MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, FEBRUARY 2, 2024

8:30 A.M.

1215 0 STREET, 11TH FLOOR

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MEETING ROOM 1181

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AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Darcy Delgado, PsyD, Interim Chair

Larry Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD

Maria Dinis, PhD, MSW

Catherine Hess, PhD

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Lucila Martinez, Outgoing Interim Administrator

Agnieszka Rykaczewska, PhD, CDH Deputy Director and CPHS Administrator

Sussan Atifeh, Staff Services Analyst

Sheryl McCarthy

Nicholas Zadrozna

ALSO, PRESENT

Bernard Gross, IT Specialist

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Ninez Ponce, PhD, UCLA

Todd Hughes, UCLA

Jennifer Tsui, PhD, Keck School of Medicine, USC

Lihua Liu, Keck School of Medicine, USC

Adana Llanos Wilson, Columbia University

Toben Mintz, PhD, USC

Cynthia Burnson, PhD, Evident Change

Maria Lopez Gurrola, Evident Change

Joseph Zickafoose, Mathematica, Inc.

Holly Matulewicz, Mathematica, Inc.

Elisa Gonzalez, Mathematica, Inc.

Annu Van Bodegom, Mathematica, Inc.

Shannon Whaley, PhD, Public Health Foundation Enterprise WIC

Rita Hamad, MD, PhD, Harvard University

Susan Sabatier, CDPH/WIC

Wendi Gosliner, UCANR

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None

L. Projects with Request for CPHS to Rely on Another IRB
None

M. Exemption/Not Research Approvals
None

N. Final Reports - Darci Delgado, Interim Chair

Projects listed are submitted for closure and are recommended for approval by expedited review.
See attachment for list of projects - Action
None

O. Public Comments
None

I n d e x (Cont.)

INTERIM CHAIR DELGADO: Okay, I think we're ready to go. Welcome, everyone, to the February 2, 2024, CPHS board meeting.

My name is Darci. My apologies, bear with me, I have not chaired a meeting like this in a while. So, my condolences that you're stuck with me for this.

But, luckily, we have a very thorough agenda. So, why don't we start with roll call.

MS. ATIFEH: Me?

INTERIM CHAIR DELGADO: That would be great.

MS. ATIFEH: My name is Sussan Atifeh. I'm an AGPA in CPHS.

MS. MCCARTHY: Sheryl McCarthy. I'm today's scribe.

COMMITTEE MEMBER HESS: Catherine Hess, Committee Member.

COMMITTEE MEMBER LUND: Laura Lund, Committee Member.

COMMITTEE MEMBER KURTURAL: Carrie Kurtural, Committee Member.

COMMITTEE MEMBER JOHNSON: Jonni Johnson, Committee Member.

INTERIM CHAIR DELGADO: Darci Delgado, Committee

Member.

DR. RYKACZEWSKA: Agnieszka Rykaczewska, CPHS Administrator.

INTERIM ADMINISTRATOR MARTINEZ: Lucila Martinez. I'm sorry, I don't know what to say. Administrator.

DR. RYKACZEWSKA: And my guide.

INTERIM CHAIR DELGADO: Mentor for all things CPHS.

COMMITTEE MEMBER SCHAEUBLE: John Schaeuble, Committee Member.

COMMITTEE MEMBER VENTURA: Maria Ventura, Committee Member.

MR. GROSS: IT support, Bernard Gross.

INTERIM CHAIR DELGADO: Yeah, Bernard. Awesome

And then we have some folks on Zoom. If you could unmute and introduce yourselves.

VICE CHAIR DICKEY: Larry Dickey, Vice Chair.

COMMITTEE MEMBER AZIZIAN: Allen Azizian, Committee Member.

COMMITTEE MEMBER DINIS: Dinis, Maria Dinis, Committee Member.

COMMITTEE MEMBER RUIZ: Juan Ruiz, Committee Member.

COMMITTEE MEMBER PALACIO: Philip Palacio, Committee Member.

INTERIM CHAIR DELGADO: Awesome. Thank you, everyone.

COMMITTEE MEMBER LUND: Dr. Delgado, I have a question, just as a point of order. Somebody's going to have to refresh my memory, but I think that the new rules are that the people on the phone have to be onscreen.

INTERIM CHAIR DELGADO: Great. We get to see your beautiful faces, Doctors Palacio, Ruiz and Azizian. If you're not on camera, please come on camera so that we can see your beautiful faces this Friday morning.

COMMITTEE MEMBER LUND: Yeah, this is the whole they changed the law, and they can only not be on if they have an unstable internet connection.

INTERIM CHAIR DELGADO: I'm glad that --

COMMITTEE MEMBER LUND: I just want to make sure we're all on --

INTERIM CHAIR DELGADO: -- that somebody read the law.

COMMITTEE MEMBER LUND: Sorry.

INTERIM CHAIR DELGADO: Hi everybody. Good to see you, good to see you. Okay, that is great.

Okay, so I think we're good. We're good, yeah.

INTERIM ADMINISTRATOR MARTINEZ: We're good.

INTERIM CHAIR DELGADO: Stop me at any point.

Okay, so Chair updates. We're going to start with

me providing a few Chair updates. So, the first -- this came up at the last meeting, the CITI training. So, for those, just to refresh folks' memory, CITI stands for the Collaborative Institutional Training Initiative. It's actually a research training that we ask all of our researchers to have. And it came to our -- through discussion that many of us, me included, do not have the most updated CITI research training.

So, our admin team has been working hard to get that training available for everyone. So, you should be getting an email in the next, probably week or two, that will provide a link to the training.

We ask that you please have that training done before the next meeting. So, you have a solid like six to seven weeks to get that training done.

If you have any questions, you can reach out to Agnieszka and Luci, and they will help you with it.

And if you have completed it already, please just send a copy of the certificate over to our admin staff.

Thank you so much. I'm actually, in a weird nerd way, excited to get that training done again. And I think, too, just appreciating I think that it is a refresh -- it's a good refresher, but also a great reminder that there's lots of trainings available for board members. I think our admin team's been looking into a bunch of them so that we

can, especially for some of the new members, make sure you feel super comfortable with the reviews that you're doing.

Okay, anybody else want to say anything on the CITI training before we --

COMMITTEE MEMBER DINIS: I have a question. Yeah, Maria here, I have a question. How long does it take? I mean I think the one at Sac State is one and a half hours or so, but I don't know how long this one is for the schedule.

INTERIM CHAIR DELGADO: I think -- yeah, I think it's about that, like one to one and a half, depending on how fast you read.

DR. RYKACZEWSKA: And I believe we'll have a variety of options. So, there's probably a core, one or two for everybody, and then some refresher, additional refresher options as as well.

INTERIM CHAIR DELGADO: So, for those overachievers in the room, who want to do more than -- more than what is asked, that will be available as well.

Good question, Maria. Any other questions?

COMMITTEE MEMBER DINIS: I have some comments to make.

VICE CHAIR DICKEY: This is --

COMMITTEE MEMBER DINIS: Sorry, I'll finish and then I'll shut up. One more comment to make is don't expect the training to help you with the application review

process. It's just a little history background, what the principles are, that sort of thing. But it's not -- that's what CITI training needs to do is actually do a module on how to evaluate applications or protocols. It does not do that at all.

INTERIM CHAIR DELGADO: Good call. Well, if anybody does have a good idea, suggestion for training in our space, I know that's something our admin team's been looking into as well.

Sorry, Dr. Ruiz, were you about to say something?

VICE CHAIR DICKEY: Well, this is Dr. Dickey, I think I was going to say something.

INTERIM CHAIR DELGADO: Go for it.

VICE CHAIR DICKEY: Just wanted to say thank you and thank the staff for arranging this. It's been something that's been in our policies and procedures for many years, but it's a start.

INTERIM CHAIR DELGADO: Onwards and upwards often.

Okay. Next item, the second Chair update. For those who have sat in the last few meetings that there has been a lot of back and forth about the Common Rule and IPA updates. Just a lot of conversation that oftentimes gets -- swept under the rug is probably the wrong metaphor. But we don't have enough time and space for it because we end up wanting to jump into reviewing projects.

And so, what we are going to do, as mentioned last meeting, but it's now officially on the books, that the first Friday in March we will be having a supplemental meeting where we will only be discussing the Common Rule/IPA update. And just hashing it out, coming to a conclusion, coming to a decision so that we can proceed and move on.

And so, you might have thought that you had March off, but we'll be meeting that first Friday in March. It will obviously be a truncated meeting since we won't be hearing any projects. But we do ask for those who have a lot background information on this topic, I forget who exactly it is, someone told me, but any background that you have, if you could email it over to our staff so that we -- to the admin staff, so that we can prepare it and have all the materials posted and distributed prior to the meeting.

So, I think two weeks before that meeting it would be great, we'll be sending out reminders on -- reminders on that, but just want to acknowledge that we won't have a decision on that issue today since we'll be discussing it next month.

COMMITTEE MEMBER DINIS: What time will the March meeting be?

INTERIM CHAIR DELGADO: Regular time, 8:30.

COMMITTEE MEMBER DINIS: Thanks.

DR. RYKACZEWSKA: And if you could send it to --

INTERIM CHAIR DELGADO: Go ahead.

DR. RYKACZEWSKA: Yes. If you could send the materials to Sussan by February 16th, that will -- we'll then compile them together and make sure to distribute them.

INTERIM CHAIR DELGADO: Okay. Lots of Chair -- lots of Chair updates today. Anything else I'm missing on that one?

Okay, so we did the CITI, we did the Common Rule/IPA. Now, I want to talk about our transition for bringing Agnieszka on as the new CPHS Administrator.

And so, I think that we can all recognize, especially those of us who've been on the board a long time, that it is incredibly important to have a full-time administrator to support the work of the team. Many of us were devastated when Luci retired and couldn't be with us full time but feel super lucky that she's been able to give us her wisdom as a part-time retired annuitant for the past -- the past few months, like six months now. Yes.

INTERIM ADMINISTRATOR MARTINEZ: It was only supposed to be a six-month job.

INTERIM CHAIR DELGADO: It was only supposed to be six months and we're still stringing her along.

But super excited, and you all received the email from John Ohanian earlier this week, I think, that Agnieszka Rykaczewska --

DR. RYKACZEWSKA: Yes.

INTERIM CHAIR DELGADO: Okay, awesome. Is going to be joining us as the new CPHS Administrator. She has an extensive background in evaluation and research. But will, of course, have Luci as her mentor over the next chunk of time to help transition with all of the nuances and details. And so, just really, really happy to have you officially now in our first meeting. And also, wanted to kind of give you space just so the members can get to know you a little bit more. And, yeah, I'll hand it over to you.

DR. RYKACZEWSKA: Thank you. Well, I can say that I am incredibly excited to be stepping into this role. For me, the protection of human subjects is really an area that is close to my heart. Some of my earliest work involved working with communities who had previously experienced harm from harmful research practices.

And so, that experienced really shaped me. It made me really understand how critical this work is. And it helps me bring a passion, those memories of those folks really help me bring a passion to this work.

I am also absolutely honored and thrilled that I do get to learn from Lucila's incredible experience and her knowledge. And I'm really looking forward to collaborating with her as my mentor.

And I'm also really looking forward to

collaborating with all of you and really learning from all of you. I recognize this is a big role. It's a lot to learn and it's going to be taking me some time to get there. So, any advice that you have, any guidance that you would want to share I very much welcome, and really look forward to working with you.

INTERIM CHAIR DELGADO: Awesome. Thank you.

And Luci, you're not allowed to go anywhere.

So, for board members, any communication or things that are coming up please reach out to both Luci and Agnieszka so that we can help Agnieszka really understand some of the normal flow of questions that come in from members. And also, so we can support this dream team of these two. So, thank you for that.

Any other --

COMMITTEE MEMBER LUND: Question. Would you please send your email out to everybody because I don't have it on my list, and it would be very helpful.

INTERIM CHAIR DELGADO: Absolutely.

COMMITTEE MEMBER LUND: Thank you. Great.

INTERIM CHAIR DELGADO: Okay. I think those are all of my Chair updates unless I get a kick under the table that I'm missing anything. Nope. Okay.

INTERIM ADMINISTRATOR MARTINEZ: No, I think that's it.

INTERIM CHAIR DELGADO: So, Agnieszka, can I hand it over to you for updates that you have under Item B?

DR. RYKACZEWSKA: Absolutely. And I will be sharing some slides. They did get sent out a bit earlier. But thank you, Nicholas. Dream team is working. Technology is working. It's a good day.

So, if you'll remember, in December I did share a little bit about our Researcher Data Request Form Project that is underway. And today I'm just giving an update on where we are, really wanting to make sure we're bringing everybody along and keeping everybody updated.

Now, as a reminder, the goals of this Researcher Data Request Form is to reduce the number of applications that researchers have to complete in order to request CalHHS data.

In addition, we're wanting to ensure that all reviewers receive any updates or revisions -- oh, still on the title slide. Sorry, Nick.

Ensure that all the reviewers receive any updates or revisions, everyone having the same information as we go through the approval processes.

And then, finally, we want to make sure that we have a clear process for researchers to follow so that there's not any confusion in trying to navigate through the process of requesting CalHHS data, while ensuring that we're

still having all of the appropriate reviews and approvals in place.

Okay, now if you could do the slides. Thank you. So, in December I shared a little bit about the six components of our form. And since then, we've made some progress on drafting the actual form. So, I can now share some concrete examples of the types of questions that we're asking in each section.

Now, I do want to emphasize that we are still very much in draft mode. And I want to extend my very deep appreciations to Dr. Schaeuble and Dr. Bazzano who have been working with us over the course of December and January. Your advice and feedback have already been incredibly helpful to us as we're refining these forms, and we're looking forward to continuing that collaboration and continuing to refine the draft.

So, let me hit a little bit on each of these components. So, the first component is to streamline the common questions. So, we know that when researchers have been filling out the different applications with departments, with CPHS, a lot of the times there are some core common questions that they're having to fill out over, and over, and over.

So, we're looking across all of the different applications that researchers have to fill out and

identifying what are those questions that everybody asks pretty much in the same way, can we simplify and reduce that duplication.

And so, an example of that would be what's your data storage location? Where is the primary location where research is being conducted? Everyone asks that question.

Or even something as simple as what is the name of the principal investigator. Everybody's going to ask that question, let's have it just responded to once, and everyone will get that information.

In terms of where we're looking for these common questions, we're looking both at the CPHS application in IRBManager, as well as all of the department applications and really doing a mapping of what are those questions, where's the commonality.

The next question is the security and safeguards questions. Here our major updates are being conducted by the Agency Information Security Officer, essentially to update a lot of these questions. It has been some time since they've been revised. There's still a lot of references to floppy discs. There's not a lot of references to --

(Laughter)

DR. RYKACZEWSKA: -- some of the more updated technology, so we're wanting to make sure --

INTERIM CHAIR DELGADO: That's actually pretty funny.

DR. RYKACZEWSKA: It's great. Actually, the bulk of it is referring to floppy discs.

So, we're really wanting to make sure we're up to date in terms of ensuring the protection of sensitive research data, emphasizing confidentiality, and detailing security protocols like encryption, and access control, that are very much relevant issues today.

In terms of our sources of information, there's several sources we're pulling from. Of course, our current IRB form is one source, as well as guidance around various regulations like 853. And really relying on our Agency Information Security Officer Adam Germaine (phonetic) to guide us through this process of revising this section.

So, an example here of a question we might include was: "How will your project ensure the confidentiality and security of sensitive research data, especially when transmitting or storing electronic information?"

And so, we would be looking for specific information related to that question.

Then there is a specific section for CPHS administration. So, this is something that we usually do on the back end through emails, through an IRBManager. There's a section specific to us. And this is a lot of our

prescreening process is captured here, where we're reviewing the information. And it allows us to, maybe if the researchers didn't quite answer the way they needed to, it helps us overwrite, it helps us make sure we're screening correctly, and that the information is correct. As well as helping us really categorize like who is this review going to be conducted by and assigning things to members.

Right now, we're basing that off of the current processes in IRBManager and the IRB form. So, we're not revising or changing anything, just integrating it into the official process.

So, for example, a potential question that we might be looking at here is, is this an expedited review or a full board review. That would be something that we would determine through this section.

Then the big one, human subjects. So, here the focus -- the focus is on really dedicating a section that's asking questions for research that's involving human subjects. And that's not all research will, so we will determine previously to this section is this one that has human subjects, or not. And if it does, it would automatically prompt the researcher to complete this section.

It really is intended to highlight the importance of our ethical considerations and protective measures for

human subjects and asking the critical information that we cover here today, in these meetings, making sure that those questions are answered.

Again, we're relying on the current form, as well as the recent revisions that have been made. So, we are looking at the most up-to-date information and incorporating it into the next form.

So, here an example would be offering a detailed account of the plans and measures in place to protect the rights and welfare of our subjects.

The next big thing is the department-specific addendums. So, this is where we've already put together the common questions that show up across the different applications. This is where the department-specific questions would lie. So, this is where the differences in the forms would be determined.

And so, let's say that a researcher is needing data from HCAI and they're needing data from CPH, well, then they would answer that that's the sources of the data and it would automatically generate okay, now, you have to complete the addendums for those departments.

And an example here would be -- oh, I actually -- here we go. "Please specify how the proposed project will directly benefit the DHCS administration of the Medi-Cal Program?"

So, for DHCS this is already a component of their regular questions that they ask researchers when data is requested. It's very unique to them. And we're incorporating that into the department-specific addendum.

And the goal is for all departments to have their own specific addendum for reviewers.

And then, the final piece is the data use agreements. This is another piece where we have found that oftentimes we have to -- researchers have to complete multiple DUAs with different departments. But most of it is actually the exact same information.

So, our legal team has been working very hard to look across all of the DUAs, combined it into a single DUA. And then, if there was anything that was specific to a department's DUA that got moved into a department-specific addendum. So that everything is still being captured, but we're trying to, as much as possible, create one form, one clear piece of information.

So, that is where we are now. As I said, it's still in draft form. We are continuing to refine the questions. And we'll be sharing updates as we move along.

And I want to speak a little bit to the timeline. Next slide. So, we are approaching this through FA's approach, which I believe I shared back in December. With phase one being right now our initial attempt to create a

form we can work with. And phase two being an initial -- I call it a piloting phase.

So, we know we're not going to get it perfect the first time around. We have workflows to work through, automations to work through. So, we're taking an initial attempt with just five departments and then building up from five. In phase three, where we're going to then add the additional departments.

So, essentially we're doing this on some level twice. Because we're going to have to, again, as we add new departments readdress the common questions, readdress the department-specific addendums each time. But we're trying to build momentum over time and be carefully piloting, testing things out, getting feedback from researchers, getting feedback from departments, getting feedback from CPHS as we go along so that we're really building this up for success.

So, final slide. More concretely speaking about timeline. This is an initial timeline that we are envisioning. Now, I want to emphasize initial timeline. We want to take the time to do this right. So, we recognize that at any one of these steps there might be a curveball thrown at us, something we hadn't really understood or envisioned, and we're going to take the time to work through it.

But we wanted to have an initial timeline to work towards. And with that timeline, I think the key piece is that we're hoping to present the final version one of this form for CPHS approval in our April meeting. We're sharing it about mid-March.

So, that is my presentation, my updates. I'm happy to answer any questions you might have already.

COMMITTEE MEMBER KURTURAL: I was going to say that it was -- it's been a few years since we discussed the common app for research. And all of the departments previously prepped addendums. If you ask me like where is the Department of Developmental Services' addendum, it's been so long who knows. It's very similar. So, I really hope that you have found those.

DR. RYKACZEWSKA: We did.

COMMITTEE MEMBER KURTURAL: So, when it comes time to asking, you don't lose the work that was already done.

DR. RYKACZEWSKA: Absolutely.

COMMITTEE MEMBER KURTURAL: So, to speak, and you can streamline it faster.

DR. RYKACZEWSKA: Yes. So, for the departments we did look both at what their current forms, current processes are, as well as the previous work that had been done on the common app.

COMMITTEE MEMBER KURTURAL: Oh, good.

DR. RYKACZEWSKA: And we're integrating that. As well as I know that there's been a lot of feedback that has been given on IRBManager and the form that's in there. We've also gathered that feedback and are incorporating it there.

COMMITTEE MEMBER KURTURAL: Oh, good. Good.

COMMITTEE MEMBER LUND: I have a question. I know that at least one other data source that we review a lot, the VSAC applications, use IRBManager. Is there any talk of consolidating around that?

DR. RYKACZEWSKA: In terms of -- so, right now our pilots, we're planning to do in IRBManager, at least our initial plans are to do that.

And then, in phase three that's when we'll be reassessing. Is IRBManager the tool that really allows us to do this best? Is there other tools? We're going to do an exploration, essentially, of what are the key requirements that will be needed in terms of the system, so that we can make this smooth.

As well as exploring things like API. So, if we do end up going with something else than IRBManager, we're trying to make this the least disruptive as possible. So, potentially there might be -- one of the requirements might be that if a department is staying with IRBManager, IRBManager and this new took would need to be able to talk

to each other, so we're not requiring everybody to change everything to accommodate this.

INTERIM CHAIR DELGADO: That is a good flag, though. I mean, if VSAC is using IRBManager, I feel like someone really smarter than me would be able to like merge their stuff with our stuff.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: Right, so that people aren't having to do things twice because they're using the same tool.

COMMITTEE MEMBER KURTURAL: Yes, exactly. Exactly.

COMMITTEE MEMBER LUND: Right. So, yeah, thank you.

DR. RYKACZEWSKA: Yes, absolutely.

INTERIM CHAIR DELGADO: Any other questions? Okay, awesome. Thank you so much.

DR. RYKACZEWSKA: Thank you.

VICE CHAIR DICKEY: I just want to say that was a very well-organized presentation.

DR. RYKACZEWSKA: Thank you. Thank you, everyone.

INTERIM CHAIR DELGADO: Okay. Agenda Item 2 checked off the list.

Let's move to approval of the minutes. So, this Item C is the review and approval of meeting minutes from

the December 1, 2023, meeting. If we could have a motion?

MS. ATIFEH: Dr. Dickey is very good.

INTERIM CHAIR DELGADO: He's muted, though.

INTERIM ADMINISTRATOR MARTINEZ: We need a motion.

INTERIM CHAIR DELGADO: Motion, motion.

MS. ATIFEH: Motion.

COMMITTEE MEMBER SCHAEUBLE: I'll move to approve the minutes.

INTERIM CHAIR DELGADO: Thank you, Dr. Schaeuble. We have a motion to approve the minutes. Do we have a second.

COMMITTEE MEMBER KURTURAL: Second.

INTERIM CHAIR DELGADO: Thank you, Carrie.

Okay.

MS. ATIFEH: We do have to do a roll call.

INTERIM CHAIR DELGADO: Roll call, please.

MS. ATIFEH: Yes. Okay, I'm going to start with Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio? Dr. Palacio?

COMMITTEE MEMBER PALACIO: Abstain.

INTERIM CHAIR DELGADO: He abstained.

MS. ATIFEH: Abstained.

And Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approved.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Okay, so Item C is done.

We will move to Item D, which is projects with reported adverse events and/or deviations. So, it looks like the first adverse event is a project related to the CHIS Survey. And the PI is Dr. Ponce. Dr. Dickey, it looks like you were the reviewer. Can I hand it over to you to present the adverse event?

VICE CHAIR DICKEY: Sure. Thank you.

DR. PONCE: So, in a context, this adverse event was presented to the board I think several months ago. And the solution was not really totally defined at that point.

Recently, Dr. Ponce submitted an amendment for CHIS, which happens often, and the proposed solution -- or the solution was included in that amendment. And I just asked if they could reframe it as a follow-up report to the Committee. So, that's why they are coming today.

Dr. Ponce, do you --

DR. PONCE: Yeah, thank you so much, Dr. Dickey. And hello Dr. Delgado, and all the new Committee members, and continuing Committee members.

So, I also want to introduce the CHIS team. The first is Mr. Todd Hughes, who is the Director of the California Health Information Survey. Royce Park, who's the Assistant Director will be somewhere in here. And Mr. Andrew Juhnke, who I think you -- who actually stewards a lot of our submissions and makes sure everything happens, who is our Compliance Office and Data Produce Manager, is also here today.

So, I'd like to hand this over to Mr. Todd Hughes for the summary.

MR. HUGHES: Thank you to Dr. Ponce, and Dr. Dickey, and Chairperson Delgado, and other Committee members. We appreciate this opportunity to report back on the resolutions to the issues identified in the original adverse report last year.

As background, last year's report was related to a

discovery made by CHIS staff that the laptop configuration being used by users at one of our funders, the California Department of Public Health, or CDPH, to access confidential CHIS data files did not meet the requirements as outlined in our CHIS funder and data custodian agreement.

Specifically, although the CDPH virtual desktop infrastructure, VDI system, was compliant with our requirements, the laptops being used to access the VDI were noncompliant.

The CDPH laptops did have many of the protections outlined in our data sharing agreement, such as preventing printing or copying from the VDI.

However, the laptops were missing some important protections, including settings to limit connections to other applications, or websites, or to prevent screen sharing, or screen recording, or to block collaboration using virtual meeting software while accessing the confidential CHIS data files.

As a reminder, there was never any evidence of a data breach itself. We do not believe that any data was every inappropriately accessed by the parts of the CDPH system that were noncompliant.

But upon discovery of the issues outlined in the original report, CDPH then shut down access to the CHIS data while alternative solutions were explored. And they did

this by placing all of the VDIs into maintenance mode and then eventually turning them off. Since then, the VDIs have not been turned back on or used again to access CHIS data.

In the meantime, CHIS and CDPH have worked closely on many potential options for resolving the issue and allowing CDPH access to the confidential data files again.

And the final corrective action taken and resolutions to the adverse event to realize CDPH access to CHIS data are as follows.

So, first, CHIS held to webinars in the spring of 2023 for all of our funders, including CDPH, who had received confidential CHIS data files and who have signed the CHIS data custodian agreement.

These webinars provided an overview of CHIS compliance requirements, and they also demonstrated examples of the main technical options that would comply with the CHIS requirements, and provided a list of vendors, that needed to be met.

The webinars allowed for funders' questions, confirm compliance and explore potential options for increased security. CHIS staff also offered to meet one-on-one with any funder after the webinars to go over their setups in more detail.

Second, after the webinar CHIS asked all funders to submit additional documentation about their current

configuration. CHIS provided a checklist so that each funder could confirm compliance with each item, including requirements for any device that's used to access the CHIS data.

CHIS staff carefully reviewed the documentation provided by each funder and either approve the compliance setup or requested follow-up conversations with the funder to go over any needed additional security measures.

Again, the process and prior to the release of new confidential data files for CHIS 2022, CHIS confirmed that all funders met the storage and access requirements.

Third, we updated our data custodian agreement and data user agreement, that CHIS funders must sign, beginning with the CHIS 2022 data file delivery for October of 2023.

These documents were approved by CPHS in an amendment last year and they included more detailed and specific items for compliance.

And fourth, we developed a CDPH-specific solution for CHIS data access, and that was then also adopted by the California Department of Health Care Services. We worked closely with CDPH staff to determine the potential options for compliance setups that would re-allow CDPH access to the confidential CHIS data files.

After reviewing all the options, the final resolution decided upon is one that mirrors how CHIS staff,

themselves, access the CHIS data. And so, this solution involves the UCLA CHIS staff providing CHIS-controlled, remote access laptops to CDPH staff for their use in accessing the CHIS data files.

These laptops, which meet all the CHIS data security requirements and guidelines, allow only for the connection to the CHIS data server remotely by authorized CDPH staff, and no other functionality is possible by the laptops.

Through this process, authorized CDPH staff can connect to the data server via a remote desktop access to access and analyze the CHIS data. And any data analysis results or output can only be removed from that server in the same manner that CHIS staff uses internally, which involves data disclosure review and approval by trained CHIS staff.

After implementing the solution with CDPH, staff at DHCS then also determined that this solution as their preferred option for meeting our compliance requirements, and we worked with them as well to provide CHIS-configured laptops for their use in analyzing the confidential CHIS data.

And that is the end of our report, and I'll stop there for any questions or additional comments. Thank you.

VICE CHAIR DICKEY: So, I thought this was a very

good solution to the issue, personally. And I wanted to compliment CHIS for, you know, what they've done on this.

But I also wanted the board to have a chance to hear this and to ask any questions. So, I'll turn it over to the board.

INTERIM CHAIR DELGADO: Thank you so much, Dr. Dickey. Thank you to the entire CHIS team for your presentation, super thorough, incredibly helpful to hear. Especially for somebody who can't turn their cellphone on sometimes, that to hear this level of security is super, super helpful. So, thank you. I have no follow-up questions.

Any other questions from board members or anybody on -- any board members on Zoom?

Okay, hearing none, Dr. Dickey, would you like to make a motion?

VICE CHAIR DICKEY: Yes. I'd like to make a motion that we accept their report and the solution that they've instituted.

COMMITTEE MEMBER LUND: I second that. This is Laura.

INTERIM CHAIR DELGADO: Okay, Laura seconded the motion.

MS. ATIFEH: Okay, I'll start with Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Your motion has passed in the accepting of the adverse event. I think they get something in the mail from us, don't they?

MS. ATIFEH: Yes.

INTERIM CHAIR DELGADO: Email. You'll get an email letter in the next two weeks that describes the board's acceptance of your plan to remedy the adverse event. Thank you so much to the CHIS team.

DR. PONCE: Thank you.

INTERIM CHAIR DELGADO: Have a great weekend.

DR. PONCE: Thank you so much. I think you might see us again, later today, but thank you.

INTERIM CHAIR DELGADO: Okay, we'll look forward to that. Thank you, Dr. Ponce.

Also, shout out to whoever is doing like the highlights and like spotlighting on the Zoom, like that's pretty impressive. Thank you. I think that's Nicholas in the background, isn't it?

DR. RYKACZEWSKA: That's actually the automated system, so --

INTERIM CHAIR DELGADO: Really? Wow. Okay, awesome.

So, Dr. Dickey, I think you have the next adverse event as well.

VICE CHAIR DICKEY: Yeah, I wanted this one put on the agenda mainly to bring up an issue for the Committee.

The way our current system works is adverse events have to be approved by the full Committee. And I think maybe the staff can tell you, I think the form in IRBManager that permits approval basically it says full Committee.

But we often get reports of adverse events that are very minor or actually are not adverse events at all. And this is maybe an example of one. You know, in this

case, you guys probably have seen it, but it was just a case where they're measuring certain blood levels of certain chemicals in a project, and they give a report to the people. And on one of those reports, it had the wrong units. I think instead of -- I forget what, nanograms, it was a different unit.

And it had no real effect, but they wanted to send a letter to the people saying, sorry, we made this mistake, it doesn't affect you at all clinically, and the report we gave you is still valid except the units were wrong.

This seemed to be so minor to me it was like why do we need to, you know, waste more time on this.

But we do necessarily need to deal with this. I would like to propose that on these adverse events that the primary reviewer, in consultation with the Chair, can decide that it doesn't need full Committee review, and so that we can keep these things off of our agenda.

INTERIM CHAIR DELGADO: Would that require a change to the policies and procedures, or a change just within the kind of background of IRBManager?

VICE CHAIR DICKEY: Well, I think it would also require a change in the policies and procedures, both. But, you know, it would streamline things a little bit.

But I just want to hear, you know, the last one that Dr. Ponce presented, you know, they came back and it

was an amendment. And I could have just said, as the reviewer, fine. But I knew that it was an adverse event and it -- the Committee would benefit from hearing it.

In this case, you know, the unit sort of thing being off, I don't think the Committee would benefit very much from having to deal with it.

But I mainly put it on just for the issue of can we change the policies and procedures to say that the primary reviewer, in conjunction with the Chair, can decide whether an adverse event needs to be heard by the full Committee.

INTERIM CHAIR DELGADO: Laura has a comment.

COMMITTEE MEMBER LUND: I just have a comment. This has come up before and I think it's definitely worth consideration. I think the distinction that we would want to make is between an adverse event that either caused harm or had the potential to cause harm, and an unanticipated event, which is just something different happened but there was no potential for harm involved. Which I would, the Wu study that you're referencing right now, I would put that into that category.

So, I think the question would be how to make the determination between those two things. I think the true adverse events should certainly come to the Committee, like the CHIS Survey should certainly have come to the Committee

because that has the potential for a data breach or, you know, other kinds of things, kinds of harm. So, that's my comment.

COMMITTEE MEMBER KURTURAL: I have one comment, Dr. Dickey. This is Carrie Kurtural. Another thought would be possibly, or another alternative, rather than putting it 100 percent on the Chair, or Vice Chair, or whoever has to funnel through these, is to have a subcommittee for adverse actions to make that decision, or something of the board.

I know that would be more formalized, but I'm just thinking that how many of these do we get. Is it going to be, is it too much for, you know, when they come into review, or does it merit a subcommittee or something to be established.

VICE CHAIR DICKEY: Well, I think we get probably, I'm guessing, maybe three at most a cycle.

COMMITTEE MEMBER KURTURAL: Oh, okay.

VICE CHAIR DICKEY: And I kind of think that the primary reviewer for that project should be involved in the process, since they know the project better than other people. So, that's why I was suggesting the primary reviewer, and then with the final sign off by the Chair or Vice Chair.

COMMITTEE MEMBER KURTURAL: Okay.

VICE CHAIR DICKEY: I don't think we need a whole

subcommittee for it.

COMMITTEE MEMBER KURTURAL: Okay. Yeah, if we're not getting that many.

INTERIM CHAIR DELGADO: That's a good thought, though.

Other comments or questions?

VICE CHAIR DICKEY: Well, if I may make a motion. One, first off -- it has two parts. One, that we accept the solution for this particular adverse event. And --

INTERIM CHAIR DELGADO: Yeah, let's do that one -- let's do that motion first, please. Sorry.

VICE CHAIR DICKEY: Okay. All right. Okay. No two-part ones.

So, anybody want to second that one?

COMMITTEE MEMBER LUND: I'll second that.

INTERIM CHAIR DELGADO: Laura Lund seconded.

MS. ATIFEH: Okay. So, I'm going to do a roll call.

INTERIM CHAIR DELGADO: Yes.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Wonderful.

VICE CHAIR DICKEY: Okay.

INTERIM CHAIR DELGADO: Go ahead.

VICE CHAIR DICKEY: The second motion would be that, if it's okay with the Committee, that I prepare language for a policy change in the policies and procedures and will bring it back to the Committee at the next meeting.

INTERIM CHAIR DELGADO: Do we need --

VICE CHAIR DICKEY: I don't know if that needs a motion.

INTERIM CHAIR DELGADO: Do we need a motion for that, or do you want to just work with Agnieszka and Luci to

prepare some language, and then we can present it and vote on it next meeting.

VICE CHAIR DICKEY: Okay.

INTERIM CHAIR DELGADO: Does anybody think we need a motion? Okay.

VICE CHAIR DICKEY: Okay, good.

INTERIM CHAIR DELGADO: Thank you so much.

Okay, I believe that is the end of our adverse events. Is that correct, Dr. Dickey, are we done with those adverse events?

VICE CHAIR DICKEY: Yes.

INTERIM CHAIR DELGADO: Okay. Sounds great. Okay, so let's move on to Item E, which is new projects or those that require a full Committee review.

So, the first project, going off the agenda, Project 2023-117. I just want to give the board members a little bit of background on this project because it is actually not a new project. I believe it was the October meeting, the October meeting this project was presented.

Do we -- I'm sorry, before I get into it, is Dr. Tsui on the line?

DR. TSUI: Yeah, I am. Good morning, everyone.

INTERIM CHAIR DELGADO: Hi, good morning, Dr. Tsui. Wonderful. So, I'm just giving a little bit of background on the project.

So, this was heard by the full Committee in October. Ms. Lund and Dr. Schaeuble were the subcommittee that review the recommendations from -- excuse me, let me back up.

It was heard in October. There was a lengthy discussion about how to proceed, what recommendations were made. There was a subcommittee including Ms. Lund, the primary reviewer, and Dr. Schaeuble, who were reviewing the researcher's response to those recommendations.

There was a meeting in December with -- and again, this is just for full transparency for all of the board members. I think that we've had some back and forth with Dr. Tsui about her research team's response to the recommendations. And so, want to note that there was a meeting in December, where Dr. Tsui and her team met with the Chair and the Vice Chair at the time, not me, Dr. Dickey and Dr. Ruiz, where there was just further discussion about the project. But also, a recognition and I'll just say it again for the record, that any decisions made on this project would be brought back to the full Committee.

And so, what we are hearing today I believe, and I'll hand it over to Ms. Lund and Dr. Tsui in a second, is an adjustment to the protocol, a revision of the interview guide. And I think from the researcher's standpoint, I hope that it meets a threshold for not requiring a formal written

informed consent. Don't quote me on that. Let's wait to hand it over to the research team to go into those details.

But just wanted to call that out in case there was any confusion, or anyone having déjà vu, thinking didn't we hear this project a couple of months ago.

So, Ms. Lund, can I hand it to you?

COMMITTEE MEMBER LUND: Yes, absolutely.

INTERIM CHAIR DELGADO: That would be great, thanks.

COMMITTEE MEMBER LUND: Great. Thank you, Dr. Delgado.

So, and as Dr. Delgado mentioned, this project was heard and approved by the Committee in October, with stipulations. Changes were made to the study by the research team, and the reviewers asked that the stipulations that were specified by the Committee be included in those revisions.

And the research team has asked to come back to the full Committee because they believe that the revisions they have made no longer require those original stipulations, particularly in regard to informed consent prior to the baseline survey.

So, what I'm going to do is I'm going to ask Dr. Tsui to introduce herself and her team. And then, if you would, since we've heard the project in October, I don't

think you need to go over the whole project. What I'd like to ask you to do is describe for the Committee what your changes are and why you believe the stipulations that were made in October should be set aside.

DR. TSUI: Sounds good. Good morning, everyone. Thanks so much again for allotting the time for this February meeting to talk about this protocol once more.

I'm joined today by my Co-Principal Investigator, Dr. Dana Yanos, who is an Associate Professor at Columbia University. We are multi-PIs together on this National Institute of Minority Health and Health Disparity-funded five-year RO1 grant for which this protocol is about.

I'm also joined by Dr. Lihua Liu, who is Director of our Los Angeles Cancer Surveillance Program. I think Dr. Liu is on a cell.

Emily Kane (phonetic) and Kathy Wojic (phonetic), who are part of our USC team, and our Cancer Registry are joined as well.

It takes a village to get this kind of large study underway. And so, we appreciate everyone coming together again.

Ms. Lund, thank you so much for also just mentioning déjà vu. We went back and forth about mainly your counsel comments throughout September and October, presented this already at the October meeting. And provided

a response following that, I think November 1st.

We did take the deferred approval letter very seriously, went through each point provided by the subcommittee at that time. And I think responded and adjusted accordingly to what the full Committee had requested in that letter, with the exception of the piece of -- the piece around the requirement for written informed consent for the baseline survey. I think that is the one component that we're asked to come back to here, to discuss with the full Committee.

The reason I believe that the reviewer had asked us to provide full written -- written consent for the baseline survey was due to some of the sensitive questions and the nature of the sensitivity of specific items around discrimination, immigration, et cetera. And so, that is what we sort of outlined in our way to come back to the Committee to discussion.

RT edits between the October meeting and now to our study materials and protocols are all around reducing some of that sensitive nature, so that perhaps the risk of the baseline survey is at a different perceived risk level, and for the Committee to sort of assess whether written informed consent is required.

We are -- well, written consent is particularly important for us, for this protocol, to sort of address and

see if we can have a waiver of written consent. Because this is a two-site study, we are recruiting participants from both the Los Angeles Cancer Surveillance Program and the New Jersey State Cancer Registry, two SEER sites.

The other sites and our institutional IRB have already approved the protocol, including at baseline to not require written informed consent. And so, we just want to come back to see if this is something that we can discuss with the full Committee, and fully respect the sort of conversation that needs to be discussed here today.

INTERIM CHAIR DELGADO: Awesome. I think, actually, we're trying to pull up the recommendations on the screen from last time just to refresh everyone's memory.

COMMITTEE MEMBER LUND: That's a good idea.

DR. TSUI: Okay.

INTERIM CHAIR DELGADO: If you happen to have them on your screen, it would be super helpful. Because I do think there was more than just -- sounds like you responded to multiple aspects of the recommendations from last time.

Whoops, here we go, let's see what's on the screen share.

DR. TSUI: Are you all seeing the letter?

INTERIM CHAIR DELGADO: Yeah, here we go.

DR. TSUI: Okay.

INTERIM CHAIR DELGADO: Okay, awesome.

DR. TSUI: Okay.

INTERIM CHAIR DELGADO: So, yes, if you could just walk us through real quick, if you don't mind, Dr. Tsui, the recommendations and what you all have done to respond to them.

Is that okay, Laura?

COMMITTEE MEMBER LUND: Yeah.

DR. TSUI: Sure. Yeah, so this is -- what you're seeing on the screen is the deferred approval letter dated October 13th, the correspondence we received right after the October full Committee review.

These seven items are the pieces that the Committee and the subcommittee sort of relayed to us that they would like us to look for.

So, the first three I think have to do with edited and requirements that the Committee wanted to see with our baseline questionnaire. I can spend more time discussing those in just a minute.

I think these other items, which are more minor, or have already been addressed. So, we have modified the recruitment script so that no personal identifying information, protected information is disclosed. This is uploaded to the IRBManager as of November 1st.

Number five, modify the recruitment script so there's no (indiscernible) survey will be initiated through

the recruitment. We have modified that as well and uploaded that.

We have removed number six, the first sentence in section six of the consent form. That revised consent form has been uploaded to the IRBManager as of November 1st.

And lastly, we edited our HIPAA form, our HIPAA authorization form to include the N/A on those three sections that were requested by the full Committee. That has also been uploaded.

If we need to look at any of those, I think Emily from our team can readily pull those up in case we need to confirm any of those items.

Then we get to items one through three. So, number one was to revise the protocol to remove descriptions of the follow-up surveys to add to the consent form because I think the Committee did not want us to preemptively describe too much about the follow-up survey.

So, second is to provide final versions of the English questionnaire. We did fully edit the questionnaire so that it is Asian participant facing now, and those have been uploaded as well. Emily can pull that up and screen share that for us, if we need.

And the last is to provide the revised materials to let people who are going to participate by telephone know that they need to return the consent form or return the

online version of the consent form which, essentially, this is the written informed consent.

INTERIM CHAIR DELGADO: Maria?

COMMITTEE MEMBER DINIS: Yeah, I was having trouble, when the pointer is being used the screen goes black.

DR. TSUI: Okay, I'm sorry.

COMMITTEE MEMBER DINIS: I don't know that happened to other people, but it was on mine.

INTERIM CHAIR DELGADO: It's working here okay; we can see it.

DR. TSUI: Okay.

VICE CHAIR DICKEY: It's working okay on mine, too.

DR. TSUI: Okay. So, I think the reason we responded and then it subsequently landed on needing to come back to full review is that a lot of what I think we discussed at the full board meeting around requiring written consent, having these multiple modes of baseline data collection either through written paper format, through a QR code via REDCap virtually, and then by telephone.

If we want to be consistent -- oh, sorry, study sites -- at our two study sites, I'm sorry, then we would need to request a waiver of written consent.

We have detailed this. And let me know if you can

see my -- our response on the screen, as I switch over to our response. Can you see that as well as (indiscernible).

COMMITTEE MEMBER DINIS: Okay.

DR. TSUI: So, we came back to the subcommittee with the edits of items four through seven completed, and came back and wanted to see if we modified our baseline survey to significantly reduce and edit any of our sensitive topic items, and formatted our survey to be more patient-facing and formatted, if we could then have another open discussion on whether a waiver of written consent or a waiver -- and a waiver of written consent at baseline survey would be possible.

We are not asking for a waiver of written consent for the second contact, which is the request for medical records, the HIPAA authorization form. That second contact will still require written consent and, actually, signatures by the participants on both the informed consent form there at the contact and the HIPAA authorization.

So, we are just coming back to full Committee to discuss the waiver for baseline survey.

INTERIM CHAIR DELGADO: Got it. So, I'm just going to repeat back to you, so I understand. You want -- you are requesting a waiver of written consent for the baseline survey that you have removed the sensitive topic items.

Is that us screen sharing or is it Dr. Tsui?

DR. TSUI: That's me.

INTERIM CHAIR DELGADO: Dr. Tsui, can you walk us through the change -- actually --

DR. TSUI: The changes?

INTERIM CHAIR DELGADO: Yeah. I'm actually going to defer to Ms. Lund because I probably am the least knowledgeable on this.

COMMITTEE MEMBER LUND: Yeah, I think so. At this point I think that Dr. Tsui has described the changes and her request. And I'm wondering, Dr. Tsui, if there's anything additional you want to add before we move to the subcommittee and the Committee discussion?

DR. TSUI: I don't think so. I think our group is -- our team is here, we're ready to answer any questions or to have an open discussion. I think if you, if the Committee needs more information about which sensitive items, and so the items we've omitted or edited to comprehensively try to address any sensitive topics, we can certainly go down that route. We can have Emily pull up the survey, the same one that we've uploaded more recently -- most recently in November.

But otherwise, we're happy to have an open conversation.

COMMITTEE MEMBER LUND: Great.

VICE CHAIR DICKEY: I think that might be helpful.

COMMITTEE MEMBER LUND: So, actually, Dr. Dickey, I have another question.

So, you have reduced the number of items but you're still asking personally identifiable information, and some sensitive information and confidential information. Is that correct? It's just fewer items than previously.

DR. TSUI: It is fewer items, but we have removed several of the survey questions that I think in our August and September correspondence between your reviewer comments, Ms. Lund, and our team around immigration status, or citizenship, I think those we had -- you had some specific concerns around those, the sensitive nature.

COMMITTEE MEMBER LUND: So --

DR. TSUI: In many of our other survey items and scales we have sort of confirmed in terms of how they've been using other population and registry-based items.

COMMITTEE MEMBER LUND: So, I think my question, just it's a yes or no question, you still are collecting personally identifiable information in the survey, and you are still asking some questions that might be considered sensitive. In particular, the personally identifiable information, because that's how you're going to link the survey with the medical records data and with the CCR data. You're asking name and other kinds of identifiable

information in the survey.

DR. LIU: This is Lihua Liu, I'm here at the Los Angeles Cancer Registry, which provides the data for the study. I think the identifying information, Ms. Lund, you're referring to is what we initially had in the questionnaire to ask the patients to verify identifying information we already have, we used to contact them. And we want to make sure, you know, this is the right person but -- and record that in, you know, in the questionnaire.

We, I think we removed that because we already have the patient identifying information, that's how we reached out to them. And that was just a kind of quality control measure and that, you know, we removed that to reduce the sensitivity to, you know, qualify for -- you know, to remove the requirements for written informed consent.

COMMITTEE MEMBER LUND: So, the questionnaire is now anonymous, so there's nothing that you are asking people in the questionnaire that would provide identifiable information that could link that questionnaire with other sources of information, like medical records and CCR data. The questionnaire's anonymous.

DR. LIU: Yeah, we -- based on the Registry information we could. We already have the patient's information where they were -- where they were seen and

their medical record number in the Registry, from the Registry side. So, we don't need to recollect that from the patients, and we have to --

COMMITTEE MEMBER LUND: I want to be really clear because I'm going to ask Sussan to put up the OHRP guidelines in a minute, but it makes a difference.

So, the other point that I want to make for the Committee is that there's a difference between informed consent and written informed consent. And we can waive written informed consent, but OHRP requires informed consent. And there hasn't been an alternative to the written informed consent proposed here.

They have provided, prior to the baseline survey, what they call an information sheet. But that does not substitute for the informed consent process.

So, Sussan, I'm wondering if you can put up the OHRP guidelines. Okay, great. The source for this is the OHRP website.

And it's very specific. When can informed consent be waived or altered? All five of these conditions must be present. The research involves no more than minimal risk to the subjects. And I think when we approved this project back in October we established it as a minimal risk project.

The research could not practically be carried out without the requested waiver or alteration. And in fact, we

had lengthy discussion in October where we agreed, the Committee unanimously agreed that this research could be carried out. That there was certainly feasible, since they're contacting each and every one of these subject, to provided them with the opportunity to participate and informed consent. So, this second requirement is not met.

The other three requirements don't really apply to the study. But because one of these five conditions is not met in the study, the subcommittee was not able to set aside the stipulations that were made by the full Committee regarding requiring informed consent.

I would certainly be happy to have a discussion about how, if they are asking for a waiver of written informed consent, what their informed consent alternative would be for these people. We haven't seen that as a proposal. We've just seen a proposal that asks for informed consent to be waived completely.

And informed consent, just to remind the Committee, under the OHRP guidelines requirements that subjects be informed about everything that's going to happen to them in the study.

So, before they do this baseline survey, they need to have all of the information about what's going to be in the baseline survey. They need to know, regardless of whether or not you've removed some of the sensitive

information, they still need to know what's going to be in that survey.

They need to know what you're going to do with that survey information. You're going to link it to CCR data. You're going to link it to medical records data. They need to be made aware of the risks, they're entitled to this under law.

You can't -- you can't collect the baseline survey without informed consent and then consent them later into the subsequent parts of the study under the OHRP guidelines.

So, that's why the subcommittee declined to set aside the stipulations that were made by this Committee back in October, and it's why we're back here today.

I just want to say the second requirement, we have given waivers in the past as a Committee. They generally involve situations in which it's truly not feasible, not feasible to conduct the research unless there is a waiver.

For example, someone is looking at 20 million Kaiser records, right, and they're looking at the EHR information. That would not be feasible to consent 20 million people. Or they're looking at a population, for example there was a study we had where the researcher wanted to contact youth who had aged out of foster care. And it wasn't really possible because they were no longer at the foster care addresses. And, you know, so a waiver is

appropriate in that situation.

But here, they're sending materials to each and every one of these people, they're talking to them on the phone, so it does not meet this second condition. So, that's basically what our subcommittee found.

And I'd like to ask Dr. Schaeuble if he has additional comments regarding this?

MS. WILSON: Can I just make a clarification. I'm sorry, I'm the MPI on the project. This is Adana Llanos. I'm the MPI on the grant.

And I just wanted to clarify that we're actually not asking for a waiver of informed consent at all. What we're asking for is a waiver of the documentation of the informed consent.

So, this is a process that SEER registries use for recruiting participants when -- so, everyone that gets the materials are not necessarily going to participate or consent to participation. And so, the information document actually outlines everything that is involved in being a participant, including the follow-up study, the medical records, and all of that.

So, that basically for a participant to consent they would send back their paper survey. So, that is the consent. That is what we're deeming -- that's what the registry is deeming as consenting to the study.

What we're asking for is to not have to document the written consent, which is having them sign a document and sending that back before they complete the survey, or before they do a phone survey, before they put a link to do the baseline. But they will be consenting to having their registry record looked at and included in the analyses.

And then, if they agree to doing the medical records, they would have to sign the HIPAA document and tell us who their providers were. So, it's not a waiver of consent, it's just the documentation of it. I hope that helped.

COMMITTEE MEMBER LUND: So, the documentation of informed consent is a requirement of the Common Rule unless there is a reason inherent in the study design that would not allow that documentation to occur.

So, for example, the 20 million, you know, EHR records, clearly those people can't be consented, or consent would not be feasible to document.

But in this case, you're actually asking people to return a paper questionnaire. I don't see any reason inherent in the study design why they couldn't also return a signed consent form.

INTERIM CHAIR DELGADO: Why don't you just have them return a signed consent form? I'm confused.

DR. LIU: I think there's a confusion right here,

you know, about what is the baseline survey that we're asking the Committee to review this time. You know, the process in order for the research to proceed, to start with a, you know, baseline survey. Because this is a five-year study and there are different ways of surveys.

And so, we're right now at the first set, you know, to conduct the baseline survey. And as Dr. Tsui already, I think I heard her clarify a couple times or emphasize a couple times that we're asking the waiver for written informed consent for the baseline survey.

The second set, you know, after baseline survey, 12 months or 6 months later, we're going to start contacting patients who seek the HIPAA release, whether we can inform the consent to be able to do the set, you know, the next of patient contacts, you know, sorry, the study activity, which is re-abstracting the medical records, now we need that.

So, we're not there yet. We're only asking for, you know, the review, for the questionnaire, you know, contact procedures, protocols for the baseline survey, which is that's -- you know, that condition definitely is a minimal risk. We're not collecting biospecimen and anything. It's just -- yeah, just wanted to make that clear.

COMMITTEE MEMBER LUND: Great, thank you. Thank you. I wanted to let Dr. Schaeuble comment, but I do want

to point out that your team just said two different things. One person just assured me that you're not asking for a waiver of informed consent. And you are saying that you're asking for a waiver of informed consent. So, I just want to say there seems to be some confusion on the part of your team.

I understand that this is a five-year study. One of the things that is a requirement, or when people are enrolled in a study they be aware of everything that's going to happen to them. So, you can only be approved for what you already have planned and what you are able to consent people to.

So, Dr. Schaeuble, do you have anything else?

COMMITTEE MEMBER SCHAEUBLE: Part of what I'm hearing makes it sound like the researchers are looking at only the baseline survey as an entity by itself, instead of the first phase, at least for some or many of the participants, of what will be an extended study that includes more extensive surveys and medical records at a later time.

Since --

DR. TSUI: Thank you, yes.

COMMITTEE MEMBER SCHAEUBLE: Since you are contacting people and asking them to return a baseline survey, there doesn't seem to be any reason why they cannot

return a signed consent form at the same time.

And this seems to be very important because there should be acknowledgement on the part of people answering their baseline survey that they are fully aware that they are not just answering questions on the baseline survey, but their responses may, in the future, be linked to many other pieces of information about them that could be collected at a future date. I think that's why the reviewers are saying it's not appropriate to waive the requirement or written consent given the total nature of the study that will take place over a period of time. So, those are my thoughts.

COMMITTEE MEMBER HESS: I agree with Dr. Schaeuble. But also, in particular in light of the fact that some of the questions, many of the questions on the survey are fairly invasive.

This is extensive information. This is asking about police encounters. As a survey researcher I look at this and I would feel really uncomfortable administering a survey like this without written informed consent.

COMMITTEE MEMBER KURTURAL: I can add, like from more of the privacy perspective, legal perspective on that point, Dr. Hess, that a lot of folks think that PII is just a direct identifier like an account number, or a name, or an address.

But there's another point, which is more indirect,

and it's called characteristic information. It's in our IPA and it is something that folks frequently forget about. But when you start getting into a survey that dives into specific personal experiences and situations like you were describing, Dr. Hess, and as the survey asks, we live in a different world these days of AI, and connecting, and identifying.

So, I actually do think, Dr. Lund, with the elements and on the HIPAA waiver that there's not only a problem with number two, but there is potentially a PII problem.

COMMITTEE MEMBER LUND: Thank you.

Dr. Delgado, anybody else?

INTERIM CHAIR DELGADO: I just would love to ask the research team. I mean, we want to get to yes with your project, but I still have zero understanding as to why, when people are mailing in the baseline survey, why they can't also mail in a written informed consent. If the research team could --

DR. TSUI: I'm happy -- I'm happy to answer that. And just to start us off all on the same page, we absolutely are on the same page of protecting the participants that enroll in this study. We absolutely want to make sure that privacy is ensured. We are in no way trying to ask for anything that is going above or outside of what we hope is,

you know, human subjects protection. So, I want to ensure that as a team we're all here on the same page.

If I could screen share again, just get to number three. Throughout, to clarify, in our written response we have been trying to particularly consistent that what we are requesting is a waiver of written consent. So, just to go back to where we were two minutes ago.

Written consent, absolutely in the paper version they can sign that first form, send it right back with the survey. On the virtual REDCap version, where they go to the QR code, absolutely we can have the first page be written consent via REDCap, and they can go ahead and sign.

Where this issue really comes up around written informed consent is this third load of data collection here around the telephone survey. We haven't gotten to the part of this protocol where we've been approved to do the survey in multiple languages, yet.

The crux of this study is to understand why, for a cancer that can be eliminated, it is still persistently here, cervical cancer, and disproportionately affecting marginalized, non-English speaking, low-income women.

In order to reach those populations and understand the factors that contribute to these persistent disparities, in a cancer that can be eliminated, we are asking questions around healthcare experiences, structural barriers, et

cetera.

And we have, in particular in trying to keep the telephone version there, it is a mode that we know from our communities may be a requirement for data collection.

Of course, certain participants are more prone to paper surveys. Others are more prone, in the younger population, to do the virtual version. But we do have segments of our target patient population, our target individuals who have the diagnosis of cervical cancer who may prefer to do this over the phone.

It is when we do this over the phone where, if we require written consent, production of a physical document of consent, that will limit sort of the adult -- and I absolutely know that protection is first and foremost. We do not intend to waive informed consent, just written consent. That is where this is issue comes up.

I know one of the Committee members just mentioned, you know, we haven't given the justification why we care so much about this waiver. It really boils down to two things, right.

One is how do we take telephone participants but make it accessible to them.

And two, how do we keep consistent sort of the approvals that we've received for our protocol with our other study site, and the other review entities that have

already approved the protocol that we've put forth.

INTERIM CHAIR DELGADO: Go ahead, Laura.

COMMITTEE MEMBER LUND: Yeah, so I have one more comment. And then, if there are no other comments, we may be ready to move forward.

We thank you, Dr. Tsui. We discussed this extensively at the October meeting. Everyone agreed that your telephone modality was approved. But because you are very specifically speaking to vulnerable and marginalized populations, who are the people that this Committee is instructed in federal law to provide the highest protection, the Committee agreed unanimously that they need to go through the same informed process as the participants in both the written questionnaire and the online version of the questionnaire had available to them.

Your informed consent form is five pages long and it's just not possible for you to verbally consent these people over the telephone in a way that ensures that they have a complete understanding of the study and what they are engaging in when they provide you with the baseline survey information.

It was the Committee's recommendation that you get their contact information, get the consent form from them, and then call them back. If they want to participate by telephone, the Committee did not have any objections to

performing the survey using that modality.

It's the documentation of the informed consent that is required here.

So, Dr. Delgado, do you have anything else? Are we ready?

INTERIM CHAIR DELGADO: Any other board members?

VICE CHAIR DICKEY: Yeah, this is Dr. Dickey.

INTERIM CHAIR DELGADO: Go for it.

VICE CHAIR DICKEY: Yeah, you know, I think that there's -- you know, there is a history of us approving waiver of written informed consent on telephone surveys. And if we're to take the stance on this one and try to apply it to all the rest of them, we're going to have a lot of work to do, as well as a lot of researchers in terms of changing their approach.

So, I'm just saying it has wider implications. And we haven't only just granted these waivers of written informed consent for things -- data studies with 20,000 people. We've granted them for lesser numbers.

And part of, I think part of the issue has been this word "practicality" that is contained in the -- in those guidance from OHRP. If you can't -- if the research subjects will respond over the phone, but won't return a written form, then your response rate may go way, way down. So, that's an issue of practicality that I think in the past

that we have considered.

And it's really been a matter of balancing, you know, practicality with the information that's being collected and how sensitive it is.

DR. LIU: Thank you, Dr. Dickey. I also would like to add another clarification. And our study protocol is to send the patients of the study, you know, a patient packet. In the very beginning, that's what we do first.

So, on the telephone with the patient is not the first time that, you know, the patients have heard about the study. They should have already received the package and reviewed them, and they chose to, you know, do the telephone instead of returning them.

So, what's Ms. Lund's concern that five pages long informed consent, you know, we can't read it over the phone, and they've never seen it, which is not -- you know, is not true or is not all the protocol. They have seen it, they have received it, and they just chose to be talking over the phone to answer the questions instead of return the paper version.

COMMITTEE MEMBER LUND: Thank you. Just because they've received it doesn't mean they saw, and read, and understood it.

I think Dr. Schaeuble has one more comment and I think we're ready to move forward.

COMMITTEE MEMBER SCHAEUBLE: I guess I would have a different point of view than what Dr. Dickey just expressed because I don't see that a decision on this particular project says anything about what the Committee might do in other circumstances that involve a telephone survey.

This is a particular situation in which the survey, if given by phone, is not an isolated event, but the first portion of a much larger study with data to be connected from this survey to much more information at a later time. And information that we, as a Committee, have talked about as sensitive information throughout the project.

This is not the same situation as others, where the Committee has waived written consent for a telephone survey. At least in my view it's not the same situation. And I would want to look at the particulars we're dealing with here, rather than any thought that this is a policy decision of some sort about what people can do for telephone surveys.

VICE CHAIR DICKEY: Can I respond to that?

INTERIM CHAIR DELGADO: Go for it.

VICE CHAIR DICKEY: Yeah. They are getting consent for the medical record information and it's my understanding that part of that would be acknowledged that

it would be linked with other information, but I'm not exactly sure of that.

But it's not uncommon, I believe, for these studies with the Cancer Registry to have this situation. I don't know if anybody from the Cancer Registry wants to speak to that. But you're right, it's not a policy decision, but we do try to be consistent across projects.

INTERIM CHAIR DELGADO: Well, some may be feeling frustrated right now. I actually feel like we're making some progress. So, I just want to confirm --

DR. TSUI: Can I make a comment.

INTERIM CHAIR DELGADO: But just to confirm with the research team, you're good with having the participants send in the written informed consent for the REDCap modality or at least on the REDCap. For the written responses, those we'll send in.

So, now we're just only talking about the telephone, right. Am I -- I guess I'm just looking for clarification.

COMMITTEE MEMBER LUND: Yeah. And at the -- yes. And at the October meeting the Committee was unanimous. So, we looked at the consent form. It's very complicated. The study is complicated. It is not possible to read a five-page consent over the telephone in a way that the participant is going to be able to retain and understand

that knowledge prior to doing the baseline survey.

So, what the Committee recommended, after much discussion and stipulated as a requirement of approval, was that the contact by telephone would allow the research team to connect with the participants and send them a consent form. Either they can do it either via their REDCap system or as a written paper consent form. And once they receive the consent, they can proceed with the telephone interview.

This could be a matter of same day or even, you know, within the same telephone interview situation if they do it via REDCap and email. Hang on, you know, we'll get you up online and show you the form.

But the Committee was not willing to set aside informed consent for a proportion of the participants. Right. So, you would wind up with a situation where some people were consented into the survey one way and others were consented another. And that wouldn't be fair either to the participants or consistent with what the OHRP guidelines say.

So, I think that as a subcommittee what we are recommending to the Committee is that we -- that the motions and stipulations that were made at the October meeting for this study remain in effect. I don't think that the researchers have presented anything in regard to changes that they made that would set aside the, we can put the OHRP

thing up on the screen again but would set aside this requirement for informed consent.

I will remind again, I already said this once, that there has to be -- if they don't want to sign a written informed consent, there does have to be documentation of informed consent. That's in the Common Rule. And they haven't provided any alternative. Just sending back the survey is not documentation of informed consent. You don't know that the person read those materials prior to filling out and returning the survey.

So, I think -- I think that that's where we are, unless the Committee members have something else.

DR. TSUI: Okay. So, I fully hear -- I fully hear the Committee's discussion, and we respect that, it is an important matter.

I think to Dr. Dickey's point, we provided other Registry-based studies that have similar protocols, The CHIS Study, Project Forward, the Respond Study (phonetic), who all have similar protocols where the baseline survey has a waiver of written consent.

I think to Ms. Lund's suggestion, though, in order to have consistency across our three baseline survey data collection modes, if the Committee would allow for it, if we could -- we could add in a question, have you read the information sheet or have you read the consent form, check

yes or no as, you know, one of documentation. The same for the virtual.

And I think for the telephone, if allowed something where we collect verbal informed consent, have you read the information sheet, yes or no, the interviewer over the telephone marks that.

Yeah, what I'm hearing is we did not propose an alternative to written informed consent.

The Committee -- our research team is not trying to waive informed consent altogether. Just for the baseline survey we are asking for a waiver of the written consent.

We understand our information sheet for our consent form, as stated, is long. I will -- I will like to relay that it is long because we have tried to be extremely responsive to the reviewer's comments of what else needs to be in our consent form. Between the months of August and October we have added to that consent form several times in response to a reviewer's feedback.

Participation is optional. Right. No participant is required to move on to step two, the medical record piece, if they don't want. Participation in the 12-month survey is optional. They don't need to come back. There is no requirement for them.

Our information sheet explains that fully. There are these other pieces, you do not have to participate, if

you -- participation is fully optional.

And so, at each stage we are going to provide informed consent. It's just at the baseline here. Inconsistent -- you know, in a consistent manner with other Registry-based studies and with our current other site, New Jersey State Cancer Registry. For this consistent study we are just asking for a waiver of informed consent.

If that means the alternative is to obtain verbal consent for telephone, we're happy to edit our protocol to provide an alternative.

COMMITTEE MEMBER LUND: So, your -- for the telephone people, and this was the concern again, to remind everyone, in October, your consent form is too long to be understood, if read over the phone. How will you know that they have read and understood that form? Is it possible for you to text them some sort of e-sign technology, so that you will know that they have actually reviewed, and read, and understood?

One of the requirements of informed consent is that they have the opportunity to have the consent form reviewed with them, you know. So, it's the telephone people I think that we're especially concerned about since you have pointed out that you expect those to be some of your most vulnerable people, we want to make sure that the informed consent process for them is particularly followed.

DR. TSUI: Everybody, including the telephone outreach, will have already received the mailed package. So that's the first piece is that they should have a paper version of that document already.

COMMITTEE MEMBER LUND: I understand. But how will you know that they have actually looked at and understood that paper version of the document?

DR. TSUI: We can ask them -- I mean, I think -- I don't mean to be -- you know, in other studies do we ask do you fully -- we can ask them have you read the consent form? I could go over it with you. I'm happy to answer any questions. I think in standard recruitment protocols, other studies, other projects we train our team and our interviewers to any questions to confirm that participants have read and understood.

I think -- I mean, this is not a siloed situation where we need to test our participants on accessing that Information. This happens in all research study protocols. So, maybe -- maybe I'm not understanding the question here.

COMMITTEE MEMBER LUND: Yeah, so I think that we're particularly concerned, there's PII, there's sensitive information in the baseline and people are entitled to an informed process that allows them to understand everything that will happen to them, including what you're going to use their information for, the fact that you're going to link it

to medical records and CCR.

And I just don't believe that the procedures you've outlined for the telephone people get there. I, personally, still believe we need written informed consent for everyone in the survey, in the study. You know, that's you're asking for written documents from the paper people and from the online people, and I think I'm still not convinced by anything I've heard today, that we don't also need to ask for it for the telephone cohort.

So, are we ready for a motion. We can see how the rest of the Committee feels.

DR. LIU: Sorry, this is Lihua Liu again. I think we came in, as Dr. Tsui laid out in her initial statement for this Committee, our purpose today is to ask the Committee for waiver of written consent for the baseline survey, period, regardless of both.

COMMITTEE MEMBER LUND: Oh.

DR. LIU: That was our goal. You know --

COMMITTEE MEMBER LUND: Yeah.

DR. LIU: -- we don't think written informed consent is justified and necessary for this baseline survey. Okay.

When, you know, you mentioned the PII, when PII (indiscernible) -- I think that any survey study patients contact study, PII is a given, right. We already have that

information in order to reach out to the patient.

And in the questionnaire, itself, we do not ask additional PIIs. And I don't see this baseline survey as any different from many other patient contact studies utilizing the Cancer Registry records that this Committee has approved over and over, you know, over the years, and many different studies, and PIs, and myself is one of them.

So, we also, especially when we contact patients, and we hold utmost respect for patients. We appreciate their willingness to share their experience, to help with the cancer control, to help with any other patients. And especially cervical cancer is such a preventable, curable disease. And we have vaccines, we have screening methods. No patient should die or diagnosed with cervical cancer anymore. But, unfortunately, we're facing still people die from this and that's why it is so important to do this type of study. That's why NIH funded this project.

And when we reach out to these patients, we understand, you know, most of them may be on the lower socioeconomic status and want to treat them. We want -- we, you know, respect them, we appreciate the effort of these patients. And we want them to feel respected, as well.

So, we never doubted when they say I did, you know, read -- I did read it and I received it, and I consent. We never question them. We never text them. And

I don't want to treat the telephone participants any different from the other one.

Our goal is to freely involve them, invite them into the study. And also, in terms of the recent (indiscernible) -- informed consent that, you know, it was some members of this Committee, earlier in a conversation mentioned, you know, why it's not feasible to have them, you know, just send in their questionnaire.

I think in the University of Southern California IRB, they have -- in these kind of circumstances they would approve waiver of written consent because they do not want to have another piece of document have the patient's name and linked with the study. That's part of the patient protection of patient confidentiality.

So, returning patients -- the return questionnaire as consent for participation has been used and been approved over and over, for different, many different studies and over many, many years. And I don't see why it's different for this study.

INTERIM CHAIR DELGADO: Understood. Thank you. And I get your frustration. I know that we, oftentimes, in this Committee, through our reliance agreements we are the -- you know, when we do reliance agreements with some of the universities within the State of California, our statute actually requires that we be the decision maker over some of

the UCs for our state data.

Many researchers proceed not using state data because of the high bar that we set, due to the sensitivity and the protection of Californian's data.

So, appreciate your comments. I just do want to make one -- one thing that you said was a little triggering for me and I'm just going to call it out. That when you said that your team was wishing to proceed regardless of the board's recommendation on the waiver of informed consent, just want to make sure I'm super clear with everyone on the phone and everyone on the board that the cancer -- the California Cancer Registry data cannot be released without CPHS approval. So, I just want to be very clear about that for this research team and for this board.

So, I'm going to hand it to Ms. Lund to make a motion, please.

COMMITTEE MEMBER LUND: Okay, great. Thank you.

DR. LIU: Sorry, excuse me, can you clarify what is that? We know the release of Cancer Registry data for research cannot be done without CPHS approval. That is a given, we understand that. What was your point? I did not --

INTERIM CHAIR DELGADO: My point was that -- I'm sorry, maybe I misunderstood. But I was triggered by your comments when you said that your team was going to proceed

regardless of any decisions that the board makes about your requests for written -- excuse me, request for a waiver of written informed consent. That was what was triggering for me.

DR. LIU: Sorry, that's not what I said. And I wouldn't say we can proceed without the approval. No.

INTERIM CHAIR DELGADO: Okay. My apologies for my confusion. Thanks for clarifying.

COMMITTEE MEMBER LUND: Great. So, I'm going to make a motion. My motion is that all of the stipulations made in October regarding this study remain in effect.

The second part of my motion is that the waiver of written informed consent is denied. Written informed consent is required for all three modalities of the study. That's it.

INTERIM CHAIR DELGADO: Okay, that's the motion. Do we have a second.

COMMITTEE MEMBER KURTURAL: I second.

INTERIM CHAIR DELGADO: Thank you, Carrie. Carrie seconded.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Abstain. And the reason I abstain is because I was the Chair who made the decision for

this to come back to the Committee. And I'll say something about that later, but I abstain on this.

MS. ATIFEH: Okay. Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: The motion passed.

INTERIM CHAIR DELGADO: Okay, the motion passed.

Dr. Tsui, I know you and your team are probably going to be frustrated with this, but we will continue to try to get to yes with your team, with a subcommittee of Ms. Lund and Dr. Schaeuble. Encourage you to continue your communication with the board because we want to help your project be successful in a way that we can -- we can ensure the protection of human subjects for the state.

DR. TSUI: We absolutely respect the Committee's decision. We appreciate the time that was spent today. I think we're all in agreement that first and foremost we want to protect the participants of any research study, especially as it's related to the Cancer Registry data.

INTERIM CHAIR DELGADO: Wonderful. And would just encourage working with your subcommittee to really -- to develop some procedures for the telephone arm where everyone is feeling comfortable. That you feel comfortable with the procedures, but also we feel comfortable that those set procedures will ensure an understanding of the informed consent.

So, thank you for your continued collaboration and patience. Thank you to your team for spending the time with us this morning.

DR. LIU: Will we give -- will we receive a written letter of condition from this Committee?

INTERIM CHAIR DELGADO: Yes, it will come within two weeks. But also, it's going to look exactly like the last one you received, pretty much.

COMMITTEE MEMBER LUND: Pretty much.

INTERIM CHAIR DELGADO: Thank you guys so much.

DR. TSUI: Thank you.

INTERIM CHAIR DELGADO: Have a great weekend.

Dr. Dickey, you said you wanted to make a comment

operationally before we move on to the next project?

VICE CHAIR DICKEY: Yes. I just wanted to make it clear why I wanted this to come back to full Committee, which is that the Common Rule states that a subcommittee cannot reject a project. And so, any rejection of a project has to occur by the full Committee.

INTERIM CHAIR DELGADO: Got it.

VICE CHAIR DICKEY: And in this circumstance, the researchers called and asked, you know, and they wanted to come back to the full Committee and, you know, it's their right. And I think we all need to inform researchers that if they disagree with us as a subcommittee, they can ask for a hearing with the full Committee.

INTERIM CHAIR DELGADO: Understood. Thank you for the clarification and the comments.

DR. LIU: I would request in the justification for, you know, required for written informed consent be specified so we can, you know, study among ourselves and which part, you know, we need to specifically address. Thank you.

INTERIM ADMINISTRATOR MARTINEZ: Justification of the study?

INTERIM CHAIR DELGADO: Okay, thank you so much to your team.

We are going to move on. Project 2024-003. Dr.

Ponce, are you on the line?

DR. PONCE: Yes, I'm still on the line. Thank you.

INTERIM CHAIR DELGADO: Wonderful. Okay, Dr. Ponce, this is Dr. Azizian's first project that he is presenting. He looks incredibly scholarly with his background of many books. Hopefully, his background reflects the great support he's given you as the primary reviewer.

(Laughter)

INTERIM CHAIR DELGADO: So, Dr. Azizian, do you want to kick us off on this project.

COMMITTEE MEMBER AZIZIAN: Good morning. That's a virtual background --

(Laughter)

INTERIM CHAIR DELGADO: Really? Is it?

COMMITTEE MEMBER AZIZIAN: It's a great pleasure of mine to having the opportunity to review this project. And I have to admit I'm familiar with Dr. Ponce's research and I've used it, actually, in my classes. So, it is a great pleasure to have the opportunity to review that.

Dr. Ponce, this project is about assessing health related behaviors and challenges in American Indian and Native Alaskan populations.

If I may, please, ask you to present a summary of

that in a focus on recruitment, and consent, and interactions with human subjects.

DR. PONCE: Thank you very much, Dr. Azizian. I'm going to start this off with a quick summary and then hand it off to my colleague, Todd Hughes, who you all met earlier.

This is a 15-minute follow-on survey to the 2023-2024 California Health Interview Survey of American Indian/Alaskan Native adults, residents of California. I believe that we are using any mention of American Indian/Alaskan Native in the base CHIS.

We are doing this with a partnership with the California Tribal Epidemiology Center, which is housed in the California Rural Indian Health Board, or CRIHB.

And the purpose of this study, as Dr. Azizian has said, is to understand experiences from American Indian and Alaskan Natives in their health conditions, health behaviors, mental health, and alcohol or drug use.

The survey's going to help us also increase accurate data collection on this population and the data quality on AIA and contributions to these challenges and barriers. So, we're quite excited about this study.

I'm going to turn it on -- turn it to Todd Hughes.

MR. HUGHES: Great. Thank you, Dr. Ponce and Dr. Azizian.

Approximately 570 adult CHIS respondents from the 2023-2024 CHIS cycle, representing 200 from the Central and Southern Regions each, and 170 from the Northern Region will be interviewed for this study.

The survey will be similar to CHIS modes. A focused administered (phonetic) survey or interviewer administered CATI survey and will be conducted in English or Spanish.

For eligible CHIS 2024 respondents, if they agree to participate at the time of completing their CHIS survey, respondents will continue the online survey, with the follow-on survey questions, and telephone respondents will move directly into the survey questions by telephone.

For either mode, if they agree, but which to participate at another time, we will contact them later via a standard CHIS mail-in protocol with an invitation letter, a reminder postcard, a reminder letter, and a reminder postcard.

Those who have not completed the survey, again this mailed protocol, and we have a matched phone number, will receive up to six calls to try and complete the survey.

If the eligible respondent refuses to participate in the follow-up survey, one refusal conversion letter will be sent to the adult respondent and ask them to reconsider their decision to participate from the follow-on survey.

For eligible 2023 CHIS respondents, if they consented to be recontacted for future studies, the protocol will follow the same series of four mailings and six phone calls, as for CHIS 2024 respondents who wish to participate at another time.

The follow-on study data will be linked to some degree to the -- they will be linked to the existing CHIS data for follow-on respondents. And this will happen within the secure UCLA Data Access Center, this linkage with the (indiscernible) -- or DA being followed the same procedure as previous CHIS follow-on studies. Data editing (indiscernible) -- waiting for the follow-on survey, they will be done in a manner consistent with the main CHIS data.

And then, as far as consent goes, so as they are invited to participate in the study, at the end of their original CHIS interview we will provide the (indiscernible) respondents written informed consent on the screen, and then they will be asked if they would like to continue with the study and will answer affirmatively or not.

And for the telephone respondents, that information will be provided orally in the CATI interviewer's script, and they will be asked if they would like to continue with the survey, yes or no. So, informed consent will be provided through both modes. For telephone respondents they will be provided orally. We do record. We

ask for a consenter report for the CHIS interview overall, so we will record and capture their consent to continue with the survey as documentation of their receiving informed consent.

I'll pause there for comments or questions.

COMMITTEE MEMBER AZIZIAN: And be patient with me. As Dr. Delgado pointed out, this is my first run with this. I'm not fully familiar with the telephone research methodologies.

But in the protocol, if I'm not mistaken, there was a comment in there that if the respondent is contacted and has not participated in the previous study, they are asked if there's someone from their household who has previously participated. Is that correct? Is that -- or maybe my misunderstanding.

MR. HUGHES: Right. So, this is a circumstance where in the original CHIS interview they agreed to participate in the follow-on study, but they weren't able to participate at that moment and they wanted us to do it in a later time.

So, in those later contacts with them, we start with a series of mailings to try to reach the same person who participated in the original CHIS interview, or we'll do the phone calls.

So, as we then recontact that household, we do ask

for confirmation that we're speaking with the right person, through a combination of their age and gender, of the original respondent. It is not required for CHIS respondents to give us their actual name during the original CHIS interview, so we don't always collect the name to be able to confirm that we are speaking with the person as who participated in the original CHIS interview.

And so, with a combination of, you know, we're looking for a person of this gender and this age who may have participated in the California Health Interview Survey in our attempts to confirm that we've reached the right respondent.

This is a similar approach to what we have done for other CHIS follow-on studies in previous years that has been approved by the CPHS.

COMMITTEE MEMBER AZIZIAN: Yeah, thank you very much for that information.

The other question that I have, so I didn't understand that the survey could be conducted in English or in Spanish languages. And I'm guessing that the process for preparing the consent form in Spanish is still pending. That has not been finalized, is that correct?

MR. HUGHES: That's correct. We were going through this process to seek approval of all the materials in the English first, and then we will submit, via

amendment, the Spanish translation of the materials.

COMMITTEE MEMBER AZIZIAN: And if we were to approve this, this would be only presently for the English version of it until you have submitted the forms in Spanish, is that correct?

MR. HUGHES: Yes, that's just fine.

COMMITTEE MEMBER AZIZIAN: Were you going to present any additional sections of the protocol?

MR. HUGHES: Not at this point, unless there are other questions you would like us to address.

COMMITTEE MEMBER AZIZIAN: There was one more comment that I had about I understand that a part of it is going to be subject of quality assurance, which is not going to be used for research purposes. People who will be conducting the quality assurance part, would they be research team members, have gone through the same confidentiality training and everything else?

MR. HUGHES: Yeah. But there are, there are two components of the quality assurance. The primary being done by our research team. Here at UCLA, we randomly collect a series of the recorded interviewings -- recorded interviews, excuse me, to provide that quality assurance.

And then there is a standard quality assurance that's conducted by the supervisory staff at the telephone centers to ensure that their interviewing team are following

the protocols as they're trained to do. All of the individuals who do that have the same training required and protocols for ensuring the confidentiality of CHIS data.

COMMITTEE MEMBER AZIZIAN: Now, there were some minor comments that I sent back and saw that you had responded. So, for the sake of time I'm not going to ask those things.

But at this time, I would like to invite my colleagues, who are more experienced at this type of thing, to see if they have any questions or any feedback to provide.

INTERIM CHAIR DELGADO: Nice summary, Dr. Azizian.

Other board members, any questions or concerns for the researchers that you'd like to bring up?

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: Oh, Dr. Schaeuble, go right ahead.

COMMITTEE MEMBER SCHAEUBLE: Several questions, if you can bear with me. I don't recall seeing any designation about vulnerable populations at the beginning of the protocol. And maybe I missed it. I'm assuming American Indian/Alaskan Native would be considered a vulnerable population in your view?

MR. HUGHES: I'm sorry, we're having a little difficulty hearing you.

INTERIM CHAIR DELGADO: I think Dr. Schaeuble said that there was no vulnerable population box checked on your protocol but, yet, some of the populations that you described could likely be considered vulnerable. So, just curious.

Am I rephrasing correctly?

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: So, just wondering if that's --

DR. PONCE: Yes. Sorry. I think we should fix that, we should check the vulnerable population box.

COMMITTEE MEMBER SCHAEUBLE: Okay.

INTERIM CHAIR DELGADO: Great.

COMMITTEE MEMBER SCHAEUBLE: Going on, then, I noticed that one of the options for a security question on the login was mother's maiden name. And I'm wondering about the wisdom of having that as a possible security question when it's so often linked to financial information about people. You have other alternatives there and, presumably, could add other alternatives if they were need, but -- I'm going to suggest -- I'm going to suggest removing mother's maiden name as a security question for that kind of reason.

Is that something that makes sense to you?

MR. HUGHES: I think we're happy to request that request. It is -- these are the -- I believe the same set

of questions that have been approved by CPHS for use in the main CHIS survey.

DR. PONCE: But perhaps for a vulnerable population, so we are hearing you, that this may be more sensitive. So, we will consider removing that for the follow-on.

INTERIM CHAIR DELGADO: Thank you.

COMMITTEE MEMBER SCHAEUBLE: Going further, there was an extensive list of variables in the linkages section of the protocol about what the survey responses would be linked to. A much shorter description in the scripts. And I think it would be helpful if the description in the scripts could be expanded, at least somewhat, to be a little closer to what you described in the protocol. Again, this --

MR. HUGHES: So, the (indiscernible) list that's included in the protocol, you know, is a very E-tablet (phonetic), that goes question by question. Whereas the information that's presented in the informed consent document is intended to be more topic based, rather than question by question based. And so, I think we will --

COMMITTEE MEMBER SCHAEUBLE: And I think that's fine. I think that's fine. I think if I were to request something, it would be for what's in the scripts to be more fully representative of the topics that are reflected in the

linkages section of the protocol, if that is something that you could work on.

MR. HUGHES: Yes.

COMMITTEE MEMBER SCHAEUBLE: The information sheet actually didn't seem to say anything at all about survey responses being linked to anything else. And perhaps that should be in the information sheet.

DR. PONCE: Yes, I think we -- we can add that, if it's not there.

MR. HUGHES: Yes, it's in the informed consent script, and not in the information sheet.

COMMITTEE MEMBER SCHAEUBLE: And can you clarify for me a little bit here about SSRS and whether that company has a file of linked identifiers to the surveys? And if so, whether that file of identifiers is -- when or if it is destroyed? I couldn't tell, I think, from trying to read the information in your study.

MR. HUGHES: It's a little difficult to hear you but let me restate what I believe I heard your question to be. That the SSRS, you know, they retain identifiers to be able to link the follow-on study to the main CHIS, and what is their disposable agreement regarding those identifiers. Is that correct?

COMMITTEE MEMBER SCHAEUBLE: Yes, please.

MR. HUGHES: So, yes, the SSRS organization is our

subcontractor for data collection for the CHIS program. So, they conduct the main CHIS interviews, as well as these follow-on studies like this AI/AN project. They do have the linked identifiers for this to match it to the sample address that was selected for the study, and the data in their files.

They do not provide the detailed identifiers, like address or name information to UCLA. All of that is with a secure identification number that those then get returned to UCLA.

They are instructed on contact with them to retain them for a period of years, I believe it is five years after they've collected the original survey data. At this point, they are required by contract to delete that information as well.

COMMITTEE MEMBER SCHAEUBLE: I guess I'm thinking two things here. My understanding from reading your information is that your university will keep the survey data apparently indefinitely. And you're also acknowledging in what you just said that SSRS has contact information, although you won't have it.

DR. PONCE: Don't have it, right.

COMMITTEE MEMBER SCHAEUBLE: But that it will be kept for a period of time. And I don't see participants being told either of these things and it sounds like they

should be told that it's your intention to keep the survey responses as long as you need to have them or however appropriately to phrase that.

And also, that there is a -- there is a linked -- contact information is kept separately by -- I don't know whether you're explaining what SSRS is or not in your materials. But contact information is being kept separately by another entity and you don't have it, but they will continue to have it.

It just didn't seem clear to me, to participants how long the survey information will be kept or that there is at least an indirect connection to another company that has contact information for all the survey responses.

COMMITTEE MEMBER SCHAEUBLE: And if I'm misunderstanding, please clarify where I'm misunderstanding because sometimes I do.

MR. HUGHES: So, first off, the contact information is from publicly available sources. They're directed via a sample for the study. And the CHIS sample comes from, you know, publicly available address lists. SSRS works to sample a set of selected addresses and mails invitations to respondents.

We then use third-party data sources to find a link to telephone numbers to those addresses, in the case that they don't respond from our mailed invitations, and

we're trying to contact them by telephone.

So, that information, those names, if they provide any names, if they -- you know, the sample addresses, the sample telephone numbers are never provided to UCLA. UCLA never has that information.

As far as the survey data that they provide, when respondents agree to participate in the study, that information we do say in the information that their data, including de-identified data may be kept for use in future research. We don't put a timeline about that, but we do inform them that the de-identified data will be kept for future research.

Have I addressed some --

COMMITTEE MEMBER SCHAEUBLE: Just for clarification, then, UCLA, of course, does not have the contact information. Would SSRS be able to link contact information to individual surveys or not?

MR. HUGHES: No, they're not. Our contractor gives them from the (indiscernible) of that information and we ask them to retain it for five years in case there are other future follow-on studies that are desired. And we would then, you know, come back to CPHS and seek approval to follow that up with those old respondents. And then, we would need to use, you know, that has been retained to contact those individuals. For them to contact those

individuals. UCLA never obtains names, addresses, or telephone numbers for respondents in the CHIS or any other associated follow-on studies.

COMMITTEE MEMBER SCHAEUBLE: So, if I'm understanding right, then SSRS has contact information, but not survey data.

MR. HUGHES: They host the web survey platform, they host the telephone interview platform, so they do collect the survey data. So, they house the survey data and the contact data.

My screen just went blank. I hope you can still hear me.

INTERIM CHAIR DELGADO: Yup, we can.

DR. PONCE: You kind of froze, but we can, yes.

MR. HUGHES: Okay. All of you, I'm resetting on my laptop here.

So, they collect the data directly from the respondent. They retain any of the contact information, the de-identifiable address, telephone, name information they deliver to UCLA, they survey information.

INTERIM CHAIR DELGADO: Okay.

DR. PONCE: And Todd is talking about the whole main CHIS, not this particular project that's in our protocol.

COMMITTEE MEMBER SCHAEUBLE: I guess I hate to

belabor the point here, but what I'm trying to establish is whether SSRS, acting as a contractor for you, has survey data linked to contact information. Because if that's the case, the survey data are potentially identifiable, at least through SSRS, even though UCLA does not have any contact information. And I'm not clear from what you're saying whether that is the case.

So, can you try one more time to explain that to me?

MR. HUGHES: Yes. SSRS, as our data collection subcontractor, has the contact information and the survey data.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, it's sounding to me like your consent and information form would need to say that UCLA has no contact information about you, but we should advise you that SSRS does have contact information, as well as your survey data.

MR. HUGHES: Yes, that would -- I do understand the request and I imagine we would link that to a statement about how that's being retained by them, as well.

COMMITTEE MEMBER SCHAEUBLE: Yes. Thank you much. I appreciate your patience.

DR. PONCE: No, thank you. Thank you for all those concerns. I'm sorry I can't see you in the room. But thank you so much those concerns.

INTERIM CHAIR DELGADO: We're pointing to him, as you can see.

DR. PONCE: Oh, okay. So, I guess he's speaking with a shared screen now that's --

INTERIM CHAIR DELGADO: Oh, yeah, understood.

Anything else, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: No.

INTERIM CHAIR DELGADO: Okay. Other members, any comments or questions for the research team?

If not, Dr. Azizian, your first motion, please.

COMMITTEE MEMBER AZIZIAN: So, the motion would be to move forward with approving the English version of the project, considering the changes for -- and I'm sorry, I may have missed one of them (indiscernible) -- with your SL. But one of them that I captured was the changing the security password questions for the mother's maiden name, the information about --

INTERIM CHAIR DELGADO: Yeah, Allen. Hold on one second, Allen. We'll put it up on the screen so you can follow, because our scribe has been taking down some of the recommendations.

COMMITTEE MEMBER AZIZIAN: Wonderful.

INTERIM CHAIR DELGADO: So, your motion -- yeah, so maybe let's start with a deferred approval motion pending and then walk us through some of the recommendations. Some

of them may be like a request for change. Others might just be like recommendations for the research team to consider. So, just give us one second and we'll pull it up.

COMMITTEE MEMBER AZIZIAN: So, deferred --

INTERIM CHAIR DELGADO: Deferred approval, yes.

COMMITTEE MEMBER AZIZIAN: Deferred approval pending, but I still don't see the things that you're putting up there.

INTERIM CHAIR DELGADO: Is it -- can you see it now?

COMMITTEE MEMBER AZIZIAN: Well, I see the language for it, but I don't see the actual recommendations. Was I supposed to announce the recommendations as well, or no, just do the deferred approval pending the changes that were made, recommendations for the changes.

INTERIM CHAIR DELGADO: Yeah, can you just scroll up real quick. So, just to make sure that you have them all when you give your formal motion, and don't worry we all struggle with this even years into it.

Can you just scroll up a little bit?

DR. RYKACZEWSKA: So we can see the discussion.

DR. PONCE: Scroll the other way.

INTERIM CHAIR DELGADO: Yeah, there we go. So, Allen, the -- or Dr. Azizian, the first is changing the vulnerable populations box. The second is considering

changing the mother's maiden name security question. Making tweaks so that the list of variables in the linkage section represents the protocol.

COMMITTEE MEMBER SCHAEUBLE: Actually, that's tweaking the script to be more parallel to the linkages section.

INTERIM CHAIR DELGADO: What Dr. Schaeuble just said.

The info sheet talking about the survey responses, to include that in the info sheet.

Ensuring in the informed consent or being explicit in the informed consent that SSRS has the data and will retain it for five years. Is that correct?

COMMITTEE MEMBER SCHAEUBLE: Has the survey --

INTERIM CHAIR DELGADO: The survey data.

COMMITTEE MEMBER SCHAEUBLE: -- and contact information.

INTERIM CHAIR DELGADO: Yeah, I think those are the recommendations associated with your deferred approval motion, Dr. Azizian. And that the Spanish -- sorry, one last one. That the Spanish version will be reviewed once completed by --

COMMITTEE MEMBER LUND: I think it's only --

INTERIM CHAIR DELGADO: Yes, that it's English only and it needs an amendment for the Spanish version once

those are completed.

COMMITTEE MEMBER LUND: And did we get the one about the info sheet needs to have the survey responses (indiscernible) --

INTERIM CHAIR DELGADO: And the info sheet also needs to say -- sorry, we're giving you a doozey, Allen.

COMMITTEE MEMBER AZIZIAN: Fine.

INTERIM CHAIR DELGADO: The info sheet needs to reflect -- what was that, Laura?

COMMITTEE MEMBER LUND: That the survey responses will be linked to other information.

INTERIM CHAIR DELGADO: The survey responses are linked to other information.

COMMITTEE MEMBER LUND: And it's minimum risk.

INTERIM CHAIR DELGADO: And it's minimum risk.

Sorry, to the research team, you'll get all of this in writing, but we do just have to make sure it's verbalized in the motion that Dr. Azizian makes.

So, while we look a bit discombobulated, we're actually totally covering all of our bases.

Okay, Dr. Azizian, go for it.

COMMITTEE MEMBER AZIZIAN: I make a motion for deferred approval pending the following changes. Checking the vulnerable population, to see them changing the security question for the mother's maiden name. Linking the script

to be more parallel to the protocol, including the linkages to the information sheet states that the SSRS has survey data and contact information. The Spanish version of the forms will be reviewed. And this will be for approving this English version only. Information sheet will need to reflect that survey responses are linked to other, and it's a minimal risk study.

INTERIM CHAIR DELGADO: Great motion.

COMMITTEE MEMBER SCHAEUBLE: Could I --

COMMITTEE MEMBER AZIZIAN: Thank you very much, Dr. Delgado, for your help.

INTERIM CHAIR DELGADO: One year, minimum -- can you adjust your motion to be one-year, minimum risk.

COMMITTEE MEMBER AZIZIAN: That it would be a one-year, minimum risk.

COMMITTEE MEMBER SCHAEUBLE: Darci?

INTERIM CHAIR DELGADO: Yes.

COMMITTEE MEMBER SCHAEUBLE: Maybe a word change, third line, include linkages in the information sheet to --

INTERIM CHAIR DELGADO: Linkages in the info sheet.

COMMITTEE MEMBER AZIZIAN: In the information sheet.

COMMITTEE MEMBER SCHAEUBLE: And on the line above, tweaking the script to be more parallel to protocol

about -- I'm losing my train of thought here.

COMMITTEE MEMBER AZIZIAN: The topics of survey questions that will be --

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: Perfect. About the topics of the survey question.

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER SCHAEUBLE: Thank you.

INTERIM CHAIR DELGADO: So, we have a motion on the table. Would anybody like to second it?

VICE CHAIR DICKEY: I'll second it.

INTERIM CHAIR DELGADO: Thank you, Dr. Dickey. And we can vote.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Wonderful. Thank you so much to the research team. I know you're staying on. But you will receive a letter with all of these details. Dr. Azizian is more than happy to answer any questions that you may have and follow up. And thank you for your patience with us.

DR. PONCE: Thank you so much, Dr. Delgado. Thank you, Dr. Azizian, that was great. Thank you for the team effort. Dr. Schaeuble, as always thank you for your insights for the survey.

So, can I move on?

INTERIM CHAIR DELGADO: Yes, let's move on. And we'll save, we'll do a copy/paste if any of the same recommendations happen to pop up this time as well.

So, I'm going to hand it over to Dr. Ventura for her first protocol presentation. Go ahead.

COMMITTEE MEMBER VENTURA: Okay. Thank you, Dr. Ponce and team for the opportunity to review your submission. This is the CHIS Hate Incident follow-on study

that we will be discussing.

Dr. Ponce or Mr. Hughes, if you'd like the opportunity to just briefly introduce this follow-on study to the full Committee, you can do so now.

DR. PONCE: Thanks, Dr. Ventura. In keeping with the pattern, I'm going to start us off and then have Todd go into the details of the study.

So, UCLA recently recently received funding from the California Civil Rights Division to conduct a follow-on study to the 2024 California Health Interview Survey. The California Civil Rights Division has actually funded us and the previous CHIS to include questions on hate incidents in the main CHIS, but this is a follow-on to the 2024 survey.

This is a little different. It's a qualitative study designed to gain a more nuanced understanding of the realities faced by Californians who have reported experiencing hate incidents, as well as to learn more about the most important part of what supports, or access are needed after such an incident.

So, Todd.

MR. HUGHES: Thank you. And apologies, whatever happened to my laptop in the last half hour, I'm not able to use my camera. But I'm here and encourage you to look at Dr. Ponce's, it's a more attractive face than --

(Laughter)

MR. HUGHES: So, participants from this study are CHIS 2024 survey respondents aged 18 and older, who report that they've experienced one or more hate incidents within the 12 months preceding the CHIS survey. And who are willing to participate in an audio recorded, qualitative interview, individual interview.

So, we classified participants into two separate recruitment groups. Tier one respondents are those who are age 18 to 75 and meet one of these criteria; they identify as transgender, identify as LGBTQ, report having a disability, report having instability, report limited English proficiency, are noncitizens without a green card, live in low-income households, identify as Jewish, or identify as black or African American.

Tier two respondents are those who do not meet any of those criteria or who are age 76 years of age or older.

The distinction between tier one and tier two is just for us to give higher priority for scheduling of these qualitative interview appointments to the tier one candidates to ensure that we obtain sufficient representation from those respondents.

Upon completing the CHIS, eligible tier one respondents are provided general information about the qualitative study. We then ask if they would like to schedule an interview and then ask for permission to send

them the detailed written informed consent materials via text, via email, or by mail to their home, and then schedule their follow-on survey.

They're also given the option to call back to schedule the interview at a later time.

Tier two respondents are given general information about the study at the end of the CHIS survey, and we ask permission to contact them later about the study.

During the later contact of these tier two respondents we provide more information, ask permission to send them detailed study information for informed consent via text, email, or mail to their home, and then schedule their follow-on interview.

All tier one and tier two respondents will also receive an email or a text reminder prior to their interview appointment.

The qualitative interview will be conducted using Zoom. Respondents can log in to video or call in for the session. At the start of the session, we orally provide, again, the informed consent information. And we record the participant's verbal consent to participate.

Interviews will be conducted in English, Spanish, Chinese, Korean, Vietnamese and Tagalog. Where possible, study stuff will interview in the respondent's preferred language. They will use an interpreter when language

capacity is lacking among the study team.

In English, we estimate the entire session should take about 75 minutes, up to 15 minutes for introductions and consent, and up to 60 minutes for discussion.

Non-English language sessions will take longer but will be at two hours in total.

Consent to be audio recorded will be a criterion for eligibility. And this is because audio recordings are necessary to ensure we accurately capture the respondent's thoughts and opinions, especially in the non-English interviews. Audio recordings will be transcribed, and transcriptions used for analysis.

For non-English language interviews, transcripts will be translated for analysis.

The interviews will consist of open-ended questions that ask the respondents to describe the hate incident they experienced in the past year that had the biggest influence on them. Describe how the hate incident impacts them, including their feelings about what happened, any changes they have made to their behavior or daily routine, and any associated costs they may have incurred. And describe the support they may or may not have received from authorities, family and friends, or others, and whether or not they reported or discussed the hate incident with others.

Participants can stop the interview at any time if any question they're not comfortable answering and take a break as needed.

Resources will be offered to respondents at the end of the interview.

Study logs, notes, audio recordings and transcripts will be stored on the UCLA CHPR secure box site accessible only by the study team. Transcripts will be auto-transcribed using Zoom.

A third-party (indiscernible) experienced in medical or HIPAA, and academic research transcription will transcribe and translate the non-English language interviews.

A summary of age, race/ethnicity, household incident, hate incident question responses from the original CHIS study will be aggregated from all study participants to produce a profile of the participants who participated in the qualitative study, but they will not be individually linked to the study participant's qualitative response data.

I will pause there, then, and welcome your comment and questions.

COMMITTEE MEMBER VENTURA: Thank you for that summary. So, I'll just go over some of my main revisions and kind of open it up for discussion with the Committee.

Thank you for -- one of my main concerns was that

this qualitative data would be linked to the main CHIS study, but you've clarified that point that it will not be linked.

Thank you for also acknowledging that this is a vulnerable population. Initially, you did not have that checked. So, thank you for making that revision.

But one -- and thank you for also clarifying that participants will receive the study information well before they complete the interview on Zoom. This was discussed in an earlier submission, but the issue of that waiver of informed consent.

So, you are sending the informed consent and study material prior to the interview and then verbally asking if they have any questions about the study, and if they verbally consent to participate. Is that correct?

MR. HUGHES: Yes. We will restate the informed consent material verbally during the recorded Zoom session and ask them if they are willing to participate.

COMMITTEE MEMBER VENTURA: Okay. So, in this situation the waiver for written informed consent, then, would be appropriate? I'm kind of asking the Committee.

MR. HUGHES: We are not requesting -- I'll just clarify. We're not requesting signatures to be returned to us. We're providing by text, email or mail, depending on the respondent's preference, the written informed consent

materials ahead of the appointment time. And then, we are verbally repeating that during the Zoom interview and asking them verbally to provide consent. So, I just want to be clear the approach that's being proposed.

DR. PONCE: And it's recorded, too.

MR. HUGHES: Yeah.

COMMITTEE MEMBER LUND: So, they're getting informed consent and documentation of that.

COMMITTEE MEMBER VENTURA: Okay.

INTERIM CHAIR DELGADO: But good job clarifying that.

COMMITTEE MEMBER VENTURA: Thank you. And then, one other point. So, the English and Spanish versions of study material I believe the Committee can do. But for the other languages, there's Chinese, Vietnamese, and Tagalog, and maybe even Korean. Is that correct?

Vietnamese and Tagalog, yeah.

COMMITTEE MEMBER VENTURA: How do we approach that review of study material and approval for other languages?

INTERIM CHAIR DELGADO: So, they use -- yeah, no, that's a good question. So, researchers will normally get the approval of the English version and then they will do an amendment to their protocol, where they will included the translated versions, as well as the CV of the translator who translated them.

Sometimes we've had subject matter experts on the board who can review certain languages. But probably the multitude of languages we won't have subject matter expertise, so we'll just rely on the CV of the translator to ensure --

MS. ATIFEH: The certificate.

INTERIM CHAIR DELGADO: What was that?

MS. ATIFEH: Certificate.

INTERIM CHAIR DELGADO: Oh, yes, sorry, a certificate by the language translator. So, they'll just submit an amendment later.

COMMITTEE MEMBER LUND: And CHIS has done this historically because they do the survey in multiple languages, as well.

COMMITTEE MEMBER VENTURA: Thank you. Yeah, my familiarity of it is --

INTERIM ADMINISTRATOR MARTINEZ: The Spanish version Dr. Dinis, and Dr. Bazzano, and Dr. Ruiz are all certificated.

COMMITTEE MEMBER VENTURA: Yeah, I was just -- there's a lot of other languages, so wanted to clarify that.

I wanted to open it up to the other Committee members, if there were any other questions regarding this protocol.

VICE CHAIR DICKEY: This is Dr. Dickey.

INTERIM CHAIR DELGADO: Go for it.

VICE CHAIR DICKEY: Hi. So, over the years I've been the main reviewer on the CHIS survey, so I've seen the hate incident questions on the main survey. And one of the things -- and the way this process has gone over the years, it's just there's so many changes, et cetera. As long as the processes of the interview doesn't change or the study doesn't change, basically the questions are not coming back to the full board.

But I did have a concern on these questions about hate incidents that they needed to make it clear to the respondents that they shouldn't identify the offender, the person who perpetrated the hate incident. And they did some things in the regular CHIS survey to basically make that clear.

I don't see those things, necessarily, in this follow up. So, in the questionnaire there's -- there is -- it is acknowledged at one point, do not identify the offender. But I think it would be better if it was put higher up, right at the start of that section for the questionnaire about you would not be -- you should not identify the offender.

And also, on the consent form perhaps add something that says you will not be asked to identify the offender and you will -- and you should not do that.

So, that's my main concern about this is make it more clear that the offender is not going to be identified.

DR. PONCE: Thank you, Dr. Dickey. We can do that.

INTERIM CHAIR DELGADO: Awesome.

DR. PONCE: Not even consider that, but we can do that.

INTERIM CHAIR DELGADO: Great. Anything else, Dr. Dickey?

VICE CHAIR DICKEY: No, I think that also not only on the consent form, but also on the recontact form, maybe, consider putting that on as well, something like that.

INTERIM CHAIR DELGADO: Thank you. Any other Committee members? Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: So, thank you, Dr. Dickey, I think what you said was very important. And I thank Maria, also, for obviously a very thorough review of the protocol.

Just two very small things to ask about. The vendor you're using, SSRS, I don't know what that stands for and that acronym appears several places, the information sheet, the tier one and tier two recruitment documents. I think it would be helpful for people to know what the acronym is for. I think you did spell it out for other places that you had acronyms there.

MR. HUGHES: If I could just respond to that, briefly. So, SSRS is their company name. It is not an acronym.

COMMITTEE MEMBER SCHAEUBLE: Oh. That's interesting.

MR. HUGHES: Historically we had included an explanation of an abbreviation for that, Social Science Research Services, or something like that. That is not actually their company name. So, we're actually going to move away from any definitions of SSRS in future materials, and it will just remain SSRS.

DR. PONCE: Yeah, Dr. Schaeuble, I have raised this before and that's what I was told as well.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I don't remember, without looking back at the materials, is it clear then that when you refer to SSRS, you are talking about a company that is contacting participants on your behalf or some explanation of what SSRS is?

MR. HUGHES: Sure, we can review the materials and be sure that that's clear.

COMMITTEE MEMBER SCHAEUBLE: And the only other small question I had, or request actually, is in the consent forms part of your protocol, what you attached there was the beginning of the interview, but actually it's your information sheet that is a substitute for a consent form in

this kind of project.

So, would you make sure that you attach the information sheet, instead of the shorter beginning of the interview at that point in the document.

MR. HUGHES: Yes, certainly.

COMMITTEE MEMBER SCHAEUBLE: And that's all.

INTERIM CHAIR DELGADO: Great. Thank you, Dr. Schaeuble. Any other questions or comments? Carrie.

COMMITTEE MEMBER KURTURAL: I just had one quick one. I'm not quite sure, and you might have updated the protocol, so I apologize. I'm looking at a .pdf version of your protocol.

How are you de-identifying any results of this research project?

MR. HUGHES: Sure. So, in the summary report -- first of all, when respondents connect to the Zoom, the facilitator who runs (indiscernible) ensuring that they get connected is going to change their Zoom name information to ensure that, you know, there is no name provided on their Zoom window when they connect. So, we'll make sure that prior to any of the other research team members joining there will be no name information visible, and we'll make sure that's not available to the interviewers of the qualitative component.

But then, as far as when there are summary

findings for the study, we -- our historic pattern has been to just come up with a respondent ID that we refer to, you know, throughout their study report.

Participant 23 said XYZ. But we'll also ensure that there is no citation of any, you know, specific quotes that could be potentially identifiable, whether that be through a geographic location or a specific place where something occurred or other, you know, related identifiable summary information will be descriptive, and but certainly prevent any identification of either the incident itself, or of the individual.

COMMITTEE MEMBER KURTURAL: It sounds like you're going to use a Safe-Harbor methodology, which I'm okay with. Thank you.

INTERIM CHAIR DELGADO: Thank you, Carrie. Any other questions or comments?

Hearing none, Dr. Ventura, and no problem if you need help with your motion.

COMMITTEE MEMBER VENTURA: Okay.

INTERIM CHAIR DELGADO: But definitely start it off with like deferred approval, minimum risk, one year.

COMMITTEE MEMBER VENTURA: Okay.

INTERIM CHAIR DELGADO: And then go for it.

COMMITTEE MEMBER VENTURA: So, I make a motion for deferred approval, minimum one year --

INTERIM CHAIR DELGADO: Minimum risk, one year.

COMMITTEE MEMBER VENTURA: Minimum risk, for one year.

INTERIM CHAIR DELGADO: Thank you.

COMMITTEE MEMBER VENTURA: We are asking that researchers revise the questionnaire to state that participants are to not identify the offenders of the hate crime.

And we also ask the researchers to modify the consent form to also include that language to not identify the offender.

This is for approval of the English version, with approval of Spanish, Vietnamese, Chinese, and Korean, and Tagalog to be submitted as an amendment for future review and approval.

DR. PONCE: You need to add Vietnamese. Do we have Vietnamese, sorry.

COMMITTEE MEMBER VENTURA: Okay, Vietnamese. That was Chinese, Korean, Tagalog.

Did I leave any other languages out, Dr. Ponce?

COMMITTEE MEMBER LUND: I think you can just say and any other languages.

DR. PONCE: English, Spanish, Chinese, Tagalog and --

COMMITTEE MEMBER LUND: If you can just say and

any other languages.

COMMITTEE MEMBER VENTURA: Okay. Any other languages, okay.

DR. PONCE: Okay, thank you.

COMMITTEE MEMBER VENTURA: All right.

VICE CHAIR DICKEY: But we usually put something in about who's going to approve the amendment or the -- just be a subcommittee of yourself or --

COMMITTEE MEMBER VENTURA: I will need assistance. Just Dr. Schaeuble? Yes. Okay.

So, a subcommittee for approval will be myself and Dr. Schaeuble.

INTERIM CHAIR DELGADO: Good job. Okay, we have a motion. Would somebody like to second that motion.

COMMITTEE MEMBER LUND: I'll second.

INTERIM CHAIR DELGADO: Thank you, Ms. Lund.

MS. ATIFEH: Okay, Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: And Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio? I think Dr. Palacio is

--

INTERIM ADMINISTRATOR MARTINEZ: I think he had an appointment.

MS. ATIFEH: Dr. Palacio?

INTERIM ADMINISTRATOR MARTINEZ: Dr. Palacio.

MS. ATIFEH: Okay. Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Wonderful. Okay, you will receive a letter within the next few weeks that describes all of -- describes the deferred approval. Thank you so much to your research team for spending almost the entire morning with us. So, thank you.

DR. PONCE: Thank you. Thank you for your careful review. We know there's copious pages of material that we send, so thank you so much for your review, your feedback, and just making us be more responsive to the protection of human subjects. So, thank you.

INTERIM CHAIR DELGADO: Great, thanks. Good job, Dr. Ventura.

Okay, moving on.

DR. PONCE: We're leaving, now.

(Laughter)

INTERIM CHAIR DELGADO: I mean, you could -- you could --

COMMITTEE MEMBER RUIZ: You finally get a break.

DR. PONCE: Yeah.

INTERIM CHAIR DELGADO: We have applications to join the board, should you so wish to do so.

(Laughter)

INTERIM CHAIR DELGADO: Okay, so moving on to Project 2024-008. Dr. Hess, I'll hand it over to you.

COMMITTEE MEMBER HESS: Okay. We should have Dr. Mintz from USC on the line. There he is. Hi, Dr. Mintz, thank you for joining us.

DR. MINTZ: Hello.

COMMITTEE MEMBER HESS: So, this is a new project that is effectively identical to a previously approved CPHS project that was not renewed during the pandemic. So, the protocol has already been seen by the board. This is -- I did read through the previous project, it is identical.

So, this is about language acquisition in -- language development in infants. And Dr. Mintz, if you'd like to give a brief description of the project, please do so.

DR. MINTZ: Yes, thank you. Good morning and

thank you for reading through my proposal. And I also just want to thank the staff for bearing with me when I was submitting all the materials. The data security letter from my institution was quite delayed, but we were able to get it in, in time.

So, yeah, so my -- the research that this protocol is targeting is looking at early (indiscernible) -- and early language acquisition capacities in infants starting from about 6 months to 15 months.

The request here is for birth record information for L.A. County, for recruiting families into the study. And typically, the way these studies in my lab work is we have a sound attenuating booth. The infant is seated in the caretaker's lap. And we have loudspeakers on either side of the small booth which play usually artificial languages that we contrive to have certain properties that are similar to natural languages, in order to assess what kinds of patterns in these stimuli that are relevant for -- we think are relevant for acquiring languages, infants are processing and forming representations about.

So, typically, infants are exposed to this language at a comfortable volume for about anywhere from one to two minutes. And then, in the test phase we are simply measuring their preference for listening to new sounds that either conform to some of the patterns that were in the

original sounds that we familiarized them to, or that had -- that didn't conform to those patterns.

And these patterns are often abstract, having to do with how certain words in our artificial language relate to other words and how they depend on each other, just as they do in real languages.

And so, the new sounds that we play them either have these properties or not. And we are measuring how long they are willing to turn their head in the direction of the speaker that the sound is coming from in order to continue hearing that sound. Okay. So, they basically get to choose how long they listen to all the test items by exerting just a little bit of effort, turning their head where the sound is coming from. When they turn their head away, when they get bored, the sound stops. And then, we go on to the next test item.

And there is a video camera where we -- in another room the experimenter is observing how long the infant is attending to the sound. And the computer that the experiment operator is indicating the child -- the infant looks to, is timing that.

And it turns out that with infants at the age that we're testing, these difference in preferences actually can be revealing about the underlying representations they are building up. Which is to say that if they are registering

something that is familiar, and are interested in it, and looking longer that tells us that they actually picked up on that pattern that we're looking for, or that we were testing for in the original familiarization sounds that we played.

So that, basically, is the gist of that. And we're looking at several different areas in language acquisition. The one is word segmentation in the younger infants. Simply how and when someone is speaking in continuous speech, infants know when one word begins and another ends, how to segment the individual words out of a continuous speech segment.

And we also look for -- sorry, the older infants, how they start to learn what the ordering patterns are, you know, what the dependency is of one word or another. So, we start to look at sort of more in the area of grammar, syntax.

And that's sort of basically the kind of research that we're talking about.

And so, yeah, so we need to recruit parents. Yeah, sorry.

INTERIM CHAIR DELGADO: We were just coughing; you can keep going.

DR. MINTZ: Oh, okay. Okay. Yeah, so the request here is the way we carry out the research is we are reliant on families to be interested and bring their infants into

the lab.

The experiments, themselves, take about 15 minutes. But first, we describe it, we go over the consent form, and we also give the infant the opportunity to play in our lab, which is quite infant friendly, afterward. So, all told, it's 30 to 45 minutes for a session.

We provide parking at USC campus for the families that come in.

But we need to recruit them, and so what we do and what we've done before with CPHS approval, is we get from Department of Health Services the birth records. And the fields that we request are simply the date of birth and the parents, one of the parents' last names, and the address. So, we don't know the child's name ahead of time.

And then, we send out recruitment flyers. And the parents, if they're interested, can either respond with a business replay envelope. That was years ago. Now, we also provide QR codes, and they can go on our website.

And in doing so, they are simply saying that they're interested in hearing more about the studies. They provide their child's name; they confirm their child's birthdate. And then, they give whatever contact information they want to for the best way for us to get in touch with them. That could be telephone, that could be email.

And then, we enter them into our database, which

is encrypted and secured, and kept only on our lab computers. And then, when we are -- have a study going and we're looking to recruit infants, we go to the database and we see what infants are in the right age range, and then we contact the parents about a week or two before we actually are ready to have them participate, and we see if they're interested in coming.

And I'd be happy to answer any more questions if any more detail is needed.

COMMITTEE MEMBER HESS: No, that was great. Thank you. I just want to point out that you're also requesting death data, so that you are not contacting parents whose infant may be deceased.

DR. MINTZ: That's right.

COMMITTEE MEMBER HESS: Yeah.

DR. MINTZ: That's right. That's an important detail. Yeah, my lab does screen death data against all the birth data that we have, so that --

COMMITTEE MEMBER HESS: I, personally, did not have a lot of changes that I requested on this protocol. I asked that the language in the informed consent be simplified. It was reading at too high of a reading level for kind of my comfort. I asked that they aim to get it much lower, Dr. Mintz did. I asked for some clarification around HIPAA identifiers.

And that was my primary feedback. I will open it up to the board for any additional questions.

COMMITTEE MEMBER LUND: I just have a couple of questions and a clarification. So, I noticed that your name was the only name listed. Do you have other research staff, or will you be the only person handling the birth data and all of the associated activities with the birth data?

DR. MINTZ: No, my graduate students. And that was an oversight if I didn't include that. My graduate students, who are running the projects, will also be able to access this information.

COMMITTEE MEMBER LUND: Great. Will you please be sure that the names of anyone who will have access to the birth data be on the protocol.

DR. MINTZ: Yes.

COMMITTEE MEMBER LUND: Thank you. I noticed on the MacArthur short form you asked for some PII. And I'm wondering if it's necessary to have PII on that form, if you could just not -- anonymize it with a study ID. And that way, the personally identifying information would never be associated with those responses.

DR. MINTZ: Absolutely. And in fact, somewhere, it may not have been in every single section of the protocol, and there obviously are some inconsistence, we do actually ask them not to put the child's name, but to put

the coded identifier that we use to track the data. So, that must not have made it into every section where we talk about the NCBI, but that is certainly our practice. So, if you can point out where or I will -- I can go through and make sure that that's clear everywhere.

COMMITTEE MEMBER LUND: Yeah, well, I saw it was actually on the documents. It's labeled MacArthur short form up in the --

DR. MINTZ: Ah, yes.

COMMITTEE MEMBER LUND: -- corner it asks for names. So, if you could just change that so that it's the study ID and not PII, that would be great.

DR. MINTZ: Yeah, that is a copyrighted form, but we can -- and we certainly do instruct them to put the code. But we can certainly modify the form, yeah.

COMMITTEE MEMBER LUND: Great, thank you. Just a note, DHS hasn't been DHS for many years. If you could change the name of the agency to the California Department of Public Health.

INTERIM CHAIR DELGADO: I think it might have been referring to LADHS.

COMMITTEE MEMBER LUND: No, you can't get the data from them. You have to get the data from CDPH.

INTERIM CHAIR DELGADO: Okay. Sorry, I'll shut up.

COMMITTEE MEMBER LUND: No, no, no that's okay.

(Laughter)

COMMITTEE MEMBER LUND: Thank you so much. And if it's LA, it's LACDPH, so it's still -- so, right, yeah. So, if you could just make sure that I think in the protocol, and it might even be in your consent script that you saw DHS. So, if you could just change that, that would be great. Thank you.

DR. MINTZ: Absolutely, I will do that.

COMMITTEE MEMBER LUND: And you mention that you keep the video recordings indefinitely. What does that mean and why do you need to keep them indefinitely?

DR. MINTZ: Well, we -- okay, so the video recordings, when parents' consent, are used for offline coding checks to make sure that the data were originally coded correctly because it is -- it does involve, as I described, the human experimenter indicating when and where the infant is looking. And so, we typically keep those for after-the-fact validation. We sometimes also keep them if the parents consent to use, just to demonstrate our procedure to any -- you know, to train new experimenters in the process.

So, we just don't have a prescribed date when we delete those data, but we certainly could consider, you know, having, say, a five-year window or something where the

video data are kept.

COMMITTEE MEMBER LUND: That would actually -- a five-year window would be great, if that meets the needs of your study team. It also provides assurance for the research subjects that their images aren't floating out there indefinitely. So --

DR. MINTZ: Sure, absolutely.

COMMITTEE MEMBER LUND: Yeah. And you've already addressed the language level in the consent form, so I think those are all of the questions that I have. Thank you so much.

DR. MINTZ: Thank you.

COMMITTEE MEMBER VENTURA: I had a question regarding PII on the brochure. Is collecting the child's name and date of birth minimally necessary just for contact? Because the brochure says that this is information just so we can contact the parent and gauge interest in participating in research. I understand you want to get children in the right age range, but can that be asked not on the brochure, just like a contact form?

DR. MINTZ: We could do that. You know, is the concern that that information would then mailed in the reply mail?

COMMITTEE MEMBER VENTURA: Yeah, there's just -- you're asking for, you know, address, all the contact

information, phone and email, and then also the children's name and date of birth on a form that, yeah, once mailed in, you know, do you store it also in locked file cabinets or, you know, with other study. Just kind of there's a lot of information that's floating around potentially, and they're not yet in --

DR. MINTZ: We do, yeah. So, when the information comes in, you know, in the hardcopy form, which we do store them in locked file cabinets in our locked lab. And then, you know, we have -- and basically, when they age out we destroy that, we destroy that information.

We certainly could pare down what we asked for in that return via envelope. I should point out when they do -- if they do choose to scan the QR code or go online to register, they are providing all that information but that's going through our secure -- that's going through the secured website for our Qualtrics, which enters the information into our database.

So, but yeah, we could certainly pare down what we ask for when they're returning those forms.

COMMITTEE MEMBER HESS: Just to build on that, like how -- if you're providing a QR code, I would assume most parents of infants are relatively young and relatively tech savvy. Is there an actual need for a paper return form?

DR. MINTZ: Well, I considered that and then I thought that in terms of -- I mean, we want to be able to recruit a diverse as possible population, so there could be families that don't have easy access to a computer. I know that seems hard to believe in this day and age. But we thought it would just leave open the possibility that if someone did not want to do it that way, that we would give them the opportunity to mail something in. In point of fact, it very rarely happens.

COMMITTEE MEMBER HESS: Oh, we could just remove that, if you're comfortable with that. I mean if it really rarely happens, and it won't provide a barrier to recruiting --

DR. MINTZ: Yeah.

COMMITTEE MEMBER HESS: -- then just perhaps just not having mail in -- information mailed in at all would be preferable.

DR. MINTZ: Yeah, that would certainly reduce our costs on not having to send in all the extra business reply envelopes. So, yeah, I think that's something that we could do. I don't think it will really, in fact, affect our (indiscernible) --

COMMITTEE MEMBER HESS: Okay, that's all I have. Thank you.

COMMITTEE MEMBER JOHNSON: I had a question.

Under future use of data on your consent form you have, "We would like to make the data available for other research studies." And then, "These studies may be done by researchers at this institution or other institutions, including commercial entities."

Can you elaborate on that?

DR. MINTZ: Yeah.

COMMITTEE MEMBER JOHNSON: And is that something that everyone has to approve to be in your study?

DR. MINTZ: Well, so this is -- this is -- to be clear, this would be the completely anonymized data. So, it would just be a list of, you know, stimulus, a number and a code from what the infant was hearing and what the listening times were. There would be absolutely no identifying information.

And this is standard practice now for open science. So, typically, when a paper is published not only will the paper be published, but there's, you know, a publicly access repository that has the data, the anonymized data. And so, it's that data that we're talking about. Nothing about personal identifying information, nothing that could at all be linked back to the infant.

So, that is just something that we put in there because this is standard practice that we carry out. It would be -- it wouldn't really be possible to do this in a -

to do that open science in that way, if we couldn't use all the data that we collected.

Does that answer the question?

COMMITTEE MEMBER JOHNSON: Yeah, that helps clear things up. I'm just a little -- it just kind of seems like it is a condition for them to be a part of your study is that they also agree to having that contributed to this open science.

DR. MINTZ: Yes, that is --

COMMITTEE MEMBER JOHNSON: So, is it possible for them, for you to maybe collect additional consent, like you do with the recording of the data, that they permit that to go into an open science.

INTERIM CHAIR DELGADO: Like a box where they can opt out.

COMMITTEE MEMBER JOHNSON: Yeah.

INTERIM CHAIR DELGADO: Like a little box underneath that clause that just says I would like to opt out of this option.

DR. MINTZ: Okay. And so, that would be a situation where we collect their data, but we just can't use it for analysis. So, yeah, we could certainly add that choice so that they could participate, but then not have their data used.

Would it be okay, then, to specify in the wording

of that box that then their data would not be analyzed and used in the study?

COMMITTEE MEMBER JOHNSON: Yeah, I think that would need to kind of like know the full amount that they're agreeing to contribute.

DR. MINTZ: Right. Okay. Okay.

COMMITTEE MEMBER HESS: I mean would it --

DR. MINTZ: Yeah, we could --

COMMITTEE MEMBER HESS: Yeah, would it just be at that point, would you not just want to make them ineligible for the study, rather than have them go through the full process and not have their data used.

COMMITTEE MEMBER LUND: It seems burdensome.

COMMITTEE MEMBER HESS: Yeah, yeah.

COMMITTEE MEMBER JOHNSON: I thought it was future studies. It's different.

COMMITTEE MEMBER LUND: That's what I thought, too. So, maybe we need clarification on this. So, my --

DR. MINTZ: Oh, right. So, it's -- yeah, so this is a question of sort of meta-analyses. So, there option, you know, meta-analyses of infant data that are looked -- experiments that have looked at XYZ. And so, a researcher will go through all the studies and analyze the data to the degree that they're available.

And so, that is in the sense a new study using

this data.

COMMITTEE MEMBER LUND: Yeah. So, you would be able to use the data for your purposes, but this open science would allow others to tap into your data, as well. And I think that's what Dr. Johnson was --

DR. MINTZ: Right.

COMMITTEE MEMBER LUND: -- wanting to make sure that people understood and agreed to, is that they -- they're enrolling in your study and they're aware, and agreed to have you provide their data to open science for other researchers to use as well.

DR. MINTZ: Correct, right, yes. And that we can clarify.

COMMITTEE MEMBER LUND: Okay, that would be great. And can I just ask you for clarification of one more thing because I don't know if I saw it explicitly in your protocol. You're not retaining any of the birth data as part of your study data. You are only using the birth data that you receive from CDPH for recruitment purposes. Is that correct?

DR. MINTZ: That is correct.

COMMITTEE MEMBER LUND: Okay, great.

DR. MINTZ: And then, we will use the birth information to go along with our anonymized subject identifier, which will then -- the link between that and the

data we use for recruitment will only be kept on file as we're recruiting, and then we destroy that.

COMMITTEE MEMBER LUND: Okay, great. So, yeah, my concern was just to be very clear because over the past several years we've been working on ironing out some of the issues around using birth data in research studies. And I just wanted to make sure that no data fields from the birth data will be in your analysis file.

DR. MINTZ: That is absolutely correct.

COMMITTEE MEMBER LUND: Okay, great, thank you for that.

INTERIM CHAIR DELGADO: Actually, can you -- Dr. Mintz, aside from your study, Laura can you give like, especially for the new members, like a 60 second -- sorry, we're diverting from your project --

COMMITTEE MEMBER LUND: The history of birth data.

INTERIM CHAIR DELGADO: -- but it's a really good learning -- I think it's a really good learning opportunity for those of us who need the reminder about the importance of this one specific data piece because it has statutory requirements that other state data doesn't have.

COMMITTEE MEMBER LUND: Yeah. So, the Vital Records Data, both the birth and the death data, when researchers receive those data there are limitations on how they can use the data, and prohibitions on ever sharing

those data, even if they're de-identified. There seems to be a lot of belief in the research community that once you de-identify something it can be shared endlessly.

So, even if the data are de-identified, even if it's only one data field, a researcher may not share any Vital Records data with another researcher in a data file. The second researcher has to go back to CDPH and make their own request, through the VSAC process, for those data fields.

So, actually, for folks who are new to the Committee, it's taken us a lot of years to iron this out because the statutes are somewhat complex. And we have historical studies that have been approved for things that might not be approved under current statute. So, we occasionally have those things come up.

We've had at least one serious adverse event that involved the unauthorized release of multiple data files to multiple researchers, so that's part of the impetus to making sure that we adhere to these requirements.

We actually, now, have a really good statement for researchers on our website that describes what all of the rules are around using Vital Records data, and refers them to the VSAC process to get things from CDPH.

INTERIM CHAIR DELGADO: Awesome. So, for new reviewers, if you ever get a project with birth or death

data, Laura used to run the VSAC program and has a lot of experience with it. So, it's always so free to reach out if there's questions.

Okay, back to your project.

VICE CHAIR DICKEY: This is Dr. Dickey, can I --

INTERIM CHAIR DELGADO: Go ahead, Dr. Dickey.

VICE CHAIR DICKEY: I just wanted to make a comment that statutes for VSAC are quite distinct. We recently received a request from the Cancer Registry because they are being asked to contribute data to a national database, the federal government. And so, we asked our legal folks to look at that. And the response was that that data could be shared if it was de-identified.

Unlike with VSAC, there's no de-identification. With other data sources, there can be. But the Committee would have to approve the de-identification methods, would have to agree that the data could be de-identified.

INTERIM CHAIR DELGADO: Thank you for that background. I think it's super helpful. Because these kind of data requests are some of the most complicated ones.

Sorry, Dr. Mintz. We thank you for your ability, or your example so that we can learn a little bit more today.

Any -- Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Hi, Dr. Mintz. Just

as an aside, I always enjoy seeing this kind of project because behavioral research was so much a part of my professional background. So, I enjoy seeing something different than what often occurs in our protocols.

I had just two comments related to things that have already been discussed by Laura and Dr. Johnson. Really, about the language in your consent form. One regarding the -- how long you keep the personal information and video recordings, which currently says for at least five years.

I think what you last relayed to us that you're intending for that to be up to five years, with five years being a cutoff point as far as keeping the data.

So, if you could alter those words in the consent form, that would be good.

And similarly, we were just talking about the sharing, potential sharing of data with other researchers. I think your discussion of that needs to say at the beginning that this will occur without any further consent from the parents, unless they choose to destroy -- ask for their data to be destroyed.

You have, it currently just says, "Sharing will occur and your child's data will be destroyed upon your request." But I think you need to add that the sharing will occur without their further consent.

That's all.

DR. MINTZ: Yes. Thank you for pointing those two points out. That's something that we can easily change.

INTERIM CHAIR DELGADO: Awesome. Okay, Dr. Hess.

COMMITTEE MEMBER HESS: Ready for a motion.

INTERIM CHAIR DELGADO: Yup.

COMMITTEE MEMBER HESS: So, I move for deferred approval, one-year, minimum risk --

INTERIM CHAIR DELGADO: Perfect.

COMMITTEE MEMBER HESS: -- pending the following changes to the protocol. And I'm going to wait until you catch up.

First, include all additional project staff names in IRBManager.

Second is to remove PII from the MacArthur short form. So, please, instead of the child's name ask parents to return the participant ID or code, or whatever number you'll use to de-identify them.

We specified a five-year maximum window for deleting the videos, so please change that in the protocol.

We agreed no return mail on the brochures. It's still fine to mail out the brochures with QR codes, but no options for those brochures to be returned by mail.

And be clear about the fact that birth data will not be retained or used in any analytical files, and it's

for recruitment purposes only.

And clarification in the informed consent that data will be used for subsequent studies -- or, sorry, de-identified data will be used for subsequent studies without further consent on behalf of the participants.

MS. MCCARTHY: I got some of the things.

COMMITTEE MEMBER HESS: Okay, wait, wait, let me see where we are. Okay, so de-identified data will be used for subsequent studies without further consent.

And that's all I had. Were we asking that participants who do not consent to their data being shared as part of open data, or by subsequent research projects, to be deemed ineligible?

INTERIM CHAIR DELGADO: No, I think that the opt-out box is just for future studies within that portal thing.

COMMITTEE MEMBER HESS: Okay. That, I think I got everything.

INTERIM CHAIR DELGADO: Okay. Great motion.

COMMITTEE MEMBER HESS: Unless anyone can think of anything that I didn't include.

INTERIM CHAIR DELGADO: To be reviewed by a subcommittee.

COMMITTEE MEMBER HESS: To be reviewed by a subcommittee of I guess me.

INTERIM CHAIR DELGADO: Okay, sounds good. Do we

have a second?

COMMITTEE MEMBER LUND: I'll second.

INTERIM CHAIR DELGADO: Thank you, Laura. Okay.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio? Okay.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

INTERIM ADMINISTRATOR MARTINEZ: Dr. Azizian?

DR. RYKACZEWSKA: Dr. Azizian said "approved" in the chat.

MS. ATIFEH: Oh, okay, good. Approved.

DR. RYKACZEWSKA: He's experiencing audio problems.

MS. ATIFEH: Okay, thank you.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

COMMITTEE MEMBER HESS: Thank you, Dr. Mintz. We'll be in contact.

DR. MINTZ: Okay, thank you very much and thank you, everyone, for your time.

INTERIM CHAIR DELGADO: Thanks. Thank you, Dr. Hess, great review.

Okay, we are going to take a five-minute break. Dr. Burnson, I don't know if you're on the call, yet, but we've been going for a solid four and a half hours straight. If you give us just like --

DR. BURNSON: Absolutely. I'm here, please take your time.

INTERIM CHAIR DELGADO: Okay. Awesome.

DR. BURNSON: I'll be available.

INTERIM CHAIR DELGADO: Thank you. We will take a break. We'll be back at 12:05. So, eight minutes.

(Off the record at 11:57 a.m.)

(On the record at 12:05 p.m.)

INTERIM CHAIR DELGADO: Awesome. Okay, 12:05. We are so timely.

Thank you, Dr. Burnson for your patience with us.

Carrie, can I hand it to you?

COMMITTEE MEMBER KURTURAL: Yeah. Hi, Dr. Burnson. Carrie Kurtural, I reviewed your protocol here.

This is a project coming out of San Diego County.

When I looked at this project, I thought it was almost more quality assurance than research, but -- and Dr. Burnson's shaking her head. But I'll turn it to you, Dr. Burnson, to go ahead and give a summary. And you might want to explain how your engaging not with the direct, you know, consumers impacted in social services, but that engagement with the social workers. So, go ahead.

DR. BURNSON: Oh, thanks so much. Good afternoon, everyone. Glad you were able to take a little break. It sounds like a long morning.

I'm Cynthia Burnson. I'm a Senior Researcher at Evident Change. We're a nonprofit research and policy institution.

We have been working with San Diego's Child Welfare Services, recently renamed the Child and Family Wellbeing Department. They administer foster care and child protective services in San Diego County.

Before I go to the summer, I'd like to introduce my colleague, Maria Lopez Gurrola. Please introduce yourself.

MS. LOPEZ GURROLA: Hello everyone. My name is Maria Lopez Gurrola. I'm a local researcher working with Evident Change. Nice to meet everyone.

INTERIM CHAIR DELGADO: You are winning the background game today. I love it. It's amazing. You beat

out -- you beat Dr. Azizian. He was winning earlier, but now you have gotten the award for the day. Sorry, Dr. Burnson, please continue.

DR. BURNSON: Thank you so much. Great. So, I'll just give a brief summary before hearing feedback and questions from you all.

So, the purpose of this project, San Diego County, as part of their five-year system improvement plan, is looking at the use of a particular assessment that is used during a child's stay and out-of-home care when they are working towards reunification with their parent.

The assessment is called a Structured Decision-Making Reunification Assessment. And it is a tool that is used to assess whether or not the child -- whether it's time to consider reunification, to recommend that to the court, in a way that's safe, that shows progress on the case plan. And it's also used as a tool for family engagement.

What San Diego County is trying to address is a very low completion rate and a lack of understanding of what the barriers and facilitators are to using that assessment in their practice.

I'm glad you brought up the aspect of quality assurance, you know, is it more program assurance or human subjects research. First of all, it's the SDM reunification assessment is used in the rest of California, as well as

across the country. And so, this studying barriers and studying the implementation of this assessment is useful for more generalizable knowledge, in addition to seeking, you know, additional feedback on the protection of human subjects, which is why we submitted this protocol here. Especially since we are working with child welfare staff in a subject that could be perceived about their work performance. So, really wanting some additional feedback and an overview of this project.

COMMITTEE MEMBER KURTURAL: All right.

DR. BURNSON: So, looking at the rest of the summary, this study is going to involve protective social workers, or PSWs. These are child welfare staff who are managing cases of families where the child is in foster care and they're working towards unification.

The goal is to conduct interviews, focus groups, surveys and case reviews to get a deeper understanding of the implementation of the reunification assessment, as well as family engagement strategies that are taking place in San Diego County.

They will be those that were employed between 2024 and 2026, and really looking to sample a diverse set of roles in that process. They must be 18 years or older, comfortable in English or Spanish interviews, and have at least six months of employment with a minimum of five

assigned cases.

Our data collection methods include to informant interviews, focus groups, surveys and case reviews. We'll begin with initial focus groups with management staff to inform the interview guide. And these set of interviews done will be semi-structured and conducted over like video conferencing or Zoom.

And then, survey data, we will be collecting electronically through the Qualtrics platform.

Finally, we're looking to look at case reviews where we match, with the consent of the participants. We take a look at their case load and their experiences with the (indiscernible) -- as well the family engagement strategies, are looking at the child welfare administrative database, as well.

For potential risks. There are minimal risks. We are going to be relying on an encrypted survey data and multiple layers of de-identification, and risk minimization. We will be de-identifying this data after the interviews and focus groups and keeping any kind of linkages in a separate file.

We will use secure data practices, training study team members, and then we'll delete the recordings after transcription to further ensure confidentiality.

We're going to have participants electronically

signing informed consent. We'll be storing contact data and consent sheets securely. And then, we will ask participants to (indiscernible) for themselves during the interview and further ensure confidentiality.

We will retain data for up to five years. And then, just right after that we will analyze with qualitative analysis involving an iterative process of coding, identifying patterns, and developing an interpretive narrative. We'll look at the (indiscernible) code book using a modified, grounded (indiscernible) approach.

So, in summary, we're looking to understand the use of the reunification assessment, the SDM reunification assessment in San Diego County, and getting the information from the staff who are managing the cases of children in out-of-home care, who are going towards reunification to help identify what the barriers are to using that tool, as well as strategies for family reunification.

And I look forward to getting feedback with questions and comments.

COMMITTEE MEMBER KURTURAL: Well, thank you. I want to say that Dr. Burnson did update her protocol yesterday to address, just kind in a reasonable employment. It wasn't entirely clear under the recruiting materials and informed consent whether the employees and social workers that would be participating in these focus groups, you know,

what does their participation mean? Like, does it mean it's going to be in working hours? Is it going to be outside working hours, overtime or whatnot. And I want to thank you for updating that.

There was one, and I thought it was more clear, but there was one question I had regarding de-identification. So, there's going to be a number of focus groups an interviews talking about, I'm assuming, situations that they're dealing with in the reunification process. I'm imagining, you know, names of family and whatnot are not going to be mentioned. But, you know, specific fact patterns are.

So, could you get into a little bit how -- what I was unclear was in the protocol was how you're going to go -- are you going to publish information about those specific fact patterns or exactly what the plan was. Or, were you just planning on masking using aggregate data, masking at 11? It just seems a little unclear.

DR. BURNSON: Right. Can I just ask to clarify, you're talking about information about families?

COMMITTEE MEMBER KURTURAL: Right.

DR. BURNSON: Right, certainly. Right, so the expectation during the focus group, like you mentioned, would be to be talking about strategies and engagement at an aggregate level and pattern, and not about specific

families. So, we can reemphasize that or ensure that that's reflected in the focus group, in interview introduction, that we would expect folks not to be coming up -- not to be bringing up identifiable information about families that they're speaking about.

And we would be looking at an aggregate thematic analysis, particularly because the focus of the study is much more about staff implementation and their reasons for using or not using a particular assessment. So, we're hoping to really focus primarily on that. But agree that we would not be publishing specific family circumstances.

COMMITTEE MEMBER KURTURAL: Okay, that was the only comment that I had because you made updates to the rest. So, opening it up to the group.

COMMITTEE MEMBER LUND: I have a question.

INTERIM CHAIR DELGADO: Go ahead, Laura.

COMMITTEE MEMBER LUND: So, you're studying the PSWs. One of the data sources that you're asking for is information about their cases. And it looked to me from the information provided that you're asking for a lot of identifiable and sensitive information about their cases.

My question is does the PSW, from a human subjects protection perspective does the PSW have the right to consent to have information shared about these other people as part of the study?

I was actually really concerned because there's a lot of information on these cases. I mean I think it's like a couple hundred data fields. It's quite extensive. And I would -- I would question whether or not these people whose data are being used are even aware that they're part of a research study. You know, they're in a social worker's case file. Do they have -- did they have any reasonable expectation at the time that that information was collected from them that it would be used for research?

INTERIM CHAIR DELGADO: Did the protocol include, I didn't review it as closely as I should have, like basically -- it sounds like an administrative. Like there's the human subjects portion, but there's also an administrative data request for this.

COMMITTEE MEMBER KURTURAL: That is what I thought.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER KURTURAL: That they're seeking some data elements from social services. Social services is not a covered entity. If social services was a covered entity, I would probably edge towards making that comment that, hey, you need to get a waiver in this circumstance.

But given that they're not covered and, you know, they are -- they approved it, they're going to be entering it as a UA, I think from my standpoint was okay with that.

COMMITTEE MEMBER LUND: I would defer to your expertise.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER LUND: Because this isn't my area of expertise.

COMMITTEE MEMBER KURTURAL: Yeah, sure.

COMMITTEE MEMBER LUND: But it was a question that came up for me.

COMMITTEE MEMBER KURTURAL: If it was data, I think pulled from Health Care Services, I would take a pause on that and I feel like go back and ask for a waiver. But to, the kind of edge is, one they're not -- it's not direct information. So, the direct information they're getting is from the file, so to speak. And so, I do believe that there's an exception in this instance because they're not directly doing the human subjects research on the consumer, in this case.

COMMITTEE MEMBER LUND: Okay. Thank you for clarifying that.

I also, I didn't see the focus group questions or the interview questions, and maybe I missed it. Are they in there?

COMMITTEE MEMBER HESS: Yeah, the domains were in there. Some of the sample questions were in there, on the survey.

COMMITTEE MEMBER LUND: But not the actual instruments?

COMMITTEE MEMBER HESS: No.

COMMITTEE MEMBER KURTURAL: I saw that. I mean it was quite -- the protocol was quite robust. But I think, Dr. Burnson, that you want some flexibility, too, in the focus groups. Right?

DR. BURNSON: Right, correct. So, we have some -- we have an appendix of focus group questions, in addition to domains. I'm sorry, I'm having a little bit of trouble hearing the Sacramento group, I'm sorry.

COMMITTEE MEMBER KURTURAL: Sorry about that.

INTERIM CHAIR DELGADO: So, sometimes, Dr. Burnson, in those where we hear you want some flexibility, but it might be helpful if we get kind of a semi-structured flow of the questions that you ask. It doesn't have to be verbatim, but it's in that -- if you could provide us that as like just some supplement documentation so we can say, here's the basic focus group questions that will be asked, but also acknowledging that there could be some deviation based on group responses or potential follow up.

COMMITTEE MEMBER LUND: Or even the universe of possible questions, so that we would know the scope. And then, if they choose not to ask all of those questions then, you know, they can leave some out. You know, they can

always leave things out. But that way we'll -- it's hard for me to be able to approve a data collection when I haven't seen instruments for the data collections.

So, I haven't seen the focus group questions, and even though domains were provided, that's different than seeing the actual survey instrument that's going to be administered to people.

So, that's a real problem for me today because we haven't seen this.

DR. BURNSON: So, I just want to make sure, you know, to make sure that what I'm seeing on my side is reflective of what you all have in front of you. In Appendix D we have a focus group field guide, along with the domains. And then, it goes into research questions and then specific questions.

So, for example, you know, the first question is, "How would you describe the process of parent engagement for family reunification cases?" And then, there's a set of probes underneath them.

Is that something that you all are seeing in your version of the protocol? I just want to make sure there's not a mismatch there.

COMMITTEE MEMBER LUND: Is that for the focus group?

DR. BURNSON: Correct.

COMMITTEE MEMBER LUND: And what about for the interviews?

COMMITTEE MEMBER HESS: No, no, it's surveys.

COMMITTEE MEMBER LUND: Oh, yeah.

COMMITTEE MEMBER HESS: I think we would need the actual interview questions as they will be sort of operationalized for the interview field guide. And then, in Appendix D for the -- you have survey example questions.

DR. BURNSON: Uh-hum.

COMMITTEE MEMBER HESS: We need to see the actual final survey that will be administered.

DR. BURNSON: Sure. Sure. And given kind of the iterative or, you know, research design, given that we're that we're kind of starting with focus groups to refine those interview questions. Is that something that given that you have the focus group questions could be submitted as an amendment, or how would that work?

COMMITTEE MEMBER HESS: Yes.

COMMITTEE MEMBER LUND: Yeah, if it came back to full Committee.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER LUND: I would stipulate that it comes back to full Committee.

COMMITTEE MEMBER HESS: As an amendment.

COMMITTEE MEMBER LUND: As an amendment, yes.

COMMITTEE MEMBER HESS: Yeah, you can -- once you've -- I mean that's pretty common is to develop your survey after doing focus groups. So, yeah, but it would need be (indiscernible) --

COMMITTEE MEMBER LUND: Yeah. And I think that the protocol is in shape to be able to do that, to approve it for the focus group and then submit an amendment for the subsequent interviews, yeah.

COMMITTEE MEMBER HESS: Okay.

COMMITTEE MEMBER LUND: In my opinion, so, and those are my only comments.

DR. BURNSON: Can I just ensure I heard you correctly, just because it's spotty. I heard that it would be submitted as an amendment to the full Committee. Just a final question, is that correct?

COMMITTEE MEMBER KURTURAL: Right, after the -- the idea is that you go and start the research project, do the focus groups and then at that point, once you've sort of done your fact gathering and you're ready to establish a finalized survey you come back for an amendment. Provide the survey and then we'll do a full board review.

INTERIM CHAIR DELGADO: Yeah, so we would do like a -- not that I want to steal your motion, but like a deferred approval right now to initiate and start, and then an amendment later when she nails things down.

COMMITTEE MEMBER KURTURAL: Yeah, I think that's fair.

DR. BURNSON: Excellent, thank you. Just wanted to make sure I could hear you properly.

COMMITTEE MEMBER HESS: That would be an amendment for both the field interview and the survey, which are two separate data collections you described.

DR. BURNSON: Right.

COMMITTEE MEMBER HESS: Okay.

DR. BURNSON: Yeah, got it.

INTERIM CHAIR DELGADO: Okay.

VICE CHAIR DICKEY: This is Dr. Dickey. I hate to butt in here, but want to ask do we really need it to come back to the full Committee? This often happens with projects, and we would be -- have an awful lot of these if we didn't have a subcommittee doing it.

INTERIM CHAIR DELGADO: Why don't we defer to Carrie on that, as the primary reviewer. Do you -- knowing what you know about the project, do you feel like it could be a subcommittee of you and someone else, or do you think that like the sensitivity of the questions, the scope of the questions should come back to full Committee?

COMMITTEE MEMBER KURTURAL: I mean I'd welcome a subcommittee, actually, now that I'm thinking about it. Because it would be different if this was with the actual

families. But do you feel differently that you want to --

COMMITTEE MEMBER LUND: So, for me, to approve the project today I'm very comfortable for the focus group portion. But I don't feel that I could approve a project with whole instruments sight unseen that we don't know anything about. I mean if it were just modifications to questionnaires that had already been proposed, that kind of thing. But we haven't even -- these are hypothetical things that don't even exist yet, so I have a hard time approving that as part of the motion.

COMMITTEE MEMBER HESS: Okay.

COMMITTEE MEMBER LUND: Even with a subcommittee, I'm sure the subcommittee is great, but I do think that that's something that the whole board should be able to see.

COMMITTEE MEMBER LUND: Okay. I think given the comments that, you know, are on the side of caution and kind of segregate and have those come back to the full board.

INTERIM CHAIR DELGADO: Okay, great. Thank you for your comment, though, Dr. Dickey. It's good for us to hash you those details and the nuances.

Other questions? Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Well, really a question for Carrie, since you've been so deeply involved in the project. I just was hoping you could confirm for us that from what you've seen you would consider the data

protections to be adequate, not only for the participants, but also for the families whose information is being used. From both angles it looks appropriate to you.

COMMITTEE MEMBER KURTURAL: Yeah. I mean, I think that they're going to be uploading the information to a secured system that's HIPAA compliant, which is at a higher level, then given -- you know, we're talking about a not-a-covered-entity, right. We're talking about social services. Which to me is still important, that it's great that, you know, they get uploaded into HIPAA compliance. And then after five years, to the extent that videos on interviews are being done, or whatnot, and surveys, those are going to be deleted after five years, in accordance to the study.

So, I didn't have a problem.

COMMITTEE MEMBER SCHAEUBLE: Okay.

COMMITTEE MEMBER KURTURAL: You know, with the protocol.

COMMITTEE MEMBER SCHAEUBLE: That's fine, I just wanted to ask.

INTERIM CHAIR DELGADO: Good question.

Any other questions or comments before we move forward to motion -- or move to a motion?

COMMITTEE MEMBER LUND: All right.

COMMITTEE MEMBER AZIZIAN: Yeah, may I ask you two questions. I heard that you mentioned that participation, I

mean this may have been -- I may not have heard this correctly, that it may have work performance implication on participants. And I was just wondering how could it have implication on the work performance?

DR. BURNSON: No, that's a great question. It wouldn't. And we would -- I think we were just concerned about the perception and making sure that we really emphasized that in any consent or question answering that we wouldn't be sharing, you know, participation, or information, or anything back to the agency. Just to let people know that.

So, thank you for asking.

COMMITTEE MEMBER AZIZIAN: Yeah. Understood. Thanks for that.

And then, you know, my experiences have been more recently with any type of qualitative thematic analysis there's very much reliance on computerized programs, various commercialized programs that they do this analysis. And some of those programs retain the data. How are you planning to do the thematic analysis in relation to that?

DR. BURNSON: Uh-hum. Right, so we plan to do the -- we're now planning on uploading it to a service like that. We're going to go old school and do it in-house, if that answers your question.

COMMITTEE MEMBER AZIZIAN: A laborious process,

but interesting. Thank you very much for your comments.

DR. BURNSON: Yeah, appreciate that question.

INTERIM CHAIR DELGADO: Awesome. Okay, Carrie, do you want to make the motion?

COMMITTEE MEMBER KURTURAL: Yes. So, minimal risk, one-year, deferred approval on condition that the protocol specify that in the brochure, and informed consent, and interview that social workers, or PSWs, are not to disclose any identifiable information on the families.

INTERIM CHAIR DELGADO: Sorry, we're just having a technical issue. We just need to pause for one second.

MS. MCCARTHY: I'm sorry. My ringer's off. That was my alarm.

INTERIM CHAIR DELGADO: No worries, don't apologize.

COMMITTEE MEMBER HESS: All right, I am ready. And that researcher, once the focus groups is done, that the researcher will come back to amend the protocol by including the final interview and survey questions to the full board for approval.

Did I miss anything?

COMMITTEE MEMBER HESS: Do we want to say that this approval is for -- just for the focus groups, only?

VICE CHAIR DICKEY: Can I ask that -- excuse me. Can I ask a question?

COMMITTEE MEMBER HESS: Yes.

VICE CHAIR DICKEY: This is more of an administrative question for the staff. When they see this come in as an amendment, how are they going to know that it needs to go to the full board and not to the primary reviewer?

COMMITTEE MEMBER LUND: We'll have to remember.

INTERIM ADMINISTRATOR MARTINEZ: The primary reviewer will have to remember.

MS. ATIFEH: If it involves new contact, we ask the primary reviewer at first to see what the primary reviewers think. You know, if they say it should be discussed in the full board review, we assign it to the full board review. But if they say no, I don't have any concern then --

INTERIM CHAIR DELGADO: So, Dr. Dickey, we're basically relying on Carrie's memory. When the amendment comes in, it will end up getting asked -- the admin staff will ask Carrie and so she'll have to make sure we direct it down the right path.

COMMITTEE MEMBER KURTURAL: And Maybe I --

VICE CHAIR DICKEY: I just wanted to make --

INTERIM CHAIR DELGADO: No, it's okay.

VICE CHAIR DICKEY: I just wanted to make -- you know, make sure that we know that we're creating another

process here that we've never done in the past, which is approving a project and then specifying that an amendment has to come back to the full Committee. We've never done that before, as far as I know. But it's okay. But it's going to be a workflow thing that Carrie's going to have to police.

COMMITTEE MEMBER HESS: I would ask that Ms. Burnson please add to her amendment a reminder --

(Laughter)

COMMITTEE MEMBER KURTURAL: -- that it's to come to the full board.

DR. BURNSON: Okay.

COMMITTEE MEMBER KURTURAL: Thanks.

DR. BURNSON: You got it.

COMMITTEE MEMBER KURTURAL: Thank you.

MR. ZADROZNA: Carrie, you can do like a phase one and phase two needs to come back to the full board.

COMMITTEE MEMBER KURTURAL: Yeah.

INTERIM CHAIR DELGADO: Okay. So, we have a motion. Do we have a second?

COMMITTEE MEMBER HESS: I'll second.

INTERIM CHAIR DELGADO: Thank you, Dr. Hess. We have a second.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Well, thank you, Dr. Burnson. Thank you to you and your team. And you'll be getting a letter in the next few weeks. But if you have any problems, questions, or concerns please reach out to your primary reviewer. Thanks for your time.

DR. BURNSON: Yeah, thank you so much for your time. Have a good rest of your day. Take care.

INTERIM CHAIR DELGADO: Okay, bye.

DR. BURNSON: Bye.

INTERIM CHAIR DELGADO: Okay. Speaking of amendments coming to full board. Dr. Schaeuble, we're going to move to Project 2023-108. And I will hand it over to you.

COMMITTEE MEMBER SCHAEUBLE: Do we have Dr. Zickafoose on the --

INTERIM CHAIR DELGADO: Is Dr. Zickafoose on?

MS. ATIFEH: Yes.

DR. ZICKAFOOSE: Yes, I'm on. And my colleagues, I think, are logging on just now.

COMMITTEE MEMBER SCHAEUBLE: Good.

INTERIM CHAIR DELGADO: Great.

COMMITTEE MEMBER SCHAEUBLE: Good afternoon. And could you introduce your colleagues as they show up here.

DR. ZICKAFOOSE: Okay, great. I'll go ahead and introduce myself. And, yeah, I see the three of them joining.

So, I'm Joe Zickafoose with Mathematica. I'm the Principal Investigator for this amendment to our existing protocol for the Evaluation of the California Children and Youth Behavioral Health Initiative.

And I'll hand it off to my colleagues, who are members of the team for this survey. Holly, first.

MS. MATULEWICZ: Hi, my name is Holly Matulewicz. I'm a principal researcher at Mathematica and I'm going to

be supporting the direction of the survey, the program, and the testing, and the implementation with its hosts. Okay.

DR. ZICKAFOOSE: And Elisa.

MS. GONZALEZ: Hello everyone. My name is Elisa Gonzalez, and I am a researcher at Mathematica, also supporting the survey work.

DR. ZICKAFOOSE: And Annu.

MS. VAN BODEGOM: Hi, good morning. My name's Annu Van Bodegom. I'm a project manager at Mathematic and I'm supporting in a similar capacity for the survey. Thank you.

COMMITTEE MEMBER SCHAEUBLE: So, this is a project that involves an additional kind of human subjects contact that was not in the project previously approved by the Committee, which is why it's coming to the full board for review here.

And Dr. Zickafoose responded to a number of comments that I made earlier on the protocol, and I think you were able to see those comments and changes that he made. And having looked at those, I added some further thoughts based on reading those changes and responses.

And did you have a chance to see all of those? I tried to email you, so that you would be able to look at them before the meeting. Did you get my email message and have an opportunity to look at the comments that I added the

middle of this week?

DR. ZICKAFOOSE: Yes. Yes, we were able to see them, and we were also able to reach out to our partner organization, Ipsos, who's helping us field the survey, and have answers to almost all of them.

COMMITTEE MEMBER SCHAEUBLE: Good. Good. That should help us out here a lot.

So, if we could begin by asking you to summarize what's in this particular amendment, for the Committee, so that people understand that. And then, after the summary, if we could take a look, I think primarily, at two major areas that I wanted to discuss with you in the way of follow up. Some of the comments that I sent were smaller things that probably don't have to be discussed here.

So, if you could begin with a summary first, for people.

DR. ZICKAFOOSE: Sure, thanks. So, this amendment is to include a primary survey as part of the evaluation of the CYBHI. The objective of the survey is kind of twofold. The original proposal we included analysis of secondary data sources and this -- that address many of the objectives of the initiative. And this survey is to help provide both more timely data and also fill in some of the gaps of those secondary data related to the objectives of the CYBHI, especially around for sections of mental health stigma,

knowledge and awareness about behavioral health services and supports for children and youth, and to a lesser degree some experiences around accessing care and -- I'm blanking on the fourth, I don't have it right in front of me. But some other experiences related to behavioral health for children and youth.

The participants in the survey are three different groups. The first group are caregivers of youth ages 12 to 17 years old. The second group are youth, themselves, ages 12 to 17. And then, the third group are young adults, 18- to 25-year-olds.

As I mentioned earlier, we're partnering with Ipsos, who is a company that specializes in online data collection. And we're particularly partnering with them because they have an survey panel that includes many members in California, and then they have additional methods to increase sample sizes using some opt-in methods.

For the caregiver population, it will be a mix of about 300 folks drawn from their existing panel within California, and then about 700 additional opt-in participants that they'll be recruiting through partner organizations that have existing panels, and some other approaches to recruiting for online survey respondents.

For the youth, themselves, that will be limited just to youth who live in the households of caregivers who

participate in the knowledge -- what they call their knowledge panel, the existing panel. That will not involve any of the opt-in participants.

And then, for the young adults, it will be similar to the caregivers where it will be a group of folks that are in their existing panel, and then additional folks that are drawn in from opt-in participants.

The primary risks related to this, as we see them, the first one would be inadvertent disclosure of potentially identifiable information. Several different approaches are taken to minimize that risk. First of all, obviously, we have asked for consent for participation.

For the existing panel members, Ipsos does have their contact information that they keep to be able to maintain their participation in the panel. But they keep that information completely separate from the survey data that will be collected, and they will only deliver the survey data, that's anonymized, to us.

So that for things like name, and address, and mail address none of that information will ever reach us. And then, even then the survey data that we receive will also be kept in secure online storage within our systems.

For their opt-in participants, it's a similar -- well, the system is the same, but it's different -- the information exists in different places. But, again, the

contact information will be kept separate from the data, from the survey itself.

Additionally, the specific risks related to the youth, we are going to be using a dyadic approach where the youth that are involved are in the households of the caregiver respondents.

So, the way the survey is set up is the caregiver will respond if they consent, and then if they consent for their child to participate, they then hand whatever device they're using to respond to the survey to the child. The child will need to assent to participate, and then fill out of the survey on their own.

You know, our language encourages them to fill out the survey on their own, but we can't guarantee that the caregiver won't oversee the child filling out the survey or even, you know, review the responses when they respond.

So, for that reason, we kept the content for the youth portion of the survey with very little specific information about their, for example, behavioral health needs, anything that would be potentially sensitive or that they may not want to disclose to their caregiver.

And then, the additional risks, we do have some questions related to specifically about behavioral health, so there is some small risk about psychological discomforts. We include that in the consent and assent language, and then

we also include contact information for identifying behavioral health supports that the caregiver or youth respondents feel a need for that.

And I think I will stop there and see what questions you all have.

COMMITTEE MEMBER SCHAEUBLE: Just for a bit of completeness in your summary, could you say a little bit more for the Committee about the nature of the questions in the survey, so that people understand that.

DR. ZICKAFOOSE: Sure. Just give me one second. I had it pulled up right in front of me. So, the main domains in the survey are -- the majority relations relate to stigmatizing attitudes towards behavioral health, or behavioral health or mental health. Primarily their own stigmatizing attitudes, but a few questions related to whether or not they've experienced that.

The next most common questions relate to knowledge about available behavioral health services and supports.

There are also a few questions about skills to address behavioral health challenges. And then, experience, direct experience accessing behavioral health services particularly around challenges or delays when there have been identified needs that they've attempted to access services.

COMMITTEE MEMBER SCHAEUBLE: Okay, thanks. So,

one area I'd like to go in more thoroughly with you, then, is the recruitment of participants, which I'm just still a bit unclear about. We have an existing panel, the knowledge panel. We also have multiple other sources of people who can choose to participate in this study.

I don't totally understand how the people are selected for initial contact, what is shown to them as a recruitment or advertisement for participation in the study, and/or whether some people instead see some kind of list of available studies, with the descriptions of them instead of being specifically contacted for participation.

I guess those are a few of the questions that I'm asking you to explain more for my clarification and for the Committee to understand, also.

DR. ZICKAFOOSE: Great. And I apologize, the audio is a little bit challenging to hear. But just to reiterate, to make sure I understood the question is clarification around where the recruitment for the different -- for the different sources of respondents will be.

INTERIM CHAIR DELGADO: Yes. And like how do they know they're opting into this study as opposed to a different one. Like where in the process does the informed consent happen? Is it -- you know, if you could just walk us through how you recruit people.

DR. ZICKAFOOSE: Sure. Sure. Okay. So, for the

existing panel, what they refer to as their knowledge panel, people receive an email notification that a survey is available for them. So, they, folks that participate in this panel are eligible for all kinds of different surveys. And they receive a notification specific to this survey that there is a survey that they're eligible, potentially eligible for, and that directs them into the survey platform that Ipsos maintains for them.

At the point where they access the platform, there's initial question about their age and their location, where they live, to see whether they're eligible. And after that point they're provided the consent, the consent language. And that's true for both the caregivers' group and the young adult group.

For the youth group, they would not receive any direct contact until their caregiver has consented to participate and completed their own survey.

COMMITTEE MEMBER SCHAEUBLE: Can I --

DR. ZICKAFOOSE: They're also, they're asked -- oh, sure.

COMMITTEE MEMBER SCHAEUBLE: Could I ask, before you go ahead here, people who are contacted, are they known to be caregivers?

DR. ZICKAFOOSE: Yes. So, at the point of enrollment in the panel, Ipsos collects demographic

information about them, including their ages, and whether there are youth that live in the household. And that's updated on an annual basis. So, they're primarily reaching out to folks -- or, will be reaching out to folks that the information that they have at that time suggests that they're eligible for the survey.

INTERIM CHAIR DELGADO: So, my guess, Dr. Schaeuble, is that Ipsos a company that their main shtick is recruiting people for probably nationwide.

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: And so, you know, a research team can opt in, probably pay a lot of money, to say like give me a filter, a list of like California parents who have children under the age of 12. And then, that is the recruitment source.

Those people then get an email saying, hey, you've qualified for this survey, here's the informed consent, would you like to participate.

COMMITTEE MEMBER SCHAEUBLE: Okay, so a person receiving this email message, then, will have indicated to Ipsos at some point that there are one or more children in their household. That's one of the pieces of information and what would be used to choose for where these messages go. Do I have that right?

INTERIM CHAIR DELGADO: Is that right, Dr.

Zickafoose?

DR. ZICKAFOOSE: Yes. If I caught everything, that sounded correct in terms of description.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, go ahead, please. I didn't mean to interrupt you entirely there, but I wanted to clarify that.

DR. ZICKAFOOSE: And I'm sorry, would you like me to continue to talking about the opt-in participants?

COMMITTEE MEMBER SCHAEUBLE: Yes. Yes, please. Sorry, if you're having difficulty hearing me.

DR. ZICKAFOOSE: Okay, all right. No, yeah, that's the wonders of our online world.

So, for the opt-in participants the process is very similar, but Ipsos partners with -- has two different approaches. They partner with some other organizations that have similar panels, so they're brought in, in the same way, where there -- there's knowledge based on joining at a previous time, that they're of a certain age, and they have youth in their household.

But they also do some advertising that would indicate that a survey like this is available, if people would choose to join.

In terms of the notification, it's the same general notification that there's a survey available that they might be eligible for, and then they would enter the

survey consent at the same point in the survey system.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, one thing we did not see in the protocol, and should see, is the recruitment message that would be sent, whether it goes to the existing panel or to these other sources for the opt-in participants.

DR. ZICKAFOOSE: Yeah. And we've followed up with Ipsos and we're going to get a copy of that specific language that we can include in the -- we can put into the amendment system, as soon as we receive it from them.

COMMITTEE MEMBER SCHAEUBLE: Good. Thank you. People are contacted, are they sent a message just once, more than one time? If they ignore the message or decline to participate, is there any attempt to try to change their mind? Can you describe those aspects of the situation?

DR. ZICKAFOOSE: Yeah. So, there's a primary recruitment message and then two follow-up messages that I believe are spaced by a week apart, but we'll double check on the timing of that.

COMMITTEE MEMBER SCHAEUBLE: Okay, so potentially a total of three messages, but not anything more than that.

INTERIM CHAIR DELGADO: If you could just clarify in the protocol they won't receive more than three messages total, that would be awesome.

DR. ZICKAFOOSE: Okay.

INTERIM CHAIR DELGADO: I remember one time we had a project where they -- 17 phone calls.

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: And that's only when we stopped contact you, which starts to border on harassment.

COMMITTEE MEMBER SCHAEUBLE: Right.

INTERIM CHAIR DELGADO: Thank you.

DR. ZICKAFOOSE: Yes, we will definitely clarify that, that we're well short of that.

COMMITTEE MEMBER SCHAEUBLE: Okay. I think those were the major questions regarding the recruitment aspects of the study.

With regard to privacy considerations, there were various questions that I had asked in that regard. And you've seen those, so maybe you could -- maybe you could go ahead and answer what you have found out in the meantime, having thought about some of those questions that I sent you earlier this week.

DR. ZICKAFOOSE: Sure. And those are -- those are the ones that we have the most outstanding with Ipsos. So, and just to double check here for, I think for the questions for how Ipsos deals with -- particularly with privacy settings that folks might be using on their devices --

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. ZICKAFOOSE: -- or tools that they're using to

respond. So, we've asked them to clarify particularly around global privacy settings. So, that's an area that members of our team are not experts in, and that we've asked Ipsos' teams to clarify exactly whether, you know, folks are automatically ineligible if they're using those settings, or if they receive a notification about how those settings affect their ability to participate.

COMMITTEE MEMBER SCHAEUBLE: And that in process or do you have any answers on that so far?

DR. ZICKAFOOSE: Yeah, that's in process. Our primary contact with Ipsos had to take that to their privacy expertise team. They didn't have immediate responses to us beyond what more general information is in their general privacy policy.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, for the benefit of the Committee here, let me -- let me say a few things in this regard. As it stands now, people are told that there is a link to privacy information on the Ipsos website that they can go to, but there's not very much information about privacy protections within the materials that the researchers are directly making available to participants.

And part of what I was requesting was that the most essential features with regard to privacy be covered in the materials that are directly shown to participants in the

study. In particular,

DR. ZICKAFOOSE: And I apologize, I think we completely lost the audio.

COMMITTEE MEMBER SCHAEUBLE: So, I'll start again. Can you hear me now, or are you not able to hear me?

DR. ZICKAFOOSE: I can hear you now, yes.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I was saying to the Committee that currently your information provides a link to the Ipsos website about their privacy policy but doesn't say as much as it could within the materials that you show to participants.

And I was trying, with a variety of questions, to have that improved in the materials that you make available.

Now, I'm not sure at this point what you're going to find out when you get some responses from Ipsos on the questions that were asked. I mean, ideally, I would hope you could say something like -- and this would be in your consent information to people. Ideally I would hope you could say something like, it's not necessary to change any privacy settings you may have on your computer or smart phone. It's not necessary to accept any additional cookies, if you are asked.

And if it turns out that Ipsos actually does process and appropriately respond to global privacy control settings, maybe it's not necessary to say anything about

that if you have the assurance that they are, indeed, handling that request from participants.

But if you find out that Ipsos is not observing the global privacy control option, then I would think you would need to tell participants specifically that Ipsos is not doing that.

And I'm saying that because this -- this has become what people are trying to use as a fairly simple way of making some privacy choices without having to dig through many individual settings that may exist on a device. And companies and organizations are responding to this in different ways.

Sometimes I have seen a pop-up on a website that says, we acknowledge we've seen your global privacy control choice and are honoring it. Sometimes there's no pop-up, but if you look at the privacy policy of the company or organization it does say, we do process and honor your choice with a global privacy control.

On the other hand, we've had at least one instance of a protocol within the past half year, or so, where the company said despite California's Privacy Act, we don't think we are required to follow that particular provision, and we do not choose to observe the global privacy control.

And what I'm obviously concerned about is I hope that situation doesn't exist for your study, but if it does

it certainly is something that participants need to know about.

So, that's the reason for raising those questions. And I realize, now, you have to do some further investigation with your vendor to see what you're actually dealing with there.

DR. ZICKAFOOSE: Yeah, and I appreciate the specific examples as we did pass along your questions, and I think following up with them on those -- that specific framing will be helpful. And what we identify what exactly respondents are going to see in relation to their privacy settings, we'll craft our response and whether we need to add additional language or not.

COMMITTEE MEMBER SCHAEUBLE: So, that's a follow up that we will have to deal with when you can send the appropriate information back for review here.

Did you have any questions about other comments that I made the middle of this week, that I thought we did not need to discuss with the full Committee otherwise?

DR. ZICKAFOOSE: Let me just look quickly. I don't believe so. I think the other comments were very straight forward. And just to note, in terms of adding in the consent language to the instrument itself, we had submitted the consent and assent language in separate documents, so that they would be easier to edit as needed.

COMMITTEE MEMBER SCHAEUBLE: Right.

DR. ZICKAFOOSE: Once you are comfortable with that language, we absolutely -- we will paste that back into the main survey instruments --

COMMITTEE MEMBER SCHAEUBLE: Of course.

DR. ZICKAFOOSE: -- and then we can upload that final instrument when it's available.

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. ZICKAFOOSE: And then, the next step on that, as well, is we do have the Spanish language version of all that -- of all that consent and assent language, and the instrument itself, which we will also provide once the updates are all made.

COMMITTEE MEMBER SCHAEUBLE: That's fine. That can be a later amendment to send that in for review.

So, I think I'm ready to open it up for Committee questions at this point.

INTERIM CHAIR DELGADO: Thank you, Dr. Schaeuble. Anyone on Zoom or in the room have follow-up questions? Yes, go for it, Catherine.

COMMITTEE MEMBER HESS: I do have a question. And this pertains mostly to the way panels work. I do have familiarity with panel data. But it's always a little bit more sensitive when you're recruiting minors via their parents for panel data.

So, I understand that Ipsos has an incentive sort of structure that's based on points. I'm a little uncomfortable with parents receiving incentive on behalf of their children. It can potentially be coercive. There's no benefit to the child for doing this.

I do understand, also, the difficulty in working with a panel like Ipsos or knowledge panel, because these incentives are kind of automated. But I'm a little uncomfortable with that.

And I also would like to know more about how Ipsos verifies that it is in fact the child taking the survey and not a parent answering on behalf of the child to receive an incentive.

COMMITTEE MEMBER SCHAEUBLE: Good question.

COMMITTEE MEMBER HESS: Yeah. I don't know if you can answer either of those things or if you think that you need to --

DR. ZICKAFOOSE: Yeah, yeah, and that's absolutely something that we wrestle with a lot in considering whether to work with Ipsos on this.

So, to the first part about the compensation, I guess the piece that made us feel more comfortable with that is that these are modest incentives. So, it's $5.00 for the caregiver to participate and $10.00 for the youth. So, these are not large incentives.

That being said, yeah, absolutely there is the potential that the caregiver could, you know, encourage or push the child to participate. But the incentives are modest.

To that end, also, how they can verify whether it's the child that's completing the survey or not, it's an online data collection, so there's very limited means to do that. Ipsos has done some experiments in the past where they've included some questions that they felt like potentially get at that, around the framing of the use of knowledge questions related to pop culture is what -- an approach that they have used.

We haven't chosen to take that approach in this survey, because we were less sure about how validated that approach is. Some of it seemed reasonable in theory, but there wasn't a lot of validation work to it.

Holly, is there anything additional that you wanted to -- that you feel like we should add here?

MS. MATULEWICZ: No, you've covered it perfectly, thank you.

COMMITTEE MEMBER HESS: I think, then, the only change I would make is in the youth assent form to put the monetary value that the parent will receive for the youth. Instead of receiving 10,000 bonus points on your behalf, a kid doesn't know what that is. They don't know what

(indiscernible) bonus points are. I would be more clear about it.

And I think I would just include, maybe, a little bit more information around this in the protocol. I would be hesitant to ask you not to include any incentive, because I don't think Ipsos is doing that, opting people out of incentives on a panel. That's been my experiences with panels, and I don't want to damage recruiting. But it's just a concern that I had that I thought should be at least mentioned somewhere.

DR. ZICKAFOOSE: And I'm really sorry, I missed the second portion. I caught the piece about including the monetary value for the incentive. But then you started mentioning some additional information in the assent, but I couldn't hear.

COMMITTEE MEMBER HESS: Oh, I just would -- going to ask to put some of the language in the assent around the incentives in more plain language that youth would understand. So, instead of saying that your parent or caregiver will receive 10,000 bonus on your behalf, say your parents are going to receive $10.00.

DR. ZICKAFOOSE: Oh, okay, so they're connected.

COMMITTEE MEMBER HESS: You know, be more clear and I think like transparent on the youth portion. Because they don't know -- these are youth that don't really

understand the way the panel works, since this is something their parents are doing. I think providing the youth with more information is helpful.

And then, I think it's beneficial to put some of this -- to address some of these concerns in your protocol, in terms of that you won't be verifying that the child is completing the survey, rather than the parent, that that's not really possible. I think it's worth documenting in a protocol like this.

DR. ZICKAFOOSE: Okay. Yes, we can certainly document that in the submission to the board and buff up the assent language to make sure that it's clear, that it communicates that their parents will be receiving the incentive, and that the approximate monetary value of that will be $10.00.

COMMITTEE MEMBER HESS: And just for clarification, does the parent receive the incentive if the child does not complete the survey?

DR. ZICKAFOOSE: No, they -- I'm sorry, Holly, will you --

MS. MATULEWICZ: So, if the parent chooses to do the survey and they complete their section, they get their compensation for their part. But if the youth makes the decision not to take part in the survey, that's absolutely okay. And they wouldn't get the youth component if the

youth part is not completed.

COMMITTEE MEMBER HESS: Even if the youth starts and then doesn't complete. So, what I'm getting at is it's based on a complete survey, the incentive.

DR. ZICKAFOOSE: That's right.

MS. MATULEWICZ: Correct. A partial complete isn't included in the dataset, so they wouldn't receive compensation.

COMMITTEE MEMBER HESS: Okay, thank you. Point of clarification.

INTERIM CHAIR DELGADO: I'm glad you have experience with these panels, because I -- it's the first time I've seen something like this, so thank you.

Other questions or concerns?

VICE CHAIR DICKEY: This is Dr. Dickey. Just on this issue of the incentive, wouldn't it just be easier to just say that unless both sides are -- both parts are filled out, that the survey is not going to be used and there would be no compensation?

DR. ZICKAFOOSE: We would risk the caregiver sample in that sense. We would have to drop all caregivers whose youth choose not to respond. And that their system is set up to deal with this. So --

VICE CHAIR DICKEY: Okay.

DR. ZICKAFOOSE: -- that's why we feel like we

could still -- we could still get importation from a caregiver, even if they decide that they don't want their child to participate, or their child decides not to participate.

VICE CHAIR DICKEY: What if the parent doesn't participate, but the child does?

DR. ZICKAFOOSE: That can't happen with this set up.

VICE CHAIR DICKEY: Okay.

DR. ZICKAFOOSE: Unless they're -- well, you know, unless they're stealing their parents' passwords and breaking into their --

MS. MATULEWICZ: And Joe, just to add, and it didn't come up earlier, but just for the privacy piece that there's a stopgap in place such that the youth cannot go back into the parents' answers and see what the parent responded. So, once the parent proceeds to the youth case, it cannot go backward. And that's really to protect the privacy of the parent and the information they provided. Thank you.

INTERIM CHAIR DELGADO: Okay. Going once. Going Twice. Dr. Schaeuble, can we get a motion, please.

COMMITTEE MEMBER SCHAEUBLE: Before I start a motion, can I ask whether the Committee will accept as part of the motion for the researchers to respond to some of the

comments that I added the middle of this week, or do I have to enumerate all of them? Because I'd rather not do that, if it's not necessary.

INTERIM CHAIR DELGADO: I don't think so. I think just reflect the changes that were --

COMMITTEE MEMBER SCHAEUBLE: Okay.

INTERIM CHAIR DELGADO: -- made in IRBManager.

COMMITTEE MEMBER SCHAEUBLE: Good. Then I think we can go ahead.

INTERIM CHAIR DELGADO: Awesome.

COMMITTEE MEMBER SCHAEUBLE: So, I will move a deferred approval for one year, of minimal risk, with the following changes to be reviewed by a subcommittee of myself, unless somebody would like to join me.

The requested changes --

VICE CHAIR DICKEY: Can I ask --

COMMITTEE MEMBER SCHAEUBLE: Yes.

VICE CHAIR DICKEY: Dr. Schaeuble. On amendments we don't typically have an approval period. It's just when they come back for continuing review, then it's reviewed.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, we'll change that to deferred approval of the amendment at minimal risk, with changes to be reviewed by -- yeah, you can take out the one year, Dr. Dickey says.

VICE CHAIR DICKEY: Yeah, I would take the one

year out of it.

COMMITTEE MEMBER SCHAEUBLE: There we go. Deferred approval of the amendment, at minimal risk, with the following changes to be reviewed by a committee of myself.

First, provide the recruitment message that will be sent to potential participants and clarify the recruitment procedures in the protocol as discussed today.

Second, clarify the privacy aspects in the consent forms about the impact of various settings people may have on their computer or smart phone, with information that has been requested from Ipsos.

Third, indicate a dollar value of the reward for participation, instead of just points. This was particularly for the children, but I think probably for anybody, really.

Catherine?

COMMITTEE MEMBER HESS: I think the adults, it's fine to have the points because they're already a member of the panel.

COMMITTEE MEMBER SCHAEUBLE: So, they already understand that?

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Okay.

COMMITTEE MEMBER HESS: But the youth wouldn't.

So, it's really for the youth assent.

COMMITTEE MEMBER SCHAEUBLE: Okay. Okay, so we make this item three, indicate dollar value, instead of points, for the youth in the study.

And I'm blocking on the other part of what you were talking about was. I'm sorry, I interrupted you. Trying to catch a snack here to fortify yourself.

COMMITTEE MEMBER HESS: Sorry, a mouthful of bagel.

So, I just --

COMMITTEE MEMBER SCHAEUBLE: Oh, I know, you wanted to clarify in the protocol that there is no way in these processes to be certain that it is the youth who is completing the survey.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER SCHAEUBLE: That was it, wasn't it?

COMMITTEE MEMBER HESS: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: And fifth, respond as appropriate to other comments added by the primary reviewer to the amendment.

Does that sound, Committee members, like it covers everything we talked about?

INTERIM CHAIR DELGADO: That's the motion of the day. That was a good one.

(Laughter)

INTERIM CHAIR DELGADO: Do we have a second for the motion?

COMMITTEE MEMBER LUND: I'll second.

INTERIM CHAIR DELGADO: Thank you, Ms. Lund. Okay, we have a motion and a second.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund -- oh, sorry. Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Azizian?

INTERIM CHAIR DELGADO: He's out.

COMMITTEE MEMBER AZIZIAN: Approve.

INTERIM CHAIR DELGADO: Oh, he's still, he approved.

MS. ATIFEH: Approved, okay.

INTERIM ADMINISTRATOR MARTINEZ: Uh-hum, he approved.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Thank you so much to the research team and to Dr. Hess -- excuse me, Dr. Schaeuble and Dr. Hess for their background in review and information.

You'll receive a letter in the next two weeks that details everything that we talked about. And have a great weekend.

COMMITTEE MEMBER SCHAEUBLE: Thank you, again.

DR. ZICKAFOOSE: Thank you, to you, too.

MS. MATULEWICZ: Thank you. Bye.

INTERIM CHAIR DELGADO: Okay, guys, hang with us we have one project left to review, because one of the other projects is getting tabled, so this is the last one. We're on the home stretch.

So, I will hand it over to Laura to introduce project -- amendment 2023-025.

COMMITTEE MEMBER LUND: Great. Thank you, Dr. Delgado.

So, this amendment is coming to full Committee because it involves new contact with human subjects that wasn't previously approved as part of the project.

So, is Dr. Whaley on the phone? Or, in the room?

DR. WHALEY: I'm here.

COMMITTEE MEMBER LUND: Hi, Dr. Whaley. So, what I'd like to ask you to do, please, is you don't need to describe the full study, if you could please just describe for the Committee your amendment, what you plan to do and particularly in regard to any human subjects considerations.

DR. WHALEY: I happy to. It's nice to see you all, most of you in the room together again. This is a first. And I wanted to give a special hi to Agnieszka. Agnieszka, I have the privilege of working with you for years at -- (indiscernible)

THE REPORTER: Can we get her volume adjusted up?

INTERIM CHAIR DELGADO: Can you turn your volume up a little bit, if possible, or speak louder into the mic. Thanks.

DR. WHALEY: Wow, that's the first I've had that experience. Usually, people tell me to be quiet. Is that any better?

(Collective no)

THE REPORTER: No.

DR. WHALEY: I'm not sure what to do.

THE REPORTER: Everybody else is just loud enough. No, it's the same -- I'll try and just crank up your microphone on my end.

DR. WHALEY: All right, now is that? Is that any

better?

THE REPORTER: No. But I'm just turning up my mic, so let's just go for it.

INTERIM CHAIR DELGADO: Yeah, so let's just go ahead.

DR. WHALEY: Great. I also, I want to welcome and thank Susan Sabatier for being here. She's the with the Data Analysis Research and Evaluation Branch at CDPH/WIC and a wonderful partner in this work.

So, thank you, Laura. I will not go into all the details of the past study, just to say it went really well, and thank you all for your support of the main study.

We're now in the position of wishing to follow up with an up to 614 members who completed the 2023 California WIC Survey. Why on 614, instead of the 3,000? This work is being funded by First 5 LA, and the First 5 LA funds work in L.A. So, these 614 participants from L.A. County, from the California Survey that was completed, these are participants in L.A. County. So, we are only seeking to follow up with this group of folks.

All 614 indicated on the final question of the 2023 survey that they would be willing to be contacted again. So, we removed the very few people who said no to that question, already.

So, our ask is to follow up with them. You may be

paying attention to the news, with congress not making all its decisions about WIC funding. We are always concerned about the fruits and vegetable benefit going away for our WIC participants. So, we are eager to get back into the field and talk to our participants about fruit and vegetable intake, the fruit and vegetable benefit, access to fruit and vegetables. Can you tell fruit and vegetables is the theme here?

So, that is why we're interested in doing this follow up for the group that we identified.

So, Laura, jump in any time to tell me to stop. But what our plan is, is to reach out to these 614 and ask them to complete a brief survey. It will be online. The questions are specific to fruit and vegetable access, fruit and vegetable intake, food security, and feelings about the cash value benefit for fruits and vegetables.

The last question in the survey does ask participants if they'd be willing to participate in a conversation with other WIC participants, basically a focus group. And so, anyone who says yes to that would be invited to participate in one of two focus groups. So, we can just do a deeper dive and really understand from families what's happening out there with fruit and vegetable purchasing and the WIC benefit. That will be one focus group in English and one focus group in Spanish.

Let me pause there and, Ms. Lund, jump in and tell me what I've left out.

COMMITTEE MEMBER LUND: Thank you, Dr. Whaley. So, first, I want to thank Dr. Whaley because I had a bunch of questions, that's a technical term, about the original wording of the amendment, and Dr. Whaley responded to all of my questions.

So, as she mentioned, they're recruiting based on people who responded to the original survey and said they would be willing to be contacted again. She's provided the recruitment scripts.

The survey that you plan to do will be a text survey only. Am I correct about that? It does not have any kind of online component, other than the text link to the survey instrument itself. Is that correct?

DR. WHALEY: Correct.

COMMITTEE MEMBER LUND: Yeah.

DR. WHALEY: So, it's a text link to, you know, a SurveyMonkey survey, right.

COMMITTEE MEMBER LUND: Yeah. And I reviewed -- she made revisions to the informed consent language that I've reviewed, and I'm comfortable with what she's provided. But that's certainly something the group could weigh in on, if there are other things that should be in there.

Right now, I believe that we have received the

English documents, but not the Spanish documents. So, you plan to provide the Spanish versions after approval in an amendment. So, today's approval would be for English only.

And I don't have any additional questions. You responded to everything that I had in IRBManager. So, I think I'll open it up to the group at this point to see if anyone else has questions for you.

INTERIM CHAIR DELGADO: Any questions?

COMMITTEE MEMBER VENTURA: I have a question on the IRBManager. So, minors were selected as vulnerable populations. Is that because the questions pertain to minors? I mean --

COMMITTEE MEMBER LUND: I believe that's correct. Dr. Whaley? Did we lose Dr. Whaley? Nope, there she is up in the corner.

DR. WHALEY: Hi.

COMMITTEE MEMBER LUND: Did you hear the question, Dr. Whaley?

DR. WHALEY: I think so. It's very difficult to hear the room. But yes, we have. Because kiddos are part of the WIC population, we always check yes to that box.

I would love any guidance from your Committee as to when to check that box and when not to.

COMMITTEE MEMBER LUND: Yeah.

DR. WHALEY: I tend to err on the side of wanting

to be fully disclosed of who we are. But the women answering the survey are all over 18.

COMMITTEE MEMBER LUND: Yeah, thank you. So, I think that is a confusing box and we don't give a lot of guidance. But I believe the intent of that box is to be checked if you're actually performing the research on participants who will be minors. So, minors may be part of your greater service plan, but if you're not actually asking them the questions, you don't need to check that box.

DR. WHALEY: Super, thank you.

COMMITTEE MEMBER LUND: So, for future reference because I know you'll come back to us again.

Any other questions from the Committee?

INTERIM CHAIR DELGADO: No questions, let's go for a motion.

COMMITTEE MEMBER LUND: Okay, I'm ready to make a motion. So, since Dr. Whaley has already made the changes that I requested and I don't hear any additional requests for change, I'm going to say the motion is to approve and that's it. Since it's an amendment, it's there's no deferred approval, there's no time frame, and it's minimal risk consistent with the study that's already been approved that it's a part of.

INTERIM ADMINISTRATOR MARTINEZ: (Indiscernible).

INTERIM CHAIR DELGADO: Great. We have a motion.

Do we have a second?

COMMITTEE MEMBER HESS: I'll second.

INTERIM CHAIR DELGADO: Okay, Dr. Hess seconded.

MS. ATIFEH: Dr. Hess.

INTERIM CHAIR DELGADO: Okay, roll call, please.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

INTERIM CHAIR DELGADO: He said approved, yeah.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

INTERIM CHAIR DELGADO: He is not here anymore.

MS. ATIFEH: Okay. Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great.

DR. WHALEY: Great.

INTERIM CHAIR DELGADO: Thank you, Dr. Whaley.

DR. WHALEY: Thank you all. And, Ms. Lund, I appreciate the back and forth before today, that helped me quite a lot. So, thanks all, Happy New Year, and we appreciate working with you. I'll send you the Spanish version post haste.

COMMITTEE MEMBER LUND: Great.

DR. WHALEY: Bye all.

INTERIM CHAIR DELGADO: Great, thank you so much.

Okay, I see we have a couple of members of the research team for 2023-161. I'm going to hand it over to Dr. Hess. We are tabling this amendment today. But Dr. Hess has a bit of an explanation. And also, want to give the research team just a chance, if they have any questions, to give them space to do that.

COMMITTEE MEMBER HESS: Yeah, thank you. And welcome research team. I apologize for the kind of late minute nature of this. I did send you an email about 20 minutes ago. We received some updated information and guidance that we had been seeking from OHRP and USDA on using WIC participants for research and, in particular, recruiting by text.

We need to seek further guidance from USDA on this, formally as a board. And as such, then we would not be able -- be in a position to make a decision on this

today.

I will say that we do have concerns about texting WIC participants to participate in research, just cold texting, and use of WIC data by outside researchers for that purpose. Which is what we're seeking further guidance on.

It's sort of precedence setting for us as a board, so we need to make sure that we get it right.

If you have any questions, please feel free to ask and I will actually reach out to you to give you further information and to stay in contact with you about this.

DR. HAMAD: Sorry, as Dr. Whaley said, it's a little hard to hear because (indiscernible). Did you say you already sent us an email or you're going to send us one?

COMMITTEE MEMBER HESS: I sent you an email about 20 minutes ago, so I apologize.

DR. HAMAD: Okay.

COMMITTEE MEMBER HESS: We just received guidance, quite literally, about 25 minutes ago. So, I sent you an email just letting you know. I will provide more information to you offline about what exactly our concerns were and what -- who we're reaching out to or why. But we're not at a point today where we can make a decision on this amendment.

DR. HAMAD: Okay. I think none of us received that email. I just texted my colleagues, so maybe that's

part of our confusion. If you don't mind checking, that would be helpful.

COMMITTEE MEMBER HESS: I sent through my CDPH email and sometimes it can take 30 minutes for that to be received.

DR. HAMAD: Okay. Okay, if we don't see it, we'll check in again.

COMMITTEE MEMBER HESS: Yeah, I will -- I will check in with you after this meeting and forward you that email. And we'll be in contact. It just came up after our meeting started today. We were prepared to discuss the amendment with you, but we got some new information that we need to seek further guidance on.

DR. HAMAD: Okay. And just to give us just because, as you might know, this study is like something that is very time sensitive. We have to launch during tax, this tax season, as in like before April, so really in the next few weeks. So, do you get the sense that this is something that's going to take like weeks or longer to resolve with USDA? If so, then I might actually have a request for a slightly different amendment than what we originally talked to you about.

COMMITTEE MEMBER HESS: Yeah. I mean and that's because this is greater than minimal risk, right. So, any amendment has to be heard by the full board. And our next

board meeting would be April, unfortunately.

DR. HAMAD: Okay. So, it sounds like there's no way that it could be -- if we go with the texting, there's no way it could be approved before the April meeting?

COMMITTEE MEMBER HESS: No.

INTERIM CHAIR DELGADO: I don't think we'll get a response from -- because basically, and Dr. Hess will email you this, but the -- our federal partners are going to be requesting some clarification and information. And so, I mean it --

COMMITTEE MEMBER LUND: We could have a special meeting just to do that.

INTERIM CHAIR DELGADO: I mean, we're having a special meeting in March, anyways. We could potentially add this on, if we can get responses.

So, I think maybe, why don't you connect with Dr. Hess after the meeting today. If we can expedite getting information to our federal partners to get a response, we may be able to hear it in March, which could still -- it sounds like it could maybe work for you.

But if I were you, I'd also start thinking about contingency plans should that not happy.

COMMITTEE MEMBER HESS: Yeah.

DR. HAMAD: Okay, so the main contingency plan -- can I just back up a little bit because I don't know if

everybody has the context. Does everybody know what the context for it is, or should I give a little background?

COMMITTEE MEMBER HESS: Okay, I can provide a little bit of background because this is an amendment. They are reaching out to WIC participants to encourage take up of the earned income tax credit. We approved this protocol in I believe December. And we approved a protocol for them to contact with participants via email.

In a different project that they are undertaking with WIC, they have had terrible response rates via email with WIC participants. And so, the researchers have asked that since text messaging is the primary means by which WIC communicates with its participants, whether they could text to recruit participants, rather than email.

There is -- texting is a gray area for a lot of IRBs for contacting participants because it can incur a cost and we can't guarantee that it doesn't.

COMMITTEE MEMBER LUND: Prior to informed consent.

COMMITTEE MEMBER HESS: Yeah, costs prior to informed consent.

COMMITTEE MEMBER LUND: That's the key issue.

COMMITTEE MEMBER HESS: So, I assume the contingency plan would be for you to move forward with email recruiting, although that isn't idea.

DR. HAMAD: Yes, that would be the contingency.

The issue is that in our original IRB application that you all approved we had -- I can't remember the exact number, but I think it was like, you know, email -- sending emails to like 5,000 people. But as Dr. Hess just mentioned, we've been getting response rate of less than one percent to email. That's how many people are actually doing the other survey.

And so, to reach the sample size of 300, we would have to send 30,000 emails. And so, the contingency plan is can we just up the number of people that we send an email to, by the time we figure the texting out.

I mean, so that's one question. And, you know, the secondary thing is that we've actually, in the past month, have done a ton of research and it appears that there are no longer plans in the U.S. that charge people for texting. We contacted major carriers, minor carriers, pay-as-you-go carriers, the burner phones, like nobody is charging for texting anymore.

So, in your communications with USDA, I don't know, if that's like a major concern, maybe that can be passed on and we can share what we've found. But that's sort of -- if that's like impossible to decide today, that's fine. And then I would just ask like, while we're here, can we instead amend it just to be able to contact more people. Otherwise, we're not going to be able to enroll enough

people during this small window that we've been funded to do this work.

COMMITTEE MEMBER HESS: I mean, if we can make such an amendment today, then I think yes, that's absolutely reasonable.

INTERIM CHAIR DELGADO: And upping the number of participants doesn't even need to be a full Committee. I mean, that can be done in IRBManager, and you can just approve that without any confirm.

COMMITTEE MEMBER HESS: Yes. And I don't know, Laura, if you want to provide more context about your conversations with the USDA about what the concerns are there.

COMMITTEE MEMBER LUND: Sure. So, I have actually reached out to a whole bunch of people on this because I -- and I don't know if everybody on the Committee knows that we've had this request from people are involved in the EITC research in the past, and the Committee has not approved their request to text prior to informed consent because Title 45 says that you can't -- researchers cannot cause research subjects to incur costs prior to informed consent. People have to be told that there's going to be a cost before researchers incur that cost for them, on their behalf.

So, it would be good to have the information on

text, it's free to everybody to receive texts, that would go a long way towards alleviating that particular concern.

But I reached out to OHRP, who reviewed this from a Common Rule perspective, and their advice was that we, as a Committee, reach out to USDA because OHRP has some privacy and confidentiality concerns regarding a federal program providing personal information that was provided to program, a federal program for the purposes of program administration, then being given to a third-party researcher. And they wanted to make sure that we were in contact with USDA regarding any concerns they might have on that.

So, we reached out to USDA and let me -- let me see if I can pull up their email. So, their concerns about -- they had preliminary concerns about how the proposed study would protect the PII of these disadvantaged, they called them disadvantaged recipients. Whether the recipients would incur texting costs.

And they were very concerned about the link between the research and the WIC program. This has come up before, that they want to make sure that the WIC -- they are concerned about the potential perception by the WIC participants where they might somehow perceive the text messages to be official correspondence about their WIC, and/or a requirement to continue to receive WIC. Since

these messages are being sent on behalf of WIC, that they're actually research and not WIC program.

So, they go on to describe what the Committee needs to do if we would like the USDA to provide an official position on this, and Dr. Hess and Dr. Delgado will work on that.

So, those are their concerns, and we really need, I think, to find this out from them before we proceed.

Certainly, I would say if we can arrive at an agreement about an amendment that doesn't involve texting, but merely involves something, you know, more emails to try and increase the sample size, that that's fine. We've already improved email. And they can go in and change it in IRBManager if they have a desire to do that.

But that's the context and that's the background to the Committee.

DR. HAMAD: I think, it looks like our collaborator at WIC is on, and she has her hand raised. And I also wanted to -- I have a follow-up comment about that.

MS. SABATIER: Hi. Yeah, Susan Sabatier, from WIC.

Laura, what you shared is like really, really incredible and very informative. I cannot hear you. It's going in and out, and in and out. I have a lot of the gist, but I have no detail.

So, is this what you're going to be sending us, you'll be sending us actually a copy of what USDA has responded to you? Because I would like to see exactly what their comments are, because I will need to be reaching out to my own Western Region as well. So, is that what you're going to be sending us?

COMMITTEE MEMBER LUND: So, I think Dr. Hess will send you a summary of what they've said and what the next steps are.

INTERIM CHAIR DELGADO: So, don't worry, even if you missed some of it, we'll provide you all the details.

COMMITTEE MEMBER LUND: Yeah, you'll get all of this information. Dr. Hess will be working with you to provide you with all this information.

MS. SABATIER: And why would we -- would we not be able to see all the actual communication as has happened between CPHS and USDA?

COMMITTEE MEMBER LUND: So, I will leave it to Dr. Hess. Some of this is on like a private email, so I don't think that I want my private email shared lightly. It's not on a CDPH email. So, Dr. Hess will be able to provide --

MS. SABATIER: Is that appropriate? I'm sorry but --

COMMITTEE MEMBER LUND: Yeah, I'm not a CDPH employee. And CPHS doesn't offer an email option to

Committee members. So. Anyway, Dr. Hess will share all of this information with you.

MS. SABATIER: Okay, thank you.

DR. HAMAD: I was going to make one other comment about the cost issue, since it sounds like that was one of their concerns. Which is that in our research we found that not only does it appear that text messaging is like free for everybody, but that in fact email is the thing that's more likely to cost people because these disadvantaged populations are the ones who are least likely to have a computer at one. And their only means of internet access is their smart phones. And that a lot of the cheapest cell phone plans actually do charge for data or have a cap on data. So that if anything, if we want to keep it free for participants, it would involve texting rather than email. So that if the primary concern is texting, from the USDA, or the IRB, that again in our research we found that in fact another route, the texting route would address that.

So, anyway, so yes, going back to the other amendment. So, it sounds like that we don't need to talk to all of you guys today, but Dr. Hess would be able to like just approve separately since it's just increasing the number of people contacted.

COMMITTEE MEMBER HESS: That's correct, yeah. And I will say that the cost of the text messages was only one

component of the concern. And that is, the other concern is that these texts could be perceived to be official communication to WIC participants about the WIC program when, in fact, they are not. And whether or not WIC participants have opted in or agreed to receive texts that are not directly about their WIC plan, but from a WIC program.

It's the sort of air of officiality of these texts coming from WIC that is part of the concern.

DR. HAMAD: Okay.

COMMITTEE MEMBER HESS: And certainly post-consent, I think there is no problem with text messaging these participants. It's just this initial contact that is problematic.

DR. HAMAD: Yeah, although to me it's a little confusing because I would see that to be true with email as well, if WIC are the ones sending the initial invitation regardless, so that doesn't seem like the means of the messaging is the issue, as much as like carefully wording it.

COMMITTEE MEMBER HESS: And that's, I mean that's what --

DR. HAMAD: And we're happy to work with you guys to respond to the USDA on that and provide whatever we need to.

COMMITTEE MEMBER HESS: That's part of the additional clarification that we'll seek from them on this.

INTERIM CHAIR DELGADO: But appreciate having a backup plan. It sounds like that will be something. And then, Dr. Hess will follow up.

So, I do also just want to comment on -- I'm not sure if it's Dr. Sabatier or Ms. Sabatier's comment earlier. I would just like to acknowledge of our board is made up of members who are retired from state government, after having very lengthy careers in state government. And we are very appreciative of their service, despite the fact that they are no longer receiving benefits, like emails, from the state. And more than happy to have current state employees apply for the board, should you wish to help participate in this volunteer position.

Any other questions from the research team?

COMMITTEE MEMBER SCHAEUBLE: Darci?

INTERIM CHAIR DELGADO: Yes.

COMMITTEE MEMBER SCHAEUBLE: Just one comment with regard to the cost aspect that the researchers were discussing here. A countervailing piece of information from personal experience, because in my household I have -- in much more on top of changes in computers over the years and smart phones, and in our case we have one smart phone with a fairly current plan, that's like so much of what she's

describing, unlimited text or voice messages, and some cap on data. And another cell phone that's -- because it's not used very often, it's on an old legacy plan started a number of years ago and, unfortunately, it does charge for each individual call and each individual text message. But since we don't use it very much doesn't matter, but they are still out there.

INTERIM CHAIR DELGADO: But appreciate that we started this conversation. It sounds like it will continue specific to the text messages. We will help the researcher get a backup plan. And Dr. Hess will be in contact.

COMMITTEE MEMBER HESS: Do we need to --

MS. SABATIER: I'm sorry, but I think I have one more comment.

INTERIM CHAIR DELGADO: Sure.

MS. SABATIER: Sorry for my -- maybe my harsh reaction about the email because it -- well, it took me by surprise that someone -- I get it, you're retired and maybe using personal emails.

My request would then be is that I think it's only appropriate that we get to see exactly the communication that was occurring between CPHS and USDA. And so, what you could do then is remove the email address of Ms. Lund and you could send us the actual communication that was going on. I think that's only appropriate, especially for me to

see as part of CDPH. And you're actually -- you're working with our funder, as well, and I really need to understand what the communication was about because it does impact, sometimes, the work that we do as well, not just external researchers.

INTERIM CHAIR DELGADO: Understood. Thank you for your clarification.

Okay, sorry, we said we were going to table and then took up another 25 minutes of your time. But, hopefully, this was helpful. And I think that we'll have Dr. Hess as your primary point of contact so that we can come to a resolution.

COMMITTEE MEMBER LUND: We need a motion to table it.

INTERIM CHAIR DELGADO: Oh, we need a motion to table.

COMMITTEE MEMBER HESS: I move to table this to the March meeting.

INTERIM ADMINISTRATOR MARTINEZ: Laura seconds.

COMMITTEE MEMBER LUND: Yes, that's fine.

COMMITTEE MEMBER HESS: If USDA gets its response to us by March. If not, then it will have to be April.

INTERIM CHAIR DELGADO: That sounds good. We have a motion. Do we have a second? Laura seconded that, thank you.

MS. ATIFEH: Okay, Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

INTERIM CHAIR DELGADO: No, gone.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

MS. GOSLINER: May I make one request? This is Wendi Gosliner, one of the principal investigators.

INTERIM CHAIR DELGADO: Sure.

MS. GOSLINER: Thank you. And thank you for your time and attention on the project. I'm just wondering the protocol, just for future reference, for example USDA, because we're working closely with WIC and it's part of their program, if we had known that this was an issue that we needed USDA approval, we'd have been -- we could have

also been working that channel. And now, our study basically can't happen in the way we were intending because of this.

And so, just a request that if there's something like that in the future for us, or other research teams, if you could let people know what the issues are so that we can also pursue it and be able to do the work we're trying to do. I know we all have the best interest of Californians in heart, and we're really trying to help people get access to benefits that they're entitled to.

And this is, you know, it's a little bit devastating for us not to be able to do the work we were intending, on the timeline we were hoping for.

INTERIM CHAIR DELGADO: Thank you.

COMMITTEE MEMBER HESS: This is new for us, too, as a board, I think, text recruiting.

COMMITTEE MEMBER LUND: Yeah, this is the first time that we were aware of the USDA.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Yes, I think we all appreciate your concern here and your request. And certainly, if we could do so, we would. It appears that this information came to us at a very late stage, which is why you didn't hear about it earlier from us. So, I hope you understand that, too.

INTERIM CHAIR DELGADO: But we hear you. And, hopefully, in the coming weeks we can find some resolution that might decrease some of the crappy feelings that you might be experiencing.

But thank you, Wendy, appreciate it.

MS. GOSLINER: Thank you.

INTERIM CHAIR DELGADO: Thanks.

Okay, I think that concludes a -- wait, hold on. Okay, so we have now reviewed, gone through Agenda Items A through K. And so, now, I'll pause to see if there's any questions related to Items O through N -- or P.

INTERIM ADMINISTRATOR MARTINEZ: No questions.

INTERIM CHAIR DELGADO: Okay, no questions. I will note on the agenda that the next CPHS meeting is actually going to be in March. Yep, the first Friday in March. So, we'll correct that in the agenda.

I guess, do I open for public comments? I'll pause for a second if there is any public comments, if folks would like to unmute. There's nobody in the room, but if there's anyone virtually that would like to make public comment, now is the time.

INTERIM ADMINISTRATOR MARTINEZ: I guess the March 1st meeting, just to clarify, was in addition to the April 5th meeting.

INTERIM CHAIR DELGADO: Oh, yes. Thank you. In

addition to, not replacing.

INTERIM ADMINISTRATOR MARTINEZ: Right.

INTERIM CHAIR DELGADO: Thanks for the clarification.

Okay, seeing no -- no one coming off mute for public comment, can we -- do I make a motion to adjourn. I would like to -- no.

INTERIM ADMINISTRATOR MARTINEZ: Just to say --

INTERIM CHAIR DELGADO: Okay, no motion to adjourn. We are just adjourning. Thank you all who joined on Zoom. Thanks for having patience with me.

(Thereupon, the meeting was adjourned at 1:56 p.m.)

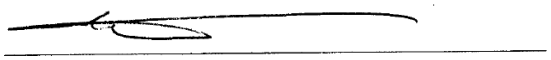
--oOo--

REPORTER'S CERTIFICATE

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 19th day of March 2025.



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TRANSCRIBER'S CERTIFICATE

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 transcribed by me, a certified transcriber. 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 18th day of March 2025.

Barbara Little Certified Transcriber AAERT No. CET**D-520