MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, OCTOBER 3, 2025

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AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Larry Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD

Maria Dinis, PhD, MSW

Jonni Johnson, PhD

David Lang, PhD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

Lemeneh Tefera, MD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Nicholas Zadrozna

Karima Muhammad

ALSO PRESENT

CalHHS

Liz Lott, Daughter of Late Former Commissioner Dr. Lois Lowe

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Consultant Present

Joshua Fedewa, Advarra Consulting

OTSI

David Haynes, Senior Attorney

ALSO PRESENT

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Amber Ivy, Social Finance, Inc.

Matthew La Rocque, Social Finance, Inc.

Sarah Osborn, Social Finance, Inc.

Rachel Vogel, University of Minnesota

Helen Parsons, University of Minnesota

Kimberly Berger, Sequoia Foundation

Hannah Wohl-Sanchez, Sequoia Foundation

Rosemary Castorina, California Department of Public Health (CDPH)

Danielle Oleskiewicz, California Department of Aging

Elon Ullman, CDPH

Sara Tepfer, CDPH

Kathleen Tebb, University of California, San Francisco

Katelyn Wiliford, Tulare County Office of Education/California Friday Night Live Partnership

ALSO PRESENT

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Emily Putnam-Hornstein, University of North Carolina (UNC), Chapel Hill

Regan Foust, University of Southern California (USC)

PUBLIC

None Present

I n d e x

P R O C E E D I N G S

VICE CHAIR DICKEY: This is the October 3, 2025, meeting of the Committee for the Protection of Human Subjects. I'm Dr. Larry Dickey, Chair.

If we could go around and --

DR. RYKACZEWSKA: Do a roll call?

VICE CHAIR DICKEY: Hmm?

DR. RYKACZEWSKA: Roll Call?

VICE CHAIR DICKEY: Do a roll call, yeah.

DR. RYKACZEWSKA: Okay.

MS. ATIFEH: Okay. I start with Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Good morning, everyone. Present.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Present.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Present.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, a quorum is established.

VICE CHAIR DICKEY: Okay, we have a quorum.

Since Dr. Hess is not able to be here today, I'll be chairing for today.

I thought we'd start out with some -- talking about some losses and some gains. And the biggest loss is Dr. Lois Lowe. Okay. And as you all know, she passed away last month.

She was a -- actually, we think she had been a member since 1986. I joined the Committee in 19-, I believe, -97. She had been here for 11 years already.

But for all of those years she was just an incredible member. She served as my vice chair when I was the chair from 2000 to 2010, and I got to know her very well as a Committee member.

And she was just so thorough in her work, and so comprehensive, and was both an advocate for the public, and

subjects, and for the researchers.

There are a lot of graduate students who were mentored by her as she came through trying to get their projects approved. And she always put out a lot of extra effort to help new researchers.

But she was very meticulous. I can remember, in those days we did everything by paper. And we would have -- and our meetings were a lot longer. We may have a paper this high, almost. And she was a small woman, and she would come with a cart, with this paper, and stack it all up and organized. And she had pretty much read it all. I mean, you know, that was who she was, she was just very meticulous.

And she was actually an alternate member up until the day of her death. So.

She's -- there's going to be a memorial service, I think it's October 17th. You'll see this on the left side. Maybe go down a little further, it talks about the memorial service. October 17th. And I plan to go to that, representing the Committee.

And I think, Agnieszka, you're planning to send some flowers to the family?

DR. RYKACZEWSKA: That's correct.

VICE CHAIR DICKEY: If anybody wants to contribute to the flowers. And Agnieszka's brought some cards that are on the table

back there, for people to sign, if they want.

And, you know, we'll get them to the family. I plan to go, like I said.

So, with that, I thought I would open it up to the rest of the Committee. I know a number of you knew her actually, personally, better than I did. So, if there's anything anybody would like to say.

COMMITTEE MEMBER DINIS: There's so much I could say. You know, I knew Lois since I think 1988, '87, '88, so for a very long time. And I worked with her in the State Alcohol Program. She was my mentor, but not in terms of this Committee -- eventually for this Committee, but before that as a graduate student at Berkeley and throughout my life. But she was more like a second mother to me, so I can't even -- I can't even talk about it right now.

I was shocked because I had talked to her, you know, a week before and what's astonishing to me is, you know, I didn't even know she had a hernia. That day I called her, and I said, you know, Kelly's in surgery in L.A. having, repairing a hernia, umbilical hernia. And the very next Friday, you know, Lois died. I mean it was just amazing. It was something that might have been able to be taken care of if she had good doctors, but this is where medicine is in the United States these days.

So, that's a great disappointment to me because she was in otherwise, you know, pretty good health. And so, I'm very, very upset about it.

And anyway, I know Liz is here. And it's kind of interesting, Liz, as you get older you start looking more like her. So, I'm just seeing a mini Lois out here. It's kind of really lovely, actually.

But, yeah, she is going to be greatly missed in more ways that I can say and it's just a great loss to me, personally, and to us.

The Committee is another matter. She mentored so many people and was here for so many of us throughout the years. Already, when I met her, in our college program, she was talking about this Committee, and she used to go to Berkeley. Because the Committee, in the old days, they used to go to Berkeley and then go between Berkeley and Sacramento.

So, this has been a very difficult loss for me this summer. Thank you.

VICE CHAIR DICKEY: Liz, many we should acknowledge you. I actually -- you want to introduce yourself?

MS. LOTT: I'm Liz, Lois's daughter of almost 70 years.

VICE CHAIR DICKEY: Right. Okay, well, Liz, thank you for sharing your mother with us.

MS. LOTT: Oh, you're so welcome.

COMMITTEE MEMBER DINIS: Liz, are her animals -- what is happening to her animals? Can you tell us? I think everybody on the Committee knew about her love of the animals.

MS. LOTT: The 50 chickens all went to one farm, a 10-acre farm, and people who will be really, really great. They wanted the sheep, but we had promised someone else the sheep, but that person's not getting back to us. So, we're now looking for homes for the sheep.

She's got some barn kitties and she's got some indoor kitties, which we're still trying to find some homes for as well. And then just, you know, continuing to work on her farm and her home, and dealing with that.

COMMITTEE MEMBER PALACIO: I'd like to share a little bit about Lois. I first got to meet her as a graduate student working on my doctorate, when this Committee had to go through my project.

VICE CHAIR DICKEY: So, you were one of the ones I'm talking about.

COMMITTEE MEMBER PALACIO: I am a living proof of what you talked about. And needless to say, I was able to successfully get through this Committee. And she ended up becoming a member of my dissertation committee when someone dropped out.

So, of the three people who were on my committee when I

defended, she is the only person that I kept in touch with because she subsequently mentored me on this Committee and throughout the rest of her -- up to her passing. So, I was very close to her.

And I visited with her, along John, the day before she died. So, we were there at her bedside and were able to say a prayer with her.

So, I'm grateful for Liz for sharing her mother with us and for her always being there for all of us and giving us an example of how somebody who has been blessed with so much can give to others so that they, too, can pass it on. Thank you very much.

VICE CHAIR DICKEY: Okay. Well, I, once again, thank you, Liz, and thanks for everybody who -- you know, for your remarks.

We've had another loss, not as anywhere near as significant, but still a loss. Carrie Kurtural has resigned from the Committee for personal reasons. So, this will be the first time I think in maybe the whole time I've been on the Committee that there hasn't been a lawyer on the Committee.

But we do have some gains. And I'll turn this over to Agnieszka.

DR. RYKACZEWSKA: Thank you. So, first of all, thank you everyone for sharing your memories of Dr. Lowe. And thank you, also, to Ms. Kurtural for her service.

So, at our last meeting Dr. Hess shared an update that after an extensive recruitment process the secretary appointed two new members to the Committee for the Protection of Human Subjects.

And today we will complete the final step of the process by formally swearing in Dr. Lang and Dr. Tefera as full board members.

So, with that, we're going to go over to the flags. I apologize if the video will not follow us there. But I promise you we're standing in front of the flag of California and the United States.

And Dr. Lang, Dr. Tefera. So, this is the oath for the office of full board member for the Committee for the Protection of Human Subjects. Please repeat after me.

(Whereupon Dr. Lang and Dr. Tefera are
administered their oaths of office by
Dr. Agnieszka Rykaczewska)

DR. RYKACZEWSKA: Congratulations. Welcome to the Committee.

COMMITTEE MEMBER LANG: Thank you.

COMMITTEE MEMBER TEFERA: Thank you.

(Applause)

VICE CHAIR DICKEY: Now you have to pledge allegiance to the Federal Common Rule and the Information Practices Act.

(Laughter)

DR. RYKACZEWSKA: Thank you so much for joining our Committee.

VICE CHAIR DICKEY: Do we have some material about their backgrounds, right, in the --

DR. RYKACZEWSKA: I do have some materials on their backgrounds, but maybe I can give it over to them to introduce themselves.

COMMITTEE MEMBER LANG: Happily. My name is David Lang. I currently act as Research Manager for Cradle to Career California, the state's longitudinal data system.

My training is as an economist. I did my PhD in the economics of education at Stanford. And previously worked as a researcher at the Federal Reserve Bank of San Francisco.

Thank you very much. And I very much am looking forward to serving on the Committee.

DR. RYKACZEWSKA: Thank you, Dr. Lang.

Dr. Tefera.

COMMITTEE MEMBER TEFERA: Sure. My name Lemeneh Tefera. I am the Chief Medical Officer and Deputy Director for Clinical Innovation at the Department of Health Care Access and Information, which sits in the California Health and Human Services Agency. I'm also a practicing emergency medicine physician.

And I'm pleased to join the Committee and supporting research throughout California and the United States. It's a pleasure to be here.

DR. RYKACZEWSKA: Thank you, Dr. Tefera.

VICE CHAIR DICKEY: Welcome. I'm happy to have another physician, particularly an emergency room physician here. We actually had a chair who actually died at one of the meetings many years ago, he had a heart attack.

COMMITTEE MEMBER TEFERA: Good to know.

VICE CHAIR DICKEY: So, be ready.

(Laughter)

DR. RYKACZEWSKA: We will be avoiding those situations moving forward, please.

I have one more introduction to make. I believe David Haynes, are you online? Just double checking.

MR. HAYNES: Yes.

DR. RYKACZEWSKA: Hi, David.

COMMITTEE MEMBER HESS: Hi.

DR. RYKACZEWSKA: I wanted to give a quick introduction to David. He is a Senior Attorney at OTSI. And as part of our transition into the OTSI space he has started working with Maggie to help support the Committee. And so, we wanted to make sure that you had a chance to meet him, to see him so that you would not be

surprised if you see his name, or if he reaches out to you.

David, is there anything you'd like to share.

MR. HAYNES: Yeah, I just wanted to just quickly say hello. As Agnieszka said, that I work at OTSI and since CDII has come under our small umbrella of CalHHS, Office of Technology and Solutions Integration, I've been coming up to speed on just everything about CPHS and, you know, what is gone, and just all the issues that are facing the Committee.
Along with all related issues that kind of come out from that.

So, anyway, I just wanted to come on and say hello. And along with our Chief Counsel, Mark Owens, who I don't think will be able to come today. Yeah, so if you see my name, as Agnieszka said, you know, that's who I am. Thank you.

DR. RYKACZEWSKA: Thank you.

Okay, so that is, I believe, it for introductions for today.

I have one more administrative item. So, at our last meeting we also discussed the launch of an initiative to conduct a review of our CPHS policies and procedures to ensure they're up to date with any regulatory changes and reflect best practices.

We also introduced the Advarra Consulting team, who is support us in these efforts.

So, since then the team has been very busy reviewing our

policies and procedures documents, other supporting documents, and interviewing the chair and the staff.

The next step is to speak to all of our board members. So, you should be hearing from them soon to schedule an interview, if you haven't already. They're really hoping to gather your perspectives and experiences.

And then, additionally, we'd also like to learn from our researcher community about your experiences with CPHS. And so, to this end we're going to drop an email in the chat. But we'd ask you or I'd like to invite you to reach out to Joshua Fedewa, from Advarra, if you would like to participate in an interview.

Now, while we can't guarantee that we'll be able to interview everyone interested, we are seeking to have multiple interviews to gather diverse perspectives and experiences. And your insights really are very important towards helping us learn and improve. And so, we're hoping that you would be willing to reach out to Joshua to participate in these interviews.

Joshua, I see that you're online. Is there anything else you would like to add?

MR. FEDEWA: No. Thank you so much. I'm looking forward to talking with all the board members and any researchers who happen to reach out to us.

DR. RYKACZEWSKA: All right. Well, thank you so much.

And I believe that closes out my Agenda Item B, unless there's any public comments.

If you would like to make public comment, there's no members of the public in the room, but for those attending virtually, if you could please raise your virtual hands.

I am not seeing any virtual hands raised. I do believe we can close out this item.

VICE CHAIR DICKEY: Okay. I guess the next item is approval of the August 1, 2025, meeting minutes. And so, I'll open it up for any comments from the board, first, any additional comments on those meeting minutes.

Okay, if not, I'll open it up to the public, any comments. Okay --

DR. RYKACZEWSKA: If you have any public comment and are attending virtually, please raise your virtual hands now. Acknowledging there are no members of the public in the room. And I am not seeing any virtual hands.

VICE CHAIR DICKEY: Okay, we need somebody to make a motion to adopt them because I can't make motions.

COMMITTEE MEMBER JOHNSON: I will make a motion to approve the meeting minutes from August.

COMMITTEE MEMBER VENTURA: And I'll second.

MS. ATIFEH: I start with Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Abstain.

MS. ATIFEH: Abstain.

Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Abstain.

MS. ATIFEH: Okay, the motion passes.

VICE CHAIR DICKEY: Okay. This is usually the portion of the agenda where we talk about adverse events or unanticipated events, but we don't have any to talk about at this time. Thank goodness.

So, we'll move on to our full Committee review of projects. Some of these are new projects, some of them are

amendments. And the first one we're going to start with is an amendment, Evaluation of Committee Response Initiative to Strengthen Emergency Systems Act Grant Pilot Program.

And Dr. Johnson is the reviewer. And so, we have the researcher there? Could the researchers identify yourselves?

MS. IVY: Good morning. My name is Amber Ivy. I'm one of the researchers at Social Finance.

And I'll turn it over to my colleague, Matthew.

MR. LA ROCQUE: Good morning, Matthew La Rocque, also with Social Finance serving as a researcher on this project.

And we also have Sarah here with us.

MS. OSBORN: Hi everyone, I'm also a researcher on this project. Thanks for having us.

VICE CHAIR DICKEY: Dr. Johnson.

COMMITTEE MEMBER JOHNSON: I'll take it away.

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER JOHNSON: So, in August we looked at this amendment, which was a proposal to add a Spanish version of the survey that they were administering to people in their project, and also the addition of a more formal interview.

So, we looked at the recruitment materials, and the consenting materials, and the research team's proposal for how they would analyze the interview transcripts.

There were two issues, I think, that the Committee had concerns about, that the research team was asked to go back and discuss amongst themselves. So, at the time we had tabled a decision in August on whether to approve the study or not.

So, since then the -- Dr. Ruiz did approve the Spanish version of the survey for the participants. The team, in interim, has also submitted a Chinese version of the survey, which we did not have a person on CPHS staff to verify. But the credentials supplied by their translators look appropriate. So, I don't have issue with the Chinese version of the consent -- or, for the consent or the survey that they are proposing to add.

The main things that I had concerns about previously were since they are going to be discussing traumatic events during the interview, giving participants enough time to read through the consenting material, and getting a preview of the questions that they're going to be asked during the interview do help inform their decision if they wanted to participate.

So, the research team has modified their consenting procedure that they will give people preview of the questions that they'll receive and also will have time to go through the consenting procedure.

And then they will, at the beginning of their interviews, confirm that they are agreeing to consent, remind them that they

can skip questions, and also withdraw from the study at any time.

They also clarified that they will be off camera during -- they do intend to still record, and this will occur during or via MS Teams, Microsoft Teams.

And then, the other main concern that the Committee flagged -- so, I will say that for the consenting procedure I feel satisfied with the modifications that the team has submitted with how they're giving people enough time to think about the questions, and they are fully informed of what they're going to be asked to discuss to make a decision if they want to continue participation.

And the other issue for the Committee last time was the use of a cloud-based software called Dovetail, which was not HIPAA compliant software.

The research team has changed the software that they are going to be using. They are now proposing to use the software Dedoose, which is a HIPAA compliant data analysis platform. I wrote this down because it was -- it utilizes multiple data security techniques to ensure that third-party data is stored securely. There is an audit trail. And it has requirements that meet HIPAA requirements for privacy, security and breach notifications.

Mr. La Rocque, is there anything additional that you'd like to add about the use of Dedoose? I know this was like a major

sticking point for the Committee last time.

MR. LA ROCQUE: Yes, thank you, Dr. Johnson. I believe you've -- oh, I think I'm getting feedback from another individual. Okay.

Thank you, Dr. Johnson. I believe you summarized a lot of the issues quite well. I'll just add a few additional points.

As a reminder, our goal is to speak with approximately 24 individuals who have received emergency response services. As Dr. Johnson explained, there is an informed consent process that happens in advance. With clients' permission, during the interview we will record and take a transcript of the conversation. And so, the question then becomes how are we handling this data.

And in response to the Committee's questions and concerns at the last meeting, we have chosen Dedoose for its HIPAA compliance and security features. I can just summarize a few of those now, in terms of what we'll be able to do from a data handling perspective.

Dedoose provides several security protections, including customizable user permissions to ensure that only three members of our team who need access to our project data will be able to gain access. And we have the ability to immediately revoke access if and when a team member leaves the project.

We'll have detailed activity logs that allows our team to

monitor who is accessing the data and when. This is (indiscernible), they do regular security audits and risk assessments to identify weaknesses, as well as the ability to promptly notify project managers in the event that there's an unintended data breach.

We have the ability to delete interview transcripts from the Dedoose system at any time. And as noted in our application, we plan to delete all transcript data when the research project is complete.

Finally, we also have written assurances from Dedoose that they will never sell, share or trade our actual interview transcript data with any third parties, including any AI training services, nor will they use it for any of their own purposes. It's our data and we have control over it.

With that, happy to take any other questions the Committee might have.

COMMITTEE MEMBER JOHNSON: I did not have additional questions beyond that. I'll open it up, though, to the Committee if there are follow up.

All right.

VICE CHAIR DICKEY: Should we open it for the public comment?

DR. RYKACZEWSKA: If members of the public have any

comments on this amendment, please raise your virtual hand, given there are no members of the public in the room.

I am not seeing any virtual hands.

COMMITTEE MEMBER JOHNSON: Do I need to go by each of the approvals or just that we're approving. I make a motion --

VICE CHAIR DICKEY: You just make a motion to approve the amendment.

COMMITTEE MEMBER JOHNSON: I make a motion to approve the amendment.

VICE CHAIR DICKEY: All right.

MS. ATIFEH: Complete approval. Complete approval, right?

COMMITTEE MEMBER JOHNSON: Yes, they completed on it.

VICE CHAIR DICKEY: Is there a second?

COMMITTEE MEMBER VENTURA: I second.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: The motion passed.

COMMITTEE MEMBER JOHNSON: Okay.

VICE CHAIR DICKEY: So, you'll be getting a letter from the Committee about the approval. What, in about a week or so?

MS. ATIFEH: Two.

VICE CHAIR DICKEY: Two weeks.

MS. ATIFEH: Yes.

VICE CHAIR DICKEY: Thank you.

MR. LA ROCQUE: Many thanks to the Committee and to Dr. Johnson for all your support, appreciate it.

MS. IVY: Yes, thank you so much.

COMMITTEE MEMBER JOHNSON: Good luck.

VICE CHAIR DICKEY: Now, we move on to the new projects. This is actually more new projects than we've had in a long time. And the next project is Understanding the Experience of Ovarian

Cancer, the Life After Diagnosis Study. And Dr. Azizian is the reviewer. And Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: Good morning, everyone. I guess I'll start by welcoming Dr. Vogel and her colleagues, or key members, or maybe one of them who's present this morning. This is the first time that they're presenting to this Committee. I had the opportunity to already exchange some emails, so it's nice to see you in person.

But what I would like to do is first to invite you to provide an overview of the project, maybe with the broad goals, and then focus on protection of human subjects, the participants.

I think it would be of specific interest to the Committee to hear a little bit more about the recruitment process, as well as all that. So, please feel free to present an overview.

DR. VOGEL: Excellent. And, actually, before -- I'll give the overview and before I introduce myself, I'll let Helen introduce herself.

DR. PARSONS: Good morning, everyone. I'm Helen Parsons. I'm a faculty at the University of Minnesota and a researcher on the project.

DR. VOGEL: Good morning. I'm Rachel Vogel. I am an Associate Professor at the University of Minnesota and Co-PI on this project with Dr. Parsons. We have no conflicts to report.

This project is funded and in partnership with the CDC. So, I think that's important to know that this is a U funded project, so it's in collaboration with scientists at the CDC.

The objective of this project is to assess the unmet needs of individuals diagnosed with ovarian cancer, focused on describing the long-term physical and emotional concerns, and identifying barriers and facilitators for receiving supportive care.

So, the overall design is a mixed methods approach. So, using a cross-sectional survey and then follow up interviews among a subset of those participants.

This is population-based recruitment of individuals diagnosed with ovarian cancer in California. We're specifically looking for individuals diagnosed with ovarian primary (indiscernible) or fallopian tube cancer, they're all lumped together under this diagnosis of ovarian cancer, who were adults 18 and over at the time of their diagnosis. And diagnosed between 2014 and 2025.

Additionally, they need to be able to read or write in English or Spanish.

And for this study we will recruit individuals known to be alive in the registry.

So, our goal is to survey about 2,000 participants

through the California Cancer Registry. We expect that through this timeframe about 25,000 individuals in the state will have been diagnosed with ovarian cancer, of whom about 8 to 10 thousand should still be alive.

And so, our request from the California Cancer Registry would be data on all of those 25,000 individuals where -- so we would be able to compare, understand who had died before being able to participate in our study. And then, among those who are known to be alive contact information so that we can work with them for the survey, demographics and cancer characteristics.

Just, I guess, one note is that we inadvertently left name and telephone variables off our initial request. We included address, but we do intend to request those data.

And then, our approach then is among those about 8 to 10 thousand participants, we will randomly sample 5,000 of them to do a mailing. And we will be over sampling individuals near time of diagnosis or closer to time of diagnosis. So, you know, diagnosed in the last couple of years.

American Indian or Alaskan Natives, non-Hispanic black, or living in rural areas.

And we are requesting the full datasets because we want to understand potential selection bias and response biases. And that will also help us to have those characteristics so that we're

able to over sample.

And so, I'll get into the actual recruitment details in just a minute. But I do think it's important to share with you that this survey was co-developed with ovarian cancer survivors, and advocates, and we've done extensive pilot testing.

It's a comprehensive survey, it's long. It's about 30 to 45 minutes to complete. And that really was in partnership with our advocates. They really felt there are a lot of areas that have been understudied in this population and so there's a lot of things they want us to ask about.

The survey will be available both online, in REDCap, and paper. And again, all study materials will be available in English and Spanish.

So, for the recruitment, we're following a modified fill-in method. And then, the entire process will be conducted by our research team at the University of Minnesota. We will assign study IDs to all individuals and then we will mail introductory letters, including the purpose of the study, including (indiscernible) for everybody. Include the California Cancer Registry brochures and then also an information sheet about emotional health resources available in California.

We will use this -- I guess, so this letter will provide a link for completing the survey online. We plan to include, or

there is already, part of this survey is a built-in consent and HIPAA document. And they will be requested to enter their study ID at the time of starting the survey. And then, there's also information for how to contact the study coordinator, both telephone and email, if they have any questions.

After the initial letter, one week later we'll send them a thank you card to everybody, with an additional reminder to complete the survey, if they have not.

Three weeks after the initial letter we'll send a follow-up letter to everybody who has not responded. And that will include a paper copy of the survey, and paper copies of the consent and HIPAA form.

And then, following, two weeks after that we will do one final letter to non-responders.

All of the survey participants then we -- we do not have sufficient funds to provide compensation to everybody, and so their (indiscernible) will be entered into a lottery for a $200 gift card. And the weekly winners will be randomly selected among all participants who completed the survey that week.

And then, finally, among participants who agree to be contacted for a follow-up interview, we'll select up to 40 of them to complete a 30- to 45-minute interview with our study staff. These interviews will be conducted through Zoom, or phone, and

digitally recorded. Verbal consent will be obtained prior to starting the interview.

These participants will be compensated a $50 gift card. And the recordings will be captured via Zoom and initially transcribed using its AI companion, and then manually reviewed and corrected by the research staff.

Phone interviews will be manually transcribed verbatim by our research staff.

And then, I want to note for the informed consent we are providing informed consent and HIPAA information to all participants. However, we request a waiver of documentation of written consent because a signed consent form would actually be the only link between participants in the research survey and interview data.

And so, we want to minimize the risk of harm resulting from a breach of confidentiality. And the waiver would allow all identifying identification to remain completely separate from the research data.

And, finally, we identified two primary risks for participants. The first being a risk of confidentiality. Obviously, we will do everything we can to minimize that. All of our staff are fully trained in data security. But we also wanted to acknowledge that that is a possibility.

We are also minimizing that by the use of the study ID, so that the data from the California Cancer Registry will be kept in a totally secure, separate data shelter monitored by the -- or managed by the University of Minnesota.

And then, in all of our environments, including REDCap and Box, are PHI compliant.

And then, finally, the other primary risk is discomfort with the survey questions. And so, some of the participants may be uncomfortable with some of the questions that we ask. In particular, we ask about sexual health, for example. And we make it clear that those questions -- we include some of those questions in the consent form, so that they're aware that they're coming. And we also make it very clear in multiple places that they don't have to answer any questions that they don't want to.

And for those reasons, that's also the reason our local IRB, the University of Minnesota IRB, requested that we include that information sheet with the resources available in California.

And so, with that, I guess we'll take any questions.

COMMITTEE MEMBER AZIZIAN: Thank you very much, Dr. Vogel for your introduction. And I'm sorry, Dr. Parsons, I forgot to acknowledge you. My screen was muted, and I saw you later on. Good to meet you as well.

I guess, you know, just to break things down, because

although your proposal has this clearly spelled out, it took me a few attempts because of the complexity of the design. And I think it would be helpful to just go over some of the overarching aspects of this, so Committee members are familiar and then they can ask more specific questions.

Broadly, you're asking data from the registry for about 25,000 patients who are registered there. And the variables that you have listed on there, which is about also 150, you will be obtaining all that information from the registry for about 25,000 people, correct?

DR. VOGEL: Yes, with the exception of the contacts. We don't need the contact information for those who are known to have already died.

COMMITTEE MEMBER AZIZIAN: I see. And then, from that point on somehow randomly you will be selecting about 5,000 people. And then, there would be a survey that would be sent to this 5,000 people. Now, that survey has a fair number of questions in there about their experiences.

And at that point you're providing them with a consent form, but you're not required to sign, with the exception of there's two screening guides in there and you'll decide whether you'll be using the data or not. Is that correct?

DR. VOGEL: So, they are -- you know, we feel pretty

confident that if they're identified and included in the California Cancer Registry that they're eligible for a study. But we do also have them confirm that. And so, there's two places that they can check, yes, I'm an adult, yes, I was diagnosed with ovarian cancer.

And it does say in there, you know, if you're not eligible, don't return this. Or, let us know and we won't contact you again.

COMMITTEE MEMBER AZIZIAN: Understood. And you're anticipating about -- I'm sorry, 2,000 people out of those 5,000 people that they have been invited to complete the survey, they'll be completing the survey.

DR. VOGEL: Yes. So, I mean, historically, we -- you know, cancer survivors are really good participants and they typically -- you know, we used to see response rates of 40 or up to 60 percent. It's a little hard to known in this environment what we will expect, but we're hoping 40 percent, yes.

COMMITTEE MEMBER AZIZIAN: Okay, yes. And then, from that you will have 40 people or so that will be participating in this more qualitative type of interview.

DR. VOGEL: Correct. And they have to opt in to that. So, there is a separate form from the survey where they will let us -- they would provide us with their information if they wanted to be included in the lottery. And then, they would let us know if

they would be interested in participating in the interview.

COMMITTEE MEMBER AZIZIAN: And I guess I'll ask one more question and then open it up for Committee members to weigh in.

What stood out for me is the process of consent. And I have to go back and forth on this that what it's like, half you're providing them with a document of nine pages about various aspects of it, minimal risks, and all the different aspects of data they can (indiscernible).

But the reasoning that you're not -- you're not documenting or getting a signed consent form is because that this may somehow compromise confidentiality. So, they're providing them -- you're providing them with a consent form, but they're not signing it. And the reasoning for that is this would minimize any type of a breach or something?

DR. VOGEL: Yes. And I will say that this team, from actually our community advocates, it was they were the ones that requested if we can do this, please do it. Primarily because they were concerned about people being to participate in the current political environment.

And so, it was requested by our community advocates that we try to do this.

COMMITTEE MEMBER AZIZIAN: I see. And I guess my thinking on this, because I have to be honest, look into this more

carefully in terms of various state regulations, federal regulations. But it seems like under Common Rule and other federal regulation, the notion of documented and signed consent it's specified in there.

And did you think about this or did anyone brought this up that this is actually a requirement under various regulations? Or, no one has brought this up so far from your own university.

DR. VOGEL: So, I mean, we had an extensive conversation with our IRB --

COMMITTEE MEMBER AZIZIAN: Yeah.

DR. VOGEL: -- about this topic. And they decided that it was okay for us to not document consent in this situation because the risks of consenting were greater. It was really our biggest risk, actually. You know, our biggest is risk of breach of confidentiality and this is a way for us to reduce that.

COMMITTEE MEMBER AZIZIAN: May I ask Committee members, a few follow-up questions that I have as well, but I think this is a time period for people if they seek clarification or any comments.

COMMITTEE MEMBER AZIZIAN: Yeah, go ahead.

DR. RYKACZEWSKA: Oh, Ms. Lund, we can't hear you.

COMMITTEE MEMBER LUND: Okay, now you can.

DR. RYKACZEWSKA: Yes.

COMMITTEE MEMBER LUND: I'm back. So, thank you for that

explanation. I wanted to -- I have several comments. First, I wanted to circle back to the consent form. I'm concerned about this consent form. I, personally, found it confusing and I want to talk through some of the ways that I had concerns about it.

First, you have HIPAA in there. Why was HIPAA in there? There's nothing, nothing in what you described in the procedures that involved a HIPAA covered entity. And I found the HIPAA information to be extremely confusing. So, why is that in there?

DR. VOGEL: So, that is in there because the State of Minnesota has very strict HIPAA laws. And our IRB has deemed that this needs to -- that this falls under that. And so, we have to include that language.

I -- we have gone back and forth many times with them about how extensive and confusing that language is. It is all standard language from the University of Minnesota. None of it is written by us.

COMMITTEE MEMBER LUND: So, my concern about that is -- I understand what you're saying. But the purpose of a consent form for informed consent is that it must be understandable by the person who's reading it. And if I didn't understand it, and I was confused, and I'm a very experienced person in all of this, I can't imagine that somebody reading the form, especially you're not -- they're not interacting with a person. My understanding is they're

on their own with this 9-page form.

I just didn't feel that this form was understandable by the audience for whom it's intended.

I'm wondering about -- again, Minnesota may have HIPAA laws, but HIPAA is a federal law. HIPAA only applies to HIPAA-covered entities. So, CCR is not covered by HIPAA. And the self-disclosure of personal health information is not covered by HIPAA.

And those are the only two, if I read your protocol correctly those are the only two sources of information that you have.

So, again, I find the presence of HIPAA in this consent form to be extremely confusing and especially the way that it's presented in written.

I also share the concern about documenting consent. So, again, this is an extremely long form. It's confusing and it's a complex study. A lot of people will look at this form and look past it, and go this is way too confusing to me, I'm not going to even read it. But they may then go on to participate in your study.

And I don't think that's fair to the participants. So, I would argue for the need, even though it may represent a risk that doesn't otherwise exist for the potential disclosure for personal information, I'm assuming that you have adequate procedures in

place with industry standards to protect any information that you collect.

I think it would be more important to make sure, by documenting the consent in some way, through a signature, or a staff, which is also a way to administer these things. So, that a study staff person can interact with a someone so that questions can be answered.

And in other cases if a study member interacts with a participant we don't need to have them sign it. A study member can document that they heard the consent and agree. So, documented consent doesn't necessarily mean signed.

But I am concerned both about the complexity of the length of the consent that if you don't document, in some way, that folks have read it and understood it, a lot of people will not read it and understand it.

And my final comment is you mentioned that there will be a data repository of study data, and I just wanted to point out that you may not, even in de-identified form, retain the state data that you get from the CCR if there were any, and there are, Vital Records data fields.

So, while you can create a data repository of any information that you collect for future researchers, you may not retain the state data, even in de-identified form, in that

repository for future use. Okay, I'm done.

DR. VOGEL: Thank you for making that clear. Helen, I don't -- do you have any thoughts about how we can shorten or go back to our -- we've had extensive conversations on our side.

DR. PARSONS: Our IRB has --

DR. VOGEL: We know our HIPAA is ridiculous.

DR. PARSONS: Yeah. We've had extensive conversations with our IRB about exactly this issue and we have not -- and Rachel and I have been at the university now for over a decade. And we have not made a lot of progress in terms of getting them to reduce the length of the consent form. Like we built the consent form off of their standard language.

We can go back to them, but we really haven't had much give. And so, I guess we would look to the Committee to see, you know, if we don't have any give in terms of our own institutional IRB what are -- what are our options kind of for coming to the consensus on the IRB -- or for the consent form?

COMMITTEE MEMBER AZIZIAN: And I wonder if the comment applied to both process, both to the survey components and the interview. Because the survey are -- the only way we can document it would be if the participant has signed it. And as far as I understand there's no other interaction.

But then the qualitative part, the interview, the staff

members can obtain remote consent from them. So, if the -- we have to consider both aspects in there.

VICE CHAIR DICKEY: I think it might be worth looking at the Common Rule language about this. Dr. Azizian, I assume you looked at it.

But there is a section in the Common Rule for waiving written informed consent. And I don't know if -- but I'll just read from it, I guess, since we have trouble displaying it. Well, let's see.

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all the subjects if it finds any of the following.

One, the only record linking the subject and the research would be the informed consent form, and the principal risk would be the potential harm resulting from a breach of confidentiality.

Each subject or a legally authorized representative will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.

I think that's probably the section that your IRB probably utilized.

If that's the case, do you have a mechanism to ask each subject whether they want documentation linking them to the research?

DR. VOGEL: We could do that. I mean, I will say that this path of least resistance might be if you all say we need to document this as written consent and we just do that. Because you're absolutely right, we have all the mechanisms in place for doing that. We can collect electronic signature through REDCap. You know, so I mean it sounds like that might actually be the easiest path. Does that sound correct?

With the addition -- your comment is well-taken about how hard our consent forms are to understand. I wonder if we can also almost add another document, so just a one-page summary. Like this is what you're actually agreeing to. This is in even more detail in this horrific 9-page study [sic], if something like that would also help.

COMMITTEE MEMBER LUND: Anything that you can do to make this consent process understandable for the participants would be a help. And if providing them with a form -- and you can go to our website. I think our template for informed consent is very good and you could -- and it's much briefer than what you have, and it wouldn't have to include any of the HIPAA things, which is where I think it goes off -- frankly, goes off the rails. Because I was like why is this popping up in the middle of this document, with no explanation for why it would be here.

So, yes, if you wanted to do -- even though that's

slightly more burdensome for the participants, I think that's a good solution for helping them understand. Because that's what concerns me. They need to understand what they're being asked to do and I don't think the participants (indiscernible) --

COMMITTEE MEMBER AZIZIAN: Any other questions or comments?

VICE CHAIR DICKEY: Agnieszka's just displaying that section of the Common Rule that I just cited, for everybody's information.

DR. RYKACZEWSKA: We have a question from Dr. Tefera.

VICE CHAIR DICKEY: Please, Dr. Tefera.

COMMITTEE MEMBER TEFERA: Hi, good morning, Lemeneh Tefera. Thank you for the opportunity to review the proposal.

Can you -- you mentioned that the patient groups had expressed a desire to not have the written consent. Can you please expand on that and just help -- help us understand the perspective from patients why this seemed unwanted?

And a second question is you described several mailings for nonrespondents. Are there any telephonic or other electronic follow ups, or is it just mailing, if you can just please clarify?

DR. VOGEL: Yes, so great question. So, one, I will say, you know, this study really -- this survey really got off the ground in January. And we were having a lot of meetings with our

community advisory groups January, February, March. And so, I think that that context matters here. Thinking about how a lot of things were changing politically at that time.

And so, our -- as we were talking things through, so one, for example, the CDC requested we could not -- we can't ask gender on this survey. And so, then some of our community advocates are like, okay, wait. So, you know, like if there's that threat and we took that away, but what about other pieces? Like are people going to feel safe to tell us their true race and ethnicity, for example, or provide us this detailed information about what has and hasn't worked for them, and things like that.

And they really felt like the biggest threat for participating in this study was potentially the risk of confidentiality.

And so, that was where the survivors were coming from as we were talking through this with the community. And so, that is where this came from.

And then, the second question was -- oh, about the mailing. So, we have in the protocol that -- for the potential to do a telephone call between the third and fourth mailing. That is really going to be staff dependent, whether we have the staff. And we're planning to do this in batches. You know, we don't have the staff to send 5,000 letters at one time.

And so, our initial thought is that we'll do a smaller batch, maybe 500, see what our response rate is after the full, just the mailing. And if the response rate is reasonable, we could proceed without having to do a telephone call.

And if that's not the case, let's say we get only 20 percent of responders after that first 500, then we would figure out how to make the telephone call happen.

COMMITTEE MEMBER TEFERA: Thank you for that response. The only follow-up comment is in addition to patient concerns about reporting gender or other self-descriptors, it's also important to note that now there are patients, certainly in California and throughout the nation, who are also concerned about their legal immigration status as being disclosed in engagement with researchers, or even engagement with the healthcare system. And there's been a notable decrease in folks with concerns about their immigration status to clinics, hospitals, emergency departments.

So, I think it's something to reflect on as we think about what's, you know, reasonable and unreasonable to ask of patients involved in research. Thank you.

COMMITTEE MEMBER AZIZIAN: Any other questions or comments?

Dr. Dickey, you want to -- anything specific that you want to add? I was thinking, I had the opportunity to glance over

that. But as I said, I looked at this previously as well, and that there are other sections that seemed to require documented and signed consent. But again, I figure that if you're ever in doubt, you better do it rather than leave up for interpretation.

However, if you think that that applies to the case, then I have no objection.

VICE CHAIR DICKEY: Well, no, I -- we have granted waivers of written informed consent in the past. But this, the language in there that's -- actually, may have been introduced in 2018, says, "Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject choices will govern."

I don't know how you would obtain that? You would still have to be asking every -- every subject do you want to sign this or do you not want to sign it. And how would you keep track of that? So, it sounds like you don't have a way to do that.

DR. VOGEL: I mean, yeah, I think it would be -- it would be harder. I mean, but we -- I guess we could ask that. Yeah, I'm trying to think of how we would do that. Just checking a box, essentially, saying, you know, I have read this but I'm not going to -- I would prefer to not sign it. We could do something like that.

COMMITTEE MEMBER VENTURA: Dr. Dickey, I was thinking --

VICE CHAIR DICKEY: Yes, Dr. Ventura.

COMMITTEE MEMBER VENTURA: -- my suggestion to the researchers is to have a checkbox either at the end of your consent form on REDCap, it's my understanding you're doing this electronically. So, you can have the option -- the participants can have the option to sign or check a box that I read and understood the consent form, but I choose to not sign.

At least that way --

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER VENTURA: -- they are acknowledging that they've read, hopefully understood the consent form, but that they are opting to not sign.

Is that doable?

VICE CHAIR DICKEY: Yeah, I mean I would -- that's a question for them.

COMMITTEE MEMBER VENTURA: Yeah.

DR. VOGEL: Yeah. Yes, we could do that.

COMMITTEE MEMBER LUND: And you mentioned that you were going to offer a paper administration as an option as well. So, that would need to be on the paper consent form, as well as in REDCap.

DR. VOGEL: Right, yes. For our institution those match entirely. There's no -- there can't be differences between them.

COMMITTEE MEMBER AZIZIAN: No additional comments or questions?

So, I guess we could defer a motion for approval under minimal risk, contingent on -- well, what would be the wording for this? A *Reader's Digest* pamphlet of the description of the consent form, maybe something of that nature that could be provided along with the actual consent form. So, that goes both of them that provides a summary of the consent form and then the comprehensive one.

COMMITTEE MEMBER LUND: Yes.

COMMITTEE MEMBER AZIZIAN: Would that capture it?

COMMITTEE MEMBER LUND: Yes.

COMMITTEE MEMBER AZIZIAN: Along with having that option in the consent form that's acknowledging that they have read that, but they wish not to sign the form.

COMMITTEE MEMBER LUND: Yes.

COMMITTEE MEMBER AZIZIAN: Yeah.

COMMITTEE MEMBER LUND: And I would also request that you add to the motion that they clarify which data will be retained for the data repository to ensure that it doesn't include any state data.

COMMITTEE MEMBER AZIZIAN: Very well.

VICE CHAIR DICKEY: So, you want to state the motion

again or do we have it?

DR. RYKACZEWSKA: I am also there. I'll go ahead and share a screen, though, so we have it up.

Do I have that right? And I want to confirm one year approval is the motion?

VICE CHAIR DICKEY: And also, who's going to be reviewing the -- so, the length, the risk level, how long it's approved for, one year, and then who's going to review the changes. Dr. Azizian, do you feel to do it by yourself?

COMMITTEE MEMBER AZIZIAN: Yeah, I think that should be okay.

VICE CHAIR DICKEY: Do I hear a second?

COMMITTEE MEMBER SCHAEUBLE: Second.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz? Dr. Ruiz?

DR. RYKACZEWSKA: I see him saying the word "approve".

VICE CHAIR DICKEY: I can read his lips. Thumbs up.

MS. ATIFEH: Okay, approve.

COMMITTEE MEMBER RUIZ: I'm sorry. Approve.

DR. RYKACZEWSKA: Thank you, Dr. Ruiz.

MS. ATIFEH: Okay, thank you.

Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay, thank you to the researchers. You'll receive a letter from the Committee specifying the required changes. But, you certainly can begin working on them before you get the letter.

DR. BERGER: Thank you very much.

DR. PARSONS: Thank you for your time.

VICE CHAIR DICKEY: So, the next project is Evaluating the Effectiveness of Air Quality Monitoring and Health Education on Reduced Indoor Pollution Exposure in Low-Income Housing Communities.

I'm actually the reviewer on this. And Dr. Kimberly

Berger, are you here? There's other members.

DR. BERGER: Hello, good morning.

VICE CHAIR DICKEY: The rest of your team?

DR. BERGER: I'm sorry, I might have missed -- sorry, I didn't hear.

But yes, hello, good morning. I'm Kimberly Berger, Co-PI on this project, along with Rosemary. I'll let you introduce yourself. And then, we also have a research assistant, Hannah, on with us as well.

VICE CHAIR DICKEY: Oh, you're muted. Okay, well. We can't hear you.

DR. RYKACZEWSKA: We can't hear you, Dr. Castorina.

DR. BERGER: Why don't we go to Hannah and, hopefully, Rosemary can call back.

MS. WOHL-SANCHEZ: Good morning, everyone. My name is Hannah Wohl-Sanchez. I'm a Community Engagement Specialist at Sequoia Foundation and a Research Assistant for this project.

VICE CHAIR DICKEY: Great. I'll have to admit that I'm not totally on top of this. We debated whether this might be considered public health surveillance and finally decided that it wasn't, and we needed to go ahead and talk about it at this meeting.

I guess for the Committee, if they understand what the

main issues of public health surveillance are, it has to be something that's conducted by a authorized public health authority under their statutes. And it has to be surveillance, as opposed to an intervention.

And in this case, there's an intervention involved in the project, which basically made it our full Committee review.

So, Dr. Berger, or others, would you please go ahead and summarize for us the project?

DR. BERGER: Sure, I can do that. I see Rosemary's back in. Do you want to try to say hello?

DR. CASTORINA: Can you hear me now?

VICE CHAIR DICKEY: We can.

DR. CASTORINA: Great. Terrific. Hi, everyone, sorry about that. I'm Rosemary Castorina. I'm a Research Scientist with the Air Quality Section with the CDPH Environmental Health Laboratory Branch. And along with Dr. Berger, I'm Co-PI on this project.

DR. BERGER: Thanks, Rosemary.

Yeah, so let me give you an overview of what the project is about. So, the background, the premise of the work is that indoor air pollution is a substantial contributor to risk for disease like asthma, cardiovascular disease, and for higher morbidity of those diseases as well.

A lot of research and regulation of air pollution has focused on outdoor sources, but indoor air is what we are exposed to the most and can contain higher concentrations of may pollutants, as well.

The goal for our study is to try and understand some very low-cost ways to reduce indoor air pollution among low-income housing units.

And to do that, we're going to study two interventions. So, both are going to involve installing an air monitor inside people's homes, in their kitchens, near the stove, which is a big contributor of indoor air pollution, to measure levels of several pollutants in the home.

And so, one intervention, the participants will be able to see the concentrations of those pollutions live when they're cooking, or lighting incense, or opening or not opening a window, et cetera.

And then, the other half of the participants will not have that feedback. We'll still be measuring the air in their homes, but they won't see those measurements.

And then, both groups will get a education -- an educational video on what is air pollution, indoor air pollution, why do we care about it, how is it got for us, and how can we reduce it. So, things like opening windows, using the exhaust fan

in your kitchen, when you're cooking, or smoking outside, things like that.

So, that is the kind of background of why we're doing it and general overview of what we're doing.

So, I can walk you through, now, how human subjects will be involved. I can start with recruitment. We're planning on recruiting about 300 people from, mostly from the open area into the study.

So, that recruitment is going to be done by a community-based organization called Higher Ground. They're very involved in the open community. They do a lot of events around nutrition or other kind of public health, or school-related things. And so, we -- you know, they're going to have recruitment tabling at the existing events, where they can tell people about the study. And we've submitted flyers and scripts for those events.

Participants will be directed towards, then, online eligibility screener that will see if they quality to enter the study. So, those eligibility criteria are that they are below 50 percent of the area, the income for their county. That they're 18 and over. That they're not planning on moving in the next three months. That they live in the counties that we're targeting.

And that they can communicate in English, Spanish, or Cantonese. So, we plan on translating participant-facing materials

into Spanish and Cantonese, once we get the English approval.

And, finally, that they're responsible for cooking at least half of the meals in their homes, since that is such a big factor in indoor air pollution.

So, once they are found eligible through this online screener, then we will contact them via phone or email to set up a time where we can talk on the phone to walk them through the informed consent.

The consent form will be hosted on the same online platform as the eligibility screener, and all of our questionnaires, which is called the Zoho Survey. We can talk about that in a bit.

And so, they will have the -- they'll be able to read the consent form, and we can walk them through it over the phone, make sure they're understanding everything. And then, they will sign online, and we'll note that on the phone. And then, we'll be able to save those signed consent forms for our records.

And on that same phone call we'll schedule they're first visit. There will be two visits to the homes. In the first visit, which will mark the start of the control period, we have a two-week control period where we're gathering measurements from the air monitors that we still in their homes to get a baseline reading before we do our intervention.

So, at that first visit we'll be installing two air monitors. One is indoor, nearish the stove, and one is outdoor to -- so that we can take into account in our analysis the outdoor air pollution, the correlations with the indoor.

And so, installation will happen at that first visit. And then, after those are installed, we will also walk through the kitchen together with the participants and take notes on what kinds of appliances they have. For example, their stove, and importantly that overhead exhaust fan, if they have one, if it works, et cetera. And then, some aspects of the home's construction, such as number of windows and doors, do they work.

And with permission, which we'll ask every time, we'll take photos of the kitchen appliances, the air monitors that we place, and we'll have staff instruction every time they're prompted to take a photo. Not to include participants or anything that could identify them in the phone.

So, that first visit takes about an hour, start of the control period which is two weeks. So, at two weeks, then we start the intervention period. And we don't do an in-person visit. But what we do is we send them the educational video that they can view online, that talks about what is indoor air pollution, why does it matter, and how can we reduce it.

And then, four half of the -- so, that goes out to

everyone. And then, for half of the participants who are getting the type of intervention where they're seeing that real time feedback, we will then turn on a feature in the air monitor that allows them to see that.

So, when we install everything the monitors are blank. They have LED screens, but they're blank. So, you know, only we are seeing that data. And then, at the start of that intervention half the participants are now able to see the, you know, green, orange, red, purple, how good or bad the air quality is in their homes.

So, that will then continue for another two months, where we will continue to read that data in from the air monitors. At the end of that period, that's the end of the study. We return to collect the air monitor.

And then, we offer -- there's a follow-up questionnaire that is also online on the Zoho site, that they will be asked to fill out. And we will also ask them in that follow up if they would like to see their results. If they do, we'll mail them their results a couple months later.

And then, we also have incentives. So, total incentive is $200, so it will be 50 at the start of the -- at the first visit. And then 50 at the end of the control period, start of intervention. And then, the remainder at the end of the

intervention.

I can next go into risks, but I just want to pause there if there's any questions at this point.

COMMITTEE MEMBER LANG: I have a question about the photographs. Are you planning on gathering any meta data from them, excess data for lat and long for downstream use?

DR. BERGER: No.

COMMITTEE MEMBER LANG: Okay.

DR. BERGER: I didn't know you could do that.

VICE CHAIR DICKEY: And you promise not to.

DR. BERGER: Yeah.

VICE CHAIR DICKEY: So, my initial issue, initially somebody may have seen it, didn't even acknowledge those photographs in the consent form or as a risk. And so, they introduced language into the consent form regarding that.

And then, initially, you were maybe going to give them the monitors.

DR. BERGER: Yes. That was the --

VICE CHAIR DICKEY: It would sound like a good deal to me but --

DR. BERGER: I know. It would have been great. That was the initial plan. However, tariffs have gotten the better of us and we can no longer afford to do that, unfortunately. So.

VICE CHAIR DICKEY: So, I actually didn't ask you this question, but I saw something in the protocol about it. They can see in the levels of, you know, contaminants, or whatever you call it.

DR. BERGER: Half of them can.

VICE CHAIR DICKEY: And some of it -- and, actually, one of the readings is unhealthy. And how do you deal with that? I mean, what support do you provide to people who are getting those readings?

DR. BERGER: Yeah, great question. So, in this -- sorry, I neglected to mention it. So, if -- with the education on what is air pollution, why is it bad, the half of the participants who will be seeing their live feedback of the -- it's PM2.5. We're going to be measuring PM -- I'm sorry, particulate matter of different widths, and we'll be -- they will be able to see PM2.5 live on their monitors. It can only display one, the monitor that we're buying. But we're also measuring nitrous oxide, and temperature, and volatile organic compounds as well.

And so, the readings that they'll see, these half of these participants, will be for particulate matter. And this, usually, you will see elevated concentrations of particulate matter when there is something like smoke in the air. So, if that's from cooking, or smoking, or incense, or something like -- it can be

other things, too, but I think that's going to be the most common.

So, the participants who are going to see that live feedback, they get another video where we explain to them how the air monitor works, what it is measuring, what they'll see. We'll walk them through kind of each thing they could possibly see each reading. So, good, fair, you know, poor, very bad, very, very bad. That the lights see that they'll see on the monitor that will indicate those things. And what to do in each of those situations.

So, you know, open a window for some of them. Or, if -- you know, if it's moderate, then maybe don't start cooking until it's gone down a bit. Or if it's in the red, then people should maybe leave that room for a while or turn on, you know, the exhaust fan, things like that.

So, that's been submitted, as well.

VICE CHAIR DICKEY: Right.

DR. BERGER: Happy to share that through a shared screen, if you'd like me to.

VICE CHAIR DICKEY: No, I think it --

DR. BERGER: But they'll get that info. And then, they also get a sticker that will be -- that they can place on the monitor as kind of a cheat sheet.

VICE CHAIR DICKEY: Right. I saw some study published this week about linking this particulate matter to all sorts of

chronic disease.

DR. BERGER: Yes.

VICE CHAIR DICKEY: Is that part of your education?

DR. BERGER: Yes, it is.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER VENTURA: I did notice --

DR. BERGER: Sure.

COMMITTEE MEMBER VENTURA: I did notice on your research staff listings that they're CDPH and Sequoia Foundation. But in your protocol, you describe that Higher Ground staff are going to be involved with recruiting and consenting. So, I think they should be -- those staff members should be included so that we know that they're trained in consenting process and enrolling people.

DR. BERGER: Sure.

VICE CHAIR DICKEY: Yeah. Right.

DR. BERGER: Okay.

COMMITTEE MEMBER JOHNSON: I had a question about the air monitor, itself. Is that battery or does that rely on the energy consumption of the people's homes?

DR. BERGER: Yeah, the outdoor one is solar paneled. And the indoor one has to be plugged into the participant's electricity.

COMMITTEE MEMBER JOHNSON: Okay. And is that explained

to them that there's -- what's the impact on them, leaving that plugged in for two months? Is it just relatively small or --

DR. BERGER: It's a very small draw of energy.

COMMITTEE MEMBER JOHNSON: Okay.

DR. BERGER: And I don't remember if we specifically tell them that, but I can add that to the informed consent, if that's the best place.

VICE CHAIR DICKEY: Yeah, it would be.

COMMITTEE MEMBER JOHNSON: Yeah.

COMMITTEE MEMBER PALACIO: When you're getting the participants, the ones who will be studied, how do you know that they actually cook? This is a society that doesn't do a lot of cooking.

DR. BERGER: Sorry, the question is how do we know if they're cooking?

COMMITTEE MEMBER PALACIO: That they cook, that they use their kitchen.

DR. BERGER: Uh-huh.

COMMITTEE MEMBER PALACIO: To be able to provide the results that you're looking for?

DR. BERGER: So, whether -- how often they cook is not a eligibility criteria for being in the study. So, we are going to welcome participants who eat out all the time or who cook all the

time. Because the goal is to be able to see how effective this -- you know, these types of interventions would be at scale, if implemented by the funder, which is US HUD. And so, however representative of their population we can get is fine.

And among people -- so, we do collect info. So, we ask them how often you cook, in the baseline questionnaire, so we'll have some information about that. So, we'll be able to see, okay, for the people for whom their PM2.5 did not change much before and after the intervention, you know, is that related to -- you know, do all of those people just not cook at all in their homes.

But there are other sources besides cooking, like smoking and incense, and other things.

VICE CHAIR DICKEY: I sort of remember you saying that they had to cook 50 percent of the time.

DR. BERGER: Yeah, so to be eligible it's -- it's not -- it doesn't matter how much your household cooks. But we want to be speaking to the person in the household that's responsible for most of the cooking.

VICE CHAIR DICKEY: Oh.

COMMITTEE MEMBER PALACIO: Okay.

DR. BERGER: Because that's the person who we're going to tell, you know, turn on the exhaust fan, or open the window, et cetera.

VICE CHAIR DICKEY: Oh, Ms. Lund, you have a question?

COMMITTEE MEMBER LUND: Yeah, actually I have two things. First, is the purpose of this study really just to inform the funder about whether or not it would be a good idea to move forward with a program to install these detectors in as many homes as possible?

DR. BERGER: I would say that that is one purpose. And the other purpose is research results, so seeing how effective something like this is.

COMMITTEE MEMBER LUND: Okay. I was trying to give you a public health out.

(Laughter)

DR. BERGER: That's okay.

COMMITTEE MEMBER LUND: My second question is, is there a literature that suggests that people will modify their behavior if they see results?

So, for example, if they have a monitor and they see the results are bad that they will modify their behavior accordingly?

DR. BERGER: Yeah, so there hasn't been, of course, a study exactly like this. But there are indications in literature that people want to know what they're exposed to and that they will change behavior based on that information.

I believe there was a study, I can pull it up later, it's

MSU. But there was a study where people wore air monitors around them constantly for a couple of days. And part of the feedback after that study, I think it was a pilot study, but part of the feedback from the people who participated in that study was, you know, a reason why I wanted to be in this was because I want to know how I can reduce the air pollution that I'm exposed to.

So, we've seen in literature that there are indications that people are motivated towards reducing this exposure.

VICE CHAIR DICKEY: And there are studies in --

COMMITTEE MEMBER LUND: And the --

VICE CHAIR DICKEY: I'm sorry.

COMMITTEE MEMBER LUND: The basis for my questions -- I'm sorry, I just wanted to finish my thoughts. The reason for my question is that in one group they'll be able to see one of the particulate levels and they'll know when it's unhealthy. The other group is blinded to the information. And from an ethical perspective, I mean I just wanted to raise it and make sure the Committee thinks it through, if it's known that people will modify their behavior to a more healthy behavior if they can see the information, is it ethical to withhold that information just to do this comparison test?

If it's not known that people will modify their behavior to do a more healthy thing based on the information that's

provided, then it's not a problem and you can do the test. Right. Oh, here's information and here's no information.

So, my concern is are the people that you are measuring, you know real time what that monitor would say in the kitchen, they don't have access to it and they might have chosen to change their behavior.

For example, lease the room if it's red, or not good, or whatever that is.

So, that's my -- are you getting information in a way that actually harms people?

VICE CHAIR DICKEY: I just wanted to add that there is literature, like glucometers, people with diabetes wearing glucometers. They do have somewhat better outcomes from being able to monitor their blood glucose.

But this is probably a different, whole different set. And it sounds like it's not yet established whether something like this is necessarily effective. I mean, if it's effective we may have these things on all of our stoves, right.

DR. BERGER: That would be great. So, what -- you know, the study that I spoke of, you know, that one was where they wore the air monitor constantly with them, you know, wherever they walked 24/7.

We don't have, either has been anything before that has

looked specifically at the indoor air monitor in the kitchen related to sources of indoor air pollution.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER LANG: So, I wanted to build on Dr. Lund's questions. Are there any plans to disclose information at the household level back to the participants, after the cessation of the study?

DR. BERGER: Yeah, we are going to offer them the opportunity for results returns.

COMMITTEE MEMBER LANG: Okay.

DR. BERGER: In the follow-up questionnaire, we ask them if that's something that they want.

COMMITTEE MEMBER LANG: Okay.

VICE CHAIR DICKEY: And that's regardless of what group they were in?

DR. BERGER: Uh-hum.

VICE CHAIR DICKEY: Any other questions?

COMMITTEE MEMBER TEFERA: Hi, good morning, Lemeneh Tefera. For the intervention study do they get to keep the device? And if they do, are they able to monitor it?

DR. BERGER: Yeah, that was the initial intention was to offer people to keep the air monitors and then to offer, you know, about half of the group then turn on the feature that the other

half had had the whole time, so that they can now live see the monitor readings for themselves, as well.

But, unfortunately, we're no longer able to do that because of cost of the air monitors has risen substantially. They're manufactured overseas and with the tariffs that we have to pay, now, we are going to have to recover our monitors from individual homes instead of offering them to keep.

COMMITTEE MEMBER TEFERA: Thank you.

VICE CHAIR DICKEY: I guess one, maybe not as good as giving them the monitors, would be if you have any advice for if they wanted to purchase one themselves, how they could do it.

DR. BERGER: Yeah, actually, that's a great idea. Because Ikea makes one. There's a couple that are made -- I mean, the ones that we're ordering obviously are, you know, pretty sensitive instruments, you know, very high quality. But that's not necessarily required if you're just kind of looking for something in your home afterwards. So, yeah, we can make some recommendations in the -- where would we do that? I guess in the follow-up questionnaire.

VICE CHAIR DICKEY: Right. At the end of the follow-up questionnaire.

DR. BERGER: Uh-hum.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: So, what is the range of cost on these devices?

DR. BERGER: Range of cost. The ones that we're ordering are $300 to $400. They can get far higher. And, Rosemary can speak to that, if you'd like.

And then, at the low end, I'm not sure how low they get, but I would imagine that there are ones below $50.

DR. CASTORINA: Of course, it depends how many pollutants you're measuring. Yes, there are homes, low-cost, monitors now for less than $100.

VICE CHAIR DICKEY: I'm not seeing any more questions from the Committee. I'll open it up to the public, if there's any members of the public who would like to ask questions or --

DR. RYKACZEWSKA: Acknowledging no members of the public in the room. If any of our virtual attendees have any comments or questions, please raise your virtual hands?

I am not seeing any public comments.

VICE CHAIR DICKEY: I, actually, officially, can't make a motion. So, Dr. Palacio, would you do the honor?

COMMITTEE MEMBER PALACIO: I move approval.

DR. RYKACZEWSKA: Approval deferred.

COMMITTEE MEMBER PALACIO: Deferred approval.

VICE CHAIR DICKEY: What would be the change that we

would want?

COMMITTEE MEMBER PALACIO: Based on the -- do we have changes that --

VICE CHAIR DICKEY: I think there was the one --

DR. BERGER: I have three, if you'd like my --

VICE CHAIR DICKEY: Yeah, could you hear us? Could you read them to us?

COMMITTEE MEMBER PALACIO: Yes, please.

DR. BERGER: One of them was to include Higher Ground, the recruitment staff in the application.

VICE CHAIR DICKEY: The other, the next one?

DR. BERGER: The next one is to add to the informed consent that there will be a small energy draw from the indoor air monitor.

And then, finally, to the follow-up questionnaire adding recommendations to low-cost air monitors that they can purchase.

COMMITTEE MEMBER PALACIO: Perfect. So, we'll add to the deferred approval minimal risk, one year, pending the following changes.

VICE CHAIR DICKEY: Right. And for review by myself, I guess.

COMMITTEE MEMBER PALACIO: Okay, yeah.

VICE CHAIR DICKEY: Okay.

So, a second?

COMMITTEE MEMBER TEFERA: Second.

VICE CHAIR DICKEY: Okay, great. We'll call the roll.

MS. ATIFEH: Sure. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay. Well, thank you very much. And you'll be getting a letter from us about that. But go ahead and make the changes and send them in, and I'll look at them.

DR. BERGER: Sounds good. Thanks, everyone.

VICE CHAIR DICKEY: Good luck with your project.

DR. BERGER: Thank you. Have a good one, bye.

VICE CHAIR DICKEY: So, the next project is Cal Community Connect: Advancing California's Aging and Disability No Wrong Door System. And Dr. Ventura is the reviewer?

COMMITTEE MEMBER VENTURA: Yes, I am.

Good morning, is Doctor, oh goodness, Oleskiewicz --

DR. OLESKIEWICZ: Oleskiewicz.

COMMITTEE MEMBER VENTURA: Thank you. thank you.

DR. OLESKIEWICZ: No problem. Yes, I'm here.

COMMITTEE MEMBER VENTURA: Good morning. Do you have --

DR. OLESKIEWICZ: Good morning.

COMMITTEE MEMBER VENTURA: Do you have any other team members with you this morning?

DR. OLESKIEWICZ: It's just me today.

COMMITTEE MEMBER VENTURA: Wonderful. Okay, thank you for joining us. Happy to have reviewed your project.

If you wouldn't mind just giving us a brief overview of the project for the Committee, and then we'll get into our discussions and some changes requested.

DR. OLESKIEWICZ: Sure, yes. Thank you so much. And I want to also thank you and the Committee for your thoughtful

feedback on the first round.

So, just to give you a quick background of the project, Californians has struggled to know which long-term services and support options they are eligible for. And so, one way to improve access to these services is through a No Wrong Door System.

So, CDA, or the California Department of Aging, applied for a two-year grant through the Administration for Community Living to expand California's No Wrong Door System. And we call this Cal Community Connect. And we were awarded the grant starting June of 2025.

And part of this grant is evaluation of the program. So, the program involves training and certifying community health workers at three area agencies on aging sites. These sites include San Diego, Sacramento, and Sonoma.

So, these community health workers will be providing No Wrong Door navigation services to older adults, adults with disabilities, and caregivers who are seeking or in need of long-term services and support.

So, the purpose of this project is to conduct an evaluation of the Cal Community Connect program. So, in particular we'll be tracking process measures like training, outreach, referrals, and services, services rendered. And we also want to know whether participation in this project is associated with a

number of outcomes like quality of life, caregiver burden, institutional care status, and hospitalizations, and ER visits, among others.

So, participants will be older adults, ages 60 years or older, adults with disabilities, and caregivers who are seeking services.

And so, our goal right now is to recruit 335 older adults, adults with disabilities, and caregivers across all three of the sites.

And so, to kind of get into how they will participate, participants will be recruited through flyers, social media posting, postings on the AAA website, 1-800 numbers, and through targeted outreach. And this will be done by the AAA sites, themselves, through employees on their sites.

Participants who are screened and meet the eligibility for the program will be asked if they would also like an evaluation. We're not -- we're not excluding them from the program if they don't -- if they choose not to participate in the survey part of the evaluation.

If they are, they will either go through an informed consent or accept process, and two surveys will be administered. One at baseline and one six months post.

The surveys will either be given via a paper format or

through Survey Monkey. And altogether, the surveys should take no more than an hour.

And so, I'll stop there before I get into risks and ask if there are any questions.

COMMITTEE MEMBER VENTURA: And I just want to clarify for the Committee that the No Wrong Door navigators, as well as the area agency staff members have not yet been identified.

DR. OLESKIEWICZ: Correct, yes.

COMMITTEE MEMBER VENTURA: Those recruiting and enrolling in the study. So, they will be added to the IRB once identified.

DR. OLESKIEWICZ: Exactly, yes. Yeah. So, we're still in the ramp-up period of the grant. So, we haven't -- we actually haven't hired the No Wrong Door navigators yet, as well. So, once they have been identified and trained, they will be added to the IRB approval or to the IRB protocol.

COMMITTEE MEMBER VENTURA: Sounds good. Go ahead and continue, Dr. Oleskiewicz.

DR. OLESKIEWICZ: Good. So, the risks are minimal. All data will be kept on secured servers. Paper surveys will be kept in locked rooms at each AAA site. So, of course, we can't guarantee that data will not be seen after that link. But if that happens we would, of course, inform the participants immediately and remove the data from wherever it's been released.

We'll also be providing a list of counseling resources, local to each participants, as some of the questions may be upsetting.

I guess, thank you, I look forward to answering any questions and appreciate your time.

COMMITTEE MEMBER VENTURA: Thank you for also reducing the reading level of the consent form, as appropriate to eighth grade. And also, clarifying that any questions can be skipped.

DR. OLESKIEWICZ: Yes.

COMMITTEE MEMBER VENTURA: Those were some of my concerns with the consent form.

DR. OLESKIEWICZ: Yes. And also, they will have the No Wrong Door navigator there to answer any questions, they go through the consent process, as well.

And we're giving them the option, if they want the researcher to read the consent form aloud, they can also do that, too.

COMMITTEE MEMBER VENTURA: And once you have all Spanish, all study material translated into Spanish that will be submitted to us for review and approval, as well.

DR. OLESKIEWICZ: Correct, yes.

COMMITTEE MEMBER VENTURA: I had --

COMMITTEE MEMBER LUND: I have a --

COMMITTEE MEMBER VENTURA: Oh, go ahead.

COMMITTEE MEMBER LUND: In regard to your questionnaires, why is it necessary to ask specific date of birth? In the interest of not collecting unnecessary PII, would age be sufficient?

DR. OLESKIEWICZ: We could ask age. I said date of birth just in case -- yeah, and we could switch that to age, if we want to avoid PII. That's a good point.

COMMITTEE MEMBER LUND: Thank you.

DR. OLESKIEWICZ: Yes, of course.

COMMITTEE MEMBER VENTURA: And --

VICE CHAIR DICKEY: Any other questions? Additional questions from the Committee? You may want to note we can't really vote until Dr. Palacio comes back.

DR. RYKACZEWSKA: He just briefly stepped out and so we lost quorum.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: So, any question is welcome.

DR. RYKACZEWSKA: Why don't we take a five-minute recess.

VICE CHAIR DICKEY: Okay. If there are any -- well, yes, we'll take a five-minute recess until Dr. Palacio returns.

(Off the record at 10:17 am.)

(On the record at 10:25 a.m.)

VICE CHAIR DICKEY: We're resuming the meeting.

So, we haven't asked yet if the public, members of the public have any comments or questions.

DR. RYKACZEWSKA: Acknowledging no members of the -- sorry, acknowledging that there's no members of the public in the room, if any members of the public have -- attending virtually have any questions or comments, please raise your virtual hand, now.

And I am not seeing any virtual hands.

COMMITTEE MEMBER VENTURA: Okay. So, I will propose this motion for deferred approval, minimal -- oh.

DR. RYKACZEWSKA: Oh, Dr. Azizian?

COMMITTEE MEMBER VENTURA: You're not --

COMMITTEE MEMBER AZIZIAN: My apology for that.

COMMITTEE MEMBER VENTURA: Okay. Sorry, where was I. Deferred approval, minimal risk, one year, pending the following changes.

To remove the date of birth question on the survey and replaced with just asking for age.
Adding all recruitment staff and navigators to the IRB's protocol once identified and hired.

DR. RYKACZEWSKA: Should that be an amendment, then?

COMMITTEE MEMBER VENTURA: Yes, in an amendment.

And all, for all study related material, Spanish related -- sorry, Spanish study material to be reviewed and approved before

beginning the study.

DR. RYKACZEWSKA: To be reviewed by --

VICE CHAIR DICKEY: To be reviewed by yourself, a subcommittee of yourself.

COMMITTEE MEMBER VENTURA: To be reviewed by myself.

VICE CHAIR DICKEY: Is there a question.

MS. ATIFEH: Agnieszka, I have a question. Do they need to submit an amendment?

DR. RYKACZEWSKA: Yes, it's noted as an amendment.

MS. ATIFEH: If it's necessary, they cannot, because we eventually return the application.

DR. RYKACZEWSKA: Because they're not hired yet, or they're not identified yet.

COMMITTEE MEMBER VENTURA: Yeah.

MS. ATIFEH: Oh, okay.

COMMITTEE MEMBER JOHNSON: Second.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

DR. RYKACZEWSKA: Dr. Dinis has left for her class.

MS. ATIFEH: Okay.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Just to explain, somebody who is remote can leave. We have to have a quorum in the room, though.

DR. RYKACZEWSKA: In person.

VICE CHAIR DICKEY: In person. Those rules may change come January 1, we don't know. Just to let you know. We can talk about that, maybe, at the next meeting.

DR. RYKACZEWSKA: Uh-hum.

VICE CHAIR DICKEY: Okay, the next project is Comparing the Effectiveness of N95, KN95, and KF94 respirators. Dr. Johnson is the reviewer.

COMMITTEE MEMBER JOHNSON: Thank you. Mr. Ullman, you

are there? If you can say hello to the Committee and introduce anyone else on your research team who's joining you today.

MR. ULLMAN: Good morning, everyone. My name's Elon Ullman. I'm an industrial hygienist and research scientist at California Department of Public Health, in the Occupational Health Branch.

I'm also joined by Sara Tepfer. Would you like to introduce yourself and your role?

DR. TEPFER: Sure. Good morning, everyone. My name is Sara Tepfer and I'm an intern with the Occupational Health Branch at CDPH, and I'll be a research assistant on the project.

COMMITTEE MEMBER JOHNSON: Great. So, this was actually one of the more clear and concise studies that I've reviewed on the Committee thus far, so thank you for selecting me as the reviewer.

So, Mr. Ullman, if you would briefly give the Committee a short overview, description of, first, what the study is, and then I'll move into the flags that were in IRBManager.

MR. ULLMAN: Yes, great. Thank you.

Well, for this study we plan to recruit 20 male and 20 female over the age of 18. Our main population is going to be CDPH Richmond employees and UC Berkeley environmental health students. That's mostly for convenience, although it is open to the general public.

They're going to be recruited via Listservs, the CDPH employees, and the CDC Berkeley students. These Listservs are universal Listservs, they're not specific for research recruitments. But there is precedence on both these Listservs for sending out of materials and a call for recruitment.

We'll also be posting live around the CDPH Richmond campus, the UC Berkeley campus.

All these flyers and the Listservs will have a shared email address for the study. So, after we get an interested individual who emails us, we're going to set up a prescreen phone call with them to ensure that they don't have specific medical conditions that would make them unable to wear a respirator. And that's a big reason why we're choosing to do this via a phone call is we're not going to be recording if they are excluded because they have one of these medical conditions. Where if we do over email, that would leave more of a paper trail.

For participation in this study, it's going to happen either at UCH campus or UC Berkeley.

The main part of this study is going to be doing what's called a quantitative test with five different models of respirators. These five respirators are going to be KN95 respirators, KF94 respirators and 95 respirators in order to understand the differences in effectiveness between these types of

respirators.

These respirators, especially the international respirators, which have the ear loops, compared to the N95 that has head straps. And due to the U.S. market, even though public health has continued to recommend their use, there's not a lot of data on their effectiveness compared to more traditional N95 respirators.

For the fit test, itself, what is it is it's generating non-toxic cell particles in a room. And then, we use a device called Protical (phonetic) that then measures the concentration of the cell particles outside the respirator versus inside the respirator in order to quantify what the reduction in concentration is from wearing that respirator, and the breathing done with the respirator.

While the participants are wearing each respirator, they're going to do a series of four different movements. These are standard and approved by OSHA. To see how well it fits when doing different activities.

And at the end of the study, non-CDPH employees will be paid with a $30 gift card. And we have been informed through the lawyers here at CDPH that we cannot give a health department, public health employees these gift cards.

In terms of the risk, it's very minimal risk. So, quantitative testing, this is considered to be the gold standard

whenever there's what's called a respiratory protection program in occupational environments. So, whenever workers are exposed to hazardous chemicals, they have to wear a respirator. And a quantitative test has been used for a long time, now, because it is very quick and very minimal risk. It's really the least risky way of doing a fit test. It's made to do a fit test, is what's called a user steel track, which is more subjective where you're asking them to breath in and out, but it doesn't give -- get you the quantitative measurements.

The biggest risk that we see is discomfort from the respirator, itself, being too tight. We are using different sizes and not all respirators fit every individual. So, to address this potential risk, we're asking participants to rate the comfort of every respirator model on a scale from 1 to 10. With 1 being unbearable uncomfortable, 5 being that they could wear it all day, or wear it for a moderate amount of time. Like wearing it to work during a smoky day. And 10 being that they could wear it all day without discomfort.

And any ratings of 1 to 3 will just result in a termination of the test for that model.

Each of the tests takes about 2 and a half minutes, and we really are trying to discomfort for each test. So, thank you very much.

COMMITTEE MEMBER JOHNSON: So, one thing, could you elaborate on the nonpayment? That's news and different from what's in the protocol. So, in the protocol you have that everybody is receiving payment. But is that now not the case for CDPH employees?

MR. ULLMAN: Yes. Unfortunately, it is now -- it is not the case. And I apologize, that's an oversight on my end. We got that news pretty last minute from the lawyers here at CDPH. And, unfortunately, we won't be able to pay the CDPH employees. And I apologize, that was an oversight that I just noticed on the application, itself.

COMMITTEE MEMBER JOHNSON: Okay.

MR. ULLMAN: But in the application, it does say all participants.

COMMITTEE MEMBER JOHNSON: Yeah, it's in the application and also in the recruitment materials. So, those will need to be slightly adjusted to have that be final approved.

I think the other things that were originally flagged was how you were obtaining their names in the first place, which I think that that has been addressed in the application, of describing the Listservs and their purposes.

You also added that CDPH employees, who decline to participate in the study will not be impacted in their jobs with

declining.

And then, I was wondering, too, if you could also describe in more detail for the Committee how you plan to, you know, collect information like names, and their consent, while not associating that with the data that you intend to keep beyond the study.

MR. ULLMAN: Yes, that's all in. So, starting with the recruitment period, as I said, we're going to be using a shared, you know, inbox. All the, you know, inbox can only be accessed through CDPH laptops.

Or for Sara, for example, she gets into our system through a virtual client that has the same amount of encryption and approved IT protocols.

Besides to do the shared email inbox, just to standardize recruitment and minimalize just having a path around things like a phone number. Let's say, one person on the team gets contacted, but then another person is doing the follow up, it makes it so all being in one, that one inbox. And so, that would have their name pretty much by default as they email us, and then their phone number as well for that -- for recruitment purposes.

During the phone call we're also going to be asking for their sex defined at birth and their age. Those are only going to be noted if they pass the inclusion and exclusion criteria in our

study.

And for the age, and name, and sex assigned at birth, all of that's going to be written down on a physical sheet of paper, which we're calling the master subject ID form. And the purpose of having that via physical piece of paper is it's -- it makes it so that we're able to keep it in a secure location on the CDPH campus, with the plan being that we're never going to be pairing the subject's name or any other PII with the result of the study.

Our plan at this point in time, which I put into the project application, is that ID, is that master sheet is never actually going to enter the room where the study is being done. The researcher is going to write down just the subject's ID number that's paired to the name, onto a Post-It note. And then, they're only bringing that Post-It note with the subject's ID number.

So that when we're running the Protical software that's doing the actual test, we can just put that subject ID on there and it won't associate their name with it.

In terms of the data that we're going to be getting from the -- from the testing, itself, that's going to be the fit factor, which is that comparison of the concentration of particles in the room, along with the comfort of each model, as well. And that's going to be shared on a restricted SharePoint drive that's only accessible to the researchers who are involved.

COMMITTEE MEMBER JOHNSON: Sorry, just following up on the materials.

MR. ULLMAN: Yes.

COMMITTEE MEMBER LUND: Thank you for that explanation. Does anyone of the Committee have any questions?

VICE CHAIR DICKEY: I have one. You explained the comfort scale in 1 to 10, I believe.

MR. ULLMAN: Yes.

VICE CHAIR DICKEY: I was noticing on the consent form you just say if the comfort is greater than 3, you will receive a fit test. I don't know that they would understand what 3 means. You might want to --

MR. ULLMAN: Yeah. So --

VICE CHAIR DICKEY: -- put it in -- you might want to put it in simpler language, like if you achieve a certain comfort level, then we'll go ahead and do the test, without --

MR. ULLMAN: Yeah, that's a great -- that's a great idea. We do expand on that during the test, itself. But it is important for them to have an awareness of what the expectation is going to be as they're signing the consent form.

VICE CHAIR DICKEY: Yeah.

MR. ULLMAN: So, that's a great suggestion to add, to kind of flesh that out more on the consent form.

COMMITTEE MEMBER LUND: So, I have a question. I'd like to circle back to the compensation issue. This is an equity issue for participants. And it's unfair for some participants to be given a compensation and other participants not to be given a compensation for the same thing, right. Or, they're being exposed to the same level of risks, they're being asked to do the same activity.

So, if you can't give legal reasons compensations, I don't think that you should be offering compensation to any of them.

And I don't know, other Committee members may have another opinion on that. But I do think it's unfair to ask some participants for free while you're providing compensation to others.

COMMITTEE MEMBER JOHNSON: Yeah, that is news with today. Is it possible to not use CDPH freshmen employees as part of your -- and stick with UC Berkeley? And also, your application describes UCSF public health students.

MR. ULLMAN: I had removed that based off the --

COMMITTEE MEMBER JOHNSON: Okay.

MR. ULLMAN: -- comments that I had received from you. However, if we do remove the CDPH employees as subjects, then we would probably want to extend it out to multiple campuses in order

to get the 40 participants.

DR. RYKACZEWSKA: Just trying to better understand the concern brought up by the lawyers. Is part of it that they are already being compensated because they're doing it during work time and so they're --

MR. ULLMAN: Exactly. It's that they would be getting double paid.

DR. RYKACZEWSKA: Ah, okay. Better, trying to better understand. Okay.

VICE CHAIR DICKEY: And you don't want to do it outside of work time?

MR. ULLMAN: I'd be happy to do it outside of work time, especially since many employees do live in Berkeley, and so it would be easier for them to do it on the CDC Berkeley campus outside their working hours.

DR. RYKACZEWSKA: I don't know if that would appease their --

COMMITTEE MEMBER JOHNSON: That sounds like a good --

VICE CHAIR DICKEY: Would that satisfy the lawyers, I don't know.

MR. ULLMAN: I would have to -- yeah, I'd definitely have to put that past the lawyers. The main issue from the lawyers was the fact that they're getting double paid.

COMMITTEE MEMBER JOHNSON: Hm. Okay, so -- so you would need to check with CDPH lawyers on possibly if there would be an issue with offering time slots to CDPH employees to come in during non-working hours to be compensated --

MR. ULLMAN: Uh-hum.

COMMITTEE MEMBER JOHNSON: -- for their participation in the study.

DR. RYKACZEWSKA: I see a hand from Dr. Tefera.

VICE CHAIR DICKEY: Dr. Tefera.

COMMITTEE MEMBER TEFERA: Yeah.

COMMITTEE MEMBER LUND: So, then would it be -- I would have a hard time voting on this today not knowing that, because the compensation would go directly to the human subjects. So, I think if we're going to vote on it today there needs to be a contingency plan.

So, if you talk to the attorneys, the CDPH attorneys, and they say no, right, it's still not okay, then what happens? Do you exclude CDPH employees from the study so that you can compensate everybody who participates, so you're only going to recruit from the study opportunities. What's the plan B? Just so that we can get that clear here, so that when we vote we know what we're voting on.

MR. ULLMAN: Uh-hum. I would -- I would say that in

terms of recruitment and getting the number of individuals that we need for this study, it would actually be realistic to do only CDPH employees, if it's okay with the Committee for them to not be compensated.

We do have precedence of doing the testing of respirators during COVID on CDPH employees and this was public -- this was -- because so many different models were being sent to us that we do -- we've already had a lot of different people, when we talked about this, who have volunteered to be a part of this study. And to kind of, realistically, I think it would be a lot easier to get these subjects through CDPH, and not compensate, as a contingency plan.

COMMITTEE MEMBER LUND: So, that seems reasonable to me. So, then, your recruitment materials, and I'm sure Dr. Johnson will go over all of this with you, you know, as you always would. So, then, your recruitment materials will need to reflect what the situation is, whether or not there's compensation, extremely minimal risk. And I -- and it doesn't take much time. So, I'm very comfortable that no incentive is needed for this study. It just makes harder to recruit people. But it would be good to hear from the rest of the Committee.

VICE CHAIR DICKEY: Well, I think -- oh, I'm sorry, Dr. Tefera.

COMMITTEE MEMBER TEFERA: Sure. Good morning, Lemeneh

Tefera. And this is perhaps a question for the more senior members of the Committee. But are there precedents of other work where the employer, not the researchers or their study is prompting an issue with incentives like this. And if -- you know, if we found a way to move forward with those, it seems like there could be an opportunity to find a way to move forward with this study, as well.

VICE CHAIR DICKEY: Yeah, I mean we have had projects where that's the case. I'm thinking of the Infant Botulism project where they actually collected serum from employees.

It has to be absolutely clear, though, that this is voluntary and that it will not affect their employment any way, whatsoever, if they don't participate.

COMMITTEE MEMBER TEFERA: That seems like something the research team could make clear for participants. And likely, the participants would also have insight that this would not be particularly meaningful for their employment, as state employees.

VICE CHAIR DICKEY: Yeah, I mean, the other step is they, you know, say they need to get permission from their supervisor if they're doing this during work hours. I don't know if that's something too onerous, but how would that be if they had to get the supervisor's permission.

COMMITTEE MEMBER JOHNSON: Signed.

MR. ULLMAN: Yeah, I would say that it wouldn't be too

onerous to get the supervisor permission.

COMMITTEE MEMBER TEFERA: But how would that affect -- how would that affect the concern about the monetary incentive?

VICE CHAIR DICKEY: Well, they're not getting an incentive. But at least if they get a supervisor approval, then they're not going to get dinged for doing it outside -- you know, when they should be doing something else.

COMMITTEE MEMBER TEFERA: And then, would that allow the project to continue in its current format, then?

COMMITTEE MEMBER JOHNSON: Not its current format, it has to be amended to included that transparency in the consent and recruitment that they're not getting paid, and it's completely voluntary.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER JOHNSON: Are there any other comments?

COMMITTEE MEMBER PALACIO: Is the pay factor necessarily a motivator for the people who will be affected?

VICE CHAIR DICKEY: How much is it?

COMMITTEE MEMBER JOHNSON: It's $30 for an hour for being posted or emailed to graduate students.

MR. ULLMAN: Yes, graduate students.

COMMITTEE MEMBER JOHNSON: For a meal, for a month, for some graduate students.

I think that you'll have a lot of cooperation from CDPH employees. I don't think that your sample size is that large to, you know -- I think that you will be able to acquire 40 people either through --

MR. ULLMAN: Yes, I agree.

COMMITTEE MEMBER JOHNSON: -- UC Berkeley student or through CDPH employees. But I do agree with the concerns that there will need to be that increased transparency in the recruitment materials and the consent forms for CDPH employees, which is already has that their employment won't be impacted. But additional clarification about compensation will need to be added.

MR. ULLMAN: Uh-hum.

COMMITTEE MEMBER LUND: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Yes.

COMMITTEE MEMBER LUND: I think (indiscernible) -- is that, yes, I understand the CDPH employees won't be compensated. But I believe that my point is that everyone has to be compensated the same. So, if they're not -- if they're recruiting those students and CDPH employees, they can't pay the students and not the the CDPH employees. It's not fair from a participant perspective.

So, if they're going to recruit from both subject pools, they need not to pay anyone, if they can't pay the CDPH employees.

If they're going to recruit students and not CDPH employees, they can pay the students. Or they could go to only CDPH employees and then they wouldn't be paying anybody.

So, but that's my concern is that there's an equity issue here. And the compensation, the incentive needs to be equitable for all the participants.

COMMITTEE MEMBER JOHNSON: Understood.

MR. ULLMAN: So, I've a question for the Committee, then. It seems to me that the easiest path forward would be to focus on just the CDPH employees, without compensation. Would we still be able to open it up to other members of the public, if they're willing to come in without compensation? Or, if we went that route, would it just be the CDPH employees?

COMMITTEE MEMBER LUND: As long as the participants are compensated in the same way. In this case what I'm hearing you proposing is that no one would get compensation, but you would recruit from multiple groups. From an equity perspective, from this thing that I'm worried about, that's fine with me. I don't see any problem with that.

COMMITTEE MEMBER JOHNSON: I think that that is equitable, and I think most of your participants will be CDPH employees.

MR. ULLMAN: I agree.

COMMITTEE MEMBER JOHNSON: Thank you, Ms. Lund, for the contribution.

So, I guess like in sum, your application of -- you know, if you still plan to include UC Berkeley public health students to be contacted, that's fine. Otherwise, then, we'll just have to make some modifications to the application, which it sounds like there are a few that will be coming in anyway.

Is there any additional comments? Okay.

VICE CHAIR DICKEY: I hope you find that the masks with the ears are just as effective as the ones without, because I can't stand the ones with the --

MR. ULLMAN: I can tell you from experience that the ear loops are significantly less effective than strapped.

COMMITTEE MEMBER JOHNSON: Well, we will look forward to your publication.

All right, I'm ready to make a motion.

DR. RYKACZEWSKA: Public comment.

COMMITTEE MEMBER JOHNSON: Or public comment, after.

VICE CHAIR DICKEY: Yes.

DR. RYKACZEWSKA: There are no members of the public in the room. If there are any members on the Zoom that would like to make a public comment, please raise your virtual hand, now. I am not seeing any virtual hands.

COMMITTEE MEMBER JOHNSON: Okay. I make a motion to deferred approval, minimal risk, one year, pending the following changes.

That the application and all recruitment and consent materials be modified to remove the payment compensation portion.

That your recruitment and consent form includes the shared email address box. I think it's listed as Mr. Ullman's at the moment.

The consent --

MR. ULLMAN: I changed that in the resubmission that I did this week.

COMMITTEE MEMBER JOHNSON: Okay.

The consent form will be modified to include that test feedback in plain language.

Confirmation in the protocol that UCSF is not part of the recruitment pool.

I think that was it. To be reviewed by a subcommittee of me.

MR. ULLMAN: I think there is one more of putting more details about comfort into the consent form.

VICE CHAIR DICKEY: I think that's what you mean by the --

COMMITTEE MEMBER JOHNSON: Yeah, that's, I think

--

MR. ULLMAN: Oh, I see, to include comfort, yes.

VICE CHAIR DICKEY: Comfort, right.

Second?

COMMITTEE MEMBER VENTURA: I'll second.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

DR. RYKACZEWSKA: Dr. Dinis has gone.

MS. ATIFEH: Okay.

Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: The motion passed.

MR. ULLMAN: Okay, thank you all so much. I really appreciate your feedback.

DR. RYKACZEWSKA: Thank you.

COMMITTEE MEMBER JOHNSON: Thank you.

VICE CHAIR DICKEY: Okay. You'll receive a letter from us.

I understand that Dr. Tefera has to step out, is that right?

COMMITTEE MEMBER TEFERA: Around 11:05, 11:10, but whenever the chair recommends as far as that.

VICE CHAIR DICKEY: And that will be for how long, do you think?

COMMITTEE MEMBER TEFERA: Roughly 15, 20 minutes.

VICE CHAIR DICKEY: So, 15 to 20 minutes. So, the question is whether we should get started with the next project, which is Dr. Schaeuble's project. Do you think that we can complete it in 15 minutes or --

COMMITTEE MEMBER SCHAEUBLE: Well, could start it. I don't know about completing it however, I'm not sure.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: I think there are several places that need some clarification.

VICE CHAIR DICKEY: Yeah, sure. So --

DR. RYKACZEWSKA: A 30-minute recess?

COMMITTEE MEMBER TEFERA: I mean, we can start and then you can choose a certain time to stop.

VICE CHAIR DICKEY: Yeah, I will say why don't we start it because that will mean we'll finish earlier, in any case. If that's okay with you, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Sure.

VICE CHAIR DICKEY: Okay. So, the next project is the Assessment and Evaluation for Youth Alcohol Access.

And Dr. Schaeuble is the reviewer.

COMMITTEE MEMBER SCHAEUBLE: Dr. Tebb, good morning, I'm John Schaeuble. Good to see you in person here.

And I believe you have someone with you from the Friday Night Live program.

DR. TEBB: Yes. I'm delighted to introduce Katelyn Wiliford.

MS. WILIFORD: Hi. Good after -- not afternoon, yet. Good morning. Thanks for being here, thanks for the invitation.

COMMITTEE MEMBER SCHAEUBLE: So, could we begin by asking you to provide a brief overview of this particular project for the Committee?

DR. TEBB: Sure, absolutely. I thank you all for your time and flexibility here.

So, basically, as most of you probably know, adolescents' use of alcohol, tobacco and other drugs is a critical public health issue, and it's the leading cause of preventable mortality and morbidity among young people.

So, the purpose of this study is to develop and implement an anonymous survey. And we will be surveying approximately 1,500 adolescents from California to assess their knowledge, their attitudes, some social norms, and perceptions of underage alcohol use, along with some substance use behaviors.

And the whole purpose of this study is to really inform a public health campaign to prevent underage alcohol use.

So, to implement the survey, like I mentioned it's anonymous, so we believe it's minimal risk. We are partnering with the California Friday Night Live partnership, which Katelyn represents. And the youth in those programs there -- so there's program in -- Friday Night Live programs in nearly every county of California.

And similar to a survey that we did last year on cannabis use, that was approved using the same methodology, we will ask -- or, the program staff at each of these Friday Night Live programs will ask their youth participants to distribute a link via QR code or web links to their peers. And they also have access to flyers that they can distribute to their peers.

It's completely voluntary. And all of the data will be housed in the UCSF secure system. We're going to be administering it through the online Qualtrics survey system.

The survey will have two components, because we do want to incentivize youth to complete the survey. So, the main survey with Qualtrics will be the completely anonymous survey that will have the knowledge, attitudes and youth questions.

And then, when the youth finishes that survey they will be offered the opportunity to be entered into a drawing to win one of $50 gift cards. And in -- as part of the introduction of the survey, we let them know their odds of winning, and we tell them that they don't have to answer any questions that they don't want to. That some of their responses might make them feel a little bit uncomfortable.

Most of the attitudes -- most of the questions are about attitudes and knowledge, but there are some questions about behavior. So, we've made those adjustments based on the initial review.

I think that covers the big picture overview. Does anyone have any questions or would like me to explain a little more about the project?

COMMITTEE MEMBER SCHAEUBLE: I think that's a good initial summary, yes. And thank you, also, for the changes that

you've already made in response to initial comments. It was helpful to see those this week, when the project came back.

There are three portions of the application that I'd particularly like to look at in a bit more detail. I think there's not a need to go over the changes that you've already made, but three places that I'd like to get into in a bit more depth.

One thing I think is very easy, in the study procedure section I had discovered earlier that your budget document mentioned this, and then most recently your cover letter, as it was revised this week, also mentions that you have plans to conduct focus groups after the survey part of the project is completed by submitting an amendment at a later time.

The study procedures part of the application should, I think, really give a complete picture of the project as a whole. So, I would ask you to include, at the end of the study procedures, something like what you had in your cover letter, saying that you do have plans to do a focus -- focus groups at a later time. So, that's documented within the application for us.

I assume that's still part of your plans and still appropriate to ask you to --

DR. TEBB: Yes, it is. It is. And the reason why we like to do focus groups with young people is we want their input in terms of interpreting survey findings, and to help get their input

and their engagement on public health messaging. So, that's an important part of the project and we'll be happy to add that at the end of the study procedures, in addition to it being mentioned in the cover letter.

COMMITTEE MEMBER SCHAEUBLE: Find. I'm looking at the time here. Is this about when you wanted to maybe have a break?

COMMITTEE MEMBER TEFERA: Sorry, I said 11:10, but whenever you like, as you like. I just have to step out around 11:10.

VICE CHAIR DICKEY: He's got five minutes.

COMMITTEE MEMBER TEFERA: Five more minutes, if you like.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, the second area that I wanted to get into is the part of your application that describes screening for participants in the study.

Your first sentence there says the survey will only allow adolescents from California, between the ages of 13 and 20. That's a rather definitive kind of statement and certainly I understand that your goal is for participants to meet those particular qualifications.

But I'm thinking that there's a real limitation, as I see it here, of online studies that you can't ever be exactly sure who is responding to an online survey. So, it seems to me that a more appropriate sentence at this point would be to say something like

we are -- we are seeking to have California adolescents between 13 and 20, but one of the limitations of an online survey is that we cannot be certain who is responding.

Is that a fair enough reflection of what the situation really is.

DR. TEBB: Yes. Absolutely. Absolutely. We do our best to try and limit it to that population because that's really the target of the public health campaign. But, absolutely, we can state that in a more accurate way in that section.

COMMITTEE MEMBER SCHAEUBLE: You go on to mention several security procedures built into Qualtrics that are designed to prevent some of the kinds of problems that can happen with online surveys. Can you give us a more complete picture of just what those provisions in Qualtrics are.

DR. TEBB: For sure. Similar to another study that I've been involved with on adolescents' sexual health, attitudes and behaviors, we had an online survey. And in that process, we discovered the potential for duplicate users and for bots.

So, we reached out to the Qualtrics system to see what, if anything, we could do to prevent unintended users. And there are actually quite a number of features available in Qualtrics, through our UCSF license, that has some bot detection features. It gives the CAPTCHA scores so you can kind of see to what extent this

may or may not be a real user. And it has some duplication prevention methods, as well.

COMMITTEE MEMBER SCHAEUBLE: Do any of these measures in any way capture any kind of identifiers, device identifier of a phone, or a computer, or anything that the person is using when responding to the survey?

DR. TEBB: Yeah, are you concerned about IP addresses?

COMMITTEE MEMBER SCHAEUBLE: That would be one identifier, yes.

DR. TEBB: Yeah. So, I am not quite entirely sure to what extent they utilize the IP addresses. That certainly wouldn't be available in the dataset, to my knowledge.

VICE CHAIR DICKEY: I think it's 11:10, so I think we have to come back.

COMMITTEE MEMBER SCHAEUBLE: Okay.

VICE CHAIR DICKEY: So, we come back at 11:30, is that right or --

COMMITTEE MEMBER TEFERA: I'll be like, hopefully, before then, 15 minutes from now.

VICE CHAIR DICKEY: Okay, well, let's set it for 11:30 then. We'll reconvene at 11:30.

(Off the record at 11:09 a.m.)

(On the record at 11:29 a.m.)

COMMITTEE MEMBER SCHAEUBLE: Well, hello again, Dr. Tebb. We're back in session here with you.

DR. TEBB: And the break was an opportunity for us to do a little bit of digging. So, I think we do have some options that we'd like to discuss with you --

COMMITTEE MEMBER SCHAEUBLE: Okay, good.

DR. TEBB: -- on the best way to handle this.

COMMITTEE MEMBER SCHAEUBLE: Good. Can you go ahead and tell us what you're thinking about here?

DR. TEBB: Sure, are we ready? I just want to make sure everybody's joined and we're ready to begin.

COMMITTEE MEMBER SCHAEUBLE: Yes, we are.

DR. RYKACZEWSKA: Yes.

DR. TEBB: Okay, terrific. So, it is true that in order for the IP addresses to be blocked, you have to enable the anonymized studies in Qualtrics to ensure that the IP address is not collected. And if you employ any of the security measures that we were describing in our procedures, the IP address is collected, and there's no way to block that. So, we were able to get that verification.

So, the way we see it, we have two options. One option would be to disclose in the introduction that we are capturing IP addresses for the sole purpose to avoid multiple and fraudulent

users. That would be -- that would be one option. We would not use it to link any participant's responses with the data that we gather.

The other option is to enable the anonymized setting and not collect the IP addresses and not employ those security settings. Our concern about that is fraudulent users participating in the survey to take advantage of the opportunity to earn a gift card.

So, those are the two options that we see in the tradeoff. I would love to -- we would love to ask the Committee their recommendation.

COMMITTEE MEMBER SCHAEUBLE: Well, I think we can look for comments here from others on the Committee, as well. When I first read the beginning of your response to this question, my first thought was how likely it might be for a teenager to provide the link to somebody who might not fall within your age range, a brother, or sister, or friend who's older than 20, who -- with a comment, hey, here's a way that you might win $50 pretty easily.

DR. TEBB: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: So, my personal reaction is that you probably have some legitimate concerns here about the potential of responses coming from people that are not your targeted people. And I guess I'll be interested to see what other

Committee members might say. But I would lean towards disclosing in the consent information, at the beginning of the survey, that they're using -- using the kind of language you suggested, you're using measures to try to prevent fraudulent responses that do involve capturing identification of the device that the person is using.

And in that sense, you really have to avoid the word "anonymous" in describing your survey, I think. And instead say that it's confidential and explain that those -- that identification is only used for the one purpose and not for anything else, as you were saying.

That sounds to me like sort of the way around it.

DR. TEBB: We do have a question, teens, when they're talking about their risk behaviors, especially on a survey, we really do want to make them feel comfortable in answering as honestly as possible.

If we're really not linking the IP address to any individual or their responses, is it still all right to say anonymous, as long as we're disclosing the only reason why we're capturing the IP address is to track fraudulent users. We're not looking at the IP address to identify any adolescent's individual responses to a survey.

VICE CHAIR DICKEY: I mean, you could probably use the

word "anonymous" but with the qualifier, right. Saying anonymous except for --

DR. TEBB: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: That might work.

So, I guess I would ask what some other people here think about that. Laura, do you have any thoughts?

COMMITTEE MEMBER LUND: Yeah, actually. Thank you, Dr. Schaeuble.

So, I -- if IP address is the only thing, I don't have a problem with the use of the word "anonymous." Because IP address, although it links to a specific computer doesn't identify the specific individual.

So, yes, the HIPAA guidelines that you suggested, it's an identifying piece of information because it's linked to a specific computer, but that -- in terms of a person providing their information to the survey, just that IP address doesn't, to me, require a qualification of the word "anonymous." The survey doesn't ask for any other identifying information.

It would be very difficult for you to paint a picture of how one of these young people, taking the survey, would be at risk for having their information, their answers disclosed based on the IP address being used in the way that it's been described here.

So, I personally think, and I do know that it's hard to

get young people to answer surveys if they think their information might be compromised. So, in an effort to help promote the study and the purpose for which the study's being conducted, I don't have a problem with using the word "anonymous" here.

COMMITTEE MEMBER SCHAEUBLE: So, if other people are thinking the same thing, then it sounds like you could retain it by saying as you were suggesting, anonymous except for the particular usage of -- well, and again, I'm not sure exactly how you want to phrase this because we're dealing with so much black box stuff here of often not knowing exactly what Qualtrics or anybody else is actually doing.

And do we know that IP address is the only thing or are there other -- there are other kinds of device identifiers. Is there any possibility that it's collecting something else, as well?

DR. TEBB: To my knowledge, no. The only thing that would be identifying would be the -- potentially, identifying would be the IP address.

Qualtrics is -- you know, they've at least disclosed that they are collecting the IP address for those purposes and they do disclose how you turn that off.

COMMITTEE MEMBER SCHAEUBLE: So, that's what they're depending on as far as preventing multiple submissions and fraudulent submissions.

DR. TEBB: Exactly.

COMMITTEE MEMBER SCHAEUBLE: Thank you.

DR. TEBB: Exactly.

COMMITTEE MEMBER SCHAEUBLE: Well, then I think we're probably on the same page here about what to do in that regard.

DR. TEBB: I really appreciate the thoughtful conversation. I think it's going to inform us on other projects moving forward, also. So, I appreciate this conversation.

COMMITTEE MEMBER SCHAEUBLE: The other part of your response here, that I also want you to say something about, is you talk about capturing longitude and latitude. Would you explain what you mean there and how that's to be used?

DR. TEBB: Yes. So, with regard to trying to restrict participants within California, they can -- Qualtrics can enable a feature, if you enter the latitude and longitude of California, it can give you a proxy of the State of California, and they can cross-reference that with the IP addresses to flag anyone that might be outside of those parameters.

So, again, it's not used to identify any participant, but it's used in conjunction with the IP address for the geo location.

COMMITTEE MEMBER SCHAEUBLE: How necessary do you think that is? I guess I'm a little concerned here that capturing the location of the person --

DR. TEBB: It's not the person, it's the --

COMMITTEE MEMBER SCHAEUBLE: Well, the location of the computer.

VICE CHAIR DICKEY: The IP address.

DR. TEBB: Well, it's actually a little bit different than that. It's sort of the flip side of that. My understanding is that you enter the longitude and the latitude of the state and that's cross-referenced with the IP address, but that's not necessarily reported. It's not critical for us to do that. If we get youth outside of California, so be it. We're still getting youth, we still have these other fraudulent detectors. So, I'm find with removing that.

COMMITTEE MEMBER SCHAEUBLE: I suppose it's possible you would get some out-of-state respondents. That just seems -- I'm guessing, off the top of my head here, it just seems much more unlikely to me than to possibly have somebody out of your age range.

DR. TEBB: Uh-hum. And if we do get adolescents outside of California, it doesn't really harm the integrity of the study in terms of a cost benefit ratio.

Unless, Katelyn, you feel otherwise.

COMMITTEE MEMBER SCHAEUBLE: So, I would be tempted, as far as this part of the protocol is concerned, to make the changes

that we've discussed about language concerning the protections that your Qualtrics system is attempting to us as the only qualifier to the word "anonymous" and to not really do anything with latitude or longitude just as an extra measure of protection here.

DR. TEBB: Sure. And then, we'll also mention our intention to do focus groups, as well.

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. TEBB: But that we will be submitting an amendment later for that.

COMMITTEE MEMBER SCHAEUBLE: So, going on, then, to the third area that I wanted to discuss with you, some specific things on the beginning of your survey, where the consent information is. Subject to whatever other changes take place here from what we've already talked about, the first paragraph of the consent form I have no problem there, the first or second paragraph.

For the third paragraph, the final sentence there says you can skip any question you do not want to answer, but you've already said that at the end of the second paragraph. It seems unnecessary to be saying it a second time.

And I would suggest that the sentence at the beginning of the next paragraph, if you do not know answer that's okay, just mark that you don't know, logically fits very well after your discussion of all of your answers are anonymous. Please answer

your questions as -- please answer the questions as completely as you can.

I think it would be logical to say, in that paragraph, if you do not know an answer, so moving from the sentence from the beginning of the fourth paragraph, to the end of the third paragraph, in place of the final sentence that's currently there.

You're looking puzzled, I think, and I'm not sure --

DR. TEBB: I'm -- I'm looking at it. I see the duplication in paragraph two and paragraph three. Which one would you like me to move it from? I didn't -- I had a hard time following.

COMMITTEE MEMBER SCHAEUBLE: What I'm -- okay, I'm sorry.

DR. TEBB: That's okay.

COMMITTEE MEMBER SCHAEUBLE: My suggestion is leave it where it is the first time that you mentioned it.

DR. TEBB: Okay.

COMMITTEE MEMBER SCHAEUBLE: That's in the second paragraph. And at the end of the third paragraph eliminate the second time and move the --

DR. TEBB: Got it.

COMMITTEE MEMBER SCHAEUBLE: -- move the second at the beginning of the next paragraph back to the end of the third paragraph.

DR. TEBB: Terrific.

COMMITTEE MEMBER SCHAEUBLE: Since those things seem to belong together.

DR. TEBB: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: The remaining part, then, of this next paragraph, I just don't understand. And I think I --

DR. TEBB: That's a -- that was an artifact, my apologies. You're referring to the statement, "And please only answer the questions that are asked on the survey."

COMMITTEE MEMBER SCHAEUBLE: Right.

DR. TEBB: That was left over from a paper-based survey. I will remove that.

COMMITTEE MEMBER SCHAEUBLE: Okay. That's why --

DR. TEBB: I apologize that I didn't remove that.

COMMITTEE MEMBER SCHAEUBLE: -- that's why I was asking, it didn't make sense to me for an online survey.

DR. TEBB: Yes.

COMMITTEE MEMBER SCHAEUBLE: So, I'm glad it's clarified.

DR. TEBB: Yes. My apologies.

COMMITTEE MEMBER SCHAEUBLE: And then, the only other thing I will mention here is you have two initial questions, what is your age and what state do you currently live in, drop down menu for indicating age. I think it would be best to have a drop-down

menu also for state, rather than a box for something to be written in. Since that might be the one kind of place where you would get some kind of identifying information you don't really want.

DR. TEBB: Well said, yes. We can do that drop down menu.

I was going to ask if it would be okay, rather than list it alphabetically, if we put California first, and then provide the list of other states so youth -- to make it easier for youth to find their state.

COMMITTEE MEMBER SCHAEUBLE: I'm wondering even --

DR. TEBB: It seems more -- yes.

COMMITTEE MEMBER SCHAEUBLE: I'm wondering even do you want to know specifically the other state if it's not California, or do you want to simply know California or some other state as a second alternative? You can ponder that, if you're not sure.

DR. TEBB: I actually like that idea. Yes, I'm from California. No, I'm not from California.

COMMITTEE MEMBER SCHAEUBLE: That seems --

DR. TEBB: That really keeps it simple.

COMMITTEE MEMBER SCHAEUBLE: It seems like the simplest approach, yes.

DR. TEBB: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: I think those are the end of

my comments and questions. And I'd like to open it up for the Committee first, and then I'll ask if there are any public comments, as well.

COMMITTEE MEMBER AZIZIAN: In some ways related to the question of anonymity and when discussing these fraudulent concerns, I was -- my mind was wondering if someone was going to pass it along, they may as well as take them themselves, multiple times, increasing their (indiscernible) -- it could make a major difference in there.

So, how does the mechanic of it work exactly, if it's anonymous and later on they're going to have the opportunity to win a gift card? How is that linked together that you're able to identify them and send it to them?

DR. TEBB: So, it's a way of setting up this Qualtrics survey, there's basically two surveys. One survey is the anonymous survey. And then, when they complete that survey they're asked if they would like be entered into a drawing to win one of 50 gift cards. And if they select yes, it takes them to a separate survey that's not linked with the primary survey, for the sole purposes of selecting -- to gather that information. So, if they do win the gift card or, you know, receive a gift card then we have a way of distributing the gift card to them, without linking their individual data with the survey data.

COMMITTEE MEMBER AZIZIAN: And the comment about that in future there may be a focus group, is this like a separate group of people or it would be collected from the same sample?

DR. TEBB: No, it would be a separate group of people.

COMMITTEE MEMBER AZIZIAN: A separate --

DR. TEBB: So, typically we utilize the California Friday Night Live Partnership for Youth, and the youth leadership group for the Friday Night Live programs.

COMMITTEE MEMBER AZIZIAN: I see. And just an area just -- just an area of California and consent, with having teenagers in there, are there any particular safeguards or requirements that -- how does consent work for minors? They can practically take it themselves or -- usually, there is this notion that if someone is a minor, they may not be able to consent.

DR. TEBB: So, I do a lot of work around analysts and confidentiality. And when you're asking adolescents about health risk behaviors, such as substance abuse, those behaviors are covered by California State confidentiality laws and protections. And so, obtaining parental consent would put the participant more at risk than would otherwise be necessary.

And because it's anonymous, we don't have a way of linking that data to any particular individual. But if a parent was to know that they were completing the survey, the parent could

pressure the young person to share their responses on that survey with them. And we don't want to put anybody in that risky situation.

COMMITTEE MEMBER AZIZIAN: Thank you very much for that.

VICE CHAIR DICKEY: Any other comments, questions from the Committee?

COMMITTEE MEMBER TEFERA: Hi, good morning, Lemeneh Tefera. Your survey is described as roughly two hours. Did I misread that?

DR. TEBB: Yes. It's not two hours at all.

VICE CHAIR DICKEY: Where are you seeing that, Dr. Tefera?

COMMITTEE MEMBER TEFERA: Oh, I just scrolled past it. It said, three times over two years -- sorry, the interview is two hours and the survey is 30 minutes is what I read. Page --

DR. TEBB: Interview? We're not doing interviews.

COMMITTEE MEMBER TEFERA: Page 14 of the .pdf. Sorry.

DR. TEBB: The same thing.

COMMITTEE MEMBER SCHAEUBLE: I wonder if you're looking --

DR. RYKACZEWSKA: Different study, maybe.

COMMITTEE MEMBER TEFERA: Do I have the wrong --

COMMITTEE MEMBER SCHAEUBLE: Different project, perhaps.

This survey is about 35 questions.

DR. TEBB: Don't see anything.

COMMITTEE MEMBER VENTURA: Study duration, 36 items, between 25 and 30 minutes is what I'm seeing.

VICE CHAIR DICKEY: Maybe that's the project that we went through.

DR. RYKACZEWSKA: So, this is the results, the non-italicized. So, there's --

COMMITTEE MEMBER TEFERA: Not the top part.

DR. RYKACZEWSKA: No, no, that's -- sorry, that's instructions and examples for the --

(Laughter)

DR. RYKACZEWSKA: Sorry.

COMMITTEE MEMBER TEFERA: Okay, thank you. Yeah, two hours seemed ambitious for adolescents, I was just wondering how you were going to do that.

DR. TEBB: We would never do that with them.

COMMITTEE MEMBER SCHAEUBLE: That would be very ambitious.

COMMITTEE MEMBER TEFERA: Yeah, I was like that seems amazing. Thanks.

VICE CHAIR DICKEY: Thank you for doing that.

Any questions or comments from the public?

Hearing none, are you about to make a motion, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I guess so. So, I will move a deferred approval for one year, at minimal risk, with the following changes.

First, under study procedures add the information that the researchers intend to conduct focus groups as a later part of the project.

DR. TEBB: And we can also add with teams that are not participating in the survey.

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. TEBB: And so, it's clear that we're not using that same group as was raised by one of the Committee members.

COMMITTEE MEMBER SCHAEUBLE: Good, yes.

VICE CHAIR DICKEY: But would you put in an -- will be amended to include the subjects -- you know, the details of the focus group

COMMITTEE MEMBER SCHAEUBLE: Yes, there's just added that, there will be an amendment.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER SCHAEUBLE: Second, to revise the first sentence in the screening part of the application as discussed by the Committee.

VICE CHAIR DICKEY: Don't we need to be a little more specific?

COMMITTEE MEMBER SCHAEUBLE: You want me to be more specific, okay. Revise --

DR. RYKACZEWSKA: Revise the first sentence on the screening part of the application --

COMMITTEE MEMBER SCHAEUBLE: To explain that the goal is for participants to be California adolescents between 13 and 20, but online surveys cannot assure that this will be the case.

DR. TEBB: That's in the application, not in the consent, correct?

COMMITTEE MEMBER SCHAEUBLE: In the application, yes.

DR. TEBB: Okay.

COMMITTEE MEMBER SCHAEUBLE: Next item, to clarify the security measures used by Qualtrics and to remove obtaining -- remove, using longitudinal and latitude parameters.

DR. TEBB: What additional information do you need when you say clarify the security measures used by Qualtrics?

COMMITTEE MEMBER SCHAEUBLE: You specified that IP address is the only kind of identifier --

DR. TEBB: Okay.

COMMITTEE MEMBER SCHAEUBLE: -- that Qualtrics works with.

DR. TEBB: Thank you. Thank you for that.

COMMITTEE MEMBER VENTURA: Specifying the IP address as the security -- that's the only, the security measure we're talking about collected by Qualtrics.

VICE CHAIR DICKEY: Well, it's --

COMMITTEE MEMBER SCHAEUBLE: The researchers are saying that's the only thing that Qualtrics is using to prevent fraudulent, or bot submissions, or multiple submissions.

VICE CHAIR DICKEY: But shouldn't she say that -- clarify that you're not going to use longitude and latitude and then have a --

DR. TEBB: Correct.

VICE CHAIR DICKEY: -- and then have a separate one that says you're going to acknowledge the use of IPA addresses in the consent form?

COMMITTEE MEMBER SCHAEUBLE: I haven't gotten to the consent form, yet.

VICE CHAIR DICKEY: Oh. Okay. I'm ahead of you.

DR. RYKACZEWSKA: This is in the application. Right?

COMMITTEE MEMBER SCHAEUBLE: Okay, so the next item in the consent form, explain that the survey is anonymous with the exception that the survey software does use identifier -- an identifier of the phone or computer to try to prevent fraudulent

submissions.

DR. RYKACZEWSKA: That's a hard word to spell. Thank you.

DR. TEBB: Fraudulent is a pretty high-level terms for many of these adolescents.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Okay.

VICE CHAIR DICKEY: What about duplicate?

DR. TEBB: So, maybe we could say to ensure --

VICE CHAIR DICKEY: That no duplicate submissions.

DR. TEBB: Yeah, to avoid duplicate users.

COMMITTEE MEMBER SCHAEUBLE: So, the next item is to remove the final sentence from what is currently the third paragraph, and replace it with the first sentence from the fourth paragraph, and to remove the remaining sentences in the fourth paragraph.

And the final item is to use a drop-down menu for the question about state, as already being done for the question about age.

And I can review the changes.

VICE CHAIR DICKEY: Is there a second?

DR. RYKACZEWSKA: Did we do public comment?

VICE CHAIR DICKEY: Oh, I'm sorry, I thought we asked for

public comment.

DR. RYKACZEWSKA: Did we formally ask for public comment? Now, I'm no longer sure.

Just in case, if there are any public comments before we vote on the motion, if you could please raise your virtual hands now, acknowledging no members of the public in the room.

I see no public comments.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER PALACIO: Yes.

MS. ATIFEH: Okay, Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay.

DR. TEBB: Thank you all for your thoughtfulness and time that you've dedicated to our project. We really appreciate it.

MS. WILIFORD: Thank you for the opportunity, it was great seeing you all.

VICE CHAIR DICKEY: Thank you. And thank Dr. Schaeuble for the review. And you'll be getting a letter from us in the next couple weeks.

COMMITTEE MEMBER SCHAEUBLE: You will also see comments in the application, itself, reflecting what we've talked about today. So, you'll have it from two angles. You'll see a letter, when you receive it. There also are comments in the application or will be.

VICE CHAIR DICKEY: But the final word is the letter. Right? So, if there's a difference between the two, I think we have to go with the letter because that's what we're taking the action on.

VICE CHAIR DICKEY: Okay, the next project is Supporting a Strong Start for California Kids. And Ms. Lund is the reviewer

DR. RYKACZEWSKA: Oh, Ms. Lund, you are muted.

VICE CHAIR DICKEY: We're not hearing you.

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: Oh.

COMMITTEE MEMBER LUND: Muted, thank you.

So, I believe that we have Dr. Putnam-Hornstein here, virtually with us today.

So, what I'd like to do is ask Dr. Putnam-Hornstein to introduce herself and her team. And then, please give us an overview of the project and we'll go from there. Go ahead.

DR. RYKACZEWSKA: Dr. Putnam-Hornstein, you are muted.

DR. PUTNAM-HORNSTEIN: Sorry about that. Good afternoon, everybody. Thanks so much. Good to see everyone. I'm Emily Putnam-Hornstein. I'm a Professor at UNC Chapel Hill.

And I am joined by my Co-Principal Investigator, Dr. Regan Foust. And we also have colleagues here who will be helping administer the survey.

I'm actually going to turn it over to Regan to provide a brief introduction to the project.

DR. FOUST: Hi everyone. Dr. Regan Foust here. And I have the honor of presenting Supporting a Strong Start project for your consideration.

Many community-based volunteer services successfully support vulnerable families. However, many eligible families don't participate, and especially those who are most at risk for poor outcomes. And we don't fully understand why.

So, in order to fill this gap we plan to use, Vital birth and death records to solicit the entire population of adult mothers who gave birth in California between May 1st and August 31st 2026 [sic]. So, that's a total of about 200,000 families.

In a brief 20 minutes, remunerated $21, and this would be administered online. The survey would probe perceptions of community-based voluntary support from services, factors include the uptake of available services, and self-reported service and support needs.

We would then apply the Strong Start index, scoring the paradigm to the birth records. And this is a scoring paradigm used based solely on birth records. And what we would be able to do then is over sample in the lower end of the assets spectrum in order to help ensure that we're hearing from the families at higher risk of those poor outcomes.

The results that would be shared with First 5 clinicians, funders, policymakers would not only better characterize the service landscape at those local and state levels, but also the needs, experiences, and challenges that appear in the state across the asset spectrum, and in an active space of available services and support.

And with the focus on families at risk of adverse outcomes, it would also help us better align those needs and

supports, evaluate and improve programs, and refining (indiscernible) strategies.

Finally, it's important to give voice to the experiences of families of young children, and for the public agencies to hear directly from families for whom those services were devised.

Overall, this work is to fill a major gap in our understanding of our most vulnerable Californians, and promote and encourage all children statewide.

So, as we move to risk mitigation, I wanted to thank you, Ms. Lund, for your incredibly helpful comments. They helped to inform the myriad revisions that we submitted last week.

So, first, to ensure confidentiality survey responses will contain no direct identifiers, only an encrypted linkage key connecting responses to birth records.

Identifiers would also be, of course, stored separately and securely, and away from survey and analytic data.

Second, to mitigate potential distress resulting from two broad questions about adverse experiences, participants would be reminded that they can skip questions, can stop at any time. And in addition, respondents would be provided with endorsement-specific resources at the end of the survey.

And then, finally, to avoid contacting grieving parents, we plan to link birth and death records to identify and then

proactively exclude cases in all (indiscernible) -- or deaths in the study.

In the unlikely event that a grieving parent is contacted, following the models of other available surveys, including MIHA, PRAMS, Fragile Families, respondents would be sensitively redirected to the survey's conclusion, receive condolences, remuneration and specific resources.

I'm happy to answer any questions and look forward to the conversation.

COMMITTEE MEMBER LUND: Great. Thank you so much. And I'd really like to thank you and acknowledge that you've done an amazing amount of work. I had a lot of questions and a lot of concerns and you've responded very thoroughly. In fact, if there are Committee members who have questions or concerns, Dr. Putnam-Hornstein submitted a very nice document that goes through my issues one by one and provides the specific information, in addition to incorporating that in the protocol.

So, I really appreciate that. Thank you so much.

So, I am, just to let the Committee know, very satisfied with the changes that the researchers have made to the protocol, and based on my questions. And I believe my concerns have all been addressed. So, I don't have anything specific here to ask them to do differently.

I did want to highlight three things for the Committee, they were always the three things that I had the most concerns about, in case there are questions from the Committee members about those things.

The first thing was the original version of this protocol had asked for an expanded variable list, and there was a very vague statement about wanting to characterize the population, and use all the additional variables that weren't directly related to the stated research questions.

And the researchers have removed that. So, now, the -- my understanding is that the request now is for variables that are directly related to the research questions and the study, as described in the protocol. And that this broader piece of using demographics and other information to characterize the population has been removed. Thank you for that.

The second thing is the -- I had concerns about the way the original contact of potentially grieving parents was described. And I am very comfortable with the changes that were made. The researchers will be doing a linkage with death data to make sure that for both -- I think, if I understood correctly, for both deceased infants and deceased mothers. The ones who could be identified beforehand will not be contacted at all.

And then, the language around asking about whether or not

the infant is -- was softened. And I really appreciate that. It was a much less shocking first question. So, that addressed my concern.

And then, some of the questions that were asked were, I felt, sensitive and potentially triggering. And especially, for parents of newborns this is a very difficult time. It's an emotional time. People are sleep deprived. They may be more likely to be triggered by certain things, emotionally, than they might otherwise be if they weren't in that situation.

So, I appreciate your attention to that and the modification that you've offered I think is adequate for the situation. So, I don't have any other concerns about that.

But I did want to raise those three things for the Committee in case other members had concerns and wanted to hear more from the researchers about those things.

And so, I'll open it up to the rest of the Committee at this point.

COMMITTEE MEMBER JOHNSON: I had a question. So, is it possible for the birth records that you're receiving from CDPH, for them to pre-filter out infants that it's already known have passed, versus sending you the information about the birth record for someone that is already known and established in the state system to be deceased? Or is that what these modifications are in

reference to?

DR. PUTNAM-HORNSTEIN: So, that is a great question. We can certainly -- I'm actually on the Vital Statistics Advisory Committee, so I feel as if I should know this.

I know that there is a linkage that is done when the annual files are released. I think because we are requesting the birth records before that file has been released that there would not be a complete linkage to the death records.

But we're certainly happy to amend our protocol to specify that if that information can already be filtered out from VSAC, that that's all we would be requesting.

COMMITTEE MEMBER JOHNSON: Yeah. It is known prior to and the date -- the death statistical file number or state file number can be added to the birth certificate, so it would be a field that CDPH could filter out prior to sending you the deliverable. It's not just in the annual file.

DR. PUTNAM-HORNSTEIN: Okay.

COMMITTEE MEMBER JOHNSON: That would be my recommendation to -- for minimum data necessary, for not even sending those birth records for the infant that's already deceased.

I also would encourage the linkage procedure to happen after the fact, since most of the deaths that are caught are more closer to the date of birth and wouldn't catch one month or beyond.

VICE CHAIR DICKEY: Just for the Committee, I just want to clarify. The Information Practices Act specifically says that we can require redactions.

DR. RYKACZEWSKA: If feasible.

VICE CHAIR DICKEY: If feasible.

COMMITTEE MEMBER VENTURA: I had a question, a clarifying question about the role of Verasight and receiving PII. And I apologize if I didn't -- I didn't see the revisions submitted, Laura. So, has that issue been clarified?

COMMITTEE MEMBER LUND: What was the specific question?

COMMITTEE MEMBER VENTURA: There was mention of Verasight. Oh, I'll have to find it now. And that they would receive PII. Has that been described, their role in the project, what exactly they're going to receive?

COMMITTEE MEMBER LUND: Yes. To my satisfaction.

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LUND: They sent -- it was modified, so yes. And the Verasight staff were added to the application as research staff.

COMMITTEE MEMBER VENTURA: Okay. Thank you.

COMMITTEE MEMBER LUND: They've been put in there.

COMMITTEE MEMBER JOHNSON: I have a future question. Because this, a lot seems like around potential services that would

be offered to children who receive Medicare or Medicaid. Do you plan to, in a future rendition of this study, link up your data with data that's in Medi-Cal, particularly around the supportive care services that would be available to both children and their mothers.

DR. FOUST: So, that's definitely something that we've considered and not included in this current application. But it does appear on the consent form so that should that be something that we amend the protocol, it would be able to be included.

But in this, definitely not under consideration for the current protocol.

COMMITTEE MEMBER JOHNSON: Was actually just curious if that's where you're headed.

COMMITTEE MEMBER LUND: Anybody else? Public comments?

DR. RYKACZEWSKA: If you have any public comments, if you could please raise your virtual hand. Acknowledging no members of the public in the room. And I see no virtual hands.

COMMITTEE MEMBER LUND: Okay, great. I think I'm ready for a motion. So, I move deferred approval, minimal risk, one year, with the following additions.

The researchers will ask CDPH to provide them with the birth data files with all of the known deceased infants removed.

DR. RYKACZEWSKA: I think I got that right.

COMMITTEE MEMBER LUND: I think it's just infants, not individuals.

Or, Dr. Johnson, did you want it to say individuals, so both the infant and maternal death?

COMMITTEE MEMBER JOHNSON: Well, I think if it's just the -- if it's the birth data -- oh, hmmm. I don't think -- I think CDPH would push back on that, that it would be burdensome. I don't think that they have linked mothers' birth records with their death certificates.

COMMITTEE MEMBER LUND: Okay. Well, and this protocol is going to be doing that linkage, anyway --

COMMITTEE MEMBER JOHNSON: Right.

COMMITTEE MEMBER LUND: -- with the information that they receive. Okay, if you're good with that, then that's fine.

And that's it.

DR. RYKACZEWSKA: To be reviewed?

COMMITTEE MEMBER LUND: Me, a committee of one, subcommittee of one.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER JOHNSON: I second.

MS. ATIFEH: Okay. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

COMMITTEE MEMBER LUND: Great, thank you. And Dr. Putnam-Hornstein, you will get a letter that describes this change. You can, if you want, go ahead and revise the protocol before you receive the letter, but just to let you know that that's going to come your way.

DR. PUTNAM-HORNSTEIN: All right, thanks. Thank you so much.

DR. FOUST: Thank you.

DR. RYKACZEWSKA: Thank you.

VICE CHAIR DICKEY: Thank you. So, that ends it for the projects. We have items I through O on the agenda. For new

members, there are a number of things that don't require approval by the Committee, but everybody needs to be informed. So, this is expedited reviews, and also exemptions and stuff that the chair and vice chair do. So, those are listed, also.

And, so, any comments or question from the Committee about any of those things?

Any comments from the public or questions?

DR. RYKACZEWSKA: If you're a member of the public and you're attending, 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, any public comments on items that are not on the agenda?

DR. RYKACZEWSKA: If you're a member of the public attending virtually, please raise your virtual hand. Acknowledging no members of the public in the room. And no virtual hands.

VICE CHAIR DICKEY: I guess I'd like to ask our new members, any questions that come to your mind right now about our procedures or things you have, want to ask us about? You don't have to have any.

COMMITTEE MEMBER LANG: I don't. I don't think I have any that come to mind at this time.

VICE CHAIR DICKEY: Okay. Well, if any come up, let us

know.

COMMITTEE MEMBER TEFERA: I think it's clear that it will take time to learn all the historical experience of the Committee and know best to apply that to each case under review. But looking forward to it.

VICE CHAIR DICKEY: Great. So, anyway, that being said thanks to everybody for your contributions, and coming here today. And I guess with that we're going to -- whoops. Oh, the next meeting is going to be December 5th.

And as I said, the rules for attendance may change after the December meeting.

DR. RYKACZEWSKA: We are awaiting further direction on that in terms of whether virtual participation will still be allowed once quorum is established.

VICE CHAIR DICKEY: It has to do with the Bagley-Keene Open Meeting Act and you guys know all about that.

Okay, so let's see, I have to say the exact time. So, we are -- now, it's 12:23 and we are adjourning.

(Thereupon, the meeting was adjourned at 12:23 p.m.)

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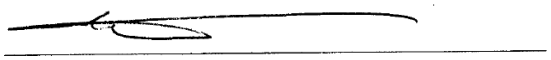
I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were reported by me, a certified electronic court reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting.

And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 17th day of November, 2025.



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