heard about in the discussion, are beyond those that I have just listed. First of all there may have been a bad experience with research in this community or in a related or nearby community, and people don’t want to go through that again or have that happen in their community. And the second one is the process of the community asserting its control its destiny, its future what it’s doing, what type of appropriate research is to be done to try to get that research done, and so on. So, those two are the two less well state or less frequently stated, but perhaps the primary motivators in my experience. And I think again, what we heard today.

Next slide, number five. I wanted to go over again from the two previous presentations summarize the challenges to form and maintain a community IRB. One is staffing, it does require staffing. Everything from copying protocols if you need to do that, getting all these protocols to members to review ahead of time, and so on. These types of support requires resources, they require a set of policy and procedures that have to be developed. PnP is what I call them. And time to develop the IRB. I think we heard that at a minimum it is one year to develop it and then to get it going, more than that. And that process does learning about IRB, about the process what has to be reviewed and so on. One of the important things to recognize is that the IRB (community or any IRB) can go beyond what the regulations state and what university IRBs normally do to consider harms to communities and benefits to communities—both are broad categories. But then again, you also want to do the basics as well.

To summarize the challenges. IRBs are person intensive, work intensive, and time intensive. These are not something done on the back of a napkin, after hours for about 15

minutes. These are very intensive entities that require a lot of work. So I've got some possible aids to address the challenges. We have already heard some in what has already been presented. First one is about policy and procedures from other IRBs, no need to start from scratch. However it is not just well we'll take their policy and procedure, insert our name for their name and that's it. No, it still requires a lot of work. You just don't have to draft from scratch what you want. Because you do have to go through and decide for your self what it is that you want, what makes sense to you, what doesn't make sense to you, what needs to be modified, given your circumstances, concerns, etc. And we've heard that community IRBs are more than willing to share their policy and procedures.

Next slide, number seven. Another possible aid to address these challenges is to attend conferences. We talked about learning about things. There are regional conferences. National conferences are less common and tend to be more expensive. One of the better ones, I believe, is by PRIM&R called "Public Responsibility in Medicine and Research." And they have a website. They do the conference once a year and they have a human project conference, that's the title of it, and this year it's in Boston December 1-4, 2007. In particular interest to community IRBs or entities thinking of establishing a community IRB. They do have a limited number of special scholarships for institutions serving medically underserved populations. You do have to apply. It is not an odious application process. The contact for the scholarship program is Maeve Luthin. I give her email address. They tell me that the webpage for the scholarship program will be out in about a month. But you can always communicate with Ms. Luthin before then.

Next slide number eight. Another aid to help with challenges is on the job experience. In my personal experience as a physician and in public health, getting my MPH and so on, I never learned statistics well in statistics class trust me. I probably forgot it right after the finals, but I did learn statistics when I had to use it. So I think we learn best when we're doing what we're supposed to be learning. So how does that work with an IRB? The thing is to have an active member on your IRB who is knowledgeable and experienced. Often that can be an IRB member, who currently or in the past, who is from a nearby (typically university) IRB. However that person is just not anyone. You will have, I hope that you will look to get, someone who really believes in and values your IRB. You're not interested in someone who is very knowledgeable and experienced but who says, "Why don't you just give it to the university IRB?" Who is willing to put in time and effort to help with on the job discussion on how to analyze this particular protocol? What are issues that IRBs are looking for, what are some of the decision points, what are some of the regulations, what is required by the regulations, and so on.

Next slide, number nine. There are also some practical challenges to form and maintain an IRB. And one of them is this is a quote from the two presentations, "Some researchers may question the need to obtain community IRB approval when they have already received university, hospital IRB approval." That's a challenge. The solution to that challenge is to get a stamp of approval from the Office of Human Research Protection, the acronym is OHRP, I give their website. The process is to register your IRB and then you apply for federal wide assurance (FWA). The full title is the federal wide assurance of compliance. What it is an agreement between you and OHRP (you, the entity that has

the IRB) that you will observe and comply with the regulations in your research. Once you get FWA status then you have a lot of power. Then federal insurance IRBs can ensure federally funded researchers are compliant with what the OHRP wants. And then either the researcher doesn't comply with the requirements or does something, then you literally illicit the power of the federal government to get that researcher in compliance because you have the funder on your side—and money, as we know, talks. The researcher and community organization, I think, and this is not necessarily the IRB, it may not directly involve the IRB, can come to an agreement on the terms of doing research in the community. By agreement I don't mean only a nice verbal, "we're all in agreement" kind of meeting, where there is verbal agreement and nothing written. If there is a particular concern about this type of research or issues or whatever, consider a mutual contract between your organization and the researcher. It needs to be in writing, and it needs to be in the form of a legal contract. I didn't know this until recently, but the lawyers tell me that if you have something in writing but it's not in the form of a legal contract you cannot enforce it legally. It needs to be in the form of legal contract. I am not an expert on that you may want to get a lawyer to do it. This is, may sound extreme and getting very technical. And notice we're not talking about the consent form now. The consent form is not supposed to be in the language of a legal document for the individual person. We're talking between the community organization and the researcher. So people get uncomfortable doing that, asking the researcher to do that, but it maybe necessary. And if you have one, again, it's legal clout if something goes wrong.

Next and last slide. For additional help there is a file, I think it's called Tribal or Community IRB. It was attached to the email that was sent to everyone and it will also be on the website. It gives detailed reasons to form a community IRB, national and regional resources including their webpages. I also had intended to have how to fill out the registrations but I wasn't able to finish updating it with current URLs. If anyone wants that latter one, please give me an email. Thank you very much.

Vanessa Northington Gamble: Thank you, Bill. And Operator, I would like to open up the lines for questions. Will you come on and tell people that procedure? Thanks

Operator: Our first question comes from ---. Please go ahead.

Caller: Hi my name is ---. Hi Bill, I enjoyed your presentation too. My question is actually for Sheila Beckham in follow-up to some comments Bill Freeman had made. In her presentation she had mentioned that research had continued to bypass their committee and, again, questioned why they needed the additional approval beyond the university IRB since it is the gold standard. I found Bill's suggestions very interesting. I'm wondering if Sheila Beckham could address how you have dealt with that in your setting.

Sheila Beckham: Basically what I meant when I said researchers attempt to bypass our research review process. And generally they come in through the back door with a different provider who is not a part of our research process. When it comes to our attention they are still brought forward to the research committee, we still review them by all of our protocols, and generally do not approval those proposals because they didn't go

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through a community sensitive process. It may be once in a while particular researchers will try to work with the committee on some of them. And others, of course they are in a rush and they say, we've gotten approval before and I'm sure they trust us. So, quite often we've been known as the committee that just says no because they have to go through it in the appropriate way.

Bill Freeman: I left out a couple things. One of thing is to get the university IRB to be your ally. I think that always helps. I think once you get established you can sit down with the university IRB or the staff people and the chairs sit down together. And suggest that, we are now here, we would like to work with you and your researchers. So if you see a researcher, could you ask them or require them (like the University of Washington requires, by the way) that it goes through the community IRB. I would also like to add, I forgot to mention, I was asked to talk about just briefly a somewhat different topic.

When a community is having trouble with a university IRB, can they form their own IRB to replace it? It's possible, but obviously you have to get started and that can take some time. But if one of the researchers, at least one, is from that university, that university IRB continues to have jurisdiction. So the researchers would have to go through, as they did with Sheila, both IRBs—not a replacement. There is one way, however, to become a replacement IRB. And that is a formal agreement with the university IRB in which you both agree that you will do the approval and the university IRB will accept your reviews. I'm finished

Vanessa Northington Gamble: Continuing this issue. Eric and Jackie, have you faced this issue of people trying to go around you?

Eric Wat: I haven't had that experience. As I mentioned earlier we mostly have been reviewing applicants who are a part of SSG or community partners. So, they are actually very excited to go through the community IRB process.

Vanessa Northington Gamble: OK, thank you.

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

Caller: Thank you. Thank you for your presentations, they were very informative. My question has to do with the data ownership. And a question that often comes up when we're coordination data research projects is that once a grant is federally funded that the data ultimately, regardless of what parameters we put in regarding community ownership of the data, ultimately the data is owned or may be taken over by the government. And I wondered if the three of you could speak to that and what parameters or provisions you've put into place to ensure community ownership of data. And really there is the raw data and then there's the products.

Sheila Beckham: This is Sheila Beckham. We actually have policies related to the data and publication. And we have right on our research forms. Again we have two bodies, the research review committee and the IRB. But right on our policies and our approval letter

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we state that the data is owned by the community or by the center if it is our patient data. We also insist that we review any publications or poster sessions or presentations prior to presentation to ensure that the data is presented in a sensitive manner.

Bill Freeman: This is Bill. In fact the problem is that congress passed a law that people can access research data, other researchers and so on. And I think that is what the question is referring to. The way it has been implemented is that if the researcher establishes a databank to deposit the data, then the federal government will simply ask that the databank release the data as the databank regulations require. In your case as ITCA, ITCA the tribe or the community can build a databank that complies with what the federal government wants. That then means that anyone who wants to get those data, we're talking about the raw data now not just the publications. Once those raw data [*unintelligible*] you have to release some of it to comply but you control how it's released. You can put parameters on it. So I think that is the way to go given that this recent congressional law that was passed.

Caller: Great, thank you so much.

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

Caller: Hi. I'm a member of the IRB with the Migrant Conditions Network. You can find more about our IRB at migrantcondition.org. I really appreciated the presentations because it reinforces some of the similar conditions we had to deal with. We represent groups and coalition that deal with the conditions of migrant and other mobile populations. So in addition to the problems you've mentioned of cultural factors, economic factors and vulnerable aspects of the population, when you have the added problem of mobility. And also in the migrant population you have the issue of non-documentation. So one of the questions I have is the issue of consent. And several of you have spoken about consent. Again the issue that we've come up against is the issue of non-documentation. So writing your name down on the consent form is a very stressful idea and actually impedes someone's ability to participate in research if they wanted to. Also we have to reassure them that it does not affect other things in terms of their care. So what we have people do is not sign the consent form, but they have two witnesses sign for them. They witness that the process took place, that the consent was in their language and various aspects of that you already know about, in terms of reassuring them that the consent form is appropriate for the population. I was wondering if any of you wanted to comment on that process and whether if you also had the same consent forms where they would sign it would not be appropriate so another mechanism has to be put in place.

[pause]

Vanessa Northington Gamble: Does anyone want to handle that question or have any comment on that question?

Eric Wat: I think what you devised was really good. Actually I might suggest this to other persons who have also come across that question. I think ultimately the IRB members are

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more concerned about whether more than just something is not documented but whether or not the person understands the process, what is being asked of them, and also the potential for harm, and also the benefits of the research process. So for us it is the language and the ability to translate, to interpret. So I think that was more of a concern for our IRB.

Caller: Yes, and we certainly looked at this also as well as how it's going to benefit the population. As you can see our organization is national so community is often hard to define since they are mobile and the migrant populations that we do serve.

Vanessa Northington Gamble: Thank you.

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

Caller: [unintelligible] presentations, they were very informative. I have a couple questions and they are primarily for Sheila Beckham and Bill Freeman. I work here on the reservation and we're just in the process of establishing a tribal research review board. And one of the requirements that we would like to add is that the PIs or PDs that come onto our reservation that they do some cultural sensitivity training. Have you any experience in making those types of requirements? And what were the reactions of the PIs?

Bill Freeman: Did you want to answer that Sheila?

Operator: Sheila is momentarily not with us.

Bill Freeman: OK. I have not personally had that experience with that. But I heard some communities and tribes in particular have done that. I feel that it is perfectly appropriate. Any IRB can establish requirements for the research that are reasonable, and that is a reasonable one. So, go ahead and do it.

Caller: Thank you. I have one other question. Because we are a tribe and we don't have the monies to hire a coordinator or anything like that. We were looking to require researchers to apply for business licenses, they would have to apply for applications fees or IRB fee. Do you have any experience what that also? Or recommendations?

Bill Freeman: I am wondering if any of the other speakers had. Again, I have not personally had it, but a lot of IRBs, university IRBs, charge. It doesn't have to be a business license, you just charge to have it being reviewed and that helps to support the IRB. That is perfectly acceptable. Often they will have actually a sort of escape clause for people who are not funded by a grant or a contract from a major organization, but are like doing it on their own. They are exempt from that requirement. University IRBs do it, so community IRBs can do it.

Caller: OK, thank you.

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Sheila Beckham: And this is Sheila. I'm back. I think we have to look at the regulations based upon the agency. And I'm sorry, all of our phones went dead a few minutes ago so I just got on. So as a federally qualified health center, FQHC, we would not be able to charge for the IRB.

Caller: OK

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

Caller: Hello, this is ---. And I sit on the Indian Health Service Portland Health Area IRB. Hello, Angie from Colorado. A couple questions. This question is for Jackie and Eric. When establishing or creating your community independent IRB, how did you train your community members to be reviewers. What strategy did you have to get community members up to speed as far as looking at protocol? And my next question is for Bill. Is there in place within any IRBs, community IRBs, and any of the panelists can potentially answer this, as far as establishing genetic research policy and how that all plays out within an IRB because that is really something that is out there and we really need to look at that. I mean within our Indian Health Service Portland Area IRB, can any of the panelists speak to that as well?

Sheila Beckham: This is Sheila. The training that we have done is within community. Everybody who is a part of the IRB or research committee, or involved in any aspect of research much go through online NIH research certification and protection of human subjects course. And we have also had a number of training sessions here in the community related to what our policies are and procedures. Again, since our community initiated this 15 years ago, many of them are sophisticated in their understanding. Even the folks, the community health workers, who help with the consenting on projects have to do that. We do not have a specific policy related to genetic engineering but we have had one proposal come before our body and we did not approve it. And a part of that was our health interest board of directors' discomfort with that.

Eric Wat: Same thing as Sheila said. They have to go through the online course and get certified. And in terms of procedure and protocol... (Jackie—I don't know if she wants to speak about this), but she did a lot of research on the protocols that are being used and are effective with other IRBs. We did something new with our procedures and protocols; we have to constantly review if what we are doing is actually effective. Or how can we improve the process. So it's more of the iterative process where the IRB members actually contribute to improving the process as well.

Jacqueline Tran: This is Jackie. And totally ditto to what Sheila said. Because of the history of research projects and the involvement of our community partners at different levels. A lot of the individuals who are engaged in the process are already aware and have some experience. So as Eric mentioned, everyone is required to do online training, we provide an internal training providing background information on why IRBs are important as well. And as Eric said it is very much an iterative process and input is provided to improve the process every time we go through the process.

Vanessa Northington Gamble: Bill, did you want to add anything before we go on?

Bill Freeman: Just on the genetic issue. It is very possible and appropriate to have special concerns about that. Usually it's about who controls the specimens in particular usage even if anonymized. Because a lot of these researchers understand, or feel that they understand the regulations to get these specimens. But don't include the personal identifiers. So William Freeman is not excluded but he's a member of this tribe. That information is kept, the community information that's with each specimen – its okay to give to anyone. So that kind of thing, especially when I talked about the contract, a legal contract with the researcher that they will not do that without the explicit approval of your IRB and/or your community review process. That can get to be very important.

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

Caller: Yes, hello. Thank you to you all for your insights today, it has been very informative. And unfortunately I was not able to participate in the first phone call and I don't know if my questions are directly related to what we discussed today but we are currently debating about whether we need to go through the IRB process for a specific project that we are doing. So I just wanted to tap into everyone's expertise here today and get your weigh-in, if that's okay.

Vanessa Northington Gamble: We only have a few minutes left in this call so make it very brief so we can get some feedback.

Caller: So is it okay if I go ahead?

Vanessa Northington Gamble: The thing is that my concern is that for us to understand fully the project that it would take more than the few minutes we have left. So what I would encourage you to do is offline contact the people on this call.

Caller: Sure, okay. I'll go ahead and do that. Especially if there's still remaining questions that need to be answered.

Vanessa Northington Gamble: I just don't want to give you the short end in terms of your question. So I think that it would be the best way to handle it.

Caller: Alright, wonderful.

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

Caller: Thank you Jacqueline Tran and Eric Wat, Sheila Beckham, and Bill Freeman for all the information. I have been listening into the CCPH conference calls for a little while now and had a question about a presentation on prevention research center, specifically a presentation from Dr. Yancey from Morehouse School of Medicine. Where she spoke specifically about community-based participatory research in that it is designed to be

effective, culturally sensitive, and promotes health as well as it emphasizes partnerships between partnering communities, the academic institution, and in my case the community-based hospital here in Cambridge, Massachusetts. I wonder if you have any feedback on your impression of or your preference for an IRB in a community setting or is there a setting where a prevention research center would be more advantageous for community members.

[pause]

Vanessa Northington Gamble: One of the problems I think with the question is that Dr. Yancey is not here. And many of the people who are on this call were not a part of that call. We switched speakers. What one of your questions does raise is where should an IRB be located? And today we talked about community IRBs and what I would like the speakers to address in the last 2 minute is about the location of the IRB and we've talked about the benefits of having a community IRB. Could the work you are doing, could it be done in another type of IRB? And if you could briefly answer the question so Kristine can wrap up the conference call.

Bill Freeman: I'll take a stab at it. I think it is possible to have it outside the community, but there are some disadvantages to that. If you are going to have it outside the community, I think it should be structured almost like a community IRB. I think it should have a lot, not just one or two, community members, that they in effect control or have a dominant voice in the IRB. Because what you have ended up with, with all due respect because as Vanessa said I wasn't there for the presentation. Like myself, I'm a researcher. I do not necessarily have all the values and understandings and concerns of community people. So I don't trust my judgments about what is appropriate and not appropriate without listening to, hearing very forcefully those concerns. So however that happens, it is possible to do without an IRB that is not located by the community. However you really need to have the community, by design, play a major role in how things are reviewed and what is done.

Vanessa Northington Gamble: Thank you Bill. And unfortunately that will have to be the final word today and this conference call. And I would like to thank all the participants for this great session. I think you've given a lot of us food for thought. I also like the way that you not only give us food for thought, but you gave us practical solutions and also case studies. And with that I'd like to turn over the call to Kristine Wong.

[Closing announcements by Kristine Wong]