MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, JUNE 5, 2026

8:30 A.M.

OFFICE OF TECHNOLOGY AND SOLUTIONS INTEGRATION (OTSI)

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CONFERENCE ROOM 2SW19

2ND FLOOR

SACRAMENTO, CALIFORNIA 95833

AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Larry Dickey, MD, MPH, Vice Chair

Maria Dinis, PhD, MSW (Remotely attending)

David Lang, PhD

Juan Ruiz, MD, Dr.PH, MPH (Remotely attending)

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

Carrie M. Kurtural, JD (Alternate)

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Nicholas Zadrozna

ALSO PRESENT

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

PUBLIC

Nicholas Zadrozna

ALSO PRESENT

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Dr. Lia Scott, UC Berkeley

Dr. Sharita Shah, Emory University

Ms. Katya Salcedo, CDPH

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS (CONT.)

Dr. Jennifer Flood, CDPH

Dr. Jennifer Tsui, University of Southern California

Ms. Amber Rockson, USC

Dr. Danny Azucar, Rescue Agency

MS. Jane Allen, Research Triangle Institute (RTI)

Mr. Vaughn Armbrister, RTI

Ms. Kim Hayes, RTI

I n d e x

VICE CHAIR DICKEY: Okay. I'm Larry Dickey. I'm the Vice Chair and I'm chairing this meeting since Dr. Hess was not available.

So, everyone who are remote, please turn on your cameras.

And Agnieszka, I would like to turn on the issue of quorum.

DR. RYKACZEWSKA: Yes, thank you. So, the Bagley-Keene Open Meeting Act allows for a member attending and participating from a remote location to count towards the majority required to hold a teleconference if both of the following conditions are met.

The member has a need related to a physical or mental disability as those terms are defined in various sections, that is not otherwise reasonably accommodated pursuant to Federal Americans with Disabilities Act of 1990.

And the member notifies the state body at the earliest opportunity possible, including at the start of the meeting, their need to participate remotely, including providing a general descriptions of the circumstances related to their need to participate remotely at that particular meeting.

Ahead of today's meeting, Dr. Ruiz has shared with the administrator reasons for participating from a remote location that

meet those two conditions and that, therefore, joining remotely will still be counting towards our quorum today.

Additionally, I would like to state for the record that Ms. Carrie Kurtural, welcome back, is serving today as an alternate for Dr. Palacio.

MS. KURTURAL: Thank you.

VICE CHAIR DICKEY: Yes, thank you, Ms. Kurtural, we really appreciate you returning. It's like Hotel California, you never leave.

(Laughter)

VICE CHAIR DICKEY: Talking about leaving -- I'm sorry, did I do something wrong?

DR. RYKACZEWSKA: Quorum.

VICE CHAIR DICKEY: Oh, a quorum, yes. Thank you.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: I think I'm here.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Here.

MS. ATIFEH: Ms. Kurtural?

MS. KURTURAL: Here.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Here.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Yes.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Here.

MS. ATIFEH: Quorum is established.

VICE CHAIR DICKEY: Great. So, anyway, I was talking about leaving and the fact that you can never leave.

(Laughter)

VICE CHAIR DICKEY: But we need to acknowledge that Ms. Lund has resigned from the Committee for personal reasons. She was on the Committee for almost a decade and we certainly appreciate her service and the time and everything that she contributed.

I have mentored a number of members across the years and I'm not sure that she might not return someday as alternate. But --

DR. RYKACZEWSKA: We can hope. We can hope.

VICE CHAIR DICKEY: It used to be when members retired we got them a plaque from the legislature. You know, a certificate they can hang on their wall. You might want to work on that.

DR. RYKACZEWSKA: I'll look into that.

VICE CHAIR DICKEY: I remember one time -- one member, who got one, and we got him this plaque that was about this big,

from the legislature, and he didn't want it. He really didn't want it. So, I had to make a trip to Berkeley to give it to him I person and I don't know what he did with it after that.

But, you know, we might work on something maybe from the secretary, just something that acknowledges peoples' service and --

DR. RYKACZEWSKA: I will get to that.

VICE CHAIR DICKEY: Moving on to the less pleasant issues, I guess, or the issue of the CITI training. It's been, I guess, almost a year and a half, not quite, since they announced that and there's still some folks who haven't completed it. So, we just want to remind you that pretty much all the researchers that come to us have done the CITI training. So, it's kind of a double standard if we don't do it for ourselves. And so, anyway, just a reminder.

So, I guess we will move on to reviewing the meeting minutes from April 24th. Is there any feedback from Committee members that we haven't received already regarding those minutes?

Any comments from the public regarding those minutes for April 24th?

DR. RYKACZEWSKA: And if you're a member of the public and would like to make a comment, if you could please raise your virtual hand. Acknowledging no members of the public in the room.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: So, could somebody please make a motion for the adoption?

COMMITTEE MEMBER VENTURA: I'll make a motion to approve the meeting minutes from April --

VICE CHAIR DICKEY: 24th.

COMMITTEE MEMBER VENTURA: -- 25th, 2026 -- 24th.

VICE CHAIR DICKEY: Any second?

COMMITTEE MEMBER LANG: Second.

THE REPORTER: Who seconded, I'm sorry?

MS. ATIFEH: Dr. Lang.

Okay, Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

MS. KURTURAL: I'm going to abstain because I wasn't at the meeting.

VICE CHAIR DICKEY: Because you weren't at it, yeah.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: I mean, I have to say since I'm acting as chair I can't actually vote. So, take my vote away on that.

MS. ATIFEH: We need --

DR. RYKACZEWSKA: Oh, because there's an abstention?

VICE CHAIR DICKEY: I'm sorry?

MS. ATIFEH: There's an abstention, so we need at least six.

VICE CHAIR DICKEY: Oh. Can I vote in that case?

DR. RYKACZEWSKA: I believe so, because it would be a tie.

VICE CHAIR DICKEY: Yeah, okay, I approve.

MS. ATIFEH: Motion passed.

VICE CHAIR DICKEY: We had to consult our parliamentarian over here.

DR. RYKACZEWSKA: Just an administrator.

VICE CHAIR DICKEY: Okay. Moving on, we have no adverse events or et cetera, to discuss at this meeting. We have had one that we've received, but we don't have enough information yet to deal with it at this meeting.

So, let's move on to review of projects. The first one is Community Workers, Healthy Homes and Healthy Families Program. And I believe, Dr. Dinis, you're the reviewer.

COMMITTEE MEMBER DINIS: This is for the amendment?

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER DINIS: Yes, hi. I think William Jardell is here, right, yeah. So, Hi.

So, this amendment came to us and there was no human subjects contact. So, I wanted to have William Jardell explain what are the changes to the amendment, first, and get some sense, sort of a short summary to the Committee. And then, I will have a few questions I believe you can answer. So, if you don't mind.

MR. JARDELL: I'm actually going to pass this to my colleague, Abbey Ramirez, to describe. If that's okay?

COMMITTEE MEMBER DINIS: Okay, sure.

MS. RAMIREZ: Hi, good morning Committee chairs and Committee members. I am Abigail Ramirez with CDPH.

And I just want to clarify, do you want a summary of the whole program or just the changes?

COMMITTEE MEMBER DINIS: Just the -- well, I think the changes. If the members decide they would like more information then we can ask, then you can do that. So, just go over the changes first, and then I'll ask them if they want more information.

MS. RAMIREZ: Yes. There's two changes. One of them is changing the end date to extend to one additional year, to be able

to continue the evaluation of this project.

And the second one is to include -- to include a focus group evaluation to really evaluate the program evaluation, itself. And that will include some of our program partners, who have been engaged in this project since 2023. That will be Kaweah and Proteus, who are also on the line.

And this, the purpose of the focus group is really to explore the enablers and barriers of implementation among key staffs, from Kaweah and Proteus who were directly involved with the Community Health Workers, and Healthy Homes, and Healthy Families research project.

This focus group will examine our collaborative dynamic program barriers and facilitators, as well as recommendations.

And we are also including -- we included a lot of different documents for the partners, including a focus group discussion guide that includes the questions that we're hoping to ask among the program partners during the focus groups.

Our partners, UC Davis and Wild Blue Evaluation, who have also been engaged since 2023, since the initial submission of this program, are going to be supporting with this focus group evaluation process.

They are also on the line and can help answer any questions.

There is no third party involvement. Again like I mentioned, all of the program partners I just mentioned, Kaweah, Proteus, UC Davis, and Wild Blue Evaluation have been key program partners since the beginning in 2023.

And we're really hoping to understand some of the barriers for implementation of this project.

And we are -- and the last thing I'll add is that we're also going to be providing additional energy efficiency services by providing portable heat pumps, air purifiers and air filters to these houses who participated in the pilot program.

And we're hoping to include -- we included additional questions to the post-survey to really understand the health impacts, not only towards their health but also the health of their home after receiving these services, in addition to the services received by Proteus through the normal weatherization pilot program that we offered.

So, I'll stop there and happy to answer any questions.

COMMITTEE MEMBER DINIS: So, one more question, then, is so before you were analyzing data, state data. What made you decide to go down this route, so the Committee can understand how you decided to then add this additional piece.

MS. RAMIREZ: Yeah, happy to answer that. So, we -- our hope that we would be able to at least weatherize ten homes. And

understanding that there's lot of limitations to actually getting approved for these services. And Proteus is also on the line, if they want to share a little bit more.

But we soon found that we only had about five homes that had been weatherized. And this limited progress was due to insufficient or exhausted state funded weatherization program funds. Additionally, complex weatherization program guidelines played into this.

And difficulty getting people to respond to programs. As we know, there are current political challenges at the federal national level that are impacting how people adopt certain programs if they respond to these programs and if they answer the door to these types of state programs.

And so, we saw a lot of that being reflected in some of our programs. And so, these challenges have led to a small sample size, which may cause misleading interpretations and greater variability, and bias. And so, we didn't feel that this small sample was really accurate -- or, accurately represented the health benefits that are experienced by participants who received these weatherization services, given the limited measures being offered.

And so, again, this is why we wanted to provide additional energy efficiency services, like the ones I mentioned, portable heat pumps, air purifiers, and why we wanted to

incorporate additional post-survey questions to really understand and if -- in addition to the weatherization services if we were able to really observe any changes in these patients.

And so, recognizing the possibility of data availability, the research team expanded their original focus on evaluating outcomes through the process of evaluation to really understand opportunities and barriers for program eligibility and program participation for those referred members. As well as the staff who were supporting and that is -- yeah, a and that is why we decided to kind of shift our evaluation focus.

COMMITTEE MEMBER DINIS: And then, were you -- can you describe a little bit about the questions you have in the focus group and then how you're going to connect that to the state data.

MS. RAMIREZ: Yes. I will refer that question to our partner, Chelsea Austin, who is on the line. She could provide more. They developed the questions and can provide more --

COMMITTEE MEMBER DINIS: Okay, sure.

You're muted so far, somehow.

DR. RYKACZEWSKA: Chelsea, can you -- we can't hear you.

COMMITTEE MEMBER DINIS: No, we cannot hear you for some reason.

MS. AUSTIN: I'm unmuted.

COMMITTEE MEMBER DINIS: Oh. Now, I can. Now, it's

coming through.

MS. AUSTIN: I hear you. Just so I understand the question, your question is how are the questions in the --

COMMITTEE MEMBER DINIS: Yeah, sort of the -- yeah, give a sort of general idea of the kinds of questions you have for the focus group and then how you're connecting that back to the state data.

MS. AUSTIN: Okay. And just so I know, when you say state data what is that --

COMMITTEE MEMBER DINIS: I mean the data that you originally had, that you are analyzing from the state and then, now, you've decided to go beyond this. Are you connecting the two at all?

MS. AUSTIN: So, not really. What we've decided to do because there were so many barriers, and challenges, and complexities to putting on this weatherization program we've decided to dig into the implementation to understand where did things possibly drop off? Where there challenges that we aren't aware of? Where did the delays and bottlenecks happen?

So, the focus group is really about getting our partners together on the phone, who were working together for several years, and figure out a bit more of their dynamics, how they handed off tasks back and forth to each other.

And then, also, their perceptions of how CDPH just ran the program. Were they effective at coordinating? Did they feel like they had clear guidance? We're really just trying to work out the full ecosystem of implementation.

Which I think the connection to, you know, any of the outcome data is simply sort of a tenuous, mushy line of why didn't we get as far as we thought we would get.

COMMITTEE MEMBER DINIS: Uh-hum, okay.

MS. AUSTIN: But there's no direct linkage.

COMMITTEE MEMBER DINIS: I see. Okay. All right, well, okay I'll open it up to the Committee. I'm not entirely sure, though, and this is to the Committee, do we have purview over this and is this something they're doing on their own and they can go through the UC system, or their own IRB?

I wasn't entirely clear, if they're not connecting to our data. But I'll ask those who maybe know more about it than me.

DR. RYKACZEWSKA: So, my understanding is that CDPH is part of the research team, if I remember correctly.

VICE CHAIR DICKEY: Yeah, so if an agency is engaged in research if they have staff that is participating in the research. So, in this case that's why they're under our purview.

COMMITTEE MEMBER DINIS: We'll have purview. Okay. Okay. All right, then I'll open it up to Committee if they have

any questions. They included a set of questions and they also included the consent form for the focus groups.

COMMITTEE MEMBER VENTURA: I had a question, Dr. Dinis.

Just for the team, who will have contact with individuals and all the research, since there are three, CDPH, Kaweah, Proteus, actually four, UC Davis are all involved. If they're all included in the IRB, just whoever is having contact with participants consenting and doing the interview for the focus groups. I would just like to know all individuals involved. Because right now I'm only seeing about four individuals, existing personnel, and not everyone is listed, not all the organizations participating in this are included.

So, if the research team could just make sure, you know, who is contacting individuals and who is going to have accessing to identifiers and the focus group data is included in the IRB.

MS. RAMIREZ: Yeah, I can add a little bit and, Chelsea, I'll hand it to you. We included a few attachments, including the focus and solution guide. One was an email to the participants, outlining all that information, who is going to be conducting the focus group, what the data will be used for. Also, in that form we included some other information.

But UC Davis will be conducting the focus groups. CDPH will help in sending those insights via email. And then, from

there UC Davis will capture and evaluate the data

We did include a line in the consent form that also highlights this. And then, yeah, I'll have Chelsea to say a little bit more on that.

MS. AUSTIN: Yes. And I just want to flag, the amendment covers two data collection streams. So, we've got the focus groups and then we also have a survey that is looking to expand the things that could have arisen more at the individual level, as well as people's perspectives on the capacity of their organization to actually put on the program that was designed by CDPH.

So, I just want to put that out there because that is covered in the consent and you will also see a data collection instrument for a survey.

So, I don't know if that will lead to more questions, but I want to make sure that's clear.

On the point of -- I think the question was about -- so, two questions. Myself, I'm a subcontractor with UC Davis. And Kathryn Conlon, I don't think she's on the phone yet because she had a doctor's appointment that conflicted.

We're the two that will be doing -- making, you know, recruiting for this, emailing the partners that we've had contact with for the last several years. And we will be the ones who like have the focus group data, the survey data.

I don't think we've actually worked out the particulars of CDPH of where the data sits. Will it sit on like a UC Davis, you know, Qualtrics platform, or will it sit somewhere with CDPH.

I think we'd like it to be separate so that people can feel open to disclosing. But it's, obviously, CDPH at the end we can zip a file of raw data over, since technically they own it.

COMMITTEE MEMBER VENTURA: And just, well, identifiable data, just to be clear in the protocol if identifiable data will be stored on both CDPH servers and UC Davis. Just if you can clarify who's going to have the raw data or just the analytic file, that would be helpful as well. I know both have secure systems, but just to kind of spell that out in your protocol would be helpful.

MS. AUSTIN: Okay.

DR. RYKACZEWSKA: In addition, I believe this is already in there, but I haven't seen any data security letters. Any institution that will be holding personally identifiable data will need to submit a data security letter. So, anybody who has any identifiable information will need to submit that.

And then, Dr. Ventura, I just want to make sure that I understood your comment. So, what you were saying is that under the existing personnel, the UC Davis -- any UC Davis staff that will be essentially having access to personally identifiable information doing recruitment or doing any of the research

activities will need to be updated on the contact.

COMMITTEE MEMBER VENTURA: Yes. Thank you.

COMMITTEE MEMBER DINIS: Any other questions from the Committee members?

MS. KURTURAL: I'm just wondering, Carrie Kurtural, you're planning, end of plan is to publish the results of the survey?

MS. AUSTIN: I don't -- (indiscernible) -- you might want to put that to CDPH. No, if we would like to publish it. There's a chance we could do like a white paper, because we've discussed putting this out to partners who work on weatherization and funding, weatherization in California.

But in terms of like a peer-reviewed manuscript, I don't know that we've decided that for sure yet. I think our first -- our first sort of -- what am I trying to say -- destination for some of this data is to report it to CDC, who is the funder, to let them know how implementation worked because we are accountable to them.

And then, we've had some discussions about putting something out on the CDPH website, but we have not gone to the peer-reviewed manuscript space, yet.

VICE CHAIR DICKEY: Were you asking that question because of --

MS. KURTURAL: Just making sure if any of the survey recruits allege that they --

MS. RAMIREZ: Yes. Yeah, I'll just add that all of the information will be de-identified. The consent form also tells that, you know, we will -- we have specific program numbers for the patients participating in the program, but also for the focus group. Only UC Davis will have, you know, direct connection with them.

You know, but when we receive the data there won't be any like identifiable names. So, we won't have that information.

So, we do post it. It will either be a validation report, really just highlighting the key -- the key things we find, but all the information won't be identifiable.

Is that correct, Chelsea?

MS. AUSTIN: Sort of. The survey we've -- what we're doing with the survey is it will be a link that's emailed after people agree or consent to it. They will be given a unique identifier and that's essentially like a token to get into the survey. So, that's the only thing we'll have connected to the survey.

Obviously, we'll have a file that has like their emails and the code that was assigned to them for a temporary period, and then that will be deleted.

Similarly, with the focus groups, within the transcripts all people will be, you know, FG0085 or something. They'll get another identifier given to them. We'll have that linked file for a short period because we need to clean the data and then that will also be removed.

DR. RYKACZEWSKA: But those files will not be published as part of the reporting that you were describing, correct?

MS. AUSTIN: No.

VICE CHAIR DICKEY: I've got sort of a related issue as to what -- if, you know, a program evaluation is considered research or not. And the criteria says designed to create generalizable knowledge, then it's considered research, regardless of whether it's going to be published or not.

But often journals ask for something from an IRB. And so, is convenient to do it ahead of time. You can't come back to an IRB and come back for permission. Right.

COMMITTEE MEMBER DINIS: Any other questions?

So, are there any changes requested that we -- that they have to make or were your questions answered, other -- I know I --

VICE CHAIR DICKEY: It sounds like Dr. Ventura has --

COMMITTEE MEMBER DINIS: Dr. Ventura, yeah. What was the -- adding personnel, right, to the --

COMMITTEE MEMBER VENTURA: Right. Just adding all

personnel from the different research teams --

COMMITTEE MEMBER DINIS: Right.

COMMITTEE MEMBER VENTURA: -- from UC Davis, Kaweah, or Proteus, anyone involved with recruiting, contacting individuals and doing the -- obviously, doing the focus groups.

COMMITTEE MEMBER DINIS: Yeah. We'll add that to the protocol.

COMMITTEE MEMBER VENTURA: Since it's not inclusive of everyone, yeah.

DR. RYKACZEWSKA: And analysis if, you know, this includes identifiable information.

COMMITTEE MEMBER VENTURA: Yeah.

VICE CHAIR DICKEY: And that would need to be amended if that changes over time, which it often does.

COMMITTEE MEMBER DINIS: Yes, so you can always send an updated amendment if there's any changes to personnel or if they're either removed or added, then you can send an amendment to that as well.

DR. RYKACZEWSKA: I was also tracking, Dr. Ventura, you mentioned specifying where the data will be stored and tell if that's also changed.

COMMITTEE MEMBER VENTURA: Yes, because I heard Ms. --

VICE CHAIR DICKEY: Austin.

COMMITTEE MEMBER VENTURA: -- Austin. Yes, thank you. Mention that it could be stored at UC Davis, or CDPH servers. And while there's the secure file transfer to exchange the data, just clarify what is being stored where. Is it the raw, you know, focus group data or is it just the analytic de-identified, once you have that dataset. I know you have the data security letters in your protocol, but just clarify what is being stored where would be helpful.

MS. RAMIREZ: Got it.

COMMITTEE MEMBER DINIS: Okay, so, this is basically like a conditional approval, and then can be approved by a committee of one that --

VICE CHAIR DICKEY: Just before we make a motion, we need to call for public comment.

COMMITTEE MEMBER DINIS: Oh, I'm sorry, go ahead.

DR. RYKACZEWSKA: If you would like -- if you are a member of the public and you would like to make comments, please raise your virtual hand. Acknowledging no members of the public in the room.

I am seeing no virtual hands.

Back to you, Dr. Dinis.

COMMITTEE MEMBER DINIS: Okay. So, I guess I can make a motion to -- well, approve -- I guess conditional. I don't know

how you do it now. Conditional approval until those changes are in placed that Dr. Ventura has mentioned.

So, let's see how we do that again. Did you write them down? I didn't write them down.

DR. RYKACZEWSKA: I'm going to propose and Dr. Dinis, if it resonates with you --

COMMITTEE MEMBER DINIS: Yeah, go ahead.

DR. RYKACZEWSKA: Conditional approval, I'm assuming one year, I'm assuming minimal risk.

COMMITTEE MEMBER DINIS: Yes.

DR. RYKACZEWSKA: It's an amendment, so we do not need --

VICE CHAIR DICKEY: One year.

DR. RYKACZEWSKA: One year, right.

COMMITTEE MEMBER DINIS: Yes.

DR. RYKACZEWSKA: Conditional on, one, listing all study personnel in the protocol.

COMMITTEE MEMBER DINIS: Yes.

DR. RYKACZEWSKA: Two, specifying where data will be stored in detail.

COMMITTEE MEMBER DINIS: Uh-hum.

DR. RYKACZEWSKA: I think that was it. Please, Dr. Dinis, review the proposal.

COMMITTEE MEMBER DINIS: Yeah, and then isn't there also

-- make sure that all security letters are in place.

Is there anything else?

VICE CHAIR DICKEY: Do we hear a second?

COMMITTEE MEMBER VENTURA: I second.

MS. ATIFEH: Ms. Kurtural?

MS. KURTURAL: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: Okay. You should be receiving --

COMMITTEE MEMBER DINIS: Oh, go ahead.

VICE CHAIR DICKEY: Dr. Dinis, I'll let you think about it.

COMMITTEE MEMBER DINIS: Yeah, I was just going to say you will receive a letter specifying the conditions. And then, when you send it make to me -- well, they'll send it to me and it will be approved, you can go on with your research project at that point. And I guess these letters go out in a week or ten days, something like that. Or sooner.

VICE CHAIR DICKEY: Okay, moving on to the next project. It's Building a Geographically Diverse Cohort to Examine the multilevel Effect of Racism on Breast Cancer. And Dr. Ventura, you are the reviewer.

COMMITTEE MEMBER VENTURA: Yes. Good morning. Do we have Dr. Scott on the Zoom?

DR. SCOTT: Yes.

COMMITTEE MEMBER VENTURA: Good morning, Dr. Scott, how are you?

DR. SCOTT: Good. How are you?

COMMITTEE MEMBER VENTURA: Good. Would you mind providing the Committee just a brief, you know, two- or three-minute synopsis of the project and proposal, and then we can go into the details of your proposal.

DR. SCOTT: Okay.

COMMITTEE MEMBER VENTURA: Thank you.

DR. SCOTT: Great. My name is Lia Scott. I'm an Assistant Professor of Epidemiology at UC Berkeley, Public Health. I'm the PI of this project.

And this proposal really aims to recruit a diverse cancer epidemiology cohort of women residing in the Greater Bay Area, who have been diagnosed with first primary breast cancer.

And we aim to follow them over five years. Initially,

the proposal said the date of 2019 to 2024, but we'll be requesting the most recent five-year data.

The long-term goal of the project is to delineate the multi-level impact of racism and discrimination on characteristics at diagnosis and then following them for subsequent outcomes.

And we plan to cover several counties across the Greater Bay Area. We will pull this data with -- data from the Cancer Registry looking at cases in Atlanta, with the hope that eventually we'll be able to implement this survey and look at these multi-level effects both looking at structural racism markers and then interpersonal experiences of racism.

And so, this specific protocol really focuses on our initial case listing out of the Greater Bay Area. And we expect to have about 14,000 cases, hopefully, over five years. We expect to recruit all women who have been diagnosed with a first primary breast cancer, also race and ethnicity.

And we are requesting patient contact, then eventually implement a feasibility -- we're going to do a feasibility study, essentially, to see whether or not we can actually ask these questions and get some answers.

So, we won't actually recruit -- we won't know how many cases will be eligible for patient contact. We won't know that until we get the data from GBACR. And either way, we only plan to

do this feasibility study in about one percent of the cases.

But subjects, essentially, will be identified through the Cancer Registry. And we will be contacting them through mail. I believe the protocol has our patient contact letter in it, and the C (phonetic) brochure, as well as the study brochure.

And we set that risk as minimal mainly because we're focusing primarily on let's just get that initial case listing, as well as the contact information for who's eligible for patient contact.

All of our registry data is going to be stored in our secure research data Compute (phonetic) platform. I think that's what an acronym stands for. Which is essentially a virtual machine hosted by Berkeley that allows us to have this protected information online. We access through a password protection. Only me and my post-doctoral fellow will keep all of the addresses we believe we'll receive from GBACR separate.

Our actual cancer data, and we've worked with research IT to try to figure out what's the best way to make sure all this stays secure. Especially thinking about when we actually want to contact them and eventually get this survey information from them.

So, I think I can stop there.

COMMITTEE MEMBER VENTURA: That's great. Thank you for that summary.

I had a few comments and I believe it was sent back to you in IRBManager. One, in particular, was the reading level of your brochure document and your consent forms. Because you are targeting an educationally and economically disadvantaged individuals, I did ask you to lower all the reading level. It was quite high on all the documents, at 12th grade. And it can be lowered to at least 8th grade level.

I don't know if that was submitted already, I haven't seen it come through yet, but --

DR. SCOTT: Yes, I redid the patient contact letter -- the consent form. That's the only one I lowered the reading level for, but I can lower it for all of them. But, definitely, the consent form has been lowered.

COMMITTEE MEMBER VENTURA: Okay. As well as the brochure because, you know, that's kind of the initial contact with individuals and we want to make sure they understand what is being -- what they're being asked to do.

DR. SCOTT: I can't lower the CPR's brochure because that's just a requirement they have.

COMMITTEE MEMBER VENTURA: So which -- oh.

DR. SCOTT: The Registry, they have their own included.

COMMITTEE MEMBER VENTURA: Right. You know, only things that are under your control.

And then you're -- you also describe, you know, recruiting a diverse sample of individuals in the Bay Area. And I had just noticed that you had identified black, white and Asian women. But was just curious if you had inadvertently left out Hispanic women in the sample, or if that should be included. Just because I know you're trying to include as much diversity in your sample.

DR. SCOTT: Yes, Hispanic women will be included. Based on the previous Registry data we expect there to be about 3,000 cases among Hispanic women.

COMMITTEE MEMBER VENTURA: I don't think that was in your protocol but --

DR. SCOTT: Um.

VICE CHAIR DICKEY: Yeah, I saw those in there.

COMMITTEE MEMBER VENTURA: Oh, did you?

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER VENTURA: Okay.

DR. SCOTT: It was in the last submission after I read through your notes.

COMMITTEE MEMBER VENTURA: Okay. I will -- yes, and then you clarified that it's just yourself, PI, and a post-doc having access to the data and it will be stored at UC Berkeley.

So, I had no other concerns as far as who was accessing

it or where it would be stored.

So, I'll open it up to the Committee, if there are any other comments on this protocol.

VICE CHAIR DICKEY: I guess I would ask, so this is a feasibility study. Is your anticipating that you will be coming back?

DR. SCOTT: Yes.

VICE CHAIR DICKEY: With an amendment, I guess, to do the real study?

DR. SCOTT: Yeah. So, this was just to make sure we could actually get the data and start to see whether or not patient contact would be even possible, see how many patients were eligible for patient contact. And then, we'll submit an amendment with the actual survey and all of the protocol for what we're going to do when we actually want to implement the survey.

COMMITTEE MEMBER VENTURA: No comments?

VICE CHAIR DICKEY: So, public comments.

DR. RYKACZEWSKA: All right, we are now moving to the public comment section of this item. So, if any members of the public have a comment they would like to make, please raise your virtual hand. Acknowledging no members of the public in the room.

And I am seeing no virtual hands. That closes public comment.

COMMITTEE MEMBER VENTURA: Okay, so I'll make a motion.

VICE CHAIR DICKEY: Make a motion.

COMMITTEE MEMBER VENTURA: I'll make a motion for conditional approval, one year, minimal risk. I need to just review the -- just the consent form and brochure for reading level. I think that was my main concern for approval. But that's it for me. I didn't hear anything else anyone was wanting. So.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER LANG: Second.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

MS. KURTURAL: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Okay, the motion passes.

VICE CHAIR DICKEY: Okay. I remember seeing Hispanic data in there, but you may want to see for yourself.

COMMITTEE MEMBER VENTURA: Yes.

Thank you. You'll receive a letter within two weeks with the subject changes.

DR. SCOTT: Thanks.

COMMITTEE MEMBER VENTURA: Thank you, Dr. Scott.

DR. SCOTT: Thank you.

VICE CHAIR DICKEY: Okay, moving on to the next project, Infectious and Social Mixing in Asymptomatic TB as a Driver of Population-level Transmission, the INSPIRE study.

Dr. Schaeuble is the reviewer.

COMMITTEE MEMBER SCHAEUBLE: Dr. Shah, are you with us today?

DR. SHAH: Hi, good morning to the Committee. And I'd also like to welcome some of our study team members who have joined us today.

So, my name is Sharita Shah and I'm a Professor of Epidemiology at Emory University. I'm the PI on this study.

And I'll ask my other team members to introduce themselves, starting with Amy Kim, and then Jennifer Flood and Katya Salcedo.

MS. KIM: Hello, everyone. My name is Amy Kim. I'm the project coordinator for this project at the Emory University. Thank you.

MS. SALCEDO: Good morning. I'm Katya Salcedo. I'm an epidemiologist with the California Department of Public Health. And I have extensive experience implementing research studies

throughout California, so I'm consulting the team on this every exciting project. Thank you.

MS. FLOOD: Hi, I'm Jennifer Flood, I'm the Tuberculosis Control Branch Chief and supervisor of the co-investigator at CDPH, Dr. Pennan Berry, who could not be here today.

VICE CHAIR DICKEY: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Are those -- has everybody introduced themselves, now?

Dr. Shah, would you provide an overview for the Committee of your project?

DR. SHAH: Yes, thank you. So, we are proposing an observational study to understand the prevalence and the social contact patterns of people who have early stage or even asymptomatic TB.

And so, we're planning to enroll 2,000 people, over a four-year period, who are close contacts, recent immigrants, or otherwise referred to TB clinics for a TB workup and evaluation.

And the staff at the local TB clinic will refer potential participants to our study staff to be screened. And those who meet the eligibility will provide informed consent or assent, based on age.

And the study procedures that we're planning to do include chart abstraction, a structured interview that will be

administered to the participant, and then some sample collection. And I'll go into a little bit more detail in a moment about that.

Just to say that there's -- the participant will have just one study visit and there are no follow ups.

And for those who are eligible for the study are anyone who has a documented test confirming that they have TB infection. They have to be over age 12 and have no prior history of TB or TB infection. And, of course, be able to give informed consent.

So, anyone who agrees will undergo a structured interview where we'll ask them about their TB symptoms in detail, if they have any. We'll also ask them where they spend time and the approximate number of people, the number of contacts they have in those locations. In addition to some sort of just basic demographic and medical history type questions.

But there will be no names collected of any of their contacts.

And then, for the sample collection we'll be collecting a spontaneous sputum sample, blood samples for TB biomarkers, and a specialized duck bill face mask that will be fitted with a filter disk that can collect TB through breath aerosols.

These are all research assays and none of these research tests will be used for any clinical decision making.

All of the samples and all of the data collection forms

will be de-identified and we'll only use a study ID number that will be assigned to each participant.

And all of the testing of the samples that would be done, either at the California Department of Public Health laboratory or specialized testing at Emory, will be through de-identified sample labels only. So, no Emory staff will have access to personally identifiable data.

At the end of the study, all of the study participants will be matched to the California TB Registry to determine if any of them develop TB after they've finished our study visit.

And do, for purposes of doing that match, the California TB Program staff will have access to the name, data of birth, and a zip code for the participants. Any matching records in the Registry will have a list of variables extracted. And there is a complete list in the application. And that information will only be using the study ID for the dataset.

And so, the data are stored in a secure database with, you know, access limited just to study staff. No personal identifiers in the database.

And we've provided a data security letter from Emory, but also at the request of our reviewer we just got a letter, yesterday, from CDPH, from their data security team, as well. So, we'll upload that after this meeting.

So, I'm happy to take any questions. Just an overview. Thanks.

COMMITTEE MEMBER SCHAEUBLE: So, thanks. I think I just heard you say, but verify for me, that you received a data security letter from CDPH. And you also now have one from Emory that is signed by an IT person.

DR. SHAH: Yes, that's correct. So, the Emory letter is uploaded in the application. We just got the CDPH letter last night, so I will upload that after the meeting.

COMMITTEE MEMBER SCHAEUBLE: Why I was asking because the letter I saw in the application seemed to be signed by you, instead of by an IT person. Is that not the case?

DR. SHAH: It should be countersigned. I'll double check that. But, yes, I know that I signed that. We had to complete all of the data security requirements under the guidance of the IT department here, at Emory. But I will double check whether they signed it as well. I believe there were two signatures, but it's been a minute so I'll have to check that.

COMMITTEE MEMBER SCHAEUBLE: Right. It's possible that I missed it, as well. But at the time I looked, I thought I was seeing only your signature.

In any case, thank you much for responding in what turned out to be a short turnaround time for you, as well as for me, and

trying to review the protocol. I appreciate the changes that you made in response to earlier comments.

Several pieces of information that were missing before have been added now. And you also made some changes that had been requested in the consent and assent forms.

I'm not sure, did you -- did you receive the last email message I sent to you, after I reviewed your most recent changes a couple of days ago? Or let me just ask, have you had time to look at the comments I added after seeing what you resubmitted this week? Have you had a chance to see those and look at them?

DR. SHAH: Yeah. So, if -- I believe we did. But we did receive your latest comments, which were related, I think, to the consent and assent forms --

COMMITTEE MEMBER SCHAEUBLE: Right.

DR. SHAH: -- and some simplifications there. Some simplification in some areas and then the addition of the patient bill of rights. I think we added that, as well. So, we have not uploaded those but --

COMMITTEE MEMBER SCHAEUBLE: Let me just ask globally. Is there anything that we need to talk about that or are you satisfied that those are changes you can easily make? They seemed not controversial to me, but I always want to be sure that's true for researchers, as well.

DR. SHAH: Yes, we're happy with those suggestions and we have added those to the consent and the assent forms, and they are -- you know, they are straight forward and noncontroversial and actually, I think, improve the forms to be able to add that information about the participant rights for medical research, in particular. So, thank you for that suggestion.

COMMITTEE MEMBER SCHAEUBLE: So, I don't have any additional concerns to bring up. And I'll open it to the Committee, then, for comments.

DR. RYKACZEWSKA: And just wanted to clarify for the record that I double checked the Emory data security letter and it is signed by their chief information security officer.

COMMITTEE MEMBER SCHAEUBLE: Oh, good. Yeah. I'm sorry, I missed that then.

DR. RYKACZEWSKA: No problem.

DR. SHAH: Thank you for checking.

VICE CHAIR DICKEY: Is there anything that you need to confirm, that you haven't seen yet, that they've submitted? I'm just asking.

COMMITTEE MEMBER SCHAEUBLE: They will need to resubmit with the revisions in the last comments that I added the middle of this week. So, yes, it will be deferred approval for those changes.

VICE CHAIR DICKEY: Do we need to be able to list those changes on the --

COMMITTEE MEMBER SCHAEUBLE: They are all in the notes that were available for Committee members to see. I mean, it's half a dozen places, so I can refer to the comments that are in the protocol, or if you ask me to list them individually it's going to be a long motion.

VICE CHAIR DICKEY: I know.

DR. RYKACZEWSKA: I think it would be okay to say Dr. Schaeuble's comments on the protocol, the final changes to the protocol.

VICE CHAIR DICKEY: My guess is the Committee's fine with that.

DR. RYKACZEWSKA: Yeah.

VICE CHAIR DICKEY: But that's the motion.

COMMITTEE MEMBER SCHAEUBLE: And after people have an opportunity to present any questions they have.

VICE CHAIR DICKEY: Yeah.

Public comment.

DR. RYKACZEWSKA: Public comment. If you are a member of the public and would like to make a comment, please raise your virtual hand. Acknowledging no members of the public in the room.

And I am seeing no virtual hands.

VICE CHAIR DICKEY: Dr. Schaeuble, would you like to make a motion, then.

COMMITTEE MEMBER SCHAEUBLE: I would move a deferred approval for one year, at minimal risk, with the following conditions. First, upload the data security letter from CDPH.

Second, make the clarifications in the consent and assent forms that were requested in comments already existing in the protocol.

And third, add the participants -- the medical version of the participants bill of rights at the end of the consent and assent forms.

And those were the only items in the comments that I added to the protocol.

VICE CHAIR DICKEY: Do we have a second?

COMMITTEE MEMBER VENTURA: Second.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

MS. KURTURAL: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: The motion passed.

COMMITTEE MEMBER SCHAEUBLE: Thank you, Dr. Shah. Since you already have all of the relevant notes in the protocol and you've pretty much said that you have already take care of those issues, you'll be ready to make those adjustments and sent the protocol back as soon as you receive the letter from the Committee. So, I think you're ahead of the game here as far as taking care of what the motion asks you to do.

DR. SHAH: Thank you very much. I have a great team. Appreciate working with you.

COMMITTEE MEMBER VENTURA: Thank you.

VICE CHAIR DICKEY: Thank you, Dr. Schaeuble.

Let's -- we're moving on to some amendments, now. Actually, yes, basically two amendments and then we have another new project, which is actually a return project.

The first one is Assessing Cervical Cancer Healthcare Inequities in Divers Populations, the ACHIEVE study.

Dr. Tsui, are you on the -- I see you.

DR. TSUI: Hi, everyone, good morning. Can you all hear me. Great. Good to see you all.

VICE CHAIR DICKEY: Is there any other -- anyone else on your team going to be here? Just you?

DR. TSUI: The rest of my team, we do have Amber Rockson

here from our Columbia site. This is a multi-site study.

I don't know if Dr. Adana Llanos will be joining us. Amber is here in lieu of her.

I'll be presenting on our amendments and speaking on behalf of our full team.

VICE CHAIR DICKEY: Okay. I'm the reviewer for this. This should be an interesting discussion. And so, Dr. Tsui, why don't you take it away.

DR. TSUI: Sure. Let me screen share my slides. And let me know if you can see them. I put together just a brief set of background slides to get everyone acclimated to remembering what the study was about and what the focus of our amendment is on.

Are we looking at my notes or the presentation version?

DR. RYKACZEWSKA: The presentation version.

DR. TSUI: Okay, perfect. Oh, that never works, so we're off to a good start. That means it's a good day already.

So, again, I'm presenting on our ACHIEVE study, the Assessing Cervical Cancer Healthcare Inequities in Diverse Populations study.

This is a study that's co-lead by myself here, at the University of Southern California, as well as with my MPI and collaborator, long-time collaborator, Dr. Adana Llanos, who is at Columbia University.

Let's see if this is working. So, really quickly, our study is really a -- it's a multi-site NIH-funded study, funded by NIMHD. It's a five-year RO1. Recruiting cancer survivors from the L.A. Cancer Surveillance Program and the New Jersey State Cancer Register.

And the overall goal is to examine how social and structural factors contribute to inequities in cervical cancer treatment and outcomes.

The three specific aims focus on evaluating how social and structural factors influence receipt of guideline concordant treatments, how these same factors influence cervical cancer outcomes, both survivorship, quality of life, survival and other treatment related outcomes.

As well as a third aim which is to identify strategies to improve cervical cancer care and outcomes through stakeholder engagement.

Our participants are recruited from the two SEER sites, as I mentioned. We identify everyone with invasive cervical cancer within the two SEER sites, diagnosed between 2021 and 2024, ages 29 to 79 years, and able to complete study materials in English, Spanish or Chinese. The Chinese is written traditional text.

There is also a telephone version, as well, and virtual surveys that are available online. All of which have been improved

by this Committee and the other IRBs that we've submitted review by.

Our overall goal is to recruit 960 survivors across the two sites over multiple years. We are also in the process of partnering and collaborating with two additional SEER sites in the country and writing new proposals to extend this research program.

So, just to jump in what our goal today is, it's really to discuss two amendment items. The first is to request an amendment to revise our current consent procedures.

Our consent procedures for recruiting participants at the LACSP is different from our New Jersey State Cancer Registry program.

We're rooting that CPHS reviews and, hopefully, approves our request to amend our protocol so that participants are provided here, at LACSP, with a study information sheet instead of the signed informed consent document.

We're also requesting that participants, upon returning their study surveys, are thereby indicating their consent to participate. And I'll get into more details around that.

Our second amendment item is to propose a reduction in our survey length. In our amendment documents, we submitted a proposed shorter baseline survey. Nearly 20 percent fewer items.

We also proposed a shorter 12-month follow-up survey

where we cut about one-third of the entire follow-up survey to minimize participant burden. And I'll get into this, as well, towards the end.

This is really both decisions made by our research team based on the data we've collected so far, but really from our community advisory board and our research partners, including patients and survivors who have given us feedback upon appropriateness of our study documents, alignment with study items and what's important in the field currently.

And really, the overall goal of this amendment is so that we can improve the participation, the representativeness and the scientific quality of the ACHIEVE study, while definitely maintaining strong participant protections.

So to give you a little bit of background, this is a multi-modal data. Multi-modal, a multiple data source study. So, we have both a baseline survey and a follow-up survey. We collect other data elements, as well. We link to the Cancer Registry data. We collect medical records for abstraction. And we also link to public data sources.

In terms of the questionnaires or the surveys, after we identify eligible cancer cases from both LACSP and the New Jersey State Cancer Registry, we send out our first contact, which is a mailed packet. Which includes the baseline recruitment.

In New Jersey, only an information sheet is required and when a participant returns their survey it's an indication they consent and they've understood the information provided in the packet.

In Los Angeles, and what's approved by CPHS currently, is that a signed consent form is required.

We follow this first contact up with six calls and a reminder mailing is after three weeks.

Upon completion of the baseline survey, we then do our second contact, which is the medical records release packet, where both sites send out the same documents requesting for a signed HIPAA authorization form and a completed healthcare source form.

Twelve months after the completed baseline survey we go back and send a third contact, which is the 12-month follow-up survey. Again, this is where the two sites diverge.

In Los Angeles, here, we are required by CPHS to obtain a signed consent form. In New Jersey, only a provided information sheet and then the returned 12-month survey is required as an indication of participants' consent to continue in the study.

We also follow these up with six calls and reminder mailings.

We have an amazing team at multiple sites and they have been phenomenal over the past two years in getting the progress

that we've gotten so far.

I'll get into the packets really quickly. So, it's a big packet for the baseline recruitment. And that's part of the reason we're both requesting to align our processes across the two sites, as well as approval to reduce our baseline and 12-month survey length.

So, both sites the first item is a language options sheets, where participants are given information on other ways to access the language, the materials in language.

There's a recruitment letter for both that have been approved. And then, in L.A. we are required to provide the survey instructions that were requested by our initial reviewer, in our first CPHS protocol submission.

We are also required to provide this five-page consent form that participants need to return. In New Jersey, it is a two-page information sheet.

And then, all participants get the paper survey. They are able to complete the survey, paper/pencil. Return it back in Los Angeles. They need to return both the paper survey and the consent form.

We do have issues where paper surveys are returned and no consent form, and thereby requiring our team to follow up with participants. Often, these surveys can no longer be used because

we do not have the signed consent form.

When they do the survey virtually, on REDCap, which is the approved mode of data collection with our protocols, the consent for is the first page. They sign it virtually and then they complete the survey directly.

And this is where we really want to show and demonstrate our progress so far. So, we've recruited three years, three diagnoses years of cases. Those cervical cancer cases who were diagnosed in 2021, 2022 and 2023. You can see in L.A. there were 965 eligible cases and in New Jersey, 869. Somewhat comparable across the two regions for our two sites.

Over the recruitment period of approximately 18 months our active refusal rate here in Los Angeles is 12 percent. In New Jersey, it's 6.8 percent. So, a much higher active refusal.

Our completed baseline surveys, which is what we use as our initial response rate, is much lower in Los Angeles. It's 15 percent compared to 22 percent in New Jersey.

In neither site have we received any reports of adverse events or participants calling to complain about anything in terms of distress, or concerns around confidentiality, or around uncomfortability around the survey measures. None of that has been reported in either site. In New Jersey, they just use an information sheet and there have been no inquiries or reports to

the IRB or the study team about concerns.

In our follow-up recruitment, our 12-month survey, you see that once we can get participants to complete that baseline survey the response rate is much better at 12 months, right. So, we do have a higher response rate here in L.A. for the 12-month survey at 65 percent.

We have quite a few number of active refusals here in Los Angeles, anywhere from participants saying they're just not interested, to no reason given. But these privacy concerns really are the initial comments that we've received. The fact that they have to sign something, that it seems like there's a lot of paperwork, the perception that there's a lot that they need to do to participate, the burden of it has been brought up.

The 17 percent of other reasons include survey length. Hence, our second amendment item of reducing that survey burden.

There's really some -- a few other concerns around unable to focus on the survey, not feeling well, a general overload of mails and spam calls. Any of us living in Los Angeles, or in California currently, know that even in the past month we've received countless numbers of voting calls. So, I can see how much of a burden, and sort of weariness about phone calls could be part of the problem.

So, input from our community advisory board and our

research partners. There was agreement, we just had a full team research meeting with our CAB and our partners in March of this year, in person at Columbia University.

And this was the general sentiment when we discussed this issue at length. First, it was that the signed consent form may be eliciting more concerns about privacy and mistrust. So, having the information sheet and not having to sign a consent form may help to reduce concerns about privacy and mistrust, and the need for what cervical cancer patients may deem as, you know, formal documents and confidentiality.

This streamlined amendment around consents, around aligning the consent processes across the two sites could create a more participant-centered and culturally responsive recruitment processes. It could reduce possible stigma related to this aspect of having cervical cancer and being a cervical cancer survivor. And it supports a more equitable participation.

We have heard that patients want to be part of this. They've never -- many of them have never been able to express their experiences with their cervical cancer journey. Unlike breast cancer, there are much fewer support groups out there for this type of -- for this cancer site and for cervical cancer in general.

But having sort of a large participant burden to participate has really been a concern raised by our CAB.

In summary, we have lower response rates at LACSP, 15 percent versus 22 percent. The use of information sheet only in New Jersey has not resulted in any reporting of adverse events.

We're hoping that a simplified consent procedure, that we're proposing here in this amendment, will reduce participant worry and burden, and that we'll be able to have a more representative recruitment moving forward with this streamlined consent process.

So, this is the summary. I mentioned this at the early slide in this presentation. And I just wanted to end on the Common Rule. This is something that we had discussed with this Committee in length, I think almost two years ago, now.

The Committee had deemed that a signed consent form was required initially. And we went through with that process over the past 18 months of recruitment and are starting to see sort of the data diverge with these divergent consent processes between our L.A. site and our New Jersey site.

The Common Rule does say that, you know, we could -- the IRB may waive the requirement for a signed consent form if there is potential harm resulting from a breach of confidentiality, or if the research presents no more than minimal risk.

These are some aspects that we're hoping the discussion today could sort of raise again, and we can think about it

collectively as a group. And this might be something we reconsider.

So, with that I'll end. I'm happy to think about how we can talk about this together. We're here to answer questions. And, really, this is, you know, a revisit. We really wanted to carry out what CPHS and what this Committee, the IRB Committee had wanted us to carry out.

We took the time to look at our data and talk to our community advisory board. There are public letters that we've uploaded from our community advisory board to support that they feel that not having a signed informed consent would be okay.

And so, and with that thank you for your time. And thank you for the Committee for sort of the concern around our protocol and our amendment.

VICE CHAIR DICKEY: Thank you, Dr. Tsui. You get the award for the best presentation, I think. It's audio/visual.

DR. TSUI: Well, I have a great team. And Amber is one to make amazing visuals.

VICE CHAIR DICKEY: I just want to say for background for the Committee, the portion of the Common Rule that you displayed does state that an IRB can waive written informed consent, not informed consent. Written informed consent is the only thing linking the patient to -- or the person to the study is the signed

consent.

And if the person is given the option of saying I want to sign this or I don't, and informed that they can do either.

Would you have a way of doing that, giving them an option of -- letting them know that it's an option to sign it or not?

DR. TSUI: You mean -- I mean, in our introduction letter we can say there's a consent form here. You can agree to sign or not sign it. I think that we clearly lay out in our introduction letter that, you know, their participation is voluntary.

VICE CHAIR DICKEY: I understand. But we need to make it explicit that they have to read the form. If they choose to -- they can choose to sign it or not. But returning the survey is it's implicitly implied that they're signing it. Do you know what I mean?

DR. TSUI: We can do that. That's the same language that New Jersey currently uses with their information sheet.

VICE CHAIR DICKEY: Awesome. Right.

DR. TSUI: Yeah.

VICE CHAIR DICKEY: So, there's a criteria for waiving informed consent. One of the criteria is you can't get adequate participation or you can't effectively do the study.

And, but that's for waiving informed consent, not waiving signed consent.

And looking at the records from the last meeting, a couple of years ago, most of the discussion was about practicality. And practically, they could do it. But now, they've shown us that they can do it, but it's not as easy doing it that way.

But the real standard for not signing consent is the only thing linking is the signature on the form.

I will also bring up that as we're finding out, if we talk to our consultants, EDvera, there is a federal requirement that the studies federally funded, which this one is, that you have to agree to have the same IRB.

DR. TSUI: I'm sorry, say that last part.

VICE CHAIR DICKEY: You have to have a single IRB.

DR. TSUI: Okay.

VICE CHAIR DICKEY: And in this case, we have two IRBs and a disagreement. So, we're kind of in a violation of that by having two different study designs.

And the whole purpose, when that was introduced in 2018, was to sort of minimize these disagreements between IRBs.

DR. TSUI: Uh-hum.

VICE CHAIR DICKEY: And that's something I believe will be reflected in recommendations for policy changes in the future by EDvera. But just we didn't discuss that previously, in the last meeting.

So, the issue of taking questions away from the questionnaire is never a problem. And so, that's not an issue. But what really is this issue is the -- how consent is obtained.

MS. KURTURAL: Can I ask a question about the New Jersey method. So, do they have some kind of acknowledgement? For example, like would the form get turned back to them and it's really the conduct they're relying upon, instead of the what signature, right.

DR. TSUI: Yes, that's correct.

MS. KURTURAL: On the staffing side of it, is there -- is there a way that, I don't know, to document, you know, the facts of the situation? That it was turned in, or that they refused to sign, or I don't know the details there. But I think it would be helpful that you have some sort of documentation saying this is what happened when they turned the form back in?

DR. TSUI: On the New Jersey side, you mean?

MS. KURTURAL: Yeah.

DR. TSUI: So, for both sides we mail out -- it's on the New Jersey side, after that baseline packet is mailed out. Their letter states that, you know, we want to ensure you, as the participant, have read the information sheet and that you understand the information. And that by completing the survey and returning the survey by mail, it is your agreement to participant

in the study.

MS. KURTURAL: Okay.

DR. TSUI: That process, and I have worked with the New Jersey State Cancer Registry, while being faculty at Rutgers, prior to coming back to California. That process is not new. That's how they have approached all of their recruitment for minimal risk studies, like non-interventional studies that are survey based, observational based.

And so, this is why having two sites, and being new to this IRB Committee and working with the LACSP, we had thought that that streamlined process could work at both sites. And had hoped that because this is a minimal risk study and that this has worked in other SEER registries that this is something we could do here.

They do document, and we do in both sites document how many baseline surveys we mail out and what we don't receive back.

MS. KURTURAL: Right.

DR. TSUI: They also, simultaneously, document through the telephone follow-up calls, which you saw was a much lower rate. They document passive refusals, just like we do here in L.A.

And so, all of the documentation of who wants to participate, who doesn't, any concerns that are raised are streamlined and aligned between the two.

The only difference is that for our L.A. site they will

-- our participants need to have that signed consent.

MS. KURTURAL: Yeah. And then, another question for what we're here doing in California. With the survey, has there been any thought that they can do it electronically?

I mean because, just historically, even on the State of California site we have a very hard time getting surveys back, you know, with our programs. Just in general, I'm just thinking out loud there. Because you get some gigantic package in the mail, with all these questions, you know, and sometimes digital it works better.

DR. TSUI: So, there is a slide that I didn't present today that shows that. So, our current protocol and in that packet it allows participants to either do that paper/pencil survey or it gives them a QR code to go online to REDCap to do the survey, in any language they want.

MS. KURTURAL: Okay.

DR. TSUI: Or, if they prefer even more to do telephone surveys. And we've done very, very few telephone surveys. Those are rare. Usually, in non-English languages.

In L.A., compared to New Jersey, we do have a higher rate of virtual surveys completed, as opposed to baseline -- as opposed to paper/pencil.

We also, though, have a sample here in L.A., our

participants here in L.A. are younger. The participants in New Jersey are slightly older, and so we have some demographic differences.

And so, we're not sure if the demographics that lean more towards wanting to do paper/pencil surveys in Los Angeles are not going them because, you know, they have to fill in that signed consent form, everything seems too much.

MS. KURTURAL: Yeah.

DR. TSUI: Yeah. So, we are also seeing a divergence in the sample characteristics across the two sites.

VICE CHAIR DICKEY: Which can affect the validity of your study.

DR. TSUI: Yes.

VICE CHAIR DICKEY: Dr. Schaeuble, I think you have a question.

COMMITTEE MEMBER SCHAEUBLE: Well, I think maybe I have several questions. Is the passive refusal rate different between the two sites?

DR. TSUI: The passive refusal rate. Amber, did we put that on our -- I think the passive --

MS. ROCKSON: No, but they're quite similar between sites.

DR. TSUI: Let me see if I could pull it up. Our

recruitment calling has been similar across the two sites. But we do see that in our L.A. site it's harder to reach people by telephone. Somehow, in the New Jersey site they have had an easier time.

I am not sure if that's because are we -- do we just live in a state where we have people trying to sell us solar panels, and getting us to vote, and New Jersey does not.

I have lived in both states and I will say I get -- I, personally, get more scamming calls here, than elsewhere.

And so, recruitment wise that has been -- you know, so our active refusals, while we've had a higher rate in L.A., there is something about the calling and the follow up that is different across the two sites, as well.

Amber, I don't remember, I think our passive rates were pretty similar. We had not highlighted them because they were not of note, of particular note.

MS. ROCKSON: Right, yeah. They're similar.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, what I'm hearing is passive refusal rate is basically the same for the two locations. Active refusals higher for the baseline survey, but lower by about an equal amount for the 12-month survey, which makes it maybe somewhat questionable as to what the reasons really are for the differences in rates between the two sites.

Am I remembering correctly that people receive a gift card following completion of the survey?

DR. TSUI: Yes. So, following the baseline survey they get --

COMMITTEE MEMBER SCHAEUBLE: And --

DR. TSUI: Yeah.

COMMITTEE MEMBER SCHAEUBLE: And that the surveys are linked to medical records and other data?

DR. TSUI: The surveys are definitely linked to the SEER data. And our SEER -- our registry teams are the ones who work as the honest broker to give us the de-identified characteristics to link back to the survey data. So, tumor characteristics, the SEER datasets.

Medical records is only accessible if the participant, upon that second mailing, they finish their baseline -- and I can put that graphic back up. This is helpful for us. Let me just do that so I'm not talking in the abstract for everyone.

Can you all see this?

VICE CHAIR DICKEY: Yes.

DR. TSUI: How about now?

VICE CHAIR DICKEY: Yes.

DR. TSUI: Okay. So, only participants who complete the baseline survey process will then be mailed a second contact

packet. That second contact packet gives them the $50 gift card for completing the baseline, and then has two forms, the HIPAA authorization and the healthcare source form.

Only upon completion of these two forms do we then request medical records. Regardless of whether participants complete the medical records release, all participants who complete a baseline recruitment get the second contact, but 12 months later also get the follow-up survey.

So, not everyone who completes a baseline survey will have medical records.

COMMITTEE MEMBER SCHAEUBLE: Do most agree? This is a side question, but do most agree or not?

DR. TSUI: It's around 50 percent.

COMMITTEE MEMBER SCHAEUBLE: Around 50 percent. Okay.

Well, in any case, to be able to mail the second packet, including the gift card and the request for access to medical records, obviously, you have to have the contact information for the person.

So, as far as name being connected in some way to the survey, the consent form is not the only place where name is in some way related to the survey.

DR. TSUI: The only people who have those mailing contact names and the surveys are our registry teams who are doing the

recruitment. On the survey side, when we get the data back that is not linked to that information. That is the, you know, research dataset. A dataset related to the research.

COMMITTEE MEMBER SCHAEUBLE: Am I misunderstanding, doesn't everybody who completes the survey receive a gift card for their work on the baseline survey?

DR. TSUI: Yes, absolutely.

COMMITTEE MEMBER SCHAEUBLE: So, you have to have their contact information to be able to send them the gift card.

DR. TSUI: Right. And my --

COMMITTEE MEMBER SCHAEUBLE: So, the survey is connected to information about the person above and beyond the signed consent.

DR. RYKACZEWSKA: Can I ask a clarifying question --

DR. TSUI: By the recruitment team, which is the registry team, in an honest broker situation similar to all other studies who have surveys. Every survey study will require some sort of thank you letter and incentive where they have to be mailed out.

I mean, there are other studies approved through LACSP recruitment where the same registry teams, the gift study, the response study, we've sort of consulted with all our colleagues here. The registry team, who work behind locked doors in the second floor of our Soto Building, here at USC, are the ones who

mail those out.

COMMITTEE MEMBER SCHAEUBLE: So, I don't know what all has been discussed in the past with you. But it's typical in research projects where the content of the survey has sensitive information in it for the consent form to be returned separately from the survey, so that they are isolated and not in the same package.

And similarly, for online surveys to have one isolated system that records the consent separate from the system that has the survey responses.

DR. TSUI: We do.

COMMITTEE MEMBER SCHAEUBLE: You do have?

DR. TSUI: We do. The consent forms in the registry office, here at LACSP, on the second floor of Soto does not keep the signed consent forms in the same file cabinet as the surveys. That is how we've conducted all of the other studies and that's how we've written it in the IRB.

COMMITTEE MEMBER SCHAEUBLE: But do people receiving your package return the consent form and the survey together?

DR. TSUI: They do. They have to mail it in one packet. We mail them a packet with a return envelope, with the consent form and the survey. We, as the research team side of it, do not see those packets. Only the registry teams see it. They mail it out

and mail it back, the same process as New Jersey.

COMMITTEE MEMBER SCHAEUBLE: So, what I'm saying is where there's a concern by potential participants about privacy related to having to sign their name on a consent form, what often is done is to make sure that return of the consent form is separate from return of the survey itself. So that people know they can send the survey form back without a document in the same envelope that has their signature on it.

And it appears that's -- I don't know whether that's been considered or not along the way, but from what you're saying that's not the way it's working for you at the moment.

DR. TSUI: That hasn't. We haven't discussed having consent forms sent back in a separate envelope than the surveys.

I think this -- when we discussed this with our community advisory board and our research team at length, in reflecting upon our recruitment over the past 18 months the concern is less about whether their consent form and their survey are tied together.

The concern, very realistically in the community right now is that signing their name on something that seems formal is scary to them.

And while they are happy to answer the questions about the survey, the minute there is a form telling them they must sign the consent form that part is scary. I mean, that's just true

transparency. That's what our community advisory board has said.

With everything happening in the community, having one more paper that requires them to put their signature on it, even though -- so, we have a third aim of this study, which I mentioned earlier in the second slide, which is to understand strategies to improve treatment and outcomes. That involves qualitative interviews and that is approved by our single IRB institution at Columbia. It has nothing -- it's separate participants from the registry, separate -- it's just community members, patients, stakeholders, providers.

And what we've heard from community members and patients is that they want to talk about how to improve their cancer journey, their cancer experiences and outcomes, but this is a scary time to do it if, you know, they have to -- if the burden is high to participate.

And so, then, that's why --

COMMITTEE MEMBER SCHAEUBLE: The problem is though --

DR. TSUI: -- this amendment includes reducing the survey length and demonstrating that in New Jersey we don't have the signed consent as part of the process.

COMMITTEE MEMBER SCHAEUBLE: So, I'm trying to listen responsibly to your concerns here. But at the same time you're very focused on one alternative strategy and I think there are

others out there that could be considered.

VICE CHAIR DICKEY: I'd just like to add, Dr. Schaeuble, this federal law is that we have to use the same -- it's a federally funded program. That's just a --

COMMITTEE MEMBER VENTURA: So, who -- which IRB then is --

VICE CHAIR DICKEY: Well, we either agree or we have to agree who's going to be the one. They've -- the USC has deferred to Columbia as their IRB. So, the USC IRB has already signed a reliance with Columbia. Because she's located at USC. And the researchers in New Jersey are dealing with Columbia. So, USC is deferring to Columbia.

It's we have not deferred to Columbia, yet.

DR. RYKACZEWSKA: Dr. Schaeuble, could I also ask a clarifying question with the two return envelopes that you're proposing. I'm assuming that's what's being proposed is that there's two return envelopes, one for the consent and one for the survey.

In that case, what I'm trying to follow then with the survey, the study, as currently written at least, the gift cards are only returned to those that have completed the survey. But if we separate the survey from the consent form, we would have no way to track who completed the survey. We would only be able to see,

yes, this individual completed the consent form.

But we don't know whether they just returned the consent form, but not the completed survey.

VICE CHAIR DICKEY: There's a problem --

COMMITTEE MEMBER SCHAEUBLE: The survey is obviously linked to contact information they have on file for the gift card and the second request.

DR. RYKACZEWSKA: But only for the people --

COMMITTEE MEMBER SCHAEUBLE: So, the survey and the consent form, presumably, could have the same linkage number at the bottom as far as being able to track that a survey and a consent form belong to the same person.

At least I think that's the way it's been done in the past.

The bigger question here, in my mind, is we have a document that was -- what I saw in the protocol, when I looked at those redline changes in the consent form to make it an information sheet was about two pages long. I don't know what is in the, what was described as a five-page consent form, currently. I don't know what's missing from that document that's in the proposed information sheet, being used -- that would be used instead.

In any case, it was described as a package of either 37 pages in New Jersey or 45 pages in California.

What I assume will happen, and I think it's a pretty realistic assumption, is that people getting a large package of information like that will see the cover letter, will see what the project is about, will see that they can receive a gift card if they send the survey back. And with a fairly high probability may simply ignore and not look at any information sheet, go directly to the survey, send it back.

The researchers would like to say, well, that indicates consent to participate in the project. But they don't really have consent if the people haven't been informed. If they haven't read the information sheet, they really haven't been informed.

So, what are we looking at here in the context of the situation where some pretty sensitive information is being requested in the nature of the survey itself. I think that's a troublesome set of circumstances.

Now, if we cannot look at this from the stand point of what are we doing to protect human participants, and instead are being told we have to defer to whatever has been decided at another institution then I don't know why we are talking about it at all. But we are going to make a determination based on what we think is fair for participants. And I think we have to at least think about these issues.

VICE CHAIR DICKEY: I'd like to point out that the issue

of sensitiveness of the survey is known. We have a number of surveys that we approve waiver of written consent, such as the CHIS survey, which is a huge survey and asked sensitive questions that are more sensitive than these. And we have approved that through a waiver of written consent.

COMMITTEE MEMBER VENTURA: But in those we've had at least a box of check for understanding, and that I am choosing to not sign, but I'm still opting in.

VICE CHAIR DICKEY: Yeah, and there needs -- and that's what --

COMMITTEE MEMBER VENTURA: That's what I'd like to see.

VICE CHAIR DICKEY: That's what the law says is --

COMMITTEE MEMBER VENTURA: Yes.

VICE CHAIR DICKEY: -- there needs to be some mechanism to prevent -- to acknowledge or at least document --

COMMITTEE MEMBER VENTURA: Right.

VICE CHAIR DICKEY: -- that they've been presented with that.

COMMITTEE MEMBER VENTURA: So, just sending back a survey for me is not -- I mean it's not a documentation of I've received a -- or the information sheet and that --

VICE CHAIR DICKEY: Uh-hum.

COMMITTEE MEMBER VENTURA: I am opting into this research

study. I know it's voluntary. Just acknowledging, but I am not signing my name. I think we've done that in previous studies.

VICE CHAIR DICKEY: Yeah, and I think that, you know, having a checkbox where they can at least check --

COMMITTEE MEMBER VENTURA: Yes.

VICE CHAIR DICKEY: -- saying I'm choosing not to sign.

COMMITTEE MEMBER VENTURA: And I think that was to kind of Carrie's point, which was what is the documentation process on the New Jersey site.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: So, I don't know if on that information sheet, two pages can subscribe consent form. I don't know, is that much less burdensome. But on the information sheet, at least, do they have a checkbox or something understanding.

VICE CHAIR DICKEY: Right. And I think that's what the law says, there needs to be something like that.

And is that possible for you to do?

DR. TSUI: Yeah. I mean, I would like to first just reiterate that first and foremost we are here to protect human subjects. I am fully on board with that. I am not trying to default to an aligned system that exists merely because it exists.

I'm very familiar with CHIS. I worked on CHIS for over five years while at UCLA. And many of our items are from CHIS.

Our survey, which we didn't talk about, has already gone through review by this Committee where we have reduced, and taken, and omitted items that were considered above minimal risk or too sensitive. That occurred in the meetings and the review process, and the amendments that happened prior to us starting recruitment in 2024. So, that's number one.

The second is, yes, I think I agree, who is to say that someone gets a packet in the mail and they read -- you know, every time we go to the doctor we have a ton of forms to sign, right. And so, having a checkbox, I'm open -- we are open as a team to what other options there are, aside from a formal signature.

VICE CHAIR DICKEY: Yeah. So, would that put you out of sync with New Jersey?

DR. TSUI: Yes. We would have to go, then, try to align New Jersey's process with this. When the CPHS approval came in 2024, we talked at length with our New Jersey site on whether we wanted the New Jersey site to align with the California site.

And they went through their own process of, well, what does it mean to balance burden, and risk, and protections. And we're not here to discuss, you know, their decisions.

But for the sake of this study and the quality of the science, and the protection of the human subjects I think to balance it all, absolutely if this Committee thinks that a checkbox

with a statement of understanding is required our next alternative is to go to New Jersey and say, could we also add this checkbox.

I guess if participants are to return a baseline survey, should that checkbox and that statement be on the first page of the survey or does it need to be separated somehow?

VICE CHAIR DICKEY: I would think it would need to be on the consent form --

DR. RYKACZEWSKA: On the information sheet?

VICE CHAIR DICKEY: On the information sheet because then it demonstrates that they've looked at the information sheet.

If it were on the survey --

COMMITTEE MEMBER SCHAEUBLE: If it's on the information sheet, the information sheet's not going back to the researchers, so they don't know that they --

VICE CHAIR DICKEY: Well, I think the information sheet would go back. Right? If they checked it and then they returned it with the survey.

COMMITTEE MEMBER VENTURA: The packet.

VICE CHAIR DICKEY: The packet, right. That would document that they've looked at the information sheet. They don't want to sign it, but in here they're including it.

MS. KURTURAL: I have kind of a foundational question on the grants. I'm assuming USC is the -- who's the reviewing IRB,

the main reviewing IRB for purposes of this study?

VICE CHAIR DICKEY: It's Columbia.

DR. TSUI: Columbia University is the prime IRB and we are multi-principal investigators. So, USC is a sub-award. And Rutgers University is a sub-award because that's where the New Jersey State Cancer Registry is.

MS. KURTURAL: Yeah. Then I think that even if there is a federal regulation on this and we don't have jurisdiction at all. Unless if there's some sort of agreement, you know, with the federal.

VICE CHAIR DICKEY: Yeah, this is something that we're going to have to deal with in the policies and procedures because we have a -- currently have a phrase in our policies and procedures that says the data is -- you know, that we have engagement, if they're using data that's under our purview to contact someone. And that doesn't --

MS. KURTURAL: There is a federal regulation.

VICE CHAIR DICKEY: It doesn't coincide with that. So, we're trying to figure out how to retain sovereignty in both. And it may look --

COMMITTEE MEMBER VENTURA: Yeah. I mean there's the one reviewing IRB and you have to comply with the federal regulations which grants --

VICE CHAIR DICKEY: I understand. I mean I was looking at different things where we're advisory to the central IRB. I mean, and I think there is that. But as to whether we can say you can't do it unless you agree with us, it's really a question.

COMMITTEE MEMBER DINIS: The federal regulations don't always supersede us, you know. SB-13, the case in point. So, it just depends.

VICE CHAIR DICKEY: Well, no, it doesn't say that we can't -- we don't have to do an IPA review.

COMMITTEE MEMBER DINIS: Right.

VICE CHAIR DICKEY: But it does say that for the Common Rule we're supposed to agree with the central IRB.

COMMITTEE MEMBER DINIS: Right. But that's a lot of -- I was going to say, I mean, a lot of surveys just say something like if you decide to return the survey to us, your consent is basically understood, or approved, or intended, you know, some language to that effect. So, they don't even check a box. But by virtue of returning the survey, we've assumed their consent.

VICE CHAIR DICKEY: Yeah, and there are under sections under that waiver that we haven't really discussed, that may allow that. There's a separate section under there that says that if it's a population that's particularly --

COMMITTEE MEMBER DINIS: Bothered, yeah.

VICE CHAIR DICKEY: -- by the -- then, you can waive the -- and you don't even have to have a checkbox.

COMMITTEE MEMBER DINIS: Right.

VICE CHAIR DICKEY: And some of the support letters from the community organization were saying, well, our populations are threatened by this particular situation and, therefore, we think you should waive the written consent. So.

COMMITTEE MEMBER SCHAEUBLE: Well, regarding your questions about who has jurisdiction, I haven't heard anything in the discussion so far suggesting that Columbia has weighed in on any of these things for either New Jersey or California. Am I missing something in that regard?

VICE CHAIR DICKEY: Dr. Tsui?

DR. TSUI: We have meetings twice a month with both cancer registries. We have research team meetings twice a month. And we have twice-a-year meetings with our full co-investigator and community advisory board team.

We have talked about this process, the balance of protection and respondent participant burden, this issue of divergent processes at length in practically every meeting over the past 18 months.

Our research team meets collectively. My MPI, Adana Llanos, is not here. Only because there's two of us and we act in

partnership along the way.

Amber Rockson is our research coordinator. She is sitting in a room at Columbia University currently, that's her office, her real office.

They are not missing. Columbia is not missing from this conversation.

Adana and I have sat down and looked at every page, edited every single aligned, every single document participant facing and research team facing together over the past three years of this grant.

So, to say that they haven't weighed in would be incorrect.

VICE CHAIR DICKEY: And their IRB has approved it. Right, I mean the Columbia IRB.

DR. TSUI: If you have questions about the Columbia IRB, the contact person is Amber Rockson right here. She is our rock star and the glue that ties the entire study together. Any questions with concerns that Columbia IRB has raised Amber can answer. So, Amber. I could just keep going.

MS. ROCKSON: And to date Columbia University has approved anything that is seen by this Committee has already been approved by Columbia University.

COMMITTEE MEMBER SCHAEUBLE: So, are you saying Columbia

has at this point approved both California and New Jersey procedures up until now? Is that the status of --

VICE CHAIR DICKEY: Have they approved signed consent?

MS. ROCKSON: Yes.

VICE CHAIR DICKEY: Then how come New Jersey is going not signed consent?

MS. ROCKSON: Because it is New Jersey's policy that -- at Columbia, they're able to defer judgment to the individual IRBs. So, in New Jersey, because it is already their policy to allow an information sheet that is why that's allowed at this point.

VICE CHAIR DICKEY: And is there another IRB, other than the -- for the New Jersey?

DR. TSUI: Yes. New Jersey goes through the Rutgers University IRB.

We have four IRBs. WE have four IRBs in this study. The New Jersey State Cancer Registry goes through Rutgers. LACSP goes through USC and CPHS. And then, Columbia is the prime.

MS. KURTURAL: I think that --

COMMITTEE MEMBER SCHAEUBLE: What I was trying to tease out here is if Columbia is the overarching IRB for everything, apparently, if I'm understanding you correctly, Dr. Tsui, I hope I'm not mispronouncing your name. Apparently, what I'm hearing from you is Columbia has willingly approved or deferred to

institutions in New Jersey and institutions in California to go ahead with the procedures that have been approved respectively there, even if they differ.

So, that would say that --

VICE CHAIR DICKEY: What's the purpose of having a central IRB if all they're doing is subcontracting to other IRBs.

MS. KURTURAL: Yeah, that doesn't make sense.

COMMITTEE MEMBER VENTURA: And they don't align.

VICE CHAIR DICKEY: Yeah.

DR. TSUI: So, in all honesty and with all due respect, the reason we have requested Columbia's IRB to approve it like this is in our initial process with CPHS they told us they don't -- there's no recognition of a single IRB. All approvals must go through this Committee, your Committee.

And so, our research team basically went to Columbia and said we're going to have these two protocols. Each site is going to have their own recruitment protocol.

Because there was -- otherwise, we were not going to recruit at this L.A. site. We were different -- with all due respect, we are -- I mean, it's a sentiment that your word is "the" word, when we started in October of 2024.

Our study actually was delayed, our recruitment was delayed by nine months because New Jersey had already received

approval, ready to recruit. And we had gone back and forth with this Committee and had started to see that divergence. And the reconciliation at that point was either we delay recruitment even more, or we have to divergent sites.

And we said, well, let's give it a go then.

VICE CHAIR DICKEY: No, I understand. I'm looking at, you know, saying maybe we should make a motion just to defer to Columbia IRB, but that would make no sense.

Plus, we also have something in our policies and procedures, currently, that we do not defer to other IRBs except federal IRBs. And that needs to be changed.

But the question is, you're not asking for us to defer to Columbia, you're asking us to align our requirements on consent with New Jersey, what's being done in New Jersey. And so, I think we do have a basis to make a decision on that.

DR. TSUI: I think for our ask is -- I think our ask is not -- it's not to align with New Jersey, but it's to reduce participant burden in two ways, the signed consent form and the survey length.

VICE CHAIR DICKEY: But, in effect, that would be aligning with New Jersey.

DR. TSUI: I think with the way that this conversation has flowed and the sentiment that there's only -- I only view one

option, which is an alignment with New Jersey. I just want to put it on the record that we are open to other processes that have been approved by this Committee, that are separate or distinct from just merely the signed consent form.

VICE CHAIR DICKEY: Okay. And putting a checkbox on that form would be one of those examples.

COMMITTEE MEMBER LANG: Yeah. So, I just want to balance the equities here. So, you're doing this survey with action across the board, right? They're going to be doing this at the New Jersey site and --

DR. TSUI: The survey has stayed the same. That is the one thing that we do not waiver in divergence, yes.

COMMITTEE MEMBER LANG: So, then maybe, I think perhaps the easiest path, if the Committee agrees, if we just have the checkbox consent with the survey as the initial item, and that way they would be in sync.

VICE CHAIR DICKEY: Well, it wouldn't be totally in sync. But it would be improved -- you're thinking it would improve their access, better response rate.

Do you want to make a motion?

COMMITTEE MEMBER LANG: I would.

VICE CHAIR DICKEY: We need to -- anymore comments from the Committee?

Can we open it up for public comment?

DR. RYKACZEWSKA: If you are a member of the public attending and would like to make a public comment, please raise your virtual hands. Acknowledging no members of the public in the room.

I'm seeing no virtual hands. But again, acknowledging the written public comments we have received. I believe there were seven of them and they were included as part of the meeting materials, shared with both the board members and posted online. So, I do want to acknowledge there was public comment, but not in person.

VICE CHAIR DICKEY: So, I can't make a motion because I'm acting as Chair. You could make one. Or anybody else could make a motion, but --

COMMITTEE MEMBER LANG: I would motion to amend the survey to contain a checkbox consent and remove the signature -- and remove the associated signature required.

VICE CHAIR DICKEY: I think you have to still give them the ability to sign it, if they wanted to.

COMMITTEE MEMBER LANG: Okay.

VICE CHAIR DICKEY: And it would have to have a checkbox saying, you can just check this or you can sign it.

DR. RYKACZEWSKA: That being --

VICE CHAIR DICKEY: Yes. And I would say not amend the survey, amend the consent. Amend the consent to be an information sheet.

DR. RYKACZEWSKA: I just want to clarify, Dr. Lang, were you suggesting to have it on the actual survey or on the information sheet?

COMMITTEE MEMBER LANG: I was recommending the survey because they're already engaged in the reduction at both sites.

DR. RYKACZEWSKA: So, I just -- okay. So, it would be amending the survey, the motion made by Dr. Lang. I want to be respectful of it. Amending the -- could we say the first page of the survey?

COMMITTEE MEMBER LANG: Yes.

DR. RYKACZEWSKA: And it's conditional approval, right?

COMMITTEE MEMBER LANG: Yes. And minimal risk.

VICE CHAIR DICKEY: So, this would mean they wouldn't have to return the information sheet?

DR. RYKACZEWSKA: Yes.

VICE CHAIR DICKEY: Is that right?

COMMITTEE MEMBER LANG: Yes.

VICE CHAIR DICKEY: Is that --

COMMITTEE MEMBER LANG: I think so.

VICE CHAIR DICKEY: You think so?

COMMITTEE MEMBER VENTURA: Can I make a suggestion to the -- so, to contain a checkbox for understanding or of like --

MS. KURTURAL: Consent.

COMMITTEE MEMBER VENTURA: Acknowledging --

VICE CHAIR DICKEY: Acknowledging -- acknowledging that they have read the information.

COMMITTEE MEMBER VENTURA: Acknowledging they've received and understand or something that they have --

MS. KURTURAL: I think it would be --

VICE CHAIR DICKEY: I don't know about understand, but have received and read.

COMMITTEE MEMBER VENTURA: Okay. The consent.

VICE CHAIR DICKEY: The information sheet.

COMMITTEE MEMBER VENTURA: Or, the information sheet.

DR. RYKACZEWSKA: Dr. Lang, this is your motion.

COMMITTEE MEMBER LANG: This is my motion.

MS. KURTURAL: I'll second.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I don't know.

VICE CHAIR DICKEY: You can abstain, if you want.

DR. RYKACZEWSKA: Would you like us to return to you, give you a moment?

COMMITTEE MEMBER SCHAEUBLE: I guess I will abstain simply because I still have some concerns that people may just check the box without looking at the information sheet.

VICE CHAIR DICKEY: Right.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: So, this is conditional. I'm assuming it's conditional on -- it could be my and somebody else looking at what they actually come up with or do you want it just to be me?

MS. KURTURAL: You want a second set of eyes?

VICE CHAIR DICKEY: Huh?

COMMITTEE MEMBER VENTURA: If you want, yeah. I would fine if it was just you, but if you'd like just a second pair of eyes, I'm in.

VICE CHAIR DICKEY: Okay, how about if -- let me see what

it is and then if I'm -- I'll probably send it to you anyway.

COMMITTEE MEMBER VENTURA: Yes, happy to look at it.

VICE CHAIR DICKEY: Give recent events, I think we need a second pair of eyes on a lot of things.

Okay, you'll receive a letter with regard to this and look forward to seeing your revisions. And once again, thank you so much for the really thorough and thoughtful presentation.

DR. TSUI: Thank you so much to the Committee for taking the time and energy on this. I know it's not easy and it feels headachy, but we'll get there. Thank you so much.

VICE CHAIR DICKEY: Okay, good luck.

I told you it was going to be interesting.

(Laughter)

COMMITTEE MEMBER SCHAEUBLE: You were right.

VICE CHAIR DICKEY: Yeah, see, you can never leave.

(Laughter)

VICE CHAIR DICKEY: The next project is Understanding Attitudes, Perceptions, and Behaviors toward Youth Cannabis Use in California. Dr. Lang, you're the reviewer.

COMMITTEE MEMBER LANG: Dr. Azucar, I invite you to brief the IRB panel on your amendment. I do have one quick verifying question. There's a differential in our correspondence about what the compensation amount would be versus your amendment.

DR. AZUCAR: Uh-hum.

COMMITTEE MEMBER LANG: I would love it if you could clarify that in your presentation.

DR. AZUCAR: Sure. Yes, so -- I see that -- what was the difference is -- I submitted the amendment and we requested a lower incentive than what I'm presenting today.

So, in the amendment we requested to increase the teen incentive from $40 to $75, and the young adult incentive from $70 to $100. Through internal discussions we realized that it might be best to just propose to the board to raise all incentives to $125 across all three audiences, which would be teens, parents and caregivers, and young adults.

COMMITTEE MEMBER LANG: Could you tell us why the difference for compensation, please. If you could just give us a quick overview of what the focus groups are and its purpose.

DR. AZUCAR: Yeah, sure. So, my name is Danny. Nice to meet you all. Good morning to the board.

And we also have Adana Fielding (phonetic) here and Jessica Hwang from California Department of Public Health, SATB.

And this study is being conducted by Rescue Agency, in partnership with the California Department of Public Health, Substance Addiction and Prevention Branch.

And the overall goal, really, is to inform the

development of a statewide public health education campaign that's focused on preventing or delaying cannabis use among youth and young adults. So, really this study is designed to better understand the knowledge, the attitudes, the beliefs, and perceptions and experiences that shape cannabis related decision making among the three key audiences. Which, again, is teenagers ages 13 to 17, young adults ages 18 to 20, and parents or caregivers of youth ages 11 to 17.

Also, in addition to exploring the perceptions of cannabis related risk we seek to understand the social influences, any communication patterns. And, really, the types of educational messages that are most likely to resonate with each audience.

And overall the project consist of three phases. So, phase one is a formative research and that phase is now complete.

So, now, we're moving into phase two which involves virtual focus groups that will be conducted with eligible participants through established, like market research panels.

So, what we're doing now, essentially, is using insights from phase one. And with those insights from the research, the focus groups and the participant feedback we develop draft commercials that are now going to be tested in creative concept testing during phase two.

As part of this process participants complete a brief

screening process. They complete a short check-in survey. And they participate in a 9-minute focus group discussion. And this is the same across all three audiences.

So, obviously, the discussion probes are different. The questions on the survey for the participants. But the components of what makes up the focus group and the planned commitment is identical.

So, the amendment that I'm presenting to the board today is limited to participant compensation for these activities. So, I'm requesting approval to increase the participant incentive for teens, ages 13 to 17, and young adults ages 18 to 25 -- 18 to 20 to $125.

So, again, currently for teens the incentive is at $40. We ask to increase it to $125. And for young adults currently the incentive is $75 and we ask to increase that to $125. And this would really align compensation across audiences.

COMMITTEE MEMBER LANG: So, I know that in February, when we discussed this item originally, we had some very extensive conversation about what level of compensation would be considered coercive.

DR. AZUCAR: Uh-hum.

COMMITTEE MEMBER LANG: You've shared in your amendment that you were having difficulty with recruitment. Could you speak

a little bit more to that topic?

DR. AZUCAR: Yeah, so we experienced challenges with recruitment of eligible teens and young adults. And we received feedback from our recruitment vendors that indicated that the existing incentive levels, again $40 and $70, were below prevailing market rates for qualitative research.

So, current industry standards for a 90-minute focus group commonly range from $100 to $150. That's what we heard from our vendors. And also, for particularly hard to reach audiences, like adolescents to young adults.

So, we heard that from our vendors. And we also heard it from some participants who like verbally expressed that the incentive was a little bit low.

COMMITTEE MEMBER LANG: So, I'm the one who makes the motion?

VICE CHAIR DICKEY: Well, we have to open it up for a discussion.

COMMITTEE MEMBER LANG: Yes, let's do that.

COMMITTEE MEMBER VENTURA: I remember this discussion because it was Ms. Lund's extensive research on the minimum wage and that now tripling the teen incentive from $40 to $125 would seem -- would go back to the point of coerce of -- and I just wanted to refresh everyone's memory of that.

VICE CHAIR DICKEY: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: So, we did talk about this rather extensively before and it seems like we're being -- being asked to go back to what had been requested for the discussions in February.

For me, the real question here is when do we cross over from if you participate in our research, we want to thank you and give you a gift as basically a token of our appreciation, into an alternative territory where what we're really saying to potential participants is this is your lucky day. If you participate in our research, you're going to receive a very substantial amount of money for doing so.

There is quite a bit of difference between those two situations. And in that regard, I'm curious, you've mentioned vendors discussing with you level of compensation for research participation. Who are the vendors we're talking about? I couldn't even see that when I tried to look at the protocol.

DR. AZUCAR: So, we work with a few different vendors, that's why they're not listed specifically in the protocol. But right now we're working with a vendor called PRC and Galloway.

So, these are market recruitment vendors that have an existing database of participants who have indicated that they're willing to participate in research studies.

So, the way that it works is we contact these vendors. We send them the screener survey that's designed by us. They administer the screener survey to participants in their database who might be eligible. And they send us the results of people who are eligible to participate in the study.

COMMITTEE MEMBER SCHAEUBLE: Okay. Well, in any case, I tried to think about this from the standpoint of the values that I saw in the request before the amount that's been increased today. And even when the postal said for 13 to 17 year olds increase the amount to $75.

Time of participation is something less than two hours.

UNIDENTIFIED SPEAKER: Ninety-minute focus group.

DR. AZUCAR: Yeah, 90 minutes per focus group.

VICE CHAIR DICKEY: I saw that we had -- I saw somewhere a total of 105 minutes, which would be less than two hours.

DR. AZUCAR: Yeah, so 90 minutes for the focus group, plus their check-in survey, which is activities that occur prior to the focus group, so we also include that. And the screener and the check-in survey which adds up to 105. We allow 50 minutes of --

COMMITTEE MEMBER SCHAEUBLE: So, $75 for that amount of time, if one tried to convert that to an annual income, we're talking about more than $75,000 as an annual income at that rate of pay for less than two hours work.

Now, I don't know many 13 to 17 year olds who have an annual income of more than $75,000.

For the 18 to 20 year olds, the request had said $100, which converts to something over $100,000 annual income. And now, we're talking about $125, which -- well, I haven't done it in my head here, but it must be approaching something comparable to $150,000 annual income.

It's hard for me to look at the those incentives of that size and not say these are very large in comparison to any income expectations that people in these groups might otherwise have.

DR. AZUCAR: So, I do want to just highlight that, and we all know this here, there is a fine difference between what we consider income and what we consider an incentive for participating in a research study. We don't give participants cash. So, there's that, we're not giving them cash.

And for teens and minors, we also give them a gift card where -- for example, you can't buy alcohol. So, maybe a gift card to the movies, a gift card to Best Buy, or something that still aligns with protections for these teens and how they can spend that incentive.

And again, it's not considered income. We're not giving them cash. It's not actual work. It's an incentive for participating in the study, a compensation for their time.

VICE CHAIR DICKEY: I have to say that --

COMMITTEE MEMBER SCHAEUBLE: Still, the question is whether people are then participating based on their -- first, their willingness to be engaged in the research with the incentive being a secondary bonus, or whether they are participating first for the amount of compensation they're going to be given, and willingness being the secondary.

VICE CHAIR DICKEY: So, it used to be that we had it phrased as compensation for sort of participating. And OHRP came out with guidance that you can give incentives, but you can't give excessive incentives.

So, the question is what's excessive. It's, you know, I think it's just enough to get them to participate.

So, the question is with teens, knowing how they are, you need to give them a little more incentive to get them to participate, because they don't participate in things otherwise.

So, I mean, I can see both the arguments. That if you're trying to get somebody to participate and you give them an incentive, you may actually need much more for a teen than you need for an adult.

DR. AZUCAR: Yeah. And if the concern is about coercing teens to participate, I will say last time I presented research findings that say most participants don't decide whether they're

going to participate based on the incentive. They decide on the perceived risk or the perceived harm that the study, itself, creates.

This study remains minimal risk and involves voluntary participation, informed consent, assent procedures. And really, the ability to decline participation or withdraw at any time without penalty. And participants are informed of that during the consent, like the very first phase of the research process, which is when they sign consent.

So, nobody's forced to stay in the study. They can leave the study at any time and still receive the incentive.

COMMITTEE MEMBER SCHAEUBLE: Those, of course, are all standard parts of any participation in research.

DR. AZUCAR: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: But I would say that we are required to think carefully about the amounts being proposed here. They simply seem too large to me.

VICE CHAIR DICKEY: You think it's excessive. The question is what's excessive and what is not.

MS. KURTURAL: Psychology, too, I think that's a big sticker. The intent is a big --

COMMITTEE MEMBER VENTURA: Or, what's in your proposal, I mean, from $45 to $75 and $75 you $100, but I thought that was

reasonable. But to just make it across the board $125 is just -- let's try smaller amounts.

MS. KURTURAL: Yeah, I don't know if I -- have you guys seen incentives for research of this type before, because I'm usually --

VICE CHAIR DICKEY: You mean for $125?

MS. KURTURAL: Or $150 they're saying, right, the market research on average $150.

VICE CHAIR DICKEY: Sure, for a 90-minute.

COMMITTEE MEMBER VENTURA: Oh, really.

VICE CHAIR DICKEY: I've seen it.

MS. KURTURAL: Okay.

DR. AZUCAR: We've had previous protocols approved by this board that approved incentives of $125 across all three audiences, including minors.

MS. KURTURAL: Well, I mean, we can't be arbitrary here and decide --

DR. AZUCAR: And I'll highlight, again --

COMMITTEE MEMBER SCHAEUBLE: Well, certainly we've seen protocols for a similar amount of time the incentive has been in the $50 to $60 range, regardless of the age level of the participant.

So, I'm not going to say we've never seen a larger amount

somewhere, but we've certainly very typically seen much smaller amounts, also.

VICE CHAIR DICKEY: Do you have any evidence that -- that teens need this higher amount to participate?

DR. AZUCAR: I don't have any like studies that say teens need this amount. I think it's a decision that we make here.

And there's reasons for that, right. For example, comparable study burden across audiences. So, all participant groups complete, really, the same study activities including the screening, the check-in survey, the 90-minute virtual focus group. And they discuss a sensitive public health topic.

So, the time commitment, the cognitive effort, the scheduling burden and participation requirements are comparable across all audiences. And I believe in equitable compensation for study burden and not equitable compensation based on age.

We also heard during our focus groups that a lot of participants said, you know, I saw that you were asking me if I've ever used weed before through the screener survey, and I didn't want to join because it's a very sensitive topic and I didn't want to get in trouble for it.

So, I think that incentivizing participants with that higher amount would increase the level of honesty and the willingness to answer these questions during the screener survey.

And again, we do have standard participant protections in place. So, I don't believe that anybody will be coerced to participate in this virtual focus group where they're looking at creative concepts for commercials about a campaign on the cannabis prevention.

MS. KURTURAL: From a business perspective, there is a psychological place of making something under $100 versus over $100. And so, I don't know if it needs to be $125. But is there -- I will say that there is a little bit of a psychological hurdle with that. And I think also at $50 for the younger teen participants.

But you could try it and if it doesn't work, then we know there's another --

VICE CHAIR DICKEY: Try what?

MS. KURTURAL: You could, you know, approve it for maybe those amounts and then see what happens.

VICE CHAIR DICKEY: You mean the lower amounts?

MS. KURTURAL: I'm saying they want teen participants from $40 -- they want to increase $40 to $75.

VICE CHAIR DICKEY: But it sounds like he's --

DR. AZUCAR: No, it's $125. And so, the reason why I mentioned it is we initially submitted an amendment with those figures. And the amendment was approved in error. And now, we're

requesting $125.

MS. KURTURAL: Yeah, I don't know. I don't know that it needs to be $125. I think the psychological hurdle is $100 for people.

COMMITTEE MEMBER SCHAEUBLE: Well, there have been some anecdotal comments here. Have we heard any excessive burden on the researchers to justify any change from what was approved several months ago?

VICE CHAIR DICKEY: Except for what the vendors are saying, I guess.

MS. KURTURAL: Yeah, have you tried any --

COMMITTEE MEMBER SCHAEUBLE: But the -- trying to make a profit for people, so --

VICE CHAIR DICKEY: But they're not getting the money.

COMMITTEE MEMBER SCHAEUBLE: They're not getting it --

VICE CHAIR DICKEY: They're wanting to get the participants --

COMMITTEE MEMBER SCHAEUBLE: But they make money if they get the business of people participating, which it makes them a rather biased --

VICE CHAIR DICKEY: Well, they're going to do what they -- they're going to say what they want to get participation.

And you are allowed to use this as an incentive, not for

reimbursement. And I mean, they are putting the evidence that vendors are telling them you need to do this if you're going to get the participation.

COMMITTEE MEMBER VENTURA: And Dr. Schaeuble, the researcher just said that they're hearing from participants, as well. Right, in terms of --

DR. AZUCAR: Actually, yeah, some participants just said I believe this incentive is a little bit low. Some said, I almost didn't answer the survey honestly because the survey was also a little bit -- I mean, the incentive was low.

So, really, it will increase participant honestly and reduce that impression management when they're completing the survey, the screener survey.

And another thing I'll add, right, let's think about it in an everyday perspective. If you go to the movies now, as a teenager, I looked it up the other day, there's no more like student discount prices. They're treated as an adult.

So, you're going to the movies, you're buying a ticket, it's 25 bucks. If you go on a date, you're spending 50. You add a comb number one, your large coke and popcorn you're at 70 bucks. You're at $70.

So, I think that providing that to a teenager twice is totally fine.

COMMITTEE MEMBER SCHAEUBLE: Your movie theater is more expensive than my movie theater.

COMMITTEE MEMBER VENTURA: No, it's real. That's real.

VICE CHAIR DICKEY: I'm not sure it's $25 for a movie ticket.

COMMITTEE MEMBER VENTURA: It's real.

VICE CHAIR DICKEY: I think they probably check you for movies, too.

MS. KURTURAL: I, myself, am heavily involved, you know, I'm in the wine business. And so, when we do events, it's funny out the hundred dollar plate range is so psychological. So, if you put an event over that hundred dollar plate, you're not going to have anyone who shows up. If it's at $95, it's fine.

You know, and this is true across the board. But it just has always been the $100 point range.

COMMITTEE MEMBER LANG: As an economist the basis is absolute real. I'd be happy to share some studies with you.

MS. KURTURAL: Yeah.

COMMITTEE MEMBER LANG: I also want to sort of frame this. I will actually say some of the comments of Dr. Azucar has actually given me slightly more hesitancy.

I would sort of frame this through the lens of opportunity cost. If individuals decide to participate in a focus

group is this compensation for like other commercial products, for the (indiscernible) games, et cetera, similar to. And I think the answer to that is yes. That is actually in the range of what that compensation looks like. Instead of if you were going to go watch a TV pilot.

And so, that's kind of the framing that I'm talking about.

COMMITTEE MEMBER VENTURA: That is comp. What is it $100.

COMMITTEE MEMBER LANG: Yeah, $100, $120.

COMMITTEE MEMBER VENTURA: Yeah.

COMMITTEE MEMBER LANG: So, I'm sort of how I'm viewing this.

COMMITTEE MEMBER VENTURA: So, for the time, like he said the study burden, for the time that they're asked to participate, yeah.

COMMITTEE MEMBER LANG: I do recognize that that's a sensitive subject and I really want to make sure we decouple that.

MS. KURTURAL: And it's supposed to be an incentive.

VICE CHAIR DICKEY: Yeah.

MS. KURTURAL: It is. I mean it's about getting participation. So, I mean, that's just my opinion. A $100 plate, whether we agree to go $125 or not.

VICE CHAIR DICKEY: It sounds like the discussion had a -- I lost the argument.

COMMITTEE MEMBER LANG: So, I think we are hearing from the researcher that certainly the current pricing is not enough. Should we just do a reverse dollar option and start at $125 and go down until we have consensus?

VICE CHAIR DICKEY: Well, why don't you make a motion. That's the only -- and that's the only way we're going to -- I think last time we engaged in a bargaining sort of thing, which could take all night. Not good.

COMMITTEE MEMBER VENTURA: No.

VICE CHAIR DICKEY: Anymore discussion from the Committee?

COMMITTEE MEMBER SCHAEUBLE: If you're going to propose a flat amount, do you want to propose exactly $100 as a flat amount?

COMMITTEE MEMBER LANG: Dr. Azucar, would you think that would be sufficient for your purposes?

DR. AZUCAR: You know, I would push for $125. Again, wanting to compensate participants for equal burden, wanting to incentive folks to not just recruit, but show up to the focus groups.

And then, also, incentivize folks for discussing such a sensitive topic, right. They're teenagers talking about cannabis.

So, they should be incentivized for giving us that insight.

VICE CHAIR DICKEY: Any more discussion from the Committee? Can we go to the public?

COMMITTEE MEMBER VENTURA: Remind me of your funding source?

VICE CHAIR DICKEY: Any of the public?

MR. ZADROZNA: Yeah. Public, Nick Zadrozna. I do want to say, in today's society $125 is like a bag of groceries, maybe two bags of groceries. As well as I've done research studies in the past and the more money you're incentivized, you're going to be a lot more honest than just trying to get that survey done as soon as possible. That's all I wanted to mention.

DR. RYKACZEWSKA: Thank you. That is a public comment from the room.

And then, if there are any members of the public who are on the virtual Zoom, if you could please raise your virtual hand.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: Dr. Lang.

COMMITTEE MEMBER LANG: Motion to approve the amendments, conditional approval to change all of the compensation to $125 for all participating groups.

VICE CHAIR DICKEY: It doesn't have to be conditional.

COMMITTEE MEMBER LANG: Okay. Though I think the forms

need to be changed.

DR. AZUCAR: Yeah, I'll update all those materials and submit it.

VICE CHAIR DICKEY: We need to make sure it's not $175 on the forms, right.

(Laughter)

COMMITTEE MEMBER LANG: Well, right now they are different numbers, I think.

VICE CHAIR DICKEY: Do we have a second?

MS. KURTURAL: I'll second.

MS. ATIFEH: I think -- I think Dr. Dinis left the meeting.

DR. RYKACZEWSKA: Yes.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

DR. RYKACZEWSKA: Could you repeat that, Dr. Ruiz? It was a little difficult to hear you. Dr. Ruiz, could you repeat your response?

COMMITTEE MEMBER RUIZ: Approve.

DR. RYKACZEWSKA: Thank you.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Against.

MS. ATIFEH: Absent?

DR. RYKACZEWSKA: Against.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: So, I'm the --

MS. ATIFEH: Oh. We have four.

VICE CHAIR DICKEY: So, you've got four votes.

MS. ATIFEH: Four in favor.

VICE CHAIR DICKEY: Four in favor and how many do you need?

MS. ATIFEH: Six. Dr. Dinis left.

DR. RYKACZEWSKA: Because Dr. Dinis left. We still have a quorum.

VICE CHAIR DICKEY: No, we don't have sufficient quorum. Unless -- even if I vote, we don't have six votes, do we?

DR. RYKACZEWSKA: Well, a quorum is based off of the membership, not a main number.

But I don't believe we have sufficient votes to pass the motion.

MS. ATIFEH: Exactly.

VICE CHAIR DICKEY: Why did we have this discussion at all?

DR. RYKACZEWSKA: Well, we could have five votes for a --

VICE CHAIR DICKEY: We could if I vote.

DR. RYKACZEWSKA: Yes.

VICE CHAIR DICKEY: I suppose. So, I mean I would vote a yes, so that would give us four votes.

MS. ATIFEH: Five votes.

DR. RYKACZEWSKA: So, we do not have a tie.

VICE CHAIR DICKEY: Right. And I can only vote -- the only other circumstance I can vote is when it's needed for me to vote for a quorum.

MS. ATIFEH: That's right.

DR. RYKACZEWSKA: Let me pull up the policies and procedures and I'll tell you exactly which -- it should just be a majority.

VICE CHAIR DICKEY: It should be a majority of those present voting.

DR. RYKACZEWSKA: Let me just check.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: It doesn't have to be unanimous. So, it could be --

VICE CHAIR DICKEY: I think it's a majority of the votes of those present. And then, if it's a tie, that could let me vote.

DR. RYKACZEWSKA: Approve -- okay, our policies and procedures explicitly say approval of a motion requires yes votes

by a majority of the CPHS present in person or remotely, excluding the Chair.

VICE CHAIR DICKEY: Right. So, we have a majority of those present.

DR. RYKACZEWSKA: Majority. So, we currently have four.

MS. ATIFEH: Altogether we had seven. Without Dr. Dinis we have six and four of them voted in favor.

VICE CHAIR DICKEY: So, that's a majority of those present.

DR. RYKACZEWSKA: Yeah.

MS. ATIFEH: Okay, so the motion passed.

DR. RYKACZEWSKA: Apologize for needing to double check the language.

VICE CHAIR DICKEY: All right. Congratulations.

COMMITTEE MEMBER LANG: Thank you.

DR. AZUCAR: All right. Yeah. No, thank you. I always appreciate these discussions. So, yeah, I thank you the first time and for reviewing. And thank you, Dr. Lang, for your review of the amendment.

COMMITTEE MEMBER LANG: Yes.

VICE CHAIR DICKEY: Well, okay, we go onto the next one, which is another -- well, this -- the circumstances with this one is it's a project that we reviewed at the last meeting. Dr. Tefera

was the reviewer. And there was some designations, changes, conditional changes in the motion that was passed. And they -- according to Dr. Tefera, they satisfied -- he's satisfied with the changes they made, except two of them were not in the motion, not compliant with the motion.

So, because it's not compliant with the motion, they needed to come back to the Committee for approval. And Dr. Tefera is not here today. So, I -- they made me the reviewer.

And I forwarded -- I think Sussan's forwarded for us, yesterday, Dr. Tefera -- remarks that had been submitted to Dr. Tefera just giving the rationale for why they want to do what they want to do.

So, and it has to do with the -- how issues of race and ethnicity, and sexual identity are or not portrayed as sensitive topics.

And so, do we have the researchers available?

MS. ALLEN: Yes, the team is here.

VICE CHAIR DICKEY: Okay. So, I'm just trying summarize the situation. Why don't you go ahead and summarize it.

MS. ALLEN: Okay, thank you very much. My name is Jane Allen. Thank you all for being here to meet with us today about this issue.

I want to introduce the team. Kim Hayes is co-leading

this project with me.

Vaughn Armbrister, you will hear from Vaughn in a little bit because I'm going to ask Vaughn to add some detail, and talk about the rationale on the specific actions we've taken in response to your previous comments.

And Laurel Curry is here with us today. She's our expert in data collection and analysis.

So, that's the team.

I want to start by just adding to the great summary that you gave, Dr. Dickey. And thank you, Dr. Dickey, for your help this week in getting us organized for this meeting today.

We're also grateful to Dr. Tefera for his help earlier.

As you mentioned, Dr. Dickey, on April 24th we were before you. You had five issues that you asked us to address in regard to our research protocol.

We addressed the first four precisely as you had requested. And the fifth -- the fifth issue is we were asked to change the consenting document to include racial/ethnic identity and sexual identity and to describe them as sensitive topics.

So, we already update these consenting document accordingly. And we are glad to do so because we agree with your assessment because this will help protect youth.

When it came to adding the same language to the parent

consent documents, we became somewhat concerned that there might be an unintended, potentially harmful effect. And that it might reduce the likelihood that we can collect data we need with the same effect among LGBTQI+ youth.

And these youth are very -- it's very important for us to collect data among LGBTQI+ use because their cannabis rates are twice that of straight and cisgender youth. We're evaluating the campaign that you just heard, that Danny was discussing.

The second issue that we had is in describing the questions, the race/ethnicity and sexual identity questions as sensitive. In our view, describing those questions as sensitive implies that aspects of our identities or aspects of some people's identity are taboo, or uncomfortable, or shameful rather than simply being descriptors of natural human diversity.

So, that's just the headline about why we're back here with you today to talk about the approach that we would like to go forward with. And I'm going to turn it over to my colleague, Vaughn Armbrister, to walk you through the details. Vaughn.

MR. ARMBRISTER: Yeah, thank you, Jane. So, I'm going to speak to both points. I'll start with the first point and then we can pause if there's any discussion or reflection.

But essentially, our primary concern is youth protection and privacy. So, we're worried that if we include some of these

details in that parent permission form, you know, to explicitly state that youth will be asked about sexual orientation, you know, gender identity that some parents may not give youth the privacy that we would expect them to have while taking the survey.

And that's what we like to provide for all of our participants, right, some degree of privacy and confidentiality.

And this, you know, could create a situation in which a young person's responses are being monitored. They're kind of being pressured to maybe disclose in ways that feel uncomfortable and, again, potentially harmful. But also could result in inaccurate data.

So, our goal, ultimately, is to honor this Committee's intent to protect youth, while also minimizing that risk of unintended disclosure.

And we also just considered how the risk of that unintended disclosure may affect participation and response patterns. So, data from CDPH actually indicated that individuals who identify as LGBTQI+ report cannabis use at substantially higher rates.

So, this underscores the importance of us including this audience in this research.

But if you believe that their parents are, you know, aware of the identity questions being asked some may choose not to

participate or they may be less comfortable responding honestly.

And so, again, you know, this unintentionally could reduce participation, it could impact data quality among this audience which is especially important for us to reach. And we just don't want to reduce our ability to understand the campaign's impact and then reduce our ability to offer recommendations to our client.

So, what we've proposed is that we include additional information in the youth assent, only, to inform youth that we will ask these questions about their identity. So, you know, such as sexual orientation and gender identity. And this approach will give youth the information they need to make an informed decision and protect their privacy. And, ultimately, they can choose to participate. They can stop at any time or they can skip questions that they do not want to answer.

So, I'll pause there. I'm also happy to kind of read an excerpt from the consent, that language that we propose adding, if that's helpful.

VICE CHAIR DICKEY: Please do.

MR. ARMBRISTER: Okay. Sure. So, what we added into the youth consent is this, we say: "In this survey we will ask questions about substance use, school attendance, and how close you feel to the adult or adults you live with. We will also ask

questions about your identity, such as race, ethnicity, gender identity and sexual orientation."

So, that's specifically what we added there. I also want to note, quickly, that within the youth survey we've also added a brief sentence to kind of let them know why we are collecting this information. So, I can read that for you now, as well.

So, in that survey, this disclaimer we have is, it says: "Now we have a few questions about your identity. We want to make sure we're hearing from all kinds of people. Sharing your background helps us include a diverse range of voices."

So, that's a disclaimer within the survey.

So, I'll pause there, if there's any thoughts.

VICE CHAIR DICKEY: Well, this is dealing with the issue of sexual identity.

You'd also requested not to identify the race and ethnicity questions as sensitive because basically those questions are now required by state law, is that right?

MR. ARMBRISTER: Yes, state and federal recommendations. So, we expect more surveys across the board to begin to include the detailed categories that you all spoke to last time.

Would you like me to provide more rationale now or did you want to --

VICE CHAIR DICKEY: We could -- well, you can maybe take

them one at a time. Start with sexual identity and then we'll move on to the race and ethnicity.

I'd like to open it up to the Committee for questions on this.

Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Do you have on your surveys and consent documents any place for parents to be specifically instructed not to oversee what their child says in responding to the survey and to affirm that they are willing to let the child participate in the research without being observed by the parent. Do you have any place for the child to indicate that they were able to respond to questions without being observed by anyone else?

MR. ARMBRISTER: I'm going to look to my team to -- I don't have the documents in front of me and I can't recall off the top of my head. So, I just want to look to my team to see if they have that open, so we can confirm.

MS. ALLEN: I am looking at the document, now. It's clear that the study is for the child to take. I believe we ask them to allow the young person their privacy, but I don't have that language in front of me.

COMMITTEE MEMBER SCHAEUBLE: Well, you're raising concerns about, you know, people possibly disclosing information they would not want parents to see, basically a privacy concerns.

And it seems to me that that is not really impressed in what I could read of the documents that were in your protocol. Because what was said to us yesterday talked about one document being changed. When I tried to search for the protocol, I found not only that that document had not been sent to us, but that there were at least four documents that had been changed since this protocol was last seen by the Committee.

MS. ALLEN: Yes. If I could speak to that. This Committee asked us to make five types of changes. We have made four of those types of changes and many documents were involved. And so, that's why you saw numerous documents uploaded.

Those documents, we were able to edit precisely as you requested us to. So, we are not discussing those today. You can review that --

VICE CHAIR DICKEY: Right. If I can just insert, I asked Dr. Tefera specifically did he agree with the changes you had made, and he said he did.

MS. ALLEN: Yes.

VICE CHAIR DICKEY: So, and --

MS. ALLEN: And we could go over these if you want, but in the interest of time I think --

COMMITTEE MEMBER SCHAEUBLE: No, no. You were able to give the response of what I'm asking about.

You're raising concerns of privacy for the youth and what I'm saying is I think some of that concern is misplaced as far as it not being addressed within the documents that you currently have.

VICE CHAIR DICKEY: I agree. When you uploaded, it did not upload the new document, you know, regarding the -- I guess you'd call it consent or whatever.

I think you tried to last night but we hadn't released it so the thing could make a change in the system.

MS. HAYES: Yeah, and I just want to clarify. We did upload them. We incorrectly -- we included them in the incorrect section. So, they are in the, I think the study procedure section of the consent documents instead of the consent and assent.

So, they are in the application, they're just not as readily available as we would have liked.

MS. ALLEN: Thank you, Kim.

COMMITTEE MEMBER SCHAEUBLE: Well, I was looking in the study procedure section, so I'm assuming I saw what they are talking about as their most recent documents.

MS. ALLEN: Yes.

VICE CHAIR DICKEY: Well, do we --

MS. ALLEN: I'm not sure I understand --

VICE CHAIR DICKEY: Did the most recent document have

that language inserted that you just cited?

MR. ARMBRISTER: Yes.

MS. ALLEN: Yes.

VICE CHAIR DICKEY: Okay. Could we maybe just -- do you think, could we display that, maybe?

MS. ALLEN: Yeah, sure thing. Let me just get that up. I want to make sure I have the right document open, so please just give me one second. Okay.

So, this is the screener consent for youth. You'll see a number of edits throughout. Most of these are related to us reducing the reading level. We realized in our last conversation with you that the reading level was a little high. So, we want to bring that down.

But here is the language, in particular, that Vaughn has explained we added. And this is to help understand the kinds of questions we will be asking so that they can make sure they have a private, make sure they have a comfort level answering the questions in a certain setting, for example. Or, in fact, choosing not to answer, not to take the survey.

COMMITTEE MEMBER SCHAEUBLE: Could I point out, in looking at what you have on the screen now, that the sentence you added at the end of the highlighted box there: "We will ask questions about your identity" is located in that general

paragraph. It is not covered under the third bullet point where you bring up some of the questions that may be considered sensitive.

MS. ALLEN: Yes. That is the (indiscernible) of what we plan to do.

COMMITTEE MEMBER SCHAEUBLE: Could I please finish my sentence?

MS. ALLEN: I'm so sorry, sir, I'm not quite sure who is still speaking.

COMMITTEE MEMBER SCHAEUBLE: That's okay. So, you've added a sentence explaining questions that will be asked. You have chosen not to alert people that these may be considered sensitive questions.

MS. ALLEN: Correct.

COMMITTEE MEMBER SCHAEUBLE: That's a little different from what the approach while at the prior meeting had asked you to do.

MS. ALLEN: That's right. That's why we're here today.

Vaughn has not yet gotten to that -- of describing that issue. We thought you wanted to take the issues one at a time. But seeing as you are feeling that they're linked, perhaps this will be a good time for Vaughn to jump in and explain why we have not described race, or ethnicity, or sexual identity as sensitive

issues. Would that be a good time for this?

VICE CHAIR DICKEY: Well, I'd rather put off the race/ethnicity, if we could, because there's kind of an argument.

MS. ALLEN: Okay.

VICE CHAIR DICKEY: But I think the same principle would apply, right. I think, basically, you're stating that they should put something about those issues down under the third bullet, is that what you're saying?

COMMITTEE MEMBER SCHAEUBLE: Well, that's what they were asked to do at the prior meeting.

VICE CHAIR DICKEY: And this is only for the -- and this is only for the youth.

COMMITTEE MEMBER SCHAEUBLE: We're only looking at the youth form?

VICE CHAIR DICKEY: In the prior meeting it was asked to put that in all of them. And so, what they're saying is it's different than that.

COMMITTEE MEMBER SCHAEUBLE: As it turns out, they are indicating they don't want to do it in the other consent documents. And for the youth, they don't want to do it under the heading of sensitive information, they want to do it elsewhere.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER SCHAEUBLE: Can I ask, though, the

original question I asked when you were putting up the documents here was, was there a place where parents were asked to affirm that they're willing for their child to participate freely, without being -- without their responses being observed by the parent? And was there a place for the youth to affirm that they were able to respond without any other person observing what they were doing?

MS. ALLEN: We have an extensive parent permission form that over and over reiterates that it's the child who is being given permission to take the survey. And it talks about how we'll protect their privacy.

I do not know, at this moment if we -- what we have said to parents about giving their child their privacy. We can certainly add that. That is, I think --

VICE CHAIR DICKEY: Well, it's something we didn't ask you to add last time. Let me ask, is that relevant to these changes in wording or are you asking them to do something that we didn't ask them for last time?

COMMITTEE MEMBER SCHAEUBLE: I was asking about it because they -- the issue that they have raised is privacy concerns that they perceive youth might have. And I was wanting to see that those privacy concerns were being addressed by the way the project was --

VICE CHAIR DICKEY: And would that make a difference to

you in terms of not putting that in, that language on the parent form?

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. RYKACZEWSKA: And I just want to make sure I'm following. So, we had stated that they needed to include certain language on both the parent and consent -- and youth consent previously.

The researchers are now returning to us, raising concerns about privacy.

And so, what you are asking in terms of this information is what their -- the consent form has made clear expectations for the parents that as part of this participation there to have protected privacy to -- essentially, are parents aware that part of the expectation in the consenting is that they're going to give the youth their privacy.

COMMITTEE MEMBER SCHAEUBLE: Yes. So, we currently have -- sorry, my voice is cracking up.

DR. RYKACZEWSKA: Thanks, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: We've had past instances where the -- where the youth have been specifically asked, generally at the end of the survey, were you able to respond to the questions on the survey without anyone else being able to see your responses.

And we've certainly had parent permission consent forms saying I agree for my child to participate and I affirm I will not --

VICE CHAIR DICKEY: Okay. And look at the language up there, that they're displaying. Is that adequate?

COMMITTEE MEMBER SCHAEUBLE: That's fine as far as an instruction. It doesn't provide a place for the person to actually affirm that that's what's going on.

VICE CHAIR DICKEY: Even the child?

COMMITTEE MEMBER SCHAEUBLE: Well --

MS. ALLEN: We do have question -- I'm sorry. Something with the sound, I keep interrupting you.

COMMITTEE MEMBER SCHAEUBLE: What I was talking about would be more at the end of the form. The end of the consent form for the parent, what the parent is agreeing to. At the end of the consent form just say at that point, yes, my child can participation. And, yes, I will make sure that I will not --

VICE CHAIR DICKEY: And can we see what it says at the end of the form for parents?

MS. ALLEN: This is the end of the form.

DR. RYKACZEWSKA: Just a moment, it's still uploading up to the screen. Okay, there we are.

MS. ALLEN: Thank you.

COMMITTEE MEMBER VENTURA: Would it suffice to say plus one?

COMMITTEE MEMBER SCHAEUBLE: So, it would say, if item one said my child has my permission to take the survey and I will make sure that he or she can do it without anyone else observing.

COMMITTEE MEMBER VENTURA: Just in a private location, just to take the survey but --

VICE CHAIR DICKEY: I think it's implied since they've said that earlier on. Isn't it implied if they're agreeing that they're agreeing to everything above?

I mean, do we have to repeat everything that was above and below?

COMMITTEE MEMBER SCHAEUBLE: No, we certainly don't have to repeat everything above. But if we're concerned about the privacy of the --

VICE CHAIR DICKEY: But isn't that different from the issue that they're asking for now is -- how does it make a difference? I mean, we didn't ask that last time. Why are we asking it now?

COMMITTEE MEMBER SCHAEUBLE: I brought it up because they brought up as a rationale for the changes protecting the privacy of the youth in response to --

VICE CHAIR DICKEY: Well, I understand because they

identified that as the intent to do. But that doesn't negate what they have done before. I mean, it's in line with what they're proposing now. I mean, what they're proposing now is the reason we don't want to notify the parents about this is because we want to protect the child's privacy.

And they've previously said that they had the statement in there that basically the child's going to by themselves, so you can't hear. I think it's consistent with what they're asking for now.

COMMITTEE MEMBER SCHAEUBLE: I guess what I'm saying is that it seems to me it would provide extra protection for the youth if the parents were to indicate, when they are giving their permission for the child, to say, yes, it will be done in a private location.

VICE CHAIR DICKEY: But you're okay with them leaving that information off of the parent one, the language that --

COMMITTEE MEMBER SCHAEUBLE: Leaving it --

VICE CHAIR DICKEY: Leaving the information that you wanted previously about sensitive topics off of the parent form.

COMMITTEE MEMBER SCHAEUBLE: I think it could be left off of the parent form if we have the assurances from the parent and the child that they -- that the child has been able to respond with no observation by other people.

DR. RYKACZEWSKA: So, if I can make sure I'm following again. This is completely complicated, so I just want to make sure I'm tracking.

What I'm hearing is, Dr. Schaeuble, you would be okay with the parent form not including information. And right now, I'm just dealing with the sexual orientation issue.

COMMITTEE MEMBER SCHAEUBLE: Right.

DR. RYKACZEWSKA: Not including information that the survey asks questions about the sexual orientation. And given the privacy issues that were raised, adjusting this language at number one to include an assurance from the parent that they will allow the child to take the survey from a private location.

COMMITTEE MEMBER SCHAEUBLE: Yes. And I would add to that, preferably the end of the child's survey would have a checkbox for the child to be able to say, yes, I was able to answer these questions.

VICE CHAIR DICKEY: So, what would they -- what would you do with it if they clicked -- didn't check that box? Would you discard their responses?

MS. ALLEN: Yes. We already have that in our survey and that is our intention to discard responses that the youth says they were not alone when they did the survey.

VICE CHAIR DICKEY: Can you show us where you have that

in your survey?

MS. ALLEN: Yes, I'm on my way to get it right now.

VICE CHAIR DICKEY: Okay, great.

MS. KURTURAL: So, this is interesting because they can go all the way down to age 11, right, on the survey?

MR. ARMBRISTER: Thirteen.

MS. KURTURAL: Thirteen.

VICE CHAIR DICKEY: Thirteen.

COMMITTEE MEMBER SCHAEUBLE: That may have been a typo. There was one that said 11 --

DR. RYKACZEWSKA: You're right.

MS. KURTURAL: Okay.

MS. ALLEN: We have parents with children who are, but the 11 year olds.

COMMITTEE MEMBER VENTURA: No, it says we will obtain informed assent from youth ages 11 to 17.

VICE CHAIR DICKEY: It sounds like that's wrong.

MS. ALLEN: Yes, it should be 13.

VICE CHAIR DICKEY: So you need to correct that.

MS. ALLEN: Yeah.

MS. KURTURAL: Because it makes a difference because, at least with my thought process, because if they're 12 and older they have a lot more ability to just in general consent to certain

treatment, like substance abuse. And you're going to be asking about substance abuse.

COMMITTEE MEMBER LANG: Yeah, you have HIPAA and all of those other policies.

MS. KURTURAL: Yeah. And you wouldn't -- if it was 11 year olds going about it, it would cause that. And 13 to 17 --

VICE CHAIR DICKEY: So then, it's the language that's at the end of the child -- it's not exactly what you're asking for.

COMMITTEE MEMBER SCHAEUBLE: I guess I would think the item two there should say, I took the survey myself without anyone observing my answers.

VICE CHAIR DICKEY: Could it just be I took it myself in private?

COMMITTEE MEMBER SCHAEUBLE: Yeah, I guess.

MS. KURTURAL: That might help.

VICE CHAIR DICKEY: So, would it be okay for you to change that number two to say, I took the survey myself in private?

MS. ALLEN: Yes, absolutely. That's no problem. We're glad to do that.

COMMITTEE MEMBER SCHAEUBLE: And some of these don't understand the other words and --

VICE CHAIR DICKEY: To me it is but --

COMMITTEE MEMBER SCHAEUBLE: The words in whatever, what

are the words?

DR. RYKACZEWSKA: I would double check that it's eighth grade reading level at least.

COMMITTEE MEMBER VENTURA: Would that be -- your proposal was without others present?

VICE CHAIR DICKEY: It was without observing, I think.

COMMITTEE MEMBER SCHAEUBLE: Took the survey myself without anyone seeing my answers. That sounded more straight forward to me, but whatever, it's the Committee's choice.

VICE CHAIR DICKEY: Yeah, I think we're -- I think on the parent form it says that they will take it in an area where they are alone. I believe that's what it says.

So, anyway, that's why I was thinking in private was better, it's more consistent with what's on the parents' form.

But I think we're sort of playing with the words there.

But the other issue was them putting something at the end of the parent form that restates the issue that they are agreeing for the child to take -- or taking the survey and you want to put something that says that --

COMMITTEE MEMBER SCHAEUBLE: I think they already added some words from what we talked about a few moments ago.

DR. RYKACZEWSKA: If there's any further discussions, then I believe what we've talking about was adding in the parent

consent form not just that the child be able to participate, but some language that the parent will ensure that they can -- that the child can take the survey from a private location or something along those lines.

VICE CHAIR DICKEY: Yeah, would you be okay with adding "a private location" to that ending statement there?

MS. ALLEN: That's fine. I'm looking at my team. Everybody fine with that?

MR. ARMBRISTER: Sure.

VICE CHAIR DICKEY: Okay. So, and then we're dealing with where in the parent form the issues, sensitive issues are displayed. They're not under the third bullet, they're displayed higher up. Do you want them put under the third bullet?

COMMITTEE MEMBER SCHAEUBLE: No, that was the --

DR. RYKACZEWSKA: In the child.

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER SCHAEUBLE: That was in the child assent, not the parent.

VICE CHAIR DICKEY: The child, yes. I'm sorry.

So, are you okay with the location of it now in the child?

COMMITTEE MEMBER SCHAEUBLE: Can we see that page again, please?

MS. ALLEN: Sure thing.

DR. RYKACZEWSKA: And I believe the researchers have mentioned that they have additional information for why that location --

VICE CHAIR DICKEY: Yeah, we just need to hear what the rationale is.

DR. RYKACZEWSKA: -- was more appropriate. I just want to circle back to that, to give them that opportunity to express that.

VICE CHAIR DICKEY: Yeah. So, currently you have that at the end of the first paragraph. Is there a reason that it's preferable to have it there rather than under the third bullet?

MR. ARMBRISTER: To avoid classifying them as sensitive topics and be stigmatizing, potentially. Which will kind of speak to it a little. But this still ensures that the youth are informed of the topics. They can make a decision as to whether or not they're comfortable proceeding, or that information if they want to skip it, when they get to it, right. So, they still have that information to inform their decision to participate.

COMMITTEE MEMBER SCHAEUBLE: Two questions in that regard. When I looked at the -- what appeared to be the last provisions of the surveys, the main part of the survey said participants, parents or child, could refuse to answer any

question.

The screener part said there is no ability to skip a question in this section, which included some of the questions about racial identity and gender identity.

Is that the correct description of the situation? People have to answer all of the questions in the initial screening part and only have an option to decline in the --

VICE CHAIR DICKEY: I think that -- can we just stick to this and then we -- you know, you're raising a different issue. How about the way these things are displayed right now?

COMMITTEE MEMBER VENTURA: I think it's providing them the information, so --

VICE CHAIR DICKEY: The question is, is it adequately done that way?

COMMITTEE MEMBER VENTURA: Yeah, I think. I mean, the sentence in the paragraph, the last sentence in that paragraph tells them what kinds of questions will be asked. I don't think labeling it as sensitive -- I mean, anyway, they're being told what they're going to be asked about, so they can make the decision.

VICE CHAIR DICKEY: Anybody else have comments about that?

Do you agree, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Well, I would think some

youth would find those questions sensitive.

VICE CHAIR DICKEY: If they know -- if they are informed that then those questions may occur, aren't they going to know themselves whether it's sensitive or not? Do we have to tell them that it's sensitive?

COMMITTEE MEMBER SCHAEUBLE: So, where do we, somewhere on the -- somewhere in this document I'm sure the researchers are saying something about whether people have to answer a question or can skip a question.

VICE CHAIR DICKEY: That's a different issue.

COMMITTEE MEMBER SCHAEUBLE: If they're saying here, in this paragraph that we're looking at now, we're going to ask you questions about everything going from substance use through sexual orientation, it seems like we should be also saying in that same paragraph whether any of those questions are optional. I mean, it's more of -- what's needed here, I think, is more than just informing people the questions are going to be there, but do you have to answer them?

DR. RYKACZEWSKA: Can I just ask, is part of why these two things intertwined for you because if those are required and they can't opt out when the sensitivity increases, and they need to know that upfront.

COMMITTEE MEMBER SCHAEUBLE: Well, the sensitivity

increases for not, if they perceive them as sensitive and they have no option about whether to answer the question and we're not really disclosing the full information to the participant at that point.

VICE CHAIR DICKEY: So, can I ask the researchers, are those questions required?

MS. ALLEN: The only question that is required right now in our survey is race/ethnicity. And the reason we've required that question is so that we can ensure that we have racial balance in our sample. We know from experience that if we don't ensure racial balance, we'll basically have an all-white sample and we won't know the impact of the campaign among anyone except white youth. So, that is a required question.

If you insist upon it, we can make that question skippable. We have discussed it as a team. We would anticipate that many youth would then skip it and we would have a more white sample. We would be less able to tell the California Department of Public Health how their campaign worked among youth who are not white.

COMMITTEE MEMBER SCHAEUBLE: So, all of the gender identity and sexual orientation questions are optional?

MS. ALLEN: That's right.

COMMITTEE MEMBER SCHAEUBLE: Okay.

MS. ALLEN: And, of course, all of the questions are

optional.

MR. ARMBRISTER: And the survey is voluntary, so they can drop at any time.

MS. ALLEN: Exactly.

MS. HAYES: And just wanted to add that that's the reason we're including that list of the questions that we identified here, in that first paragraph. So, if they find those questions sensitive or don't want to answer them, they can choose not to participate in the study before they even get to that point, so --

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I'm satisfied with the language there.

VICE CHAIR DICKEY: Okay. And so, now let's move on to the race/ethnicity.

MR. ARMBRISTER: Sure.

VICE CHAIR DICKEY: Is there -- are people satisfied with the way that's being dealt with in terms of its 00

COMMITTEE MEMBER VENTURA: Not being identified as sensitive?

VICE CHAIR DICKEY: Not being identified as sensitive, yes. And the rationale, I guess, there is because it's virtually required. Is that right?

MR. ARMBRISTER: I can speak to that a little bit more to elaborate for the Committee. So, I mean, similarly with gender

identity and sexual orientation, we're also concerned that describing race and ethnicity as sensitive unintentionally contributes to stigma. We just don't want to frame aspects of someone's identity as problematic. These are just normal parts of being diverse humans and we want to honor that and respect that.

And California's intent with having these questions is to be inclusive, right. Like as a demographic standard we are being inclusive about our practices.

So, in the survey I also just wanted to note that when it's programmed -- it might be hard to tell as a Word document, but when it's programmed those detailed response option categories only display after someone selects one of the broader categories, such as Asian, or black, you know, those types of categories.

And this approach, it allows us to, again, collect that inclusive data. It aligns with state requirements, federal standards, but it also does not increase the survey length, and it helps us to control some of that participant burden.

So, this approach, we hope, just supports our respectful and thoughtful approach to measurements and also, you know, inadvertently doesn't contribute to stigma.

VICE CHAIR DICKEY: Okay. Does anybody have concerns or questions about that? Did somebody speak up?

COMMITTEE MEMBER LANG: I think Dr. Schaeuble.

VICE CHAIR DICKEY: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Well, the only thing I think I would say here is the notion of possibly stigmatizing people, it's a bit of a two-edge sword here in connection with the very fine distinctions of racial and ethnic categories.

On the one hand, people can very probably feel that they are part of an identity that is very meaningful to them and maybe different in ways that are not always recognized by other people. Which is obviously a very good thing.

On the other hand, if they were ever to be compromised and one has such very precise information about racial and ethnic identity, then in a society in which we're seeing people targeted for reasons that I never would have thought possible in prior years, that it's not such a good thing.

So, the possibility that somebody might think those questions are sensitive precisely because of the climate in which we live, may be a countervailing aspect to being very happy to say I am a person in category number 47, as opposed to only one of five or six categories that I might be asked otherwise to identify from.

And I would think that the way out of this, from my point of view, is for the consent document to clearly explain we are asking about -- we are asking very specific questions about racial and ethnic identity because, and we understand this is potentially

sensitive. We are not giving you a choice to skip such a question because it is essential to what we need for this research project. So that people understand okay, we're doing it, here's why we're doing it, here's why it's important to us. If, for any reason, you think that this would be a problem for you and, obviously, you can opt out of doing the research.

VICE CHAIR DICKEY: So, you're suggesting changes on the wording that are in the actual question where they collect that information?

COMMITTEE MEMBER SCHAEUBLE: No. No, in the consent.

VICE CHAIR DICKEY: In the consent. Well, I don't know why they identify it in the consent as sensitive. When they get to actually get asked in the question, then they're going to be saying, you know, you have to answer this question.

COMMITTEE MEMBER SCHAEUBLE: Well --

VICE CHAIR DICKEY: And then, this is why it's required. I can see putting something there. That's different from the whole sensitivity issue. It's like, you know, you have to answer this question because we need this information for the study. And, but I don't see how putting it -- identifying it as sensitive on the consent helps with that.

COMMITTEE MEMBER SCHAEUBLE: Well --

VICE CHAIR DICKEY: Unless you're going to put on the

consent that you're going to get a question about race/ethnicity and you're going to have to answer it.

COMMITTEE MEMBER SCHAEUBLE: I think -- I think that's what I was saying that the consent would logically say part of the -- one aspect of our research where we need to have information from you is very specifically about your racial and ethnic identity. We understand that this is sensitive information, but it is essential for the research.

And unlike --

COMMITTEE MEMBER VENTURA: I would argue that race and ethnicity is collected -- it's ubiquitous. It is asked in so many places, you know, it's not defined -- I mean, like if you're signing up for a store, you know, to get receipts kind of thing, they ask for demographics all the time. I don't know. I don't think it -- no, it's not defined as sensitive information.

MS. KURTURAL: It's not.

COMMITTEE MEMBER VENTURA: I mean, like --

MS. KURTURAL: It, no, it's not defined.

DR. RYKACZEWSKA: Could I also --

COMMITTEE MEMBER SCHAEUBLE: Would you willingly, if you were, say -- well, let's say Iranian for the moment, would you happily provide that specific piece of information rather than a more global category if you thought the data might possibly end up

in -- ever end up in somebody's hands who might be targeting Iranians?

MS. KURTURAL: I think it's cherry picking a little bit. And there's other ways that, you know, you can -- I think you don't have to -- it's not asking for a country of origin, right. Like it's asking for your basic ethnicity.

VICE CHAIR DICKEY: It's asking for your -- yeah.

MS. KURTURAL: So, you know, Hispanic people, or Iranian people could be Caucasian, right, or of eastern origin or something like that.

COMMITTEE MEMBER LANG: I'm sorry to interrupt. Would we lose quorum if I need a bathroom for a minute?

DR. RYKACZEWSKA: We would.

VICE CHAIR DICKEY: We would. We could do that, though.

COMMITTEE MEMBER LANG: Could we take a five minutes for recess?

DR. RYKACZEWSKA: We can.

VICE CHAIR DICKEY: Yes.

DR. RYKACZEWSKA: Well, let's probably -- we would need to leave very shortly.

COMMITTEE MEMBER LANG: Okay.

DR. RYKACZEWSKA: Yes, it would be -- what time is it? Yeah, I have another meeting.

COMMITTEE MEMBER LANG: Okay, let's finish this up then.

VICE CHAIR DICKEY: I wondered why you were jittering.

DR. RYKACZEWSKA: Could I also ask a clarifying question? You mentioned that the race/ethnicity question is required and the reasons why. Is the detailed categories required, as well, or is it just the parent category? Detailed as well. And I seem to remember there's a law that required CDPH to collect those categories as a state law.

MR. ARMBRISTER: That's correct, exactly as they're written.

DR. RYKACZEWSKA: Exactly as, okay.

VICE CHAIR DICKEY: So, it would be hard to classify them as sensitive if they're required.

COMMITTEE MEMBER SCHAEUBLE: Well, I -- I guess I would disagree that the fact that they're required doesn't really say anything about whether the questions are sensitive or not. I mean, we've gone from -- we're now up to close to 50 categories altogether in the way the questions are, now needing to be asked and that level of detail is just new for us to deal with, and new for respondents in these research projects to deal with.

They didn't have to disclose that kind of information in the past, when they were asked about their background.

DR. RYKACZEWSKA: And just to clarify, when I say

required, I think, well, the law requires that CDPH collect those exact categories any time they do any sort of data collection. Not just required due to the reasons stated by the research staff for the research.

I just want to -- I'm not saying that's what you were saying, I'm just wanting to clarify that aspect.

VICE CHAIR DICKEY: It's kind of more like being a pain in the ass than being sensitive. You know, I mean to have to ask that. But I think we're dancing on the head of a pin here.

Unfortunately, well, can we -- any other comments from the public -- I mean, from the Committee?

How about public comments?

DR. RYKACZEWSKA: If you are a member of the public and would like to make a comment, please raise your virtual hand. Acknowledging no members of the public in the room.

And there are no virtual hands raised.

VICE CHAIR DICKEY: Okay. I can't make the motion, but Dr. Lang can. And he needs to go to the bathroom so do it quickly.

COMMITTEE MEMBER LANG: Oh, I am without words. I would defer to one of my colleagues.

COMMITTEE MEMBER VENTURA: Okay. I'll make a motion for -- this is an amendment.

DR. RYKACZEWSKA: It is.

COMMITTEE MEMBER VENTURA: Oh, okay, yes it is. So, it is conditional approval based on the following conditions. I was tracking adding the --

VICE CHAIR DICKEY: So, I would separate them out by --

COMMITTEE MEMBER VENTURA: Okay. So, one, adding like the privacy language to the parental consent, saying that they just agree to allow their child to take the survey in private is one that I recall.

VICE CHAIR DICKEY: At the end, yeah.

COMMITTEE MEMBER VENTURA: At the end. That was point one, before they sign. So, add the privacy language.

VICE CHAIR DICKEY: So, then, the other would be where they're putting the --

DR. RYKACZEWSKA: Just stop there just a moment.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: At the end of the survey?

COMMITTEE MEMBER VENTURA: No, no, at the end of the consent add that.

VICE CHAIR DICKEY: The other is the proposed --

MS. ALLEN: It's the parent permission form, because the parent consent form is something different.

COMMITTEE MEMBER VENTURA: Oh, okay. Thank you. The other is the language around sexual -- well, separating -- or not

labeling -- hold on.

VICE CHAIR DICKEY: They language they proposed for sexual identity, race and ethnicity --

COMMITTEE MEMBER VENTURA: Okay. Is not, okay. So, just, yeah, I think -- I believe it's not labeling questions about sexual orientation or race and ethnicity as sensitive.

VICE CHAIR DICKEY: As sensitive.

COMMITTEE MEMBER SCHAEUBLE: Well, I think you can just say they have language they have proposed as a change.

VICE CHAIR DICKEY: But also adopting the language that they have proposed.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: And that's in that already.

COMMITTEE MEMBER VENTURA: That's fine, Agnieszka, keep that.

And the changes -- wait, I just lost it.

DR. RYKACZEWSKA: The youth survey into that final question, that language that indicates the youth took the survey while being --

COMMITTEE MEMBER SCHAEUBLE: Answered the questions without answers being observed by anyone else.

COMMITTEE MEMBER VENTURA: Adult, okay.

I think to the youth survey include language that they

took the survey without others present.

VICE CHAIR DICKEY: Well, it would be adding it to the existing language they have. Yeah, at the end.

MS. ALLEN: I think that Dr. Schaeuble suggested language that might work well for youth, which is without anyone seeing my answers. That might be better in case they are taking a survey in a laptop, in a room with someone else and no one was able to see their answers.

VICE CHAIR DICKEY: Okay. And then, another would be for them not to identify the sensitive issues.

COMMITTEE MEMBER VENTURA: Right, not let -- so, I thought --

VICE CHAIR DICKEY: On the -- so they don't --

COMMITTEE MEMBER VENTURA: So, not labeling questions about sexual orientation as sensitive on either, I guess.

VICE CHAIR DICKEY: On either the adult or the youth.

COMMITTEE MEMBER VENTURA: Adult or youth information --

VICE CHAIR DICKEY: Right, yeah.

COMMITTEE MEMBER VENTURA: -- what are we calling it?

DR. RYKACZEWSKA: Forms.

COMMITTEE MEMBER VENTURA: Forms, thank you.

DR. RYKACZEWSKA: I also have noted the correcting the typos about it indicates 13 to 17 year olds and not 11 to 17.

COMMITTEE MEMBER VENTURA: That's right, yeah. That was in the original protocol under assent procedures where the error included ages 11 to 17.

MS. ALLEN: Thank you.

MS. KURTURAL: Oh, yeah, sorry. Yeah.

VICE CHAIR DICKEY: Does that capture things for the research team?

MS. ALLEN: Absolutely. Yeah, I think is everyone --

MR. ARMBRISTER: Yes.

COMMITTEE MEMBER VENTURA: Oh, sorry, yes. She made that -- I'm asking, is it like one year, minimal --

VICE CHAIR DICKEY: Well, it would be moved one year, minimal risk.

COMMITTEE MEMBER VENTURA: Okay.

DR. RYKACZEWSKA: She made this motion, I wasn't sure, it would be last time.

VICE CHAIR DICKEY: Yeah. And, actually, I suppose the other motion might be to accept their changes on the four other items.

COMMITTEE MEMBER VENTURA: On the other four, okay.

VICE CHAIR DICKEY: Yeah. Which Dr. Tefera already reviewed.

COMMITTEE MEMBER VENTURA: Yeah, okay. And it was

approved by Dr. Tefera.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER VENTURA: Primary reviewer. Were reviewed, already reviewed and approved.

VICE CHAIR DICKEY: Yeah, those things had to do with language level, et cetera.

MS. ATIFEH: To be reviewed by?

VICE CHAIR DICKEY: Well, you know, to be reviewed by I guess me. I was going to say Dr. Tefera, but he wasn't here.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER LANG: Second.

(Laughter)

MS. ATIFEH: Okay. Ms. Kurtural?

MS. KURTURAL: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

VICE CHAIR DICKEY: Okay. So, you'll get a letter about this.

DR. RYKACZEWSKA: Can we have Sussan, for the record --

VICE CHAIR DICKEY: Oh, I'm sorry.

MS. ATIFEH: I need five. Let me --

VICE CHAIR DICKEY: It's a majority of those present.

MS. ATIFEH: Yes, the majority.

DR. RYKACZEWSKA: Okay, motion passed.

MS. ATIFEH: Yes.

VICE CHAIR DICKEY: Okay, moving quickly on. Items -- any questions regarding the Agenda Items G through M?

Any public comments on Items G through M?

DR. RYKACZEWSKA: If you're a member of the public, please raise your virtual hand. Acknowledging no members of the public in the room.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: Okay. Any comments on other items that were not on the agenda?

DR. RYKACZEWSKA: Again, if you're a member of the public, please raise your virtual hand. Acknowledging no members of the public in the room.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: And I am seeing no virtual hands.

VICE CHAIR DICKEY: All right. So, the next meeting is going to be August 7, 2026.

And I -- we are adjourning the meeting for the -- well, we're adjourning the meeting.

DR. RYKACZEWSKA: At 12:09 p.m. Thank you.

COMMITTEE MEMBER LANG: Thank you.

(Thereupon, the meeting was adjourned at 12:09 p.m.)

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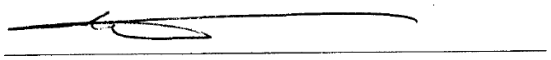

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