MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, APRIL 5, 2024

8:33 A.M.

1215 0 STREET, 11TH FLOOR

CLIFFORD B. ALLENBY BUILDING

MEETING ROOM 1181

SACRAMENTO, CALIFORNIA 95814

AND

ZOOM ONLINE MEETING PLATFORM

Reported by:
Peter Petty

PETER PETTY REPORTING, CER**D-493
4632 Freeman Way, Sacramento, California 95819
916-889-2803

APPEARANCES
COMMITTEE MEMBERS

Darci Delgado, PsyD, Interim Chair

Larry Dickey, MD, MPH, Vice Chair

Alicia Bazzano, MD, PhD

Maria Dinis, PhD, MSW

Catherine Hess, PhD

Jonni Johnson, PhD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Lucila Martinez, Outgoing Interim Administrator

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna

ALSO PRESENT

Department of Healthcare Access and Information (HCAI)

Michael D. Valle, Deputy Director, Information Services

CalHHS

PETER PETTY REPORTING, CER**D-493
4632 Freeman Way, Sacramento, California 95819
916-889-2803

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Jared Goldman, General Counsel

APPEARANCES (CONT.)

PUBLIC

Satish Kumar, Suparna Health AI, LLC

ALSO PRESENT

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Katrina Brewsaugh, PhD, Urban Institute

Bridgette Lery, PhD, Urban Institute

Sarah Benatar, PhD, Urban Institute

John Pugliese, PhD, CDPH

Robin Haynes, PhD, Harvard University

Amanda Lechner, MPP, Mathematica, Inc.

Sharon Manne, PhD, Rutgers Cancer Institute of New Jersey

Ouahiba Laribi, PhD, OEHHA

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J. Full Board Continuing Review
None

K. Amendments - Full Committee Review Required

L. Second Review Calendar
None

M. New Projects - Expedited Review Requested
None

N. Projects Requiring Continuing Review
No Projects for Review

O. Amendments - Projects with Revisions Approved Through Expedited Review

P. Projects with Request for CPHS to Rely on Another IRB
No Projects for Review

Q. Exemption/Not Research Approvals
No Projects for Review

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R. 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

S. Public Comments

P R O C E E D I N G S

INTERIM CHAIR DELGADO: Folks on the computer, are you able to hear us? Be glad that you did not show up in person because they gave me a microphone today. So, who knows what's going to happen.

Okay, welcome. We are officially beginning the April 5, 2024 Committee for the Protection of Human Subjects meeting. My name is Darci. I'll be chairing today's meeting.

So, why don't we start with Sussan doing a roll call, please.

MS. ATIFEH: Sure. Okay, good morning, everyone. I'll do a roll call to see who's present.

I start with Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Present.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

COMMITTEE MEMBER BAZZANO: Yes, present. Can you hear me?

INTERIM CHAIR DELGADO: Yep.

MS. ATIFEH: Yes.

Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Here.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Okay, good. With six Committee members attending in person and five Committee members attending remotely we have a quorum established.

INTERIM CHAIR DELGADO: Wonderful. Thank you for the quorum established, Sussan.

MS. ATIFEH: You're welcome.

INTERIM CHAIR DELGADO: Just as a reminder, in case there are any attorneys on, we're completely following Bagley-Keene appropriately, so would remind any board members that Bagley-Keene, in the new edition of Bagley-

Keene Act, that if you are zooming in that you please try to leave your camera on as much as possible, so we can see your beautiful faces.

So, I will go ahead and go through the Chair updates. There are a couple of items that are agendized, so we will -- I will not talk about those just yet. But one, just an update from our special meeting from March 1st of 2024. As part of the do outs and action items from that meeting, we requested a full analysis of the issue that was at hand, primarily the Common Rule versus IPA, when do you use each. That analysis is still underway.

And so, want to just note that it is still underway, but we do anticipate having a full -- having it as a full agenda item at the next meeting to allow for an explanation of the analysis, and a lot of time to discuss, ask questions. So, just want to acknowledge is that is where we're at with that action item.

Also, just the psychologist in me wants to appreciate everyone for holding the space. I know it was a difficult conversation in March and a lot of really strong emotions. And just really appreciate everyone feeling comfortable sharing how they felt and, also, holding space for the differing opinions. And thanks for coming back.

So, that is my item for the Chair update.

Also, just as a flag for folks, because one of the things that the admin team and I have been working hard on is to close loops. Oftentimes it's really difficult, when we're only meeting once every two months, to make sure we're closing all of the loops for all of the action items.

So, I want to say, just to kind of plant the seed for next meeting, we have been doing some work on regulations related to charging entities for using us an IRB when they're outside of CalHHS.

And so, next meeting, again just planting a seed, we'll get a presentation on cost, and fees, and how that whole process is going to work because it is incoming dollars into the board.

There are regulations that need to be addressed, so you will get a first glimpse of that at the next board meeting. So, that's my seed planting.

Okay, Agnieszka, I'll hand it over.

DR. RYKACZEWSKA: Okay. Thank you so much. So, I'm going to kick off Item B, the admin updates, which there are several on.

So, the first one is around our CITI training, or the Collaborative Institutional Training Initiative. So, as we've mentioned in past meetings, as you know for the past

few months the admin team has been working really hard to obtain access to the CITI training.

And we have been experiencing (indiscernible) -- some procurement process challenges. But I am very happy to announce that as of this week we have been able to resolve these and are now in the payment processing phase, so payment has been made, we are processing.

We do anticipate that we will have access for Committee members and admin staff very shortly. So, once we receive that access we're going -- we're able then to do this, draft out instructions and reach out to each of you so that you can now have access to those trainings.

We will have six trainings available. They are on the following topics. Number one, human subjects research. Two, information privacy and security. Three, IRB protocol review. Four, QA/QI human subjects research. Five, IRB administration, the comprehensive one. And six, becoming an effective leader.

So, those are the ones and we're really looking forward to be able to provide those, access to those.

In addition, we had received several requests from Committee members for CalHHS mail addresses in order to ensure the privacy of their own personal emails, as they're doing Committee business.

And so, as a result we really wanted to make sure that this was a resource that was available to all Committee members. So, earlier this month you should have received an email from Nick that had instructions on how to set up your CalHHS email address. And we, of course, are also available to support through that process as well.

That said, we also recognize it can be really burdensome to have to monitor multiple email addresses. And so, to mitigate this we can work with IT to set up automatic email forwarding to the email of your choice, so you don't have to log in to multiple email addresses and monitor multiple addresses.

So, if that is something you would like for us to set up, that automatic email forwarding, please connect with Nick and we are very happy to get that set up for you.

Moving right along, you've been receiving a lot of communication from us this month. An additional one of that is that I've been reaching out to every Committee member to set up some one-on-one calls. The intention of those is, number one, to give an opportunity to get to know each other. I don't really know -- I mean, it's really valuable for me to get a chance to know you, to share a little bit more about myself, as well as to be really able to hear any

questions, concerns, and especially suggestions that you have for me as I'm moving into this role.

I shared before that I'm really excited to learn from each of the Committee members. And this is just one way in which I've been trying to do that, and I'm really, really appreciative of your time.

And I just want to say I've had a few of them already and I'm incredibly grateful to everyone who's met with me already because it's been really informative, and valuable, and really helps me to see, help me really understand what to look into, what information I can seek out, as well as how can I give that support, again, in this role.

And I'm also looking forward to the meetings that are still upcoming, so please be on the lookout. And I might reach out again, as we haven't been able to schedule them, yet.

Of course, if there are any questions, or suggestions anybody has, we don't have to do them in these one-on-ones. Feel free to reach out to me at any time. I am genuinely, truly eager to learn from you and these have been really valuable in helping me learn.

And then, my final update. As part of our meeting materials, we have sent out some federal proposed rulemaking for the Committee, to be a review.

So, the background on this is that our CDII legislative staff alerted us of an opportunity for public comments on a federal proposed rulemaking. So, this is OHRP and FDA have released draft guidelines for key information that should be included to facilitate understanding in informed consent.

So, those are included. For those virtually, we included that in the email packet. And Sussan displaying them right now. As well as those who are in person, we do have a hardcopy of those for you, as well.

Now, the guidance includes seven key pieces of information that should be elements of informed consent, as well as guidance on formatting, organizing and presentation that can also facilitate understanding of this information.

So, the seven pieces that are included as key information that should be included as part of informed consent is voluntary participation and the right to discontinue participation. This is on the table of contents.

The purpose of the research, expected duration of procedures, the reasonable foreseeable risks and discomforts, reasonable expected benefits, appropriate

alternative procedures, compensation and medical treatments for research related injuries, and costs related to subject participation.

Now in addition, this guidance also addresses things like using bubbles for the key information section to really ensure that the understanding is there, and how to format and organize the information so it's not just included, but can really stand out and be easily followed by the research participants.

And if we can go to page 15, this is part of the appendix. The guidance also includes an example of what would a hypothetical informed consent look like using these guidance. So, as you can see, the sections are formatted in a specific way, bulleted. Bullets are used to really hone in on some of the key information. There's boxes, there's key labels included so that, really, the information kind of pops out at you, so that you can really easily follow it.

So, this is the draft guidance that is out there. Now, OHRP and SEFDA (phonetic) are really interested in public comment on this at this stage. So, this is -- hasn't been released as something formal, yet, but they are gathering public comment on this.

And just to be clear, this is really just guidance in terms of taking what's already been put out as the actual rules, and this is just guidance to help put that into practice.

Now, there are two options for Committee members to provide public comment, should you choose to. The first one is to comment individually. And comments are due to the federal government by April 30th. We're happy to provide all of the information in terms of how to do that, should you prefer to submit individually.

In addition, the second option is to submit a formal comment on behalf of CPHS. Now, Dr. Schaeuble, you have been very kind, earlier this week you suggested a formal comment that could be made. And so, I would like to pull this up for the consideration of the Committee. And, of course, Dr. Schaeuble, if you have any thoughts you would like to share on this.

Give me a second for the staff to pull this up. So, Dr. Schaeuble suggested the following language to be: "California Committee for the Protection of Human Subjects strongly endorses efforts to make consent information more understandable and supports in principle the proposed federal guidelines."

Dr. Schaeuble, would you like to share any other thoughts on this?

COMMITTEE MEMBER SCHAEUBLE: Well, I thought these -- the document was very good in the guidance that it suggested for people. And I hope that the Committee might have looked at it sufficiently to be able to say we're in a position to perhaps support a motion from the Committee as a whole.

I know that these comments very often tend to draw more from people who have some concerns or complaints than from people who are in support of a proposed action. So, that was my reasoning for hoping that the Committee here might in a sense to be able to say, yes, we think these are good ideas that are being proposed.

So, that was my thinking. That's pretty much it.

INTERIM CHAIR DELGADO: Can we open it up for any other comments, folks who reviewed the informed consent guidance, recommendations, any other thoughts. If you're zooming in, oh, just come off and you need to raise your hand.

VICE CHAIR DICKEY: This is Dr. Dickey. Can you hear me?

INTERIM CHAIR DELGADO: Yup, go for it.

VICE CHAIR DICKEY: Okay. And this is, I agree it's very well written. It's a nonbinding guidance. And I would support the statements that Dr. Schaeuble has proposed.

DR. RYKACZEWSKA: Any other comments?

INTERIM CHAIR DELGADO: The only other comment that I have -- agree, I thought it was really well done. And if we do accept it and it does become a final guidance to adopt it on our website as just an example. I loved the bubbles. The visual learner in me.

Any other comments? If not, if someone could give us a motion, please.

COMMITTEE MEMBER DINIS: I just have a question. So, when Dr. Dickey said it's nonbinding, then if people do it quite differently how do we resolve, if we adopt it and then other researchers look very differently than what this guidance is suggesting, how do we resolve that conflict?

VICE CHAIR DICKEY: I don't think that -- Darci, are you suggesting that we require it or --

INTERIM CHAIR DELGADO: No.

VICE CHAIR DICKEY: -- we just have it posted as a resource?

INTERIM CHAIR DELGADO: Just posted as a resource. I mean, I know when I'm reviewing informed consent documents, I'm oftentimes giving feedback like the reading level's too high, try to make it a little bit more

understandable. And sometimes the researchers struggle with that. So, this could be a helpful hint or a tool that they could use to try to increase -- decrease the reading level, so as to increase comprehension for participants.

COMMITTEE MEMBER DINIS: Okay, thank you.

COMMITTEE MEMBER SCHAEUBLE: I could mention that on our website already we have examples of consent and assent forms where it's emphasized that key information should be provided at the beginning. And those examples are in a bulleted list format.

The bubbles here in the federal proposal are very attractive visually and, obviously, there are different ways that people could do these things. And even the document itself is very clear that this suggested visual layout is one way, but not the only way of achieving the goals of providing the key information.

So, I don't see any problem here in this. In fact, the discussion in this document points out that for instances where the consent form is short, the key information approach could be the entire consent form by itself because that might be all that's needed.

If the consent form is longer, and we've seen some very convoluted ones, then of course it's very important to have something at the beginning that lays out the groundwork before people are expected to dive into very deep discussions of intricate parts of the research.

So, this all looks good to me. And I haven't heard anybody say anything with regard to the two choices in the motion about supports the guidance or supports in principle the guidance. If the Committee is willing, I would probably just say supports those guidance.

INTERIM CHAIR DELGADO: Dr. Dickey has his hand raised. Thank you, Dr. Schaeuble.

Dr. Dickey, were you raising your hand to make a motion or for another comment?

VICE CHAIR DICKEY: I think both.

INTERIM CHAIR DELGADO: Fabulous.

VICE CHAIR DICKEY: I think that this raises sort of a larger issue as to whether we might want to try to put links to other guidance that OHRP has on our website. It's really quite a resources that we really haven't used very much.

But I don't think we need to decide that right now. But I'd like to make a motion that we agree to adopt Dr. Schaeuble's statement to send to OHRP with regard to supporting this guidance.

INTERIM CHAIR DELGADO: Great. And so, just to

clarify, can you just read the sentence out loud and decide if you want to do the inclusion of brackets -- bracketed information or not.

VICE CHAIR DICKEY: Oh, okay.

INTERIM CHAIR DELGADO: It's up on the screen.

VICE CHAIR DICKEY: Yeah, okay. So, I would say we should do the message that says, "The California Committee for the Protection of Human Subjects strongly endorses efforts to make consent information more understandable and supports the proposed federal guidance."

INTERIM CHAIR DELGADO: Great. So, we have a motion. Do we have a second to the motion?

COMMITTEE MEMBER HESS: Second.

COMMITTEE MEMBER DINIS: Second. Oh.

INTERIM CHAIR DELGADO: Dr. Hess seconded. Thank you. Dr. Dinis thirded it.

But Sussan, could we get a roll call, please.

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

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Okay, thank you.

COMMITTEE MEMBER BAZZANO: Approve.

INTERIM CHAIR DELGADO: Thank you.

MS. ATIFEH: Thank you.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

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

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: You betcha.

(Laughter)

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And, oh, Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Wonderful. Okay, thank you for the motion passing. Dr. Schaeuble, thanks for taking in the lead on drafting our language.

So, what you see up on the screen will be the comment that is submitted on behalf of CPHS. But that does not preclude board members, as individuals, to submit their own public comments as individuals that are participating on the board. So, just a reminder, it's the 30th that those

comments are due. And we will send out the submission information, if you'd like to submit an individual comment.

Okay, let's move on to the next item, Item D, which is an introduction to HCAI's Health Care Payments Data.

So, I'm super excited that we have Mike Valle here. I also learned this week that when his family emigrated to the United States that they're last name was DeValle. And so, I'm going to call him Mike DeValle from now on because --

MR. VALLE: Should it please the chair.

(Laughter)

INTERIM CHAIR DELGADO: Yeah. But just really excited to have Mike here. So, just to put some context in this for the board, this concept of databases is something that we're going to be tackling in the coming months. When we talk about large databases and how we, as a board, are approving protocols, approving requests to access the data, it's going to be a lengthy discussion that is not going to all happen today.

The point of today is to have Mike here to start to give us an intro as to what the Health Care Payments Database includes, what it doesn't include.

And so, what our hope is, or what my hope is, is that the board members can start to familiarize themselves with this impressive database and really start to wrap our heads around how we, as the Committee, are going to be acting in our roles to protect the data, to protect the human subjects, while also supporting Mike and his fabulous team, and the amazing data that he'll be talking about today.

So, Mike, I don't know if that's a good enough setup.

MR. VALLE: That's fantastic.

INTERIM CHAIR DELGADO: Okay, awesome. I'll hand it over to you.

MR. VALLE: All right. Well, thank you for having me. And Chair, members, and any members of the public that are with us again, Michael Valle, Deputy Director Information Services, California Department of Health Care Access and information.

I just want to start, also, by thanking you all for your service on this incredibly important Committee.

INTERIM CHAIR DELGADO: You could join it, if you'd like.

MR. VALLE: Well, I just want to express that.

(Laughter)

MR. VALLE: And to staff, as well, who are

absolutely fantastic. I'm looking forward to a continued partnership together.

If you could go to the next slide for me, please. As you likely know, but I'm obligated to say, our department has a long history as a health data organization supporting informed decisions in the state. And I like to remind people that we were one name for almost 50 years, and we've now changed that now from the Office of Statewide Health Planning and Development in July of 2021. We like to say we graduated from an office to a department, the Department of Health Care Access and Information, or HCAI.

It's an additive change. We're expanding our portfolio of programs, doubling down on our mission to expand equitable access to healthcare for all Californians.

If you go to the next slide, please. You'll just see here a description of the various health data and transparency programs HCAI oversees. Again, by way -- by way of background and introduction, you may know that HCAI administers California's Hospital Discharge Database, and has since the 1980's, which collates over 15 million records annually of inpatient discharges and emergency department encounters. We perform outcome studies for cardiovascular procedures, like heart bypass surgery, among the other data programs you see on the screen.

In 2023, we published over 50 discrete de-identified datasets, as well as 60 online visualizations and interactive reports for public use.

Last year we also fulfilled over 200 requests for nonpublic identifiable data, many of which passed through this Committee.

And so, we're just so proud of the significant contribution HCAI data has made to the body of knowledge for health policy and practice, and for the Committee's role in helping us do that.

If you go to the next slide, please. With that, I'll now move to an overview of the Health Care Payments Database, or HPD, California's All Payer Claims Database, also known as an APCD. It's our newest data offering, a retrospective research database. The only all payer state-run claims database in California. We call it healthcare payments. Everyone else calls it all payer claims, we call it healthcare payments to reflect the prevalence of managed care and value-based payment in the state, and our goal to include non-claims based payments in the database in the future.

Twenty other states have similar data systems. This has been a long time coming. State policymakers,

others have been working since 2007 to establish a state APCD in California. We're standing on the shoulders of giants with this, learning from others and the many claims data warehousing efforts that have come before us.

In 2018, HCAI received the initial startup funding to begin studying and planning for how to build a database. In 2020, the additional enabling authority to establish the database was granted.

Since then, we've been heads down building our team, working with date suppliers and other stakeholders in engineering technology infrastructure to support the database. And I'm now very proud to say that we have four plus years, and growing, of historical data loaded into the system. That's 5 billion healthcare claims, 17 billion total records, the single largest data aggregation of our department's history -- in our department's history. And we're now successfully collecting and processing over 100 million new healthcare claims encounters each month. So, the database continues to grow.

This is data from all healthcare payers, the claims that providers submit to health plans for payment, the encounters for services provided under a managed care arrangement.

But with some limitations, as I think was mentioned, the uninsured, self-pay, self-insured, VA, for example, are not included. This is administrative data. There's no clinical data included in the database. And some health plans are also exempted from reporting.

The database includes over 80 percent of the California population. For calendar year 2021 we have over 33 million unique covered lives represented.

And we're closely monitoring data quality and completeness in the database and expecting data quality to improve, and the usefulness of the data to improve as the database matures.

I just want to say I'm really thankful to California's health plans and insurers, they've been fantastic partners in this effort, supplying high quality data according to HCAI's specifications. Without this partnership, the progress made on this work to date would not be possible.

And also, I'd like to thank partners with the California Health and Human Services Agency, the California Department of Healthcare Services, who supplied all the Medi-Cal data, fee for service, and Medi-Cal -- and for Medi-Cal Managed Care Plan. Again, just thank you. Your support is integral to the success of this work.

INTERIM CHAIR DELGADO: Can I pause you for a second, Mike?

MR. VALLE: Yes.

INTERIM CHAIR DELGADO: One thing, just again, like as I'm listening to what Mike is saying and starting to think about our role as the board, one of the questions that immediately popped into my mind is when we're -- when we will move towards looking at projects like this, Medi-Cal info is pouring into this database. And so to me, it already sparks a question of like approval for use of the data, DHCS versus HCAI. Although, I know you already house a lot of data from other departments, as well.

So, just something to put a pin in for the coming discussions.

MR. VALLE: Absolutely. And we -- we'll get to that, I think in a moment, as well.

INTERIM CHAIR DELGADO: Okay.

MR. VALLE: But thanks for flagging that.

Let's go to the next slide. HCAI's adopted a national standard for claims and encounter data, which was ratified by our Stakeholder Advisory Committee in 2020. And includes common information for billing, such as the patient's diagnosis, the procedure performed, the amount paid for a claim, provider information, pharmacy information and more.

Probably needless to elaborate on for this group, but with this information, the claims data, weighing that at the scale, at the California Healthcare Delivery System we expect it can be used to support many big data, longitudinal systemwide analyses on healthcare costs, utilization, quality access, and equity. And we're just very excited about what the research community and others will be able to achieve by using this data. I want --

INTERIM CHAIR DELGADO: Sorry, I'm going to interrupt again.

MR. VALLE: Please, yes.

INTERIM CHAIR DELGADO: I apologize. You said earlier that the database isn't holding any clinical information. But I'm confused because up here we have patient information, along with diagnosis. So, can you help me rectify those two things?

MR. VALLE: Sure, absolutely, yeah. So, it doesn't have information like lab information, clinical notes. So, we see this as an administrative database that is referencing filling information that is included in health plan systems for the purposes of billing. Which means there's some key gaps. If it's not required to pay a claim,

a healthcare claim, it may not be representative.

But things like diagnosis is, for example. And so, that can be used as a good proxy to, again, to look at utilization and cost, and can be used to generate some quality measures like --

INTERIM CHAIR DELGADO: I would just -- given that information, like I think from our perspective would probably push back on the statement that it doesn't include clinical information. Just as a given, you know, if I am diagnoses with appendicitis and Medi-Cal bills for those services, to me, just as like a regular person walking on the street, knowing that in the database is my name, with a diagnosis, to me reads as -- I would interpret that as clinical information. Sorry.

MR. VALLE: Great point.

INTERIM CHAIR DELGADO: Sorry to keep interrupting you.

MR. VALLE: No, thank you for that.

I did want to, though, note that again we've adopted a national standard for this database that is governed by the National Association of Health Data Organizations, or NAHDO, which oversees the all payer claims database common data layout.

HCAI has a sitting board member seat on NAHDO. And I just wanted to note that we're very proud to spearhead the addition, at the national level, of more granular race and ethnicity categories. And for the first time, the addition of sexual orientation and gender identity data into the all payer claims database common data layout.

This was ahead of OMB's rule recently, issuing similar guidance. And the NAHDO (indiscernible) council ratified these changes in September of 2022 for all state APCDs to adopt. And California health plans began submitting data to HCAI's HPD with the more granular categories in January 2024. So, we're very proud of California's position there.

Go to the next slide, please. The database is intended to be used by a wide variety of audiences, public and private. We want healthcare entities to use this data to help them improve and to collectively implement policies that can make the healthcare system better.

You can see the goals on the screen. These are enumerated in the California Health and Safety Code. They've further been adopted by our Stakeholder Advisory Committee.

However, the data, as used, it must provide a benefit to Californians and the use of the data must protect

individual privacy and, of course, is is part of everything we do at HCAI, as well as prior for this Committee.

Go to the next slide, please. There are two governing bodies responsible for oversight and the administration of the Healthcare Payments Database. I mentioned the Stakeholder Advisory Committee. That's on the left. It's the policy level committee that advises HCAI on program policies.

It's made up of a cross-sector group, payers, providers, researchers, consumers and others, and who meets quarterly and has been since 2020.

On the right, HPD is also overseen by a Data Release Committee. The Data Release Committee is also a diverse, cross-sector group made up of technical data, the privacy experts, also representing various part of the healthcare system and whose role is to review requests for access to nonpublic data and to advise HCAI on matters of data use, data privacy, and data security. And I'll share more about that group in a moment.

COMMITTEE MEMBER LUND: May I ask you a question?

MR. VALLE: Yes.

COMMITTEE MEMBER LUND: Are either of these groups required in statute or are these voluntary committees that HCAI --

MR. VALLE: No, these are required in statute, including the representation and their roles.

COMMITTEE MEMBER LUND: Okay, thank you.

MR. VALLE: Let's go to the next slide, please. There are two ways that the data in the HPD can be used. Similar to other HCAI data resources, our analysts and researchers internally produce public reports on topics of importance, on healthcare policy and practice, with de-identified data, that we published at HCAI website.

And we've released two public analytic reports from the HPD so far, and continue to release new ones ongoing.

Additionally, we have a data release program. As we do for our hospital data, we're in the process of designing such a program for the claims data. This program is expected to begin accepting requests later this year. And we are meeting regularly with the Data Release Committee to develop that process in collaboration with them.

Let's go to the next slide. I'd like to just give a quick overview of some of the public reports that have been published. Each of these has hundreds of thousands of rows of data available. The underlying de-identified information is downloadable, machine readable, and API enabled.

First stage we need snapshot, hcai.ca.gov/snapshot. The purpose of this product is to provide an overview of what data is available in the HPD system. If you add it up, it's over 5 billion claims encounters over a four-year period.

There are four distinct views in this report. So, for instance, you can see the number of covered lives by payer and line of business. We're working to get more granular with the filters we provide there.

You can also view by month and line of business the number of services received, and compare that to the number of members eligible for care in that line of business.

It also includes the top medical procedures and the top prescriptions filled by number of claims. So, you can see our data shows there were 334 million office visit claims billed from 2018 to 2021. It's the top billed medical service, 62 million claims of a particular statin agent during the same time period is the top billed prescription drug.

And we think this report really provides a foundational look into the data to get people familiar with the database and its contents, and may inform subsequent requests for the detailed record level data through our nonpublic data release process.

Second, HPD measures, hcai.ca.gov/measures. Presents standardized chronic condition, demographic and utilization measure categories, filters for up to 23 measures per category and additional filters for up to two simultaneous grouping dimensions, including age band, county, sex, payer and more, with the ability to compare to statewide averages.

We include several starting prompts to demonstrate what you can do with this report. For example, what percentage of Californians in my age group have a diabetes diagnosis. Or, is the number of surgical inpatient stays increasing or decreasing over time across the state.

We recently presented this report to a coalition of local health officers and there's a lot of interest in it, and we're very excited about this report, and continue to add new measures and provide more granular dimensions of filtering and analysis in future years.

Our next report will be released very, very soon, it almost made this slide deck, but not quite, on prescription drug costs. And we're workshopping the final design of that report now. Our first look at cost information from HPD data, so we're very excited about that.

And then, what's to come. Last year our advisory

committee made recommendations for three priority topic areas that HCAI should focus on in 2024 for new public reports.

First, social drivers of health and health equity. We're planning to look at the Healthy Places Index and other place-based indices for social determinants.

Second, we want to further enhance the prescription drug report. We're preparing to publish soon with more data elements.

And then, finally, looking at hospital costs. As our second foray into cost reporting from the HPD, it's certainly a known cost driver for total cost of care across the system.

We're also planning to refresh these two reports you see on the screen, snapshot, and measured with two new years of data. The 2022 and 2023 data will be out at the end of this year. So, we've very excited about that, as well.

If you go to the next slide.

INTERIM CHAIR DELGADO: Can we -- sorry. I just wanted an update here.

MR. VALLE: Yeah.

INTERIM CHAIR DELGADO: On the previous slide that -- so, when you're talking about these public reports that are currently on your database, and you talk about how there's individual line-by-line entries that are creating these beautiful graphics that you showed, can you just clarify like is what is available online. So, the individual line-by-line, is that available to download in a de-identified sense?

MR. VALLE: Right. It's de-identified at the data element level. So, there are suppressed cells in the underlying data because they need to be suppressed in any sort of measured category that might be included in an online visualization.

INTERIM CHAIR DELGADO: And do you follow the -- like, what de-identification policies do you follow?

MR. VALLE: We follow the CalHHS data de-identification guidelines and we describe that in the text and notes, as well.

INTERIM CHAIR DELGADO: Okay, got it. And then, just noting in the chat, Dr. Bazzano had put in a question about whether or not there's a bio emphasis on the DRC. And it looks like Olivia did respond.

Nick, if you're sharing the screen, can you open up that link just for -- to acknowledge Dr. Bazzano's question.

So, nobody get any ideas of hopping over to another

committee. But if we could open up that link just to see the members. So, it looks like there are folks who are -- can you just explain the committee, like how you recruited.

MR. VALLE: Sure, yes.

INTERIM CHAIR DELGADO: It doesn't look like they're all state employees.

MR. VALLE: No, no, they're not. And Dr. Barbara Koenig, who's previously with UCSF is our bio emphasis in residence and a fantastic member. Yeah, you'll see them on the screen. There's also a slide that describes their roles and backgrounds.

Again, the statute requires a cross-sectoral group. So, we have representatives, again, from the payer community, from the provider community, from the research community, and with experience in data privacy, data security, healthcare, healthcare data.

Yes, so we are so just proud, and thankful, and grateful for this group to be helping us with this project.

INTERIM CHAIR DELGADO: Thank you, Nick. Awesome, thanks.

Dr. Bazzano, did you have any follow-up questions to that? I just want to make sure there's space for your thoughts.

COMMITTEE MEMBER BAZZANO: Yeah. (Inaudible).

INTERIM CHAIR DELGADO: Oh, Dr. Bazzano, I think we have a bad connection with you.

COMMITTEE MEMBER BAZZANO: I was very curious to know, you know, how that group might -- okay, I'll --

INTERIM CHAIR DELGADO: Sorry. Maybe if you could put it in the chat. I think what we heard you say was that you were just curious to understand maybe how that group was formed, or maybe how that group would then interact with CPHS. I'm not sure what. But if you could put it in the chat, that would be awesome. Sorry about that.

MR. VALLE: I think a fantastic segue, if we could, to describe the data release program that we're in the process of developing. You'll see that also on the screen, some of the aspects of that.

I want to start with something that's foundational to our program. And that is providing access to nonpublic data in a secure online research data enclave. We're in the process of testing that system now. Our statute contemplates that this is -- this approach of providing virtual access to data, where the data remains on HCAI's servers, but can be viewed and analyzed through a remote desktop environment, with free loaded (indiscernible) tools. It's the best way to preserve individual privacy and

maintain information security.

And so, we're committed to that as it aligns with our values for providing data access while balancing the risk in use of the data. And though our statute does permit transmitting data outside the database, there will be a high bar for that, and the Data Release Committee must affirmatively approve any such request.

Additionally, the HPD statute contemplates two types of datasets for release. A standard limited dataset, with direct and some indirect identifiers removed. And a research identifiable dataset which may include direct identifiers for qualified researchers and for research purposes. And it's the request for the identifiable research data, by academic researchers, that also requires this Committee's involvement to evaluate those.

And so, that's something that we'd like for our staffs to work together to make an effective and efficient process for our programs, and members, and the researchers requesting that data.

INTERIM CHAIR DELGADO: Dr. Bazzano has a lot of great questions. Mike, I don't know if there are some of them you can speak to offhand, or if not, we can also get, maybe get some responses in writing.

Who will be allowed to utilize the info under this nonpublic data release? What are the qualifications. Questions about for-profit entities, lobbying groups. I mean I'm sure that you've, in following the Office of Health Care Affordability, understand there are a lot of interest parties in this dataset when it comes to potential users. So, just curious if you have any initial thoughts on that question?

MR. VALLE: Yeah, it's fantastic, and something we've been spending so much time evaluating and unpacking. Our committee's been really critical to that. Happy to share the materials, perhaps offline, if that would -- if that would be helpful.

I think what we feel is, you know, the statute really suggests that this data should be widely used and utilized to meet the goals of the program. And the healthcare entities have a role in controlling costs, and improving quality, and improving access. And so, they will be eligible to access the information. And there will be a case-by-case review on any harm that may come from the data use, and if the benefits of data use outweighs those.

So, that's built into our process. Again, happy to share more on that. And again, we are really going to be relying on our committee of stakeholders and experts to help

guide us through, especially those challenging edge cases which we don't know which types of ideas for use of the data will emerge.

COMMITTEE MEMBER LUND: Can I just ask one more question. Does your statute have limitations on who can receive the data? Like, in some cases state data can't be released to for-profit entities, and there are other restrictions, sometimes it depends on the dataset, itself. So, I'm just wondering.

MR. VALLE: Yes, that's a great question. So, the research identifiable data is only available to researchers for research purposes. The standard limited data does not have those type of restrictions.

And so, again, we are going to be eager to see what types of uses are proposed for use of that standard limited dataset, again within our online data enclave. That could be the goal of the program, lower costs, improved quality, improved access to care.

COMMITTEE MEMBER VENTURA: How will violations of the use of the data, if it's accessed through this controlled space, is it reporting to your -- the committee, if there is a violation?

MR. VALLE: Yeah, it's a great -- it's something we've talked about at length. And I think the, you know, sunshine is the best disinfectant. Having this public body that has a public presence, right, in terms of oversight of the use of the data.

So, of course, we're going to have data use agreements and those are -- there's going to be strength there. The enclave allows us to monitor what's happening in the analytic environment. We will be oversighting de-identification procedures for any output that comes outside of the enclave.

And yes, I think the public committee would be a good resource to use to help ensure that use of data is appropriate and protected.

INTERIM CHAIR DELGADO: Awesome. So, Dr. Bazzano put in, "There is a lot to unpack here."

We agree, which is why we drug Mike into today's meeting because we know that this is going to be a series of discussions that are moving towards, I think you said end of 2024, when you're hoping for --

MR. VALLE: So, we are racing, racing methodically, I'll say. I mean there's so much interest in this database. We're finishing the rulemaking process, which was necessary to begin our data release program. We think that will be done in Q-2. And then, we'll begin accepting requests and

going through a process that will be familiar to many of you.

Our staff will intake those requests, perform some initial triage working with requesters. You see on the screen there, Department of Healthcare Services must approve any release of Medi-Cal data. So, we're working very closely with DHCS to make that an efficient part of the process.

And then, yes, research, identifiable requests by researchers will also need to come before this body. And we'd love to work closely with you so that that is an effective process.

INTERIM CHAIR DELGADO: Awesome. Dr. Dinis -- thank you, Mike.

Dr. Dinis asked the question, "Will these datasets also be merged with existing datasets that the researchers are holding themselves, like with some kind of matching access?" That's something we've been tackling a lot recently.

MR. VALLE: Yes, absolutely. And I think that there's so much promise in that type of data linkage. We want to have a bring-your-own-data type feature in the online data enclave. We have a master person index to help facilitate some of those processes.

And I think that's one of the things where, you know, when there is linkage a higher level of scrutiny may be appropriate, depending on the type of use.

So, that's certainly the type of thing we want to support in terms of, you know, longitudinal system -- systemic research that can be done using the data.

INTERIM CHAIR DELGADO: Thank you.

Dr. Dickey, I see you have your hand raised.

VICE CHAIR DICKEY: Yes, uh-huh. I just wanted to -- you know, some of us have been involved in discussions with your staff about this earlier. And I think our attorney, Jennifer, has been in discussions, also.

But there is something that Laura brought up. It's our understanding that your data is subject to the Information Practices Act, which requires us then to -- because we're part of the Information Practices Act, that's why we have to be involved. Is that correct?

MR. VALLE: Well, Doctor, I'm not an attorney, myself, despite my fantastic sport coat, as Darci pointed out.

(Laughter)

MR. VALLE: I think that we should have our teams maybe talk more about that. I think what's unique about our

program is that the statute explicitly provides a data release program for this database, and explicitly defines this Committee's role in that process.

So, I think that may be something that the teams should discuss more.

COMMITTEE MEMBER LUND: Can I just comment?

VICE CHAIR DICKEY: Go ahead.

COMMITTEE MEMBER LUND: So, Dr. Dickey, I think this would bear -- certainly bear a little more looking at. It could be a situation that we see with Vital Stats, where they have their own legislation. So, instead of --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: -- SB 13, we're governed by the Vital Stats legislation and that might be the case here.

VICE CHAIR DICKEY: Right. And that's why we -- I guess we need the legal input on this.

COMMITTEE MEMBER LUND: Yeah, yeah.

INTERIM CHAIR DELGADO: Which, again, is why it's April and we're doing this earlier so we can continue to have these discussions.

Another question that came through, Mike, on chat. "Have you interacted with OHRP, which is the Federal Office of Human Rights Research Protection?"

COMMITTEE MEMBER SCHAEUBLE: Research protection.

INTERIM CHAIR DELGADO: So, nobody outed me that I didn't know what OHRP stood for, as the Chair of this Committee.

COMMITTEE MEMBER LUND: You were testing us.

INTERIM CHAIR DELGADO: Yes, I was. Yes, thank you.

Have you interacted with them?

MR. VALLE: I have not, myself. I'd have to get back to you and see if the program has.

INTERIM CHAIR DELGADO: Yes, sounds good.

I know Dr. Schaeuble had a question. We're going to keep you here all morning, Mike.

MR. VALLE: Love it.

COMMITTEE MEMBER SCHAEUBLE: Just a brief follow up on Laura's earlier question. It sounds to me like you're saying that identifiable data can be released to any type of researcher, there's no limitation on whatever affiliation the researcher might or might not have.

MR. VALLE: We do have definitions on the researcher. I'd have to get back to you on what the specifics are that define that.

INTERIM CHAIR DELGADO: The distinction that we make sometimes is like a research from a for -- like a for-

profit entity could hire a researcher and the be presenting themselves in a way that would change the risk level review.

MR. VALLE: Right, that's a great point. We have defined that in our rulemaking. I don't have it right in front of me, but happy to share that with the Committee.

COMMITTEE MEMBER SCHAEUBLE: But you're saying you think it would include commercial entities in addition to academic institutions, for example.

MR. VALLE: Dr. Schaeuble, I don't want to speak out of turn. I'd like to provide that to you in writing.

COMMITTEE MEMBER SCHAEUBLE: Okay. No, I'm not -- I'm not trying to ask you to say something that --

MR. VALLE: We'll get back to you.

COMMITTEE MEMBER SCHAEUBLE: Okay.

INTERIM CHAIR DELGADO: Other -- oh, that was it. Dr. Dickey, I don't know if your hand is still raised.

Dr. Dinis' hand. Let's go Dr. Dinis and then Dr. Dickey, if you have a second question. I can't tell. Nope, he's good. Okay, Dr. Dinis.

COMMITTEE MEMBER DINIS: Yeah, my question maybe was answered, you know, because somebody called me in the middle of this. But will these datasets also be merged with researchers' datasets that they already have in their possession?

INTERIM CHAIR DELGADO: Yes. Yes, Mike said --

COMMITTEE MEMBER DINIS: Okay -- (indiscernible) --

INTERIM CHAIR DELGADO: Yes. Yes, Mike said yes, the researchers will be able to do that. Generally, by bringing their own datasets into the HCAI enclave data could.

COMMITTEE MEMBER DINIS: And then they would merge with the other datasets from -- on medical information.

INTERIM CHAIR DELGADO: Possibly. Or, I mean, it could be anything, right.

COMMITTEE MEMBER DINIS: I mean like that kind of opens up a whole new can of worms of people being possibly identified.

INTERIM CHAIR DELGADO: Agreed.

COMMITTEE MEMBER DINIS: Yeah. And how are we going to be able to protect that? Wasn't it a couple of years ago there were three or four variables, they identified the medical records of one of the senators? That's all, just like, you know, we have to really be very careful how it's all done.

INTERIM CHAIR DELGADO: Agree. Agree. And I will apply HCAI. This concept of having state-owned data space

for these data merges to happen is something that we've talked about for years. And so, that's actually quite exciting to be able to turn on and off people's access and not be emailing huge datasets of 100 million data points a month.

But, no, Dr. Dinis, that's an incredibly important point.

Other questions? Should we open up for public comment?

DR. RYKACZEWSKA: I think you can take public comment.

INTERIM CHAIR DELGADO: Okay. Actually, let me just check. Mike, are you done? Are there any other slides that you wanted to touch on?

MR. VALLE: No, no other slides. I do have -- but you do have the roster of our Data Release Committee and, again, I'll just share that for your reference, and appreciative to them and all of you for your service to the State of California, and for your time. Thank you.

INTERIM CHAIR DELGADO: Awesome. Let's just, before we open it up for public comment, because I see we have a lot of folks online, and also someone in person, any board members, any other questions, comments? Acknowledging that, again, this is the first of many.

We'll have Mike's contact information placed in the chat and also emails, along with the slide deck. And expect Mike to get lots of questions from us. And please, plan on being here for our June meeting so we can follow up on this conversation, with maybe a little more specificity to statute, a little bit more specificity to procedures. And procedures specifically with how your Data Release Committee is going to interact with CPHS.

COMMITTEE MEMBER LUND: When we get your slide deck, could we get the statute that governs your work?

MR. VALLE: Sure, happy to provide those.

COMMITTEE MEMBER LUND: Thank you, awesome.

INTERIM CHAIR DELGADO: Okay. So, now we're going to open it up for public comment. I see one virtual hand raised. But we have somebody here in the room for public comment, first. So, if you could just wait one second, we'll bring the mic over to you.

And then, Katrina, you're next, so hang tight.

MR. KUMAR: (Inaudible).

INTERIM CHAIR DELGADO: Can you speak into the mic for us, please.

MR. KUMAR: Yeah, good morning, ma'am, all the board. This is a very good thing you are doing. I just

(indiscernible).

So, I just want to make one point.

THE REPORTER: Please hold the mic closer to your mouth.

MR. KUMAR: Yeah. People who need -- (indiscernible).

INTERIM CHAIR DELGADO: Great, thank you so much for your public comment. Appreciate it. And thank you for being here this week, today. Okay, thank you.

Katrina, if you'd like to come off mute to make a public comment, please.

MS. BREWSAUGH: Yes, thanks. I think I just have a question because, you know (indiscernible) -- getting data from multiple public entities. It was just because, too, as you're thinking about how the HPD Data Release Committee and CPHS will interact with each other, making it very clear for researchers which board you go to first to get approval, and that order, and what the options are if the two boards conflict (indiscernible) -- requiring a decision.

INTERIM CHAIR DELGADO: Great, thank you, Katrina. Thank you so much for that feedback. Passing it along to Mike Valley is super important and something that we'll strive to do in terms of clear communication and expectations. Super helpful.

Other public comments? If you're on Zoom, you can raise your hand or just come off mute. We'll pause for a second to see if there's any more public comments.

Okay, seeing and hearing none, thank you so much, Mike for being here.

MR. VALLE: Thank you, again.

INTERIM CHAIR DELGADO: Thank you to your HCAI team. Again, the slide deck, as well as the statute, specific statute information will be sent out to board members. And Mike, we do again thank your team and ask you to come back in June so we can have more discussion.

MR. VALLE: Thank you so much.

INTERIM CHAIR DELGADO: Thanks. Get some coffee on your way out. We have a lot of coffee today.

Okay, so let's move on to Agenda Item D. Hopefully, we still have Jared Goldman on.

MR. GOLDMAN: I'm here.

INTERIM CHAIR DELGADO: Wonderful. Okay, so Jared Goldman is the general counsel for California Health and Human Services. He will be sharing some background on Assembly Bill 352, which has a key section related to providing guidance to IRBs when reviewing data requests related to abortion, or abortion related services, when the

research is being performed out of state.

So, Jared, I will hand it over to you.

MR. GOLDMAN: Great, thank you. I'm going to share my screen. And let me know if you can see a law popping up on your screen, now.

INTERIM CHAIR DELGADO: Yes, we can see it.

MR. GOLDMAN: Great. All right. So, AB 32 -- 352 is a -- it's a bill that's a broader package of changes to the law that are (indiscernible) -- riveting disclosures of abortion-related information through electronic health records and public information to states other than California.

So, what you see in front of you is just a piece of the bill. But you should just be aware that this is the context of a broader effort to protect abortion-related implications for California.

The reason for that, generally, is that California has among some of the strongest privacy protections for abortion-related information and protections for providers of abortion.

And there is concern now, of course, that disclosures of abortion-related information, both related to individuals and providers, that are in the hands of states that have laws that are now hostile to abortion (indiscernible) -- the individuals who have had abortions, or the providers, or anyone who participated in (indiscernible) --

INTERIM CHAIR DELGADO: Jared, just so you know, your audio is going in and out a bit.

MR. GOLDMAN: Oh, sorry. Sorry, you're going to see my face really close to the screen now, as I move closer to the mic.

INTERIM CHAIR DELGADO: That's okay, no problem.

MR. GOLDMAN: You can look at the pores on my face.

So, just a quick reach out in case anyone missed any of what I said, the purpose of AB 352 is to ensure that abortion-related information is protected and not released (indiscernible) that have privacy protections that aren't as strong as those in California. We don't want abortion-related information used in states that are hostile to abortion, who may harm abortion providers or women who have had abortions.

So, with that I am going to -- you see the law in front of you, but I'm going to -- it's not a lot of law, so I'm going to read it to you real quick, for those of you are audio learners. And bear with me, this first paragraph, I think, is the longest sentence in the history of the world.

"A provider of healthcare, healthcare service plan, pharmaceutical company, contractor or employer shall not knowingly disclose, transmit, transfer, share or grant access to medical information in an electronic health record system, or through a health information exchange that would identify an individual, and is related to an individual seeking, obtaining, providing, supporting or aiding in the performance of an abortion that is lawful under the laws of this state to any individual or entity from another state, unless the disclosure, transmittal, transfer, sharing or granting of access is authorized under any of the following conditions."

So, the law then has a series of conditions. I've abridged them here. I've only included the two paragraphs that I think are relevant to you. And these two exceptions to the limitation of disclosure are that:

Disclosures can be made pursuant to a written authorization. In addition, disclosures can be made pursuant to the CMIA exception, which allows disclosures for the purpose of research.

And that's where you come in. So, the highlighted section of the law requires that when information is disclosed under this provision for the purpose of research, the IRBs, I'll just read you the sentence: "Institutional Review Boards shall consider the potential harm to the patient and the patient's privacy when the research uses data that contains information related to abortion, or abortion-related services and the research is performed out of state."

But this is your role. That when you are reviewing research that involves the disclosure of abortion-related information, patient identifying abortion-related information, either in DHR or at a health information exchange, you have a role in taking a pause and thinking about the particular impacts to the women -- or, well I should -- this doesn't cover the interests of the providers. It specifically only covers the interests of the patient.

So, you're supposed to consider the potential harm to the patient and the patient's privacy when the information is disclosed out of state.

I think it's pretty straight forward. And maybe I'll pause there and see if there are any questions so far.

INTERIM CHAIR DELGADO: I have one question and then there's another one in the chat. Jared, is this proposed legislation or is this already enacted in state law?

MR. GOLDMAN: This is on the books. This was

effective January 1st, so this a law.

INTERIM CHAIR DELGADO: Got it, thank you. Okay, and then Dr. Bazzano's question: What does research performed out of state mean? Does publication count as research performed out of state?

MR. GOLDMAN: Well, we don't know that from the law. It doesn't explain that here. So, I think we have to take a look at it on a case-by-case basis. All law is fact based, and so I would suggest if you, in your oversight and review of research, come across an abortion-related question like this that you -- that you run it through the chairs to your legal team and they can assist you.

UNIDENTIFIED SPEAKER: There's sure a lot of that --

MR. GOLDMAN: I'm sorry?

INTERIM CHAIR DELGADO: I think that was just somebody who was accidentally on mute -- unmuted. Dr. Dickey, you have your hand raised?

VICE CHAIR DICKEY: Yes. You know, the reason why there's issues about how this gets implemented, and it almost would seem like the HPD database, maybe they should have one database that's for in-California use that includes the abortion information and then another set that doesn't include it. Because it's going to be hard for us to go through every variable, et cetera, and to know whether the abortion stuff has been taken out or not, unless those people who are running the databases do that for us.

INTERIM CHAIR DELGADO: That's a great flag. And Dr. Bazzano's saying the same thing in the chat. Jared, I think you were listening to Mike Valle's presentation, but this is kind of the nexus between what we just talked about and this topic.

MR. GOLDMAN: It is a really good point. And I would flag that another portion of AB 352 includes a requirement that EHR developers are now required to develop their EHRs in California in a way that allows for the segregation of abortion-related information. So, at least with respect to electronic health records, into the future it will likely be easier to segregate abortion-related information.

COMMITTEE MEMBER HESS: How would they currently assess datasets, like the patient discharge data and emergency department data, I mean we get a lot of projects looking at that data. And it does include procedures, and diagnosis codes that would be abortion related. Would we -- and like moving forward should we be considering data releases of that data to out-of-state

researchers?

MR. GOLDMAN: Yes, for sure. If the information has -- is abortion-related and it's identifiable, and it's being disclosed out of state, you should certainly consider the potential harms to (indiscernible).

COMMITTEE MEMBER HESS: So that as a board, would we be going back to HCAI and requesting that they create a dataset for out of state?

INTERIM CHAIR DELGADO: Yeah, that's a good point. And actually, what Agnieszka just told me is that this statute, AB 352, was actually brought to CDII's attention from Mike Valle, in the development of the Healthcare Payments Database. So, it sounds like that's something that HCAI's familiar with.

But what I also hear you asking, Katie, is like do we have to go back? Like what about datasets that have already been released? Or data -- or, I guess what you're saying is like HCAI, for example, Jared, has a like 2020 emergency room discharge dataset that are prefixed, that they're releasing.

And so, do we go back and ask them to adjust that dataset for a dataset that was based on information from previous years before this law was enacted?

MR. GOLDMAN: If you're asking me, I don't know the answer to that question off the top of my head. But I'm glad that it's stimulating those questions. And certainly, with respect to individual research projects, we can take a look at that.

COMMITTEE MEMBER LUND: SB 13, the Information Privacy Act, says that we have the authority to ask state agencies under our purview to remove personally identifiable information that we think shouldn't be there. That's actually in the IPA.

INTERIM CHAIR DELGADO: So, I wonder if part of our kind of action items out -- and I don't know if this requires a vote today, for like a motion, but a motion to formally request that pursuant to AB 352 that HCAI remove that data. I don't know if that is -- I'm just throwing it out there as a discussion.

COMMITTEE MEMBER HESS: I say this, so I work with the ED data and we do get -- we do use the identifying information, the researchers do, because they want to look at repeats and patterns. So, we wouldn't want to say that they can't have that identifying information, but there needs to be a way for HCAI to go through and remove cases, whether as a diagnoses, or ICD-10 code relating to abortion services.

So, I don't know what we ask them to do. Remove those cases from the dataset or not release identifiable information to out-of-state entities.

INTERIM CHAIR DELGADO: Yeah, so there's going to be an operational piece here.

COMMITTEE MEMBER HESS: Yeah.

INTERIM CHAIR DELGADO: Dr. Dinis.

COMMITTEE MEMBER DINIS: Yeah, this will be a question of the Committee on medical doctors, right. And so, as we review these projects and having enough information that we would know that the different medical services of these providers, the datasets might be abortions, or it might not be. There might be abortions quote/unquote, because the person had a miscarriage and received services, and that might be thought of as an abortion in some states or something, and others it's a medical procedure necessary.

So, like how would we all be able to pull this apart so we would know, you know, that this information should not be sent here or there. I mean, I guess that's the reason I did worry.

INTERIM CHAIR DELGADO: And I think that's echoed by Dr. Bazzano's comments in the chat, too, where she says: "This isn't entirely easy or obvious. It's going to take resources to develop how we remove" -- but I don't think it's us removing. Like this -- you know, we should -- I wonder, too, again throwing out ideas, form a subcommittee of folks -- working group. Oh, Dr. Bazzano, we are on the same page.

A working group to put out some formal recommendations to our departments that hold this data. Because there's going to be some that don't. But, I mean, obviously, HCAI, Healthcare Services are the ones that pop into mind that would be holding data related to abortion services. So, one though.

Dr. Dickey.

VICE CHAIR DICKEY: Yeah, I don't think we can do it on a project-by-project basis. I think we have to, like you said, work out something with the data releasers so that they have a set of data that doesn't include the abortion stuff, that they have determined doesn't include it, and then a set that does that could be used in California.

Other than that, we're going to have to get rid of it even in California.

MR. GOLDMAN: Let me clarify that this law doesn't preclude disclosures of abortion-related information out of California. It just requires that you consider the

potential harm. And so, there may be a range of other solutions in your toolbox, other than stopping disclosure of the information. For example, including additional conditions.

INTERIM CHAIR DELGADO: Got it. Thank you for clarifying, Jared.

COMMITTEE MEMBER LUND: So, we could --

COMMITTEE MEMBER DINIS: Can I follow up on Jared's question because it's like how do we, as the board members, can really define what the potential harm is, because know the laws of those.

INTERIM CHAIR DELGADO: Yeah.

COMMITTEE MEMBER DINIS: And other web space, whatever, one-by-one, and then (indiscernible) -- and I mean I think that's a big ask of this Committee to assume that we would know all the intricate details of how abortion services, or those things are being handled versus some of the other states.

I mean, we're going to have to know every guideline and regulation of these individual states that don't handle abortion.

INTERIM CHAIR DELGADO: Thank you for your comment, Dr. Dinis.

Laura.

COMMITTEE MEMBER LUND: Yeah, so I think just when we're considering harm, the main harm in the release of the research data out of state, to bonafide researchers, is that that state's law enforcement institutions will subpoena the data or, you know, otherwise gain access to it. Right, that's where the harm comes from.

So, I'm wondering if we could, instead of us trying to do all of this stuff to suppress the data prior to release, if we think it's a bonafide research study perhaps we could ask for an NIH certificate of confidentiality for any out-of-state studies that are requesting access to this information. And then, they would be -- I believe that makes them exempt from subpoena.

INTERIM CHAIR DELGADO: Laura's already building tools for our toolbox. But I think that's a great, you know, option for us to have.

Go ahead, Dr. Dickey.

VICE CHAIR DICKEY: I couldn't totally hear her remarks, but were you saying a certificate of confidentiality, Laura?

COMMITTEE MEMBER LUND: Yes. Yes.

VICE CHAIR DICKEY: I don't know -- you mean the federal one from NIH?

COMMITTEE MEMBER LUND: Yes, from NIH. Because then their data, the data can't be subpoenaed by the law enforcement entities in the state in which the research is being conducted.

VICE CHAIR DICKEY: Well, I think that -- I think we have to look into that. But I think law enforcement is one of those exceptions under the confidentiality certificate.

COMMITTEE MEMBER LUND: Yeah, we'll have to look into that. I think that's only true if there's like immediate harm or danger, but we will need to look into that.

INTERIM CHAIR DELGADO: Go ahead.

COMMITTEE MEMBER DINIS: I kind of like that idea. Because if you think about it, if people are viewing it as a crime I think it could work.

INTERIM CHAIR DELGADO: Yeah.

COMMITTEE MEMBER DINIS: The certificate, I think it could.

INTERIM CHAIR DELGADO: Okay. So, for someone who is smarter than me, smarter thank I, smarter than me, do we need a motion for our workgroup, a subgroup, a subcommittee?

COMMITTEE MEMBER LUND: A subcommittee of three or more requires a public meeting.

INTERIM CHAIR DELGADO: So, a subcommittee of three or more requires a public meeting, so we're looking for a subcommittee of two.

Okay, so we're looking for a subcommittee of two. Dr. Bazzano, I hate to always put you on the spot when things come up for medical questions, but being the lone medical doctor thank you for volunteering.

Is there anyone who would like to join Dr. Bazzano in this effort?

COMMITTEE MEMBER HESS: I will.

INTERIM CHAIR DELGADO: Okay, Dr. Hess has volunteered. So, Dr. Hess and Dr. Bazzano.

Do I need to make a motion for a subcommittee formation?

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: I don't know, we just assigned it. Because we just assigned it. INTERIM C Jared's on the line making sure I'm being super legal.

And that they will pursue exploring implementation recommendations for AB 352.

And just to publicly go on record, appreciate the administration and legislature's efforts in this space to protect individuals of California who seek out abortion services. So, thank you to our legislature, and to our

governor, and to Jared for talking about this concept with us today.

Any other questions for Jared? Oh, go ahead, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: This is not related to the abortion data, but it is related to AB -- oh, sorry. Not related to the abortion data we've been talking about, but related to AB 352. And I probably should have had the good sense to ask this when Mike Valle was still here.

But I noticed in the larger text of AB 352 a reference to California Health and Human Services Data Exchange Framework that was supposed to be effective the end of January this year. And I wondered how that related to the -- what Mike Valle was talking about.

And I sort of wanted to get that question out here because I don't know the answer. Agnieszka, you may, you're sort of shaking your head as if you might.

DR. RYKACZEWSKA: So, I do not know the answer. But to clarify, the data exchange framework is under CDII, so I can read out to my data exchange colleagues and get an answer for the board in writing.

COMMITTEE MEMBER SCHAEUBLE: Okay, thanks.

DR. RYKACZEWSKA: Absolutely.

INTERIM CHAIR DELGADO: But in my data exchange for dummies knowledge, which is very limited, the data exchange is a project to connect electronic health records between entities.

So, for example, if I go to Kaiser and then I have an emergency when I'm in L.A., at a non-Kaiser hospital, they would be able to access my Kaiser records because the systems are connected. It's actually not really a -- I don't know what the reference is here, but in terms of like a general -- it's been a policy initiative that the agency's been working towards to help communication between healthcare systems.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, it seems like a different activity from what you're reading.

INTERIM CHAIR DELGADO: Yes. From what Mike -- yes, it's different from what Mike was talking about.

COMMITTEE MEMBER SCHAEUBLE: Okay. That helps.

VICE CHAIR DICKEY: This is Dr. Dickey.

INTERIM CHAIR DELGADO: Yep, go ahead.

VICE CHAIR DICKEY: It might be related if they were exchanging information outside of the state, you know, wither other states. But that's beyond our purview.

INTERIM CHAIR DELGADO: Awesome.

VICE CHAIR DICKEY: I wanted to ask the question,

is there a motion and, if so, it's certainly this subcommittee, I would say part of should be to work with legal to develop this approach.

INTERIM CHAIR DELGADO: Thank you. We did not do a motion for the subcommittee, but we'll had that to then notes to please request that Drs. Hess and Bazzano consult with legal on this topic as well.

Jared, thank you so much for joining us. Feel free to stay for the rest of the meeting. We appreciate your time, energy and efforts.

MR. GOLDMAN: Thank you very much. And thank you for the invitation to stay, but I'm going to disappear and work on some other things.

INTERIM CHAIR DELGADO: Okay, sounds good.

MR. GOLDMAN: Thanks.

INTERIM CHAIR DELGADO: Okay, moving on to Agenda Item E, acknowledging that we are 30 minutes behind, so apologies. Proposed revisions to the CPHS Policies and Procedures related to Unanticipated Problems. Again, in the vein of closing out items so that they aren't just out there in the ether, this was a topic that we had discussed for multiple meetings about adjusting our policies and procedures when adverse events pop.

So, I'm going to hand it to Dr. Dickey to level set with us. And I know there are some documents that were emailed out, pertaining to this issue. And folks who are in person have a physical copy of it as well.

So, Dr. Dickey, can I hand it over to you.

VICE CHAIR DICKEY: Great. Thanks. So, I -- we originally sent out a proposed revisions of the policies of procedures, in which we just changed the section that had to do with it said the chair, or vice chair, or the primary reviewer could decide that an unanticipated problem would not have to come to the full Committee.

And so, I just sort of inserted that language, but then Dr. Schaeuble pointed out to me that the language in the rest of the policies and procedures needed some correction. So, yesterday we sent out a different version. And so, that's what's being displayed here.

I can't see the whole version all at once. It would be nice if we could.

INTERIM CHAIR DELGADO: Can we maybe --

VICE CHAIR DICKEY: But anyway --

INTERIM CHAIR DELGADO: -- close out the faces and decrease the percentage so we can see it all in one. There you go. Thank you.

VICE CHAIR DICKEY: Okay. Well, I would just point

out that it also includes guidance at the bottom, from OHRP, which says that an IRB is free to develop their own procedures for reviewing adverse events and unanticipated events. So, it doesn't have to be the full Committee reviewing every adverse or unanticipated event.

So, the way this has been changed is to say that the -- for an unanticipated problems, but not adverse events, the chair or vice chair, and the primary reviewer may determine if review by the full Committee is not necessary, and can approve proposed revisions.

However, rejection of proposed revisions can only be made by the full CPHS.

I think this might save us a little bit of time in our meetings if we have more of this done in the background, and not requiring researchers to come to us in person for every unanticipated event.

So, an unanticipated event is something like a protocol deviation that doesn't result in any adversity. An example would be the last meeting they had one where they used the wrong measurement in a report, milligrams versus micrograms or something like that.

So, this would prevent us from having to have that occur. So, any reactions to this language.

INTERIM CHAIR DELGADO: Great, thank you so much for the summary and for even providing the OHRP reference at the bottom.

So, what I hear you saying is that the tweaks in the language, the additions in blue underlined, and the strikethroughs in red, then provide the option for chairs, vice chairs, or the primary reviewer to deem it unnecessary to come to full Committee. So, thank you.

I have no questions or comments. I would be in support of this, personally, but would love to open it up for others' thoughts.

You can raise your virtual hand. Okay, seeing none. No comments in the room.

Okay, so if someone has -- Dr. Dickey, since this was your -- you led this effort, would you like to make a motion for us, please.

VICE CHAIR DICKEY: Yeah, I would move that the Committee adopt the changes in the wording for dealing with adverse and unanticipated events in the policies and procedures.

INTERIM CHAIR DELGADO: Okay, we have a --

VICE CHAIR DICKEY: And I'm not going to read it -- oh.

INTERIM CHAIR DELGADO: Okay, we have a motion. Do

we have a second? Ms. Lund seconded.

So, Sussan, if we could have roll call, please.

MS. ATIFEH: Sure. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: App --

INTERIM CHAIR DELGADO: That was an approve from Dr. Bazzano.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve. Are you able to hear me?

INTERIM CHAIR DELGADO: Yes, great. Thank you.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: 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: Wonderful, the motion was passed. Dr. Dickey, thank you so much for taking on this effort to help expedite the work of the board, appreciate it.

Okay, moving on. Still 25 minutes behind. Okay, update on Vital Statistics Advisory Committee applications.

So, just as some background, and Laura, I'm going to already give you a heads up to use you as subject matter expert when we're discussing this topic. For those that don't know, Ms. Lund used to oversee that entire program.

So, in terms of CDPH, so within Department of Public Health there is a division called the Vital Statistics Advisory Committee. That committee has a requirement that researchers renew their approvals every five years.

We, as the board, and our administrative staff, and Laura have been doing a lot of outreach to CDPH and VSAC to determine the process for ensuring that when the researchers ask for continuing reviews from us that they have fulfilled the CDPH/VSAC requirement to get their renewals every five years.

And so, there has been a lot of conversation and dialogue over the past probably four months, four or five months.

COMMITTEE MEMBER LUND: More than that.

INTERIM CHAIR DELGADO: More than that. To try to align procedures on this issue.

Recently, in the last two weeks, CDPH/VSAC has let us know that due to resources they are not able to address our request, which is specifically to ensure that they are communicating to us and approving those five-year renewals in collaboration with, or in parallel track to, the continuing reviews that we are completing.

And so, given CPHS's limited resources it's really difficult for us to be digging through protocols to align dates. And apparently, through CDPH, they do not have the bandwidth at this time either.

And so, this is a topic that we've been discussing offline a bit and wanted to throw out for the group. Because one of the potential solutions that we've talked about is adding onto the IRBManager a self-attestation from the researcher that says that they have made CDPH/VSAC's five-year renewal requirement as part of their continuing review.

So, that was like one of the solutions that we could possible come to, but given that this is an issue that I think all of us have faced from time to time in the protocols that we're reviewing wanted to address it with the group. See if there's other ideas or comments.

And so, I'll pass it over to Laura.

COMMITTEE MEMBER LUND: And just to add on, because I think some of this actually started before you came back as Chair. So, the group --

INTERIM CHAIR DELGADO: Grab your mic.

COMMITTEE MEMBER LUND: Thank you. So, the group -- the group may remember that we had a major adverse event, about a year and a half, or two years ago where we discovered that researchers were releasing Vital Records' birth data to other researchers, and had been for years, and hadn't told us about it, hadn't told VSAC about it. And that led to us taking a look at what our procedures are around Vital Records data and how long some of these studies go.

Which means that a lot of times the people who originally got the data, even if they did understand the rules at the time, passed those data on to other people, there's a new PI, there's new staff, and they don't know the rules anymore. And all of the sudden Vital Records data are rogue in the community.

So, what we decided a while back, as the Committee, and it came before the Committee because Dr. Dickey, and Dr.

Ruiz, and I had talked to the L.A. folks and we had an adverse event, that we would ask for Vital Records -- for research projects using Vital Records data, that every five years when they come back to us to renew the project we want to see that they've gone to VSAC to make sure that they are -- they continue to be aware of the rules around the data, which they very often are not. I just want to say that one more time.

And that if there have been any changes to the study that they haven't told VSAC about, that that gives the opportunity for them to align their VSAC, their CDPH/VSAC applications with ours.

Because a lot of times what we've found in doing all of the investigative review is that when they come to use for continuing review or for amendments to those applications, they haven't told VSAC. They haven't told VSAC or their project staff, they haven't told VSAC that they're doing things with the data that, you know, they were originally approved by VSAC for one thing, and now they're doing something else which we approved them for, but VSAC didn't.

So, having them go back to VSAC every five years will help with some of the problems around Vital Records data.

But what happened as a result of that, it was really good, we're finally aligning our procedures with state law, and with VSAC requirements it significantly increased the burden on our CPHS admin staff. Right. We've got a small staff.

INTERIM CHAIR DELGADO: We have one person as the staff at CPHS, right.

COMMITTEE MEMBER LUND: And it increased the burden. So, we were -- and Sussan brought that to the Committee and we were exploring ways to try to continue to make sure that we're scrutinizing these applications and that the researchers are doing the right thing, while also not completely overwhelming our own staff.

And so, we asked CDPH to work with us on this to see if they would be willing to do what we are doing in terms of the five-year scrutiny and triggering, you know, a reapplication when necessary. And providing us with information on protocols that may be coming up on that five-year deadline so that our staff could be proactive in working with them.

And I'm looking at Sussan to make sure that I have all of this correct, because it's been several months since we visited this.

So, back to what Darci was bringing to the Committee is that CDPH is unable at this time, unable question mark, at this time to assist us in providing some of the information that would help our Committee staff be more proactive and more time efficient in being able to get in touch with the researchers who need their five-year review. Yay, I got it right.

So, at this point I'm not sure what it is that we can do, and now this is for Darci, I'm now looking at Darci, I'm not sure what there is we can do as a Committee.

I do think that now that we're finally on track with making sure that we're complying with state laws around the Vital Records data, I hate for us to back off from that.

But no the other hand, I don't want to overwhelm our staff. And if CDPH isn't able to trigger, you know, these reminders, or they were not even willing to put our statement on their website for researchers, they just don't have the time or bandwidth to do it.

So, I'm not sure that there is a solution. I want to be sensitive to what our admin staff might need in terms of help and support with that. That's it.

INTERIM CHAIR DELGADO: So, how did you feel about the self-attestation addition. Do you think that is useless or like not doable?

COMMITTEE MEMBER LUND: So, I think that the self-attestation is -- and we addressed it, a couple different versions of this, like six or eight months ago. And I think that it would help, but only if it's broken down that they have to sign off on each of the elements. Because just asking them to a check a box saying, yeah, I read it, is a waste of time. There isn't any notice because they're just going to check it. Like, you use the thing that say I accept. So, they won't do it.

(Laughter)

COMMITTEE MEMBER LUND: But I do think it's important because a lot of them, once they read through it they go, oh, I wanted to do that and now I'm not going to. Like we constantly get these requests for linkages and passing data on and it's like, oh, it specifically says I can't do that.

So, I do think it would help. I do still think that we need the five-year, to ask them for the five-year continuing review. But I also think that we had discussed, but it never got (indiscernible) by the Committee, I think it's okay for us to -- and this is for the Committee to discuss, one of the things that we had instituted was that we needed to have the approval from VSAC before we move

forward as the Committee to approve their continuing reviews. And that was hanging you guys up, I'm looking at Sussan, admin staff up.

But as long as we know that they have applied, I think that we could review in the same way we do now, right, and then pending the receipt of the letter of receipt and approval from CDPH/VSAC, and then they would get their final approval.

MS. ATIFEH: Yes.

COMMITTEE MEMBER LUND: And then, they would get their final approval. And that would make it quicker for you and quicker for them. So, I don't think we always need, in the cases of the continuing review, to have that final letter in hand for us to review and approve, as long we know that they've gone -- they're going through the approval process and will get it.

So, anyway, that's just my two cents on that. Okay.

COMMITTEE MEMBER JOHNSON: Is this something that -- is this something that would be related to like the future planning of common app that we would be able to --

THE REPORTER: I need you to speak up a great deal more.

COMMITTEE MEMBER JOHNSON: All right. Is this something that would be incorporated into the future planning of a common app.

DR. RYKACZEWSKA: I can speak a little bit to that. That is one of the pieces that we're really trying to think about as we're -- we're still very much in the early stages of building upon that work.

But one of the goals is that this is a centralized place where the information sits and so we could see, for example, once CDPH and VSAC, or component of the common app, we could see whether they've actually applied.

And more than that, the common app would guide them to apply, so that they would know that that was due, that that was something that we required of them. And basically, they wouldn't be able to proceed through the process without taking that step because it will be all part of one system that talks to each other.

So, not to replace CDPH's current systems, but rather to get those systems to talk to each other and send researchers through that process as part of the department-specific addendums to their own app.

So, essentially, if they indicate they're wanting to use or that they are using birth and death records that would automatically trigger the system to say, okay, now

we're going to have to you through the VSAC application. Here's where you go, here's where you fill out.

And once they've filled it out that would feed back to the common app system to say, yes, they've gone through that.

That is the intention. Of course, we're still building it, so I can't promise that it will work that way, but that is what we're trying to do.

MS. ATIFEH: Can I -- I just wanted to clarify that the biggest hurdle to added workload is when we have to compare the revised VSAC application with our application. That's the time consuming part.

And especially when you or our own members require some revision, again they have to go and, you know, before VSAC and provide a non-revised VSAC application. That's the very time consuming process. And especially, you know, we are not familiar with their application.

So, do you believe it's the job -- we, as staff, are required to ensure they match perfectly before assigning to the Committee members or, no, the primary reviewer can make that decision?

COMMITTEE MEMBER LUND: So, for me, I always look at those things with a fine tooth comb. Because I know that I have had the experience of researchers not having them match. So, I'm going to do that work.

So, I would -- for me, and I don't know about any other members, but for me I would be happy to have you guys just make sure that a revised application is there as part of the package, for me to take a look.

So, that would be all that I would ask because I'm going to do the comparison, even if you've already done it.

MS. ATIFEH: So, do you have any suggestion for others, other Committee members?

COMMITTEE MEMBER LUND: So, I'm interested in hearing from other Committee member what their thoughts are and whether or not they're -- you know, they feel the same way about it. That's just me.

MS. ATIFEH: Okay, thank you.

COMMITTEE MEMBER VENTURA: I was looking at a proposal that did have a VSAC application attached to it, and I also did a thorough review of that, making sure they were asking for the same data finds and the same research questions that they submitted to our Committee.

So, I think that is something that should be on the reviewers to do, not necessarily the staff. It helps to have the VSAC application and, certainly, I'm looking for also the letter once that does come through. But the

review, I think, falls on us.

MS. ATIFEH: The primary reviewer of the project?

COMMITTEE MEMBER VENTURA: Correct.

MS. ATIFEH: Okay.

INTERIM CHAIR DELGADO: So, what I hear is multiple comments -- as the mic is getting passed to Dr. Schaeuble, what I'm hearing is multiple comments that it's duplicative for staff to do a side-by-side review. And instead, potentially pivoting to staff only, making sure the document is there and deferring the side-by-side review to the primary reviewer. Just to summarize Dr. Ventura and Ms. Lund's comments.

Go ahead, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: The only thing I would add to that is in looking at the VSAC application and our application it's been easy to try to compare to see that the data request, themselves, is the same.

I have experience that the VSAC application does not necessarily show the full text that the researcher had submitted in their application in our describe the research question and procedures.

So, truthfully, I think I've just sort of glanced at those parts to try to make sure that they are consistent with our application. But I wouldn't be able to ensure that everything was the same from what I've been able to actually view when this came up.

COMMITTEE MEMBER LUND: So, it depends on how the researcher has chosen to truncate the VSAC application. And if they just say that -- there's a way that they just say that we're truncating all of that text. I always make them submit a new one so that I can see the full text of the thing. That's just a thing that I ask them for. If they submit it to me truncated, I just ask them to resubmit the whole thing.

COMMITTEE MEMBER SCHAEUBLE: Okay. Didn't know there were two versions of that.

COMMITTEE MEMBER HESS: I didn't either. That's okay.

COMMITTEE MEMBER LUND: Yes. It depends on how they save it. And I'm not conversant enough to do be able to do the tech support for them on that. I just tell them I need to see the whole thing, and they resubmit it.

INTERIM CHAIR DELGADO: Dr. Dickey.

VICE CHAIR DICKEY: Yeah. I agree with -- can you hear me?

INTERIM CHAIR DELGADO: Yes.

VICE CHAIR DICKEY: I agree with Dr. Schaeuble that

it's really hard as a reviewer to do a crosswalk between VSAC and our -- what we're approving.

I, personally, don't know that I can do that. But maybe Laura can because she's much more familiar with VSAC data than I am. And I think probably other Committee members.

I mean, so I can see requiring them to attach a copy of their VSAC applications, but it really up to VSAC, then, to determine whether we've approved what they are going to approve.

And rather than us taking that on ourselves, if we're approving it before VSAC does, then VSAC should be looking at what we've approved to make that it's on their application.

INTERIM CHAIR DELGADO: We hear you in theory, and also can't tell VSAC how to do their job, although not disagreeing.

Laura, do you have any response to that? Laura just looks like she has a response, so --

COMMITTEE MEMBER LUND: I'm just going to say that I have seen too many researchers who submit somewhat different things. And I know that it doesn't always get caught during the CDPH/VSAC process.

And so, I just want to make sure for me, on the projects that I review, that VSAC has the same understanding of how those data are going to be used when they're released that we do, and approved. So, that's it.

And I know that they do look at the CPHS protocol but, I don't know, I just have seen too many differences to feel comfortable about it.

INTERIM CHAIR DELGADO: I wonder if part of this, too, for future meetings, not necessarily for June, but for future meetings, if we have like a de-identified packet that we can share and you could do a ten-minute tutorial for the rest of the Committee members on flags, things to look for. Helpful hints, like, hey, don't send me the truncated version. If you're willing.

COMMITTEE MEMBER LUND: Sure, I would do that.

INTERIM CHAIR DELGADO: Let the record note that Laura said, yes, sure, she would do that.

So, I don't know if we need a motion on this. It's more so like kind of administratively how we're doing our work flow. But what -- and I'll summarize, again not for a motion, but just for work flow related issues.

That Ms. Lund will be helping at a future meeting of a walk-through of helpful hints and tutorials. But that administratively our admin staff will be looking for

letters, looking for applications before it's sent to primary reviewers. The onus will fall on the primary reviewer to do the side-by-side. With outreach to Ms. Lund in the next month or two, if necessary, to help.

COMMITTEE MEMBER LUND: And I would say that it is really up to the comfort level of the reviewer. Right. So, the side-by-side comparison I think is really up to the individual and the data project that's at hand and --

INTERIM CHAIR DELGADO: True.

COMMITTEE MEMBER LUND: -- what concerns it might trigger, and that kind of thing. Like, I wouldn't want to be too prescriptive about it.

INTERIM CHAIR DELGADO: Got it.

COMMITTEE MEMBER LUND: You know, and what I might do would be perhaps (indiscernible) --

INTERIM CHAIR DELGADO: Okay. Understood.

VICE CHAIR DICKEY: Can I just ask -- I'm sorry.

INTERIM CHAIR DELGADO: Yeah, go ahead.

VICE CHAIR DICKEY: I'm trying to keep in mind everything. And so, what is this going to be the -- and do we need a motion?

INTERIM CHAIR DELGADO: Nope.

VICE CHAIR DICKEY: I mean, are we changing our expectations now at all?

INTERIM CHAIR DELGADO: We are not having a motion, unless anyone disagrees. Feel free to disagree.

But in terms of just administratively on the back end how our admin team will be processing these applications, the expectation is getting tweaked a bit because the admin staff will not be doing the side-by-side comparison any longer because it does sound that -- to some degree that was duplicative of what the primary reviewer was doing.

But our admin staff will be continuing to confirm that letters and applications are attached to the protocols before it is sent to the primary reviewer.

VICE CHAIR DICKEY: And the expectation is the primary reviewer will do the crosswalk?

INTERIM CHAIR DELGADO: The primary reviewer, again without being too prescriptive, depending on the risk level of the project, the amounts, the dataset itself, all of the concerns that we waive for every project will do a comparison to the level that they feel comfortable with as the primary reviewer.

And should anybody need any help with that, Laura has volunteered to in the coming weeks, before her presentation.

VICE CHAIR DICKEY: I think as long as the word to the extent that they feel comfortable with it. Because I don't -- I think we're all going to have different levels of expertise and comfort.

INTERIM CHAIR DELGADO: Yes.

VICE CHAIR DICKEY: And as long as it's understood that it's the comfort of the primary reviewer.

INTERIM CHAIR DELGADO: Got it, comfort of the primary reviewer.

Okay. So, no motion necessary on that. Any other questions or concerns?

Hearing none. Okay, we're moving through the agenda, guys. I promise to all of those who are waiting, we're getting to you. So, thank you so much for your patience.

Okay, Agenda Item G, a review and approval of the meeting minutes from February 2, 2024. Will note we do not yet have the meeting minutes ready for the March meeting, so this is only a vote on approving the meetings minutes from February 2nd.

So, do we have a motion?

VICE CHAIR DICKEY: I move adoption.

INTERIM CHAIR DELGADO: Okay, we have a motion from Dr. Dickey to -- a motion to approve the minutes.

Do we have a second?

COMMITTEE MEMBER HESS: Second.

INTERIM CHAIR DELGADO: Dr. Hess seconded.

So, Sussan, if we could get a roll call, please.

MS. ATIFEH: Sure. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Thank you. Dr. Dinis?

COMMITTEE MEMBER DINIS: 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: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great, the motion passed. Wonderful.

So, let us move into talking about projects. So, first we will review adverse events. We have two adverse events and two amendments before we move into new projects.

Dr. Palacio, if I could hand it to you, to intro us for the first adverse event for Protocol 2023-057.

COMMITTEE MEMBER PALACIO: Yes, thank you very much. And Dr. Lery, would you introduce yourself and your team, as well as give us an overview of the event that happened, and what you did to mitigate it.

DR. LERY: Good morning, everyone. I'm Bridgette Lery, a co-principal investigator for the Evaluation of California's Guaranteed Income Pilot Program. And I'm here with my co-PI, Sarah Benatar.

And the event that occurred was that a program partner sent an email list of young people in the -- or for the program. And the list was not minors, it was people over the age of 21. It included names. And that's not part of the protocol.

The program staff in all of the pilots, all of the pilot sites have been instructed to not send an PII to the evaluators in any form. We're not sending PII at all.

And so, it was an error. And it also went through -- the program partner is a city government agency, and so they have an encrypted email system. So, you have to actually log into their encrypted email system to even open the email.

So, two individuals on our team did open the email and see the list, and then they immediately followed Urban Institute's IRB protocol to destroy the data and destroy the emails. And reported it to our IRB and then we reported it to you all.

Is there anything to add, Sarah?

DR. BENATAR: I think that covers it.

COMMITTEE MEMBER PALACIO: So, in respect to my question, in our earlier conversation, my questions were are existing procedures sufficient to prevent this from happening again.

DR. LERY: Yes, we believe that's the case. It was just sort of a misunderstanding. And we reiterated to the sites, as well as CDSS, to remind all of the sites to not sent PII in any form to the evaluation team.

COMMITTEE MEMBER PALACIO: And are these procedures in writing or should they be strengthened?

DR. LERY: I think they have sufficient. We have in our IRB protocol that's PII to be shared.

COMMITTEE MEMBER PALACIO: Okay. I'll turn it over to the Committee to see if there are any questions.

INTERIM CHAIR DELGADO: Okay, anybody in the room with questions for the research team?

I had one question, Dr. Lery, just to clarify. So, when I -- just to make sure I understand correctly that the email was over an encrypted platform? And you're nodding your head yes, okay.

DR. LERY: Right. Right.

INTERIM CHAIR DELGADO: Yes. Thanks, that was my only clarification question.

Others? Seeing none in the room, any members on Zoom? I see Dr. Ruiz came off and Dr. Dickey.

VICE CHAIR DICKEY: I guess my question to the Committee would be in light of the previous session about the policy and procedure, could this be something that the Committee might consider to be an unanticipated problem and they could be dealt with without coming to the full Committee?

COMMITTEE MEMBER PALACIO: I was thinking the same thing. It does seem like a problem that could be easily resolved.

INTERIM CHAIR DELGADO: Can we actually --

COMMITTEE MEMBER PALACIO: Without bringing it to the Committee.

INTERIM CHAIR DELGADO: Sorry. That's a great question. Can we close out, first, what we want to do with this adverse event before talking about future --

COMMITTEE MEMBER LUND: Yes, I'll hold my comments until we do that.

INTERIM CHAIR DELGADO: Okay. So, yes, that's a great question, but if we could just close out this adverse event.

Any comments or questions specific to this adverse event before we ask Dr. Palacio to make a motion?

Okay, Dr. Palacio, if you wouldn't mind making a motion.

COMMITTEE MEMBER PALACIO: Yes. I move that we accept the efforts made to mitigate this adverse event as acceptable.

INTERIM CHAIR DELGADO: Okay, so the motion is to accept the efforts and close out this adverse event.

Do we have a second?

COMMITTEE MEMBER VENTURA: Second.

INTERIM CHAIR DELGADO: Seconded by Dr. Ventura.

Sussan, if we could have a vote, please.

MS. ATIFEH: Sure. I ask, firstly, Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: (No audible answer.)
MS. ATIFEH: Dr. Bazzano?
COMMITTEE MEMBER BAZZANO: Approve.
MS. ATIFEH: Thank you. Dr. Dinis?
COMMITTEE MEMBER DINIS: Approve.
MS. ATIFEH: Dr. Hess?
COMMITTEE MEMBER HESS: Approve.
MS. ATIFEH: Ms. Lund?
COMMITTEE MEMBER LUND: Approve.
MS. ATIFEH: Dr. Schaeuble?
COMMITTEE MEMBER SCHAEUBLE: Approve.
MS. ATIFEH: Dr. Johnson?
COMMITTEE MEMBER JOHNSON: Approve.
MS. ATIFEH: Okay, the motion passed.
INTERIM CHAIR DELGADO: Great. So, the motion is passed. For the PI team, you will receive notification of this that the adverse event is -- your steps taken afterwards to mitigate the circumstances is approved.
Now, I would love to -- so, thank you, Dr. Lery, to you and your team.
Because we just talked about amending our policies and procedures for exactly this event, it's a great opportunity to say, hey, what would folks have done in this case.
So, what Dr. Dickey just said was in his opinion this is something in the future that he believes should not have to come to the board. But Laura had a comment in response.
COMMITTEE MEMBER LUND: So, the devil's in the details on this one. Because -- because it involves the potential disclosure of personally identifiable information, I would have said this would come to the board because it had the potential to harm participants. So, that would have been my call on that.
INTERIM CHAIR DELGADO: Okay. Go ahead.
COMMITTEE MEMBER JOHNSON: I just wanted to say that I agree. I think it's kind of a split. This was a difference from the standard protocol that was approved, which I think would be an unanticipated event. But since it was the specific release of personally identification that that qualifies for an adverse event.
INTERIM CHAIR DELGADO: Thank you. Others' opinions? Dr. Dickey.
VICE CHAIR DICKEY: First off, I didn't say that I thought this should be.
INTERIM CHAIR DELGADO: Oh, sorry. Let the record be clarified that I spoke incorrectly for Dr. Dickey. My

apologies, Dr. Dickey.

VICE CHAIR DICKEY: No, I just wanted to get a sense --

INTERIM CHAIR DELGADO: Yeah.

VICE CHAIR DICKEY: -- because if the chair, the vice chair, et cetera, are trying to make these determinations, it would be good to get a sense from the Committed what they consider it to be.

Unfortunately, most of -- most of these unanticipated problems involve some sort of information, possibly information breach. And if that's the standard we'll use, then they're all going to be coming to the Committee. So.

INTERIM CHAIR DELGADO: Okay. Well, I think also just to open it up for folks, you know, as we are implementing this new effort to the policies and procedures, don't ever hesitate to reach out to the chair or vice chair to get second and third opinions on things.

Dr. Ruiz, I saw you came off mute. Was there anything you wanted to add? No. He said, "No, I don't think so."

Okay. Great. So, let's move on. Dr. Ruiz, I'm going to hand it over to you to -- thank you, Dr. Lery to you and your team for attending today.

Dr. Ruiz, I'll hand it over to you to review the adverse event on Project 2022-128.

COMMITTEE MEMBER RUIZ: Thank you. Is Dr. John Pugliese on the call?

DR. PUGLIESE: I am present.

COMMITTEE MEMBER RUIZ: Hello.

DR. PUGLIESE: Hello, hello.

COMMITTEE MEMBER RUIZ: Would you please introduce yourself and anybody else to the Committee?

DR. PUGLIESE: Sure. My name is John Pugliese.

(Indiscernible.)

INTERIM CHAIR DELGADO: Sorry, sorry. One second. I'm going to interrupt you just for one second.

Dr. Ruiz, if you could mute yourself, I think that's what's causing the double echo on Dr. -- Dr. John. I'm not sure, Dr. John, how to pronounce your last name. It's a little intimidating.

DR. PUGLIESE: John Pugliese.

INTERIM CHAIR DELGADO: Do you want to try again.

DR. PUGLIESE: Yeah, I'd be happy to. My name is John Pugliese. I'm the --

INTERIM CHAIR DELGADO: Nope, sorry. I'm going to ask you to stop again. Sorry about that. Do you have like

multiple, maybe, calls in on your phone and your computer?

DR. PUGLIESE: No.

INTERIM CHAIR DELGADO: Is it up in the room. Is it us in the room that's causing the double echo?

MR. ZADROZNA: Here, let me mute the -- here try to talk. I'm going to mute us and see if we don't hear the echo when you talk.

DR. PUGLIESE: Am I echoing?

MR. ZADROZNA: Unfortunately, you still are.

DR. PUGLIESE: That's unfortunate.

(Indiscernible.)

MS. MUHAMMAD: Maybe he should call in.

INTERIM CHAIR DELGADO: Okay. Can you maybe log out and then log back in, or maybe call in? Or, I don't know if anyone else on your research team wants to try to step in.

MR. ZADROZNA: He's trying to call in.

INTERIM CHAIR DELGADO: Oh, you're trying to call in.

(Short pause.)

INTERIM CHAIR DELGADO: He's going to have to be unmuted on Zoom.

MR. ZADROZNA: He already muted himself.

INTERIM CHAIR DELGADO: But like his call in?

MR. ZADROZNA: He'll be unmuted on his phone, no problem.

INTERIM CHAIR DELGADO: Okay.

DR. PUGLIESE: Hello. Can you hear me now?

INTERIM CHAIR DELGADO: It's better. I don't know if you're like calling in from -- I don't know where you're calling in from, but you've got lots of echoing.

MR. ZADROZNA: Oh, I've got an idea. Let me us the mic and see that's it.

DR. PUGLIESE: Okay, hold on.

MR. ZADROZNA: All right.

DR. PUGLIESE: There we go, is that better?

INTERIM CHAIR DELGADO: Yes. Great, go ahead.

DR. PUGLIESE: Excellent. Excellent. I'm so sorry, but I'm glad we were able to overcome this technical challenge.

My name's John Pugliese. I'm a scientist at the California Department of Public Health and the PI for the California Family Health Study, which is a study of low-income Californians who are eligible for the CalFresh Healthy Living Program.

We were informed of a -- did you want to go beyond that? Oh, I'm joined today by the Director of our CSUS

contractor, PRC, Tina Fitzgerald. And the Operations Manager within -- who runs the protocol, and runs the survey, and recruitment process, Jessica Gollaher.

Did you want me to explain the issue?

INTERIM CHAIR DELGADO: Yes. Great.

DR. PUGLIESE: Okay, I'll keep going. So, we were informed of a deviation from protocol on February 5th. The deviation, just to kind of put it -- so, we mail out recruitment packages to recruit individuals into this study. These mailers are stuffed in envelopes and mailed out.

We had two recruitment packages where the label on the outside of the package did not match the name on the letter that was stuffed into the envelope. Those letters, themselves, do not provide any information with respect to how the household became eligible for participation. Rather, they're just a letter asking -- recruiting them into this study and providing information on how to participate in the interview, what incentives for participation are available, and instructions for other materials that are also included in the package. Which includes things like a tape measure, a food model booklet, measuring cups, et cetera.

Our review of the incident suggested that it was due to potential inattention in stuffing those envelopes. And this was really discovered through the recruitment, the follow-up recruitment process, making phone calls, follow-up phone calls with the participants. One participant indicated that they were happy to participate. Another participant was contacted, but unable to have a discussion at that time about recruitment or receiving a letter with someone else's name, essentially.

COMMITTEE MEMBER RUIZ: Okay.

DR. PUGLIESE: And in terms of reviewing the protocol with the staff that are employed by PRC, we reviewed the protocol, we reviewed the importance of confidentiality. Staff members were -- some staff members were rotated out of doing that work.

And we believe it's a relative -- we believe it's an isolated incident.

INTERIM CHAIR DELGADO: Got it. You might need to mute yourself. Okay, thank you.

Thank you for your summary of the events. Dr. Ruiz, any comments, as the primary reviewer, of this adverse event before we open it up to the Committee members.

COMMITTEE MEMBER RUIZ: I don't really have any comments and I believe that the PI explained or managed the protocol deviation correctly. I don't know if any of the

other members may have questions or concerns.

INTERIM CHAIR DELGADO: Okay, looking in the room for any questions or concerns. Seeing none, any on Zoom. Any members on Zoom wants to unmute yourself and comment? Okay, seeing none, Dr. Ruiz can we have a motion, please?

COMMITTEE MEMBER RUIZ: Yes, I move approval of the way the PI and his team has managed and resolved the protocol deviation for Study 2022-128.

INTERIM CHAIR DELGADO: Okay, thank you for the motion. Do we have a second?

VICE CHAIR DICKEY: I'll second.

INTERIM CHAIR DELGADO: Great. Thank you, Dr. Dickey. We have a second.

Sussan, if we could do roll call, please?

MS. ATIFEH: Sure. Okay, I will start with Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Thank you.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Thank you.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Abstain.

MS. ATIFEH: Abstain, okay.

Yeah, the motion passed.

INTERIM CHAIR DELGADO: Okay, great. Thank you so much, Dr. John. Thanks for coming today. Thanks for talking about your project.

Maybe we'll pause for a second, as we did the prior adverse event, any thoughts about how we would potentially review this in the future? Anyone feel strongly?

Dr. Ruiz, do you think, do you believe this was something to come to full Committee?

COMMITTEE MEMBER RUIZ: I don't believe that it needed to come to full Committee. I think it could have been reviewed and approved by the -- you know, the member of the board assigned to this project.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER RUIZ: So, that's my take on this.

INTERIM CHAIR DELGADO: Good food for thought. Anybody else feel strongly?

COMMITTEE MEMBER DINIS: I just had a thought. You know, like in a lot of projects we have like two people that do it, you know, the IPAs. Would that be another way to do this one? Like we just have like, let's say, the vice chair or the chair, and somebody else on that committee, subcommittee.

COMMITTEE MEMBER RUIZ: Uh-hum.

COMMITTEE MEMBER DINIS: As a way of (indiscernible) adverse events. And then, most all of them must be, you know, the Committee should see. Sorry.

VICE CHAIR DICKEY: No, I think the language in the policies and procedures we just looked at, I think it says the chair or vice chair and the primary reviewer.

COMMITTEE MEMBER RUIZ: The PI.

VICE CHAIR DICKEY: So, that would be --

INTERIM CHAIR DELGADO: I think what Dr. Dickey said, Dr. Dinis, is exactly what you just described in terms of in some ways like a subcommittee review of multiple individuals. What you described, Dr. Dinis, is consistent with what we just approved in the change to policies and procedures.

COMMITTEE MEMBER RUIZ: Uh-hum.

COMMITTEE MEMBER DINIS: Yeah. Yeah, thanks. Thank you.

INTERIM CHAIR DELGADO: Awesome. Okay, thank you so much to that research team. Let's move on.

Dr. Dickey, I'm going to hand it to you to talk about the amendment for Protocol 2021-219.

VICE CHAIR DICKEY: Okay. Is Dr. Haynes on the Zoom?

DR. HAYNES: I'm here. Hi, Dr. Dickey.

VICE CHAIR DICKEY: Hi. This is an unusual situation. The Committee may be aware that, you know, it's not just the Common Rule and it's not just the IPA, but at various times, in various places, the state legislature has passed statutes that require our approval, unrelated to the Common Rule, unrelated to the IPA.

And apparently, back in 1989 they passed a law that basically said that county coroners could provide samples, tissue samples for research on SIDS, without consent from the parents or the guardians of the child.

This went on for some time until I guess about a year, two years ago. The San Diego Board of Supervisors whose -- and the Sand Diego Coroner was cooperating in

research with researchers in Boston, Dr. Haynes.

And the Board of Supervisors said, wait, you didn't get approval from the Committee for the Protection of Human Subjects.

So, Dr. Haynes came to us, I don't know, I think it was about a year and a half ago. And we discussed this project and we approved it without informed consent or consent from parents. Because the law explicitly states that you don't have to get consent from the parents if there's not going to be any visible defamation of the child's body. And the coroner sent us a letter saying that there wouldn't be any.

And there was also many letters, several letters from parents of SIDS patients saying they thought having informed consent would be a barrier to research and they wanted to do everything that would help with research. So, we approved it on that basis.

And one of the whole -- the board of supervisors, I guess, in San Diego has decided they want informed consent. And that they will not allow the release of these tissues without consent. So, Dr. Haynes is back to us, now, with a proposal about how to get this informed consent.

Before we go on and hear her approach to this and solution, any questions from the Committee about the situation?

INTERIM CHAIR DELGADO: One question in the room.

COMMITTEE MEMBER LUND: Hi, Dr. Dickey, so my -- now is it on. Okay.

VICE CHAIR DICKEY: I can hear you.

COMMITTEE MEMBER LUND: So, I remember this project and I remember the very good reasons that were presented for not having to go to the parents for informed consent.

I just have a question and this may be part of what you're going to present. Is it possible for this Committee to just provide a waiver of informed consent? Would that satisfy the board of supervisors.

VICE CHAIR DICKEY: No, I don't believe so. But I'll ask Dr. Haynes --

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: -- because she's been in contact.

DR. HAYNES: Hi everyone. Thank you for having me back. And also on the phone is Elizabeth Haas, who works in California.

And, yes, that was a great summary, Dr. Dickey, thank you. But to answer the question that just came up, you actually did give us a waiver of consent a year and a

half ago. We were approved with a waiver of consent. And we went immediately to the board of supervisor with that waiver and they basically said it doesn't matter. They want consent no matter, regardless of the waiver of consent.

So, for that reason we're back here, now, looking to not revert, but just now add on the ability to get consent from families. Because otherwise, we can't do the research. The research has been stalled, now, for three and a half years. And, you know, we went back and forth with the board of supervisors, we had families petition them, write letters to them, and none of it has mattered.

So, yes, I would love to have a better answer to your question, but I do not.

VICE CHAIR DICKEY: So, we are -- what we can do is try to approve a method of consent that may not comply with all of our -- you know, the requirements under the Common Rule, since we're not reviewing this under the Common Rule, but that still would satisfy consent and be practical, and doable according to the researchers.

So, Dr. Haynes, why don't you show us what you -- you know, what we've come up with.

DR. HAYNES: Do you want me to show you the screen shot or --

VICE CHAIR DICKEY: Or could you just go ahead and demonstrate. They should have it. We may want to display it. It's a one-page sort of document. But, actually, why don't we -- I want to ask if the Committee -- if the staff would display the consent form. There's two consent forms. They're basically the same. One for -- well, depending on who's doing it. We could just see one of them.

DR. HAYNES: Right. So, while that's being brought up, I can give you a summary.

So, Elizabeth and I have worked closely with the medical examiner and he has worked closely with the board of supervisors to come up with what we think everybody is going to be onboard for, which is really important, before I came to you. I needed to make sure that you are going to approve with it.

But what we've come up with, there's two different possibilities. And our first possibility, what we think will happen is that we'll work directly with LifeShare Donation Services, who has a lot of experience talking to very acutely bereaved families. And that's the problem, we have to get consent within 24 to 36 hours after the infant death. Which, as you can imagine, is really difficult for everybody involved.

But they are really experienced with this. So, you

know, they're onboard to help us get consent in two situations. The first situation would be, you know, the infant qualified for tissue donation, which is what they typically do, they get consent for tissue donation.

And at that point they would ask for tissue donation consent and then follow that with the request for SIDS research consent. So, they would do two different things.

And then, you know, alternatively we had a little bit of problems recently that -- and possibility that that might not work out with them. And last resort, one of the research staff will be trained how to get consent. Possibly from them, they're willing to train us on how to do it, and then approach the families ourselves.

Which, you know, again that is our last option. I would really like to go through the tissue donation service, if possible.

And I can walk you through -- what we submitted was a print for either them to use or for the research staff to use. And I can walk you through that, if you wanted me to.

INTERIM CHAIR DELGADO: Yes, wonderful. We're just --

VICE CHAIR DICKEY: Well, so the script is --

INTERIM CHAIR DELGADO: Sorry, we're just pulling -- we're technically challenged for a second, but we're pulling it up on screen.

VICE CHAIR DICKEY: The script would be the same regardless of whether it was being read by the Life -- by the services or by your research staff, right?

DR. HAYNES: Right. I mean, the introduction is the same, right. So, here is -- this is a script that they provided me an example, that they provided me what they typically say when they first approach people.

And this is all done on the phone. It is recorded. There is no actual signature involved. So, it's recorded, it's stored indefinitely. And all of that has been approved by the council, the board of supervisors, so that's not an issue. So, that's the introduction.

And then, if you keep scrolling, so this is the SIDS-specific consent. And if the infants were okay for tissue donation they would be ones ahead of that, and that was the other form, and that was the consent for tissue donation. So, then, they would jump to the SIDS research.

And Dr. Dickey, you've worked with me on this form and I really appreciate your time and effort that you put in to, hopefully, get this form the way it needs to be, and address the things that we wanted to address.

VICE CHAIR DICKEY: Right. We'll give the Committee a chance to read it, if they haven't. But, you know, we wanted to get in there the basic elements of consent. So, who is doing the research, what's the purpose of it, and then what are going to be the procedures.

And although the form is not signed by the parent, it is signed by the person obtaining the consent. And then, so this would be a waiver of written consent. It's asking for the consent to occur over the phone.

One thing that we added into it, which wasn't there before, is the issue that the tissues may be used in the future for further research on SIDS or other related issues. And that it could be used, it might be used sometimes to develop a commercial product, but that the parents and families would not benefit from any -- financially in any way if that happens.

This is sort of thinking back to, you know, HeLa cells and all of that.

So, that's revealed to the parents and they put that in the hoppers whether they want to cooperate.

And also, the issue of the return of tissues. There's something in state law that says that tissues from autopsies can be returned or should be returned to the parents for religious purposes. So, that's been added in there also, right?

DR. HAYNES: Right, yes.

VICE CHAIR DICKEY: And I think there's a box further down where they can say whether they want it returned, is that right, for religious purposes?

DR. HAYNES: Right there.

VICE CHAIR DICKEY: Right. And so, her information and how to contact her, as well as our information about how to contact us if they have questions about the research, are also included.

VICE CHAIR DICKEY: So, I'll open it -- do you have any more you want to say, Dr. Haynes?

DR. HAYNES: No. Just that I really do appreciate the time and effort you've put into this in thinking about it. And I do feel like this will be approved by the board of supervisors, and then Dr. Campman, the medical examiner, has been really helpful in that regard, you know, supporting us to, you know -- and I haven't directly interacted with board of supervisors, but he has.

And so, I feel confident that this will go through, now, without any more issues. We really just want to resume -- resume collection, resume the research at this point.

VICE CHAIR DICKEY: So, I'll turn it over to the

Committee for any questions, concerns.

INTERIM CHAIR DELGADO: Okay. Thank you so much, Dr. Dickey for your work and Dr. Haynes for your perseverance on this topic, and this project, and this really important issue.

I will open it up to the board for any questions or concerns for Dr. Haynes.

Go ahead, Dr. Ventura.

COMMITTEE MEMBER VENTURA: So, I see that the line that participation in this research is voluntary, but it's kind of towards the bottom of this page. I wonder if that should be moved up earlier in the consent form. Only because you're talking to families within hours of an infant death. They're probably signing so much paperwork already, and then when they come across this, while it says "research" at the top, they might think that they have to kind of opt into this.

So, I just kind of want to emphasize that this is still voluntary and their choice, in a very sensitive, and time sensitive topics.

DR. HAYNES: I mean, I can certainly move that up, if -- I mean, I definitely see the point on that and I can move it up to the top.

INTERIM CHAIR DELGADO: Great. Thank you, Dr. Ventura for that comment and Dr. Haynes for your response.

Other -- Dr. Schaeuble was -- oh, go ahead.

COMMITTEE MEMBER SCHAEUBLE: Just a short question. You said that your first approach here might not be possible and you might have to fall back to seeking consent yourselves, as research staff. I was curious, what's the possible hindrance since in working through Life, whatever the organization is, seems like a better way to go. What's the hindrance that you might not be able to do that?

DR. HAYNES: It's definitely the better way to go for, I think, everybody involved. The -- what they originally wanted to do is to have their standard tissue consent form that was a tissue consent/research consent. So, one general form. And, you know, it just made it easier for them, less reading to the families. But we're unsure whether we want to go in that direction.

So, it was just an added thing that they would have to do. And I think we can work that out with them, and I think, you know, that's going to be possible. They were just a little unsure about it because they use the combination form for other research projects. So, that addition kind of took them aback a little bit. I think we can work through that.

And the other thing, they're just subcontracting and details of the subcontract that need to be taken care of that they're, you know, looking into and they were a little unsure about. But that is also something I think we can work out with them.

But I submitted the other research consent form just in case. And, you know, there are benefits for us doing the consent as well. You know, we know the research and we can explain, you know, directly any questions they have. Although, we are going to train LifeShare Donation as well about the research.

So, there are benefits to both. And so, I really just wanted to kind of cover both, both scenarios, you know, and hoping that both could work in the future.

VICE CHAIR DICKEY: Well, I have to take certain responsibility for this. When I read the combined form, it was really kind of an organ donation/research form and the two issues are quite different. And I thought -- I didn't think the Committee would want to have them mixed like that.

DR. HAYNES: I mean, I see that it makes sense to have a research consent as a consent form. Yeah, that's why it is the way it is.

INTERIM CHAIR DELGADO: Thank you. And I would say also covering yourself, covering the bases now with approvals in that we don't know how your board of supervisors will react.

Any other questions or concerns? Or, if not, Dr. Dickey, maybe you have a motion for us. And I see no hands raised, no internal --

VICE CHAIR DICKEY: Okay, I would move --

INTERIM CHAIR DELGADO: Go ahead.

VICE CHAIR DICKEY: I would move approval of the amendment, with the amended -- with the new consent form, with stipulation of moving the section about voluntary participation higher up on the form. With that change being reviewed by myself as a subcommittee.

INTERIM CHAIR DELGADO: Great. Thank you for the motion. Do we have a second?

COMMITTEE MEMBER VENTURA: I second.

INTERIM CHAIR DELGADO: Dr. Ventura seconds. Great.

Sussan, if we could go to a roll call, please.

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

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Thank you.

Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: I'm going to abstain.

MS. ATIFEH: Dr. Dinis?
COMMITTEE MEMBER DINIS: Abstain.
MS. ATIFEH: Dr. Hess?
COMMITTEE MEMBER HESS: 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: Dr. Johnson?
COMMITTEE MEMBER JOHNSON: Abstain.
VICE CHAIR DICKEY: I'd just make a remark. I think we have it in the policies and procedures that to abstain or to oppose you need to give your reasons.
COMMITTEE MEMBER BAZZANO: I wasn't able to hear a portion of this conversation.
VICE CHAIR DICKEY: Okay.
COMMITTEE MEMBER BAZZANO: So, I don't feel like I got enough. I would have liked to have heard it.
VICE CHAIR DICKEY: Oh, okay.
COMMITTEE MEMBER DINIS: For me, is I'm not even sure that this should -- I guess to me it sounds like it should be Common Rule review because it's identifiable specimen. So, that's why I'm like I don't know, and so I abstain.
COMMITTEE MEMBER JOHNSON: Can I abstain for personal reasons?
INTERIM CHAIR DELGADO: Yup.
VICE CHAIR DICKEY: Dr. Johnson?
COMMITTEE MEMBER JOHNSON: I abstained for personal reasons.
VICE CHAIR DICKEY: Okay.
INTERIM CHAIR DELGADO: How do we handle the vote counts where we have three abstaining?
MS. ATIFEH: We have --
INTERIM CHAIR DELGADO: Sorry, please just hold while we figure out the math related to this.
MS. ATIFEH: We have seven actual votes, which is more than half. So, it means the motion passed.
INTERIM CHAIR DELGADO: Okay, so to relay what Sussan just said, we have seven approvals which is more than half, which means the motion passes.
Great, thank you. Oh, Dr. Schaeuble.
COMMITTEE MEMBER SCHAEUBLE: If I could --
DR. HAYNES: Thank you so much, everyone, I really appreciate that.

INTERIM CHAIR DELGADO: Okay, thanks, Dr. Haynes. We have Dr. Schaeuble who is -- Dr. Schaeuble who is making a comment.

COMMITTEE MEMBER SCHAEUBLE: Well, this is a follow-up comment that doesn't have to do with the approval here. So, actually, two comments.

I'm not sure about the last thing that Dr. Dickey requested. I guess I don't understand why a member would necessarily have to give a reason for voting a particular way. That seems to me sort of an off thing to say is a requirement.

So, with regard to this particular project, I feel compelled to mention to the Committee my recollection is that the review a year or two ago, whenever it happened, was a lengthy discussion with a lot of pros and cons taking place during that discussion.

And I could be recalling incorrectly, but I believe, from my memory, that the vote was not unanimous on the approval for trying to the research without consent.

I'm mentioning this only because we -- again, not referring to this specific project, but we see a number of instances where researchers make the assertion that it just would not be possible to obtain consent, and that's their reason for requesting a waiver of consent.

And whether it's good or bad that the San Diego Supervisors chose to make obtaining consent a requirement, we can see that it was possible to work out some way to do that, that doesn't see -- well, it may be very burdensome, but it doesn't seem horribly burdensome given that the supervisors insisted on it.

So, I guess I'm asking the Committee to sort of keep in mind that sometimes when researchers say consent is not possible there may be, in fact, a way to do it that would be more protective for the participants in the study. That was my comment.

INTERIM CHAIR DELGADO: Understood. Thank you, Dr. Schaeuble.

So, just to go back, in terms of like following all procedures, Dr. Haynes and Ms. Haas, that your amendment has been approved. And we wish you the best of luck in your research project. Thank you for your commitment and for coming back to the Committee.

Our discussion, now, is just for our own policies and procedures, and administrative approach.

So, feel free to stay on, it's a public meeting. But what we are also going to do, because Dr. Schaeuble brought it up, we're going to open up, just to show a copy

of the policies and procedures regarding vote, and Dr. Dickey's comments, and Dr. Schaeuble's questioning of having to provide a reason for abstaining.

So, if you guys just hold on one sec, we're pulling up the policies and procedures. And so, you'll see at the bottom, the longer kind of paragraph, "Motions and CPHS decision, including those in favor, opposed, abstentions in members' absence, as well as reasons for abstaining and opposing."

So, I do think that that's the reason why Dr. Dickey brought that up. Whether or not it's a requirement that you provide a reason when you oppose or abstain, I'm not a lawyer, so I don't know how a lawyer would interpret that. But I do want to draw attention to that section of the policies and procedures.

And if you maybe just open up space for people who feel strongly one way or the other as to how they're interpreting that clause in our policies and procedures.

Sorry, can you scroll -- can you scroll up, Nick.

So, this is the section that describes the meeting minutes.

COMMITTEE MEMBER LUND: So, that means that when it gets down to that point (inaudible) -- the "shall" document applies.

MR. ZADROZNA: Scroll down?

COMMITTEE MEMBER LUND: Yes.

INTERIM CHAIR DELGADO: So, the last, what Laura's pointing out is that the last line in that paragraph says, "Minutes shall document the following: individual project information."

And then, Nick, if you could scroll down. "Motions and decisions" --

COMMITTEE MEMBER LUND: As well as (inaudible) -- so you do have to give one. That would be how I would view that is a "shall" document.

INTERIM CHAIR DELGADO: Okay, so -- okay, Laura -- Laura, what she said, her interpretation is that, yes, you shall be providing reasons for abstaining and opposing in your motion.

VICE CHAIR DICKEY: And we can always consider changing that. But, personally, I learn some things from hearing it. And, but on the other, if it's a personal reason or something that you don't feel comfortable sharing, I think that's a reason for not doing it.

But I do think it helps the Committee and the researchers in order to know whatever the issues are why you might have abstained or opposed.

INTERIM CHAIR DELGADO: Okay. Understood. Thanks for referencing back to policies and procedures. Always a learning moment for me, as well.

So, thank you, Dr. Dickey. Thank you to that research team.

Why don't we move on. And just want to note for the record we are now two minutes ahead of schedule. Moving to project -- thank you, Dr. Dinis, have a good day.

May the record note Dr. Dinis has to leave for class.

Protocol -- thank you, Dr. Haynes. Protocol 2023-108. Dr. Schaeuble, I will hand it over to you, so you could talk about this amendment.

COMMITTEE MEMBER SCHAEUBLE: Good morning, Dr. Zickafoose. So, are you on there?

MS. LECHNER: Hello. I'm Amanda Lechner. I am here for Dr. Zickafoose, from the same Mathematica team, and I will be our representative today.

COMMITTEE MEMBER SCHAEUBLE: Okay. Well, it's good meeting you, too. Could you begin by -- I'll actually ask you to do two things. If you could, in just a couple of sentences, mention for the Committee the original part of the study and what was added in the first amendment. And then, after very briefly doing that, go on to a summary of the additional work that the second amendment is wanting to add to the project.

MS. LECHNER: Yes, absolutely. Hello, everyone. I'm Amanda Lechner. I do have a couple other team members here as well. Would you like me to just --

COMMITTEE MEMBER SCHAEUBLE: Please introduce --

MS. LECHNER: -- state their names and then we'll -

-

COMMITTEE MEMBER SCHAEUBLE: Please introduce them, yes.

MS. LECHNER: Sure. Okay, great. So, we have Annu van Bodegom, who is our IRB coordinator and is helping on several aspects of our project.

And Gina Sgro, who is leading one of the surveys that we will be talking about today. So, they are both here with me.

And just to get into your questions, at a very high level overview we, at Mathematica, are doing an evaluation on behalf of the California Health and Human Services Agency, or Cal-HHS, of the Children and Youth Behavioral Health Initiative.

And we're doing a mixed methods evaluation that includes analysis of quantitative outcomes using secondary

data, we're also doing some document review on grant programs, funded by this initiative. And then, the primary data collection in the form of key informant interview surveys and focus groups.

We have submitted an original IRB application and two amendments at this point. The first, initial IRB application we submitted to you included analysis of publicly available data sources and some key informant interviews with state policy makers and agency staff in different departments of Cal-HHS.

And then, our first amendment we submitted back in January, added to that a statewide survey of caregivers, youth and young adults about their experiences with behavioral health services in California.

We just submitted, for review today, our second amendment. And this includes another survey and another set of key informant interviews. This new survey is -- we're calling it our Network and Ecosystem Experiences Survey. And from children, youth and family survey (indiscernible) and organizations across multiple sectors, behavioral health, education, child welfare, juvenile justice, management care plans, public health, early childhood and community-based organizations.

So, that's kind of the high level. Would you like me to say more about any of that or should we pause for any questions from there?

COMMITTEE MEMBER SCHAEUBLE: I guess we could ask the Committee members if there are any questions about the basic nature of the study before going on. I don't know whether there would be at this point, but are there?

So, if not, in working on this project with you we've had some exchanges back and forth. And most recently some requested changes, which you've incorporated into the documents that were sent back to the Committee this week.

In going through those, I really only noticed a few sort of housekeeping things that needed to be clarified before I would think of approval for the project.

So, those I can mention when we eventually get to a motion. But they were very straight forward things like, for example the researchers provided documents showing tracked changes for what they were doing in the various recruitment and consent forms. And we, of course, want to have clean copies in the protocol eventually for easier reading.

So, it's that kind of thing that I'm describing as a housekeeping kind of thing to take care of.

And I don't have any other questions that I'm

concerned about beyond what I think would be four of those minor fixes to take care of.

I'll mention two other things here, one just by way of suggestion to you for the future, if you happen to be, for instance, adding still another amendment to the project. You had to go through some sort of tortuous efforts here, I think, to reconstruct what was the original protocol, plus the first amendment, plus the second amendment.

And one of the things that I noticed, and particularly noticed, maybe, were some of the data security questions was that in attempting to reassemble all of this sometimes the same text, or very nearly the same text was copied sort of three times in an answer. And that's -- for the future, you really don't have to do that. It's, I'm sure, clearer to people if the text is just there once.

And if an amendment, for instance, adds something on top of what you've already described, or makes some kind of modification to what you previously gave as an answer, it's probably easier to have the one version of the text and then afterwards say what the addition to that is or what the modification to it is.

So, that's just by way of advice should be dealing further with having to work on the protocol here.

And then, a second sort of side comment, this is purely out of my own curiosity, I sent a research article earlier this week to Dr. Zickafoose and I was just wondering if that turned out to be helpful to you in dealing with the implications of haphazard responding and BOTs on -- when working with paid online participants that you have in your first amendment, not in the current one. The article was dealing with what can be the outcomes and what are some of the methods used to try to deal with these issues.

So, I thought it was interesting enough to pass along to you and just wondered if it turned out to be helpful.

MS. LECHNER: Yes, my colleagues have said that it is -- that that has been helpful and we really appreciate your sharing that with us.

COMMITTEE MEMBER SCHAEUBLE: Good.

So, I'm ready to open this for any questions the Committee may have and I'll mention the particular housekeeping issues later when we get to that point.

INTERIM CHAIR DELGADO: Okay, any questions. Board members that are calling in, raise your Zoom hand or unmute. Anyone here in the room? Seeing no questions or comments in the room, don't see anyone on Zoom unmuting.

If not, Dr. Schaeuble, do you have a motion?

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I will move approval of the amendment at minimal risk, with the following changes to be reviewed by a committee of myself. First, two replace any documents that still show tracked changes with clean copies throughout the protocol. I think that we've got some typos up there. Replace any documents that show tracked changes with documents that are clean copies. And the sentence can end after clean copies. Yes.

Second, under the protocol section HIPAA identifiers, delete "no identifiable materials" as a response. Delete "no identifiable materials." And that's simply because it's not consistent with adding identifiers in the data.

Third, there was a research staff member that you indicated as an addition, who had already been added in the first amendment. So, you'll see a comment from Sussan about removing that request. Remove the request to add a previously added research staff.

And finally, fourth, under "vulnerable populations", remove "not applicable." You've indicated minors are included in the study as a whole, so the "not applicable" would not make sense.

MS. LECHNER: May I ask a clarification about that?

COMMITTEE MEMBER SCHAEUBLE: Yes.

MS. LECHNER: Because for this second amendment we are not doing data collection with minors. We are for the first amendment.

COMMITTEE MEMBER SCHAEUBLE: That's right.

MS. LECHNER: So, does that change -- I'm okay either way. Just to make sure we do the proper thing, action item. Does that still stand in this complicated case?

COMMITTEE MEMBER SCHAEUBLE: Yes, the reasoning there is you've brought everything together, now, into one comprehensive document that covers the entire project, the original study that was approved, plus a first amendment, plus a second one. So, for the study as a whole there are minors involved at one point. And we don't have, you know, separate answers in that section for one part of the study versus another. So, that was the reason for agreeing that you put minors back in, but didn't take "not applicable" out, and the "not applicable" is just not consistent with saying there is some kind of vulnerable population somewhere in the study.

MS. LECHNER: Thank you, that's very helpful.

COMMITTEE MEMBER SCHAEUBLE: Does that motion make

sense to everyone?

COMMITTEE MEMBER SCHAEUBLE: H-I-P-A-A.

COMMITTEE MEMBER JOHNSON: Just a minor thing.

INTERIM CHAIR DELGADO: Okay, so Dr. Schaeuble that has a motion that is up on the screen. Is that the totality of the motion, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Yes.

INTERIM CHAIR DELGADO: Okay, great. Do we have a second?

COMMITTEE MEMBER JOHNSON: I'll second.

INTERIM CHAIR DELGADO: Dr. Johnson seconds that motions.

Sussan, if we could do a roll call, please.

MS. ATIFEH: Sure. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

INTERIM CHAIR DELGADO: Okay, thank you, Dr. Schaeuble. And thank you, Ms. Lechner, and to you and your research team for your work on this important project.

COMMITTEE MEMBER SCHAEUBLE: And Amanda, I'll just mention the four places that are described in the motion, there are already comments in the protocol at those locations about those requests. So, you'll see them there, as well as in the letter you received from the Committee.

MS. LECHNER: Okay, thank you, that's very helpful. And thank you to the Committee. And I do have one quick follow-up question, if you don't know, a procedural question. We listed nine California counties that we are doing our data collection with. One of those counties declined to participate, so we will be replacing them with another county.

I think we can just make that update. However, that may happen again. Is there anything further we need to do? Can we just take that out and just indicate it's nine counties, since they may change a little bit?

INTERIM CHAIR DELGADO: Just for procedural

purposes, you'll probably want to just submit an amendment. And that type of amendment would likely not need to come to full board.

COMMITTEE MEMBER SCHAEUBLE: No.

INTERIM CHAIR DELGADO: That's something that Dr. Schaeuble can just sign off on. So, if you communicate directly with him, that should be sufficient.

COMMITTEE MEMBER SCHAEUBLE: Do you know already what the replacement county would be or how soon would you know?

MS. LECHNER: I hope to know next week.

COMMITTEE MEMBER SCHAEUBLE: I think if you --

MS. LECHNER: We have maybes.

COMMITTEE MEMBER SCHAEUBLE: I think if you already know next week that you can include that when you send the amendment back with these other changes.

MS. LECHNER: Okay, fantastic. Okay, thank you so much.

INTERIM CHAIR DELGADO: Thank you, Ms. Lechner. Okay, moving on. We are getting through this agenda. Dr. Hess, going to pass it over to you to introduce the first new project of the day, 2024-040. And looking on the screen to see if Dr. Manne -- yeah, okay.

COMMITTEE MEMBER HESS: We have Dr. Manne here?

INTERIM CHAIR DELGADO: Yes.

COMMITTEE MEMBER HESS: Oh, okay. Okay, so this is an intervention on the skin cancer survival and self-screening by Rutgers University. And they're proposing to use California Cancer Registry data.

And Dr. Manne, if you are -- there you are. If you would like to introduce yourself and any of your team members that may be on, and give a brief description of the project to the board.

DR. MANNE: Good morning. I'm Sharon Manne, a Rutgers University -- (inaudible).

INTERIM CHAIR DELGADO: I'm sorry, Dr. Manne, we can barely hear you.

DR. MANNE: I'll keep up close. This is my voice, I'm sorry.

INTERIM CHAIR DELGADO: Perfect.

DR. MANNE: It's my voice. So, very soft. Sorry, I'm very close. So, this project was funded and our loan grant is now at the end of year two. And the first phase of this project was developing an online web-based and i-Phone app for improving skin self-examination and sun protection, and other risk-production behaviors for melanoma survivors. It is a second phase of a study and the second

phase involves a (inaudible) --

And we're looking at different areas, different ways of recruiting people into this kind of a study. So, we're considering a social media, at this point a Facebook-based intervention, with a Facebook-based recruitment versus cancer registries.

The involvement of the California Registry is in concert with our State of Registry of New Jersey. So, the second recruitment source is cancer registries.

The goal of the study, it has two aims. The first aim is to look at the efficacy of our intervention, including skin self-exam, or at this point comprehensive skin self-check. And then, we're looking at for this study 300 survivors.

The last aim of the trial doesn't really involve - doesn't involve anything related to the Cancer Registry because we're looking at just the cause and effect to get a particular uptake of skin self-check (indiscernible) --

We will be asking the California Registry to send us names and identifiable information via a secure link. And our team takes over both contacting and recruitment of subjects in the trial.

The intervention arm is an online (indiscernible) site that describes that (indiscernible) -- in some cases. Comparison arm with the generic data online intervention that is primarily educational, self-check and in some cases (indiscernible).

(Indiscernible) -- assessing self-report of skin self-check and some protection behaviors at baseline and follow up.

And that's about it in terms of the general outlines of the trial. Thank you for letting me --

COMMITTEE MEMBER HESS: Thank you. And just to clarify for the --

DR. MANNE: I'm the only person here.

COMMITTEE MEMBER HESS: Oh, okay. And just to --

DR. MANNE: I'm the only person here.

COMMITTEE MEMBER HESS: Thank you.

Just to clarify for the board, so you are requesting data from the Greater Cancer Registry of California. And you did provide an -- oh, okay, sorry.

DR. MANNE: Sorry, yes. It's not the Greater Bay Area, it's the other one, yeah.

COMMITTEE MEMBER HESS: So, we have kind of checked in and determined that you do need the letter of support. So, the Greater Cancer Registry of California cannot release the data until California Cancer Registry approves the data.

DR. MANNE: I know. There's been some (indiscernible) -- that letter and the process. I think there was a lot of confusion about the need for that letter, but the letter is in process. I understand it's a conditional approval based on that. I think we've been working on getting that letter for a little bit. We didn't realize we needed that specific letter.

We have -- as you probably know, I had a prior RO1 grant go through the registry here and we didn't have to do this. So, it's new for us. And, yes, I understand.

COMMITTEE MEMBER HESS: Okay. No, I think you --

DR. MANNE: Once it's approved --

COMMITTEE MEMBER HESS: I appreciate your patience because I was also a little confused on that, as well.

DR. MANNE: Yeah. I'm sorry, we didn't learn of this until like I think about a week and a half ago, so we're working on it.

COMMITTEE MEMBER HESS: So, I didn't have a lot of comments or edits on this project. I thank you for submitting the additional materials that I requested, the interviews that you'll be doing and walking -- providing more detail around the recruitment.

So, I will open it up to the board for any additional comments or edits that they want to make.

INTERIM CHAIR DELGADO: Just one question, Dr. Hess. Can you give us a like quick blurb or two about the suggestions that you already provided. You mentioned -- so, just to provide copies of the interviews?

COMMITTEE MEMBER HESS: Right, right.

INTERIM CHAIR DELGADO: Okay, great.

COMMITTEE MEMBER HESS: To make sure -- there were not copies of the actual interviews or surveys that they will be administering at three different time points about the intervention.

And then, I was unclear on some of the recruiting details, so how -- how exactly recruitment works via the Cancer Registry and how contact -- how participants are contacted. And they provided great details so --

INTERIM CHAIR DELGADO: Great. Thank you, thank you.

Okay, opening it up to other board members. Ms. Lund.

COMMITTEE MEMBER LUND: Hi, Dr. Manne. I have a couple of questions. Thank you for going for through CCR. Just to clarify for the board --

DR. MANNE: I'm sorry, can you just speak up a little bit, it's --

COMMITTEE MEMBER LUND: Sure. Can you hear me, now? Is that better.

DR. MANNE: Yes, thank you so much.

COMMITTEE MEMBER LUND: Okay, great. Just to clarify for board members, Cancer Registry data by law can only be released in California with the approval of the California Cancer Registry. So, CRCG can't release the data to you until CCR tells that it's okay. So, that's why we need that letter.

DR. MANNE: Yes.

COMMITTEE MEMBER LUND: And I'm just wondering why you selected CRGC instead of statewide data, especially given that you hope to increase enrollment in non-white populations, because CRGC doesn't include Los Angeles and it doesn't include the nine Bay Area counties.

DR. MANNE: That's a great question. We have a history of working with that registry and we are very comfortable working the registry. It was submitted under that registry because I had experience with an (indiscernible) -- and I'm sure everyone can appreciate that they want to know that you're worked with the recruitment (indiscernible) before.

I concur a hundred percent with what you're saying. What I did do for my young melanoma trial, one of my other trials, and also (indiscernible) -- the registry, the day after we finish the initial recruitment I'm looking -- very closely monitoring minority involvement and I will probably expand (indiscernible) -- in New York, because we've worked with that registry before. But again, I appreciate your comment, extremely appreciate your comment.

The reason I didn't was that I have a prior history with that registry. It was a grant -- it was a grant decision that I made. A grant funding, like to get funding, because they always question everything.

COMMITTEE MEMBER LUND: Right, I appreciate that. I would just encourage you maybe to work with CCR. You might find that it's just as easy to work with them because they have to approve it, anyway.

DR. MANNE: Yeah.

COMMITTEE MEMBER LUND: But that is completely, you know, your discretion. I'm just --

DR. MANNE: No, thank you -- thank you for that suggestion.

COMMITTEE MEMBER LUND: Yeah.

DR. MANNE: I appreciate the suggestion entirely and I appreciate it even more now that I've finished the other young melanoma study. And, you know, melanoma's

primarily a white person's disease, but we've struggled, and struggled, and struggled to get Hispanics into the trial.

COMMITTEE MEMBER LUND: Agreed.

DR. MANNE: Thank you for that feedback.

COMMITTEE MEMBER LUND: Yeah.

DR. MANNE: And you'll probably see me in about a year.

COMMITTEE MEMBER LUND: Oh, and I didn't see an informed consent document in the protocol. Was it in there and I just didn't see it? Okay, that's great. Okay, so those are my only comments.

INTERIM CHAIR DELGADO: Thank you. Dr. Ventura.

COMMITTEE MEMBER VENTURA: In the screening section, Dr. Manne, there's a sentence that says, "For those who decide not to participate in the study, their information will be shared and used further."

Is that supposed to say that their information will not be shared or used further?

DR. MANNE: Yes.

COMMITTEE MEMBER VENTURA: Okay.

DR. MANNE: Yes.

COMMITTEE MEMBER VENTURA: Okay, so if that could just be -- thank you. If you can make that correct, if they decided to not participate that their information will not be shared.

And then, also, on the consent form the reading level varies. It ranged from 8th grade to 12th grade in my assessment. So, I'm wondering if there are certain sections that can be simplified so that the entire consent form reads at the 8th grade level.

DR. MANNE: Yeah. Although, I have to check that out with my project coordinator. I think that is a Rutgers form. Can I -- yes, I think so. What did it say the reading level was?

COMMITTEE MEMBER VENTURA: Upon my assessment it ranged from 8th grade to 12th grade. So, there were some sections that were, I think, too high. And it needs to be consistently at the 8th grade level.

DR. MANNE: Yeah, thank you for that feedback. I don't -- I mean, that's also our requirement, so I'm curious. Thank you for that.

INTERIM CHAIR DELGADO: Okay, any other questions or comments from in the room. Or, on Zoom, board members please raise your virtual hands.

Okay, seeing none, Dr. Hess, would you like to make a motion.

COMMITTEE MEMBER HESS: Okay. I move that we

approve on a conditional approval, one year --

DR. MANNE: Am I --

COMMITTEE MEMBER HESS: Sorry.

DR. MANNE: Am I supposed to stay for this?

INTERIM CHAIR DELGADO: Yes, please stay.

DR. MANNE: Thank you.

COMMITTEE MEMBER HESS: So, we're going to make this approval conditional upon the following. First, there will be a letter of support from the California Cancer Registry. Second, there will be a sort of reexamination of the reading level of the informed consent.

And I don't -- I wasn't sure if -- is this like an informed consent form that is like standard boiler plate from Rutgers? Do you have the ability to --

DR. MANNE: I don't know, I'll find out. I'll find that out. I'm really sorry about that. It's also our requirement, so there may be some misunderstandings on the (indiscernible) --

COMMITTEE MEMBER HESS: Yeah, changes if possible, like that. Because if this is something, boiler plate language that you have to use, then that can be more difficult. So, let's say, if at all possible, we lower the reading level of the consent form.

And then, there was a typo on the screening section. So, please fix that to state that participants -- or individuals who decline to participate will not have their information kept or used subsequently.

INTERIM CHAIR DELGADO: And then, to be reviewed by a subcommittee.

COMMITTEE MEMBER HESS: To be reviewed by a subcommittee of me.

INTERIM CHAIR DELGADO: Great.

MR. ZADROZNA: Stating that if the participants decline to participate --

INTERIM CHAIR DELGADO: Their information will not be shared. Okay.

And then, as part of the motion, yup, by a subcommittee of Dr. Hess.

COMMITTEE MEMBER LUND: I'm sorry, we have one more thing. It needs to have -- would you please add the CCR brochure.

INTERIM CHAIR DELGADO: Okay. That's a requirement.

COMMITTEE MEMBER HESS: Okay. So, Ms. Lund has reminded us that all participants would need to also receive the California Cancer Registry brochure for research participants, and that explains --

DR. MANNE: Yeah, I thought -- is that not listed? I mean, we've been doing that forever. If it's not in the protocol that's --

COMMITTEE MEMBER HESS: I didn't see it in the protocol, but I will -- I can double check and make sure it's there for you. And if it's not, we'll upload it. And if it is, then we can ignore that.

INTERIM CHAIR DELGADO: Great. Okay, so we have a motion. Do we have a second for this motion, please?

Ms. Lund seconds it.

Sussan, roll call, please.

MS. ATIFEH: Sure. Dr. Dickey?

VICE CHAIR DICKEY: Approve?

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Thank you.

Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Thank you.

Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Okay, the motion passed. Thank you so much, Dr. Manne. Dr. Hess, thank you for your review.

Dr. Manne, you'll receive a letter, in probably a week or two, that details the conditional approval. And feel free to reach out to Dr. Hess directly with any questions once you get that letter.

DR. MANNE: Thank you. Thanks, everybody.

INTERIM CHAIR DELGADO: Thanks for your work on this important topic. Have a great weekend?

DR. MANNE: Thank you.

INTERIM CHAIR DELGADO: Oh, did you feel the earthquake, Dr. Mann?

DR. MANNE: Oh, my God. I was on the 16th floor of a hundred-year-old building and literally my chair was going back and forth. I thought the building was falling down.

INTERIM CHAIR DELGADO: Okay.

DR. MANNE: Yeah.

INTERIM CHAIR DELGADO: But I'm glad you're safe.

DR. MANNE: I was like -- I mean, I was fine. Nothing happened to anyone, I don't think. I'll have to go look at the news. But, yeah, you guys are used to these things and I'm not.

INTERIM CHAIR DELGADO: Yeah. Well, glad you're safe and maybe New York will develop an app, like California has, to give you warnings of earthquakes, because we have that.

DR. MANNE: That's so --

INTERIM CHAIR DELGADO: That can be your next research project. Okay, thank you so much.

DR. MANNE: Bye, guys.

INTERIM CHAIR DELGADO: Bye.

Okay, last, but not least in terms of new projects -- okay, so this project is Project 2024-043. Dr. Laribi. I don't know if, Dr. Laribi, if I'm pronouncing your last name correct.

DR. LARIBI: Yes, that's correct.

INTERIM CHAIR DELGADO: Okay, wonderful.

So, just so the board knows, this project was originally assigned to Dr. Azizian, who had a personal emergency and could not attend today's meeting. So, Dr. Azizian and I connected.

Dr. Laribi, I know that Dr. Azizian spoke with you earlier in the week. And I have also fully reviewed and prepared to present your project.

So, if you wouldn't mind please introducing yourself, any of your teammates who might also be on the call, and then if you could please give us just a brief overview of your project with specific focus on the role of human subjects, that would be awesome.

DR. LARIBI: Great. Thank you. So, my name is Ouahiba Laribi. I am the Chief of the section in Petrified Exposure Evaluation and Medical Education Team, in the Office of Mental Health Hazard Assessment, is CalEPA.

And I don't think anyone is here with me today. This project is a collaboration with Dr. Carly Hyland, from UC Berkeley of Public Health.

And so, I'm going to give you a little bit of an overview of this project, so and what my team does. We do trainings to healthcare providers, including community health workers, on pesticide-related illnesses.

And so, community health workers have asked us to include a section on farmworkers' rights and benefits as it relates to pesticide exposure. And so, we've been trying to make our training very practical. And we needed to learn more about what are the difficulties the farmworkers are

encountering making use of their rights and benefits. So, that's including worker comp's or signing complaints.

So, for this coming year trying to assess farmworkers' level of awareness and understanding of their rights, and also understand the barriers they are encountering to accessing those rights.

So, we propose to interview 20 people, 20 field workers who may be exposed to pesticides by working around or with pesticides. And we also want to include female farmworkers who are or have been pregnant while working in agriculture.

Community health organizations that we partner with will help us distribute the flyer for recruitment. The participants must be 18 years old, speak English or Spanish, and work as a farmworker in California.

And by contacted by interested individuals are -- we have a health educator, Nancy Villasenor, will confirm eligibility and go over the aim of the study, ask the person to set up a date, time, and location for their interview.

We will also ask community-based organizations to help us identify -- sorry?

INTERIM CHAIR DELGADO: Sorry, we were just coughing. Keep going.

DR. LARIBI: Okay. We will also ask the community-based organizations to help us identify safe, public spaces that Nancy can propose to the participants, such as library or media centers.

And then, as far as the interview, Nancy will go over the consent form with them and ask if they have any questions. She will consent and confirm they are still interested in the study. She will get the oral consent. And she will sign the consent form and hand it to them for their records.

The interview will take about 30 to 60 minutes. And the participant will be told they can stop at any time or skip questions if they feel uncomfortable and we'll have no (indiscernible) --

They can also let us know after the interview if they would like to be removed from the study.

So, we are doing conversational interview, and so to avoid interruptions in the note -- in the interview, we do not want to do note taking, and we will -- so we will select audio recording.

However, we take demographic questions, such as age and gender, with a note taker.

And so, when the interview is completed the subject will be thanked for their time and receive a $50 gift card

to the local grocery store.

And so, for this study we identified two types of risks, although we believe they are very minimal. So, the first risk is risk of retaliation. And to minimize this risk we are offering -- we will offer option for safe location, as I said before, such as libraries.

We will clearly state the aim of this study prior to starting the interview. We also clearly state that questions can be skipped or interview can be stopped at any time.

We will ask participants not to name people or sites. And we will delete those if they were given my mistake.

So, the second risk is really -- is the risk of breach of confidentiality. And so, for that we will use only contact information, so first name and phone number, for scheduling purposes. And delete those through shredding as soon as the interview is done.

We'll store our early reporting in a secure access computer that we have already available in our Oakland office.

We'll delete the audio recordings from the recorder within 72 hours after the interview, and from the computer after they're transcribed, and within the three months after the interview.

We will store the interview notes and demographic information in a locked cabinet in the same room until the information is typed in the secure computer. And we will destroy, shredding them immediately after uploading it in the computer.

So, what we will do in case of a breach, we will immediately contact the CPHS director by email and phone, or a phone call, and we will file a formal incident report within seven days.

And that's it. I think I took my three minutes time.

INTERIM CHAIR DELGADO: Okay, great. Thank you so much Dr. Laribi. And apologies that you've had multiple primary reviewers, with both myself and Dr. Azizian.

Want the board to know that Dr. Azizian did pose multiple questions to Dr. Laribi both through IRBManager, that you should be able to view on the protocol.

Specifically, he asked questions to the researcher to clarify aspects of the procedure in terms of the number of participants, how participants are being recruited. And he did feel confident that the researcher responded well to all of the questions that he posed in that area.

There were also some questions about the interviewing locations and he -- I know, Dr. Laribi, he spoke with you about that at length and there may be some adjustments to just some of the verbiage in the protocol, to the degree that he felt comfortable with.

And so, at least from Dr. Azizian's review would summarize that all of his concerns were addressed.

I will just add that my -- to add on to Dr. Azizian's review, I just had one question that stood out, Dr. Laribi, wondering if you could speak to. In the interview, itself, there's a final, optional question that asks the individual about their immigration status. And so, that to me, one if you could speak to why that data point, why that question is necessary. And two, how you will protect such confidential information through your research process.

DR. LARIBI: Definitely. And I'm really sorry because, actually, this question has been removed in the final version. I did not upload the final version to CPHS website.

We have asked for an IRB approval from UC Berkeley. And CPHS and UC Berkeley asked the same question, so we removed that question. And I actually should send you the new version.

INTERIM CHAIR DELGADO: Yes. Were there any other substantive changes from what the IRB at Berkeley requested?

DR. LARIBI: Yeah, on this -- actually, yeah, I thought I had done that.

INTERIM CHAIR DELGADO: That's okay. When you're juggling multiple IRBs it happens. So, no problem.

DR. LARIBI: So, the second thing that they were asking us is to remove the demographic information from the recording and have that put on a separate form. So, I mentioned that. It's in the protocol description, now, but not in the .pdf that I uploaded. That's the second thing.

And the third thing that they asked us, too, and I also already made the change, is the consent form, they asked us not to have the consent form signed by the participant. And instead, having us -- getting oral, verbal consent and having us sign the consent form for them.

INTERIM CHAIR DELGADO: Okay, thank you so much. Those were -- that was the extent of my questions, so I'll open it up to the board for any other questions that they might have.

Okay, so, Dr. Schaeuble is getting on the mic. You'll hear him in a second.

COMMITTEE MEMBER SCHAEUBLE: Okay, so just -- just

one question. In the description of risks for the study you mentioned concern about the possibility of employer retaliation. And I don't have any particular comment on this, but I wanted to ask the Committee to weigh in on whether the protections that are provided against the possibility of employer retaliation seem adequate to everybody here. I'm not specifically expressing a concern, but I thought I should raise the question.

DR. LARIBI: I'm really sorry, but I'm having really problems to understand the question.

INTERIM CHAIR DELGADO: Okay. No worries.

DR. LARIBI: Okay.

INTERIM CHAIR DELGADO: No worries, I'll repeat it. So, what Dr. Schaeuble said is just bringing to the Committee's attention that you mentioned potential employer retaliation as a risk for the human subjects.

He is not expressing concern per se, but just wanted to make sure that's elevated and ensure that the board is attending to that issue, and asking for people's opinions to be voiced should they think that the steps the researcher has described are sufficient to protect against that risk.

COMMITTEE MEMBER SCHAEUBLE: That's right. And this comes up in the last paragraph under your discussion of risks, where you say, "Despite all these efforts it's possible, although unlikely, that an employer who discovers that their employees are speaking with researchers about their employment rights, might retaliate against them."

And you go on to say what you would do in those circumstances. And I was asking the Committee to take a look at that and be sure that they were satisfied with that way of handling the situation.

DR. LARIBI: Okay, I'm not sure if this question is for me. For me, it's very hard to understand the things, I'm sorry. But is the question is targeted for me or towards the board?

INTERIM CHAIR DELGADO: I think that you've responded to it in your protocol and so I --

COMMITTEE MEMBER SCHAEUBLE: My question was more to the Committee.

INTERIM CHAIR DELGADO: So, yes, his question was more to the Committee than to you, Dr. Laribi. But thank you.

Dr. Bazzano.

COMMITTEE MEMBER BAZZANO: Yes, my question is, Dr. Laribi, about the very last point from the UC IRB, with regard to the signature. Can you explain their rationale

for that and any further protections along those lines? I'm not sure that I understand that just not writing your signature would be sufficient. Can you just explain that a little bit more.

DR. LARIBI: So, the original proposal had go over the consent form with the participant and ask the participant to sign and date the consent form, and we would keep the consent form in a secure place.

But UC Berkeley proposed that we do not keep the consent and, instead, just give the consent form to the participant, so the participant has all the information, and ask for a verbal consent to simplify and avoid an extra layer of confidential data being -- an extra layer of risk for the confidentiality data.

So, we did not think that that would -- like to us it didn't feel like -- we don't follow these people, we don't need to get back in touch with them. We're proposing, actually, at the end of the study to give them materials for them to improve their knowledge on risks and benefits. But we do not plan to go back to those participants afterwards, so we didn't feel like we needed to keep that.

And I think, from my understanding of the IRB from Dr. Hyland, they -- so, they figured the IRB as an expedited one, so they removed anything that might make the protocol more expanded.

COMMITTEE MEMBER BAZZANO: Okay. I guess my question is what happens if, well, you know, say later on there's a dispute about whether one of the participants did consent, what kinds of information would you have to indicate that, yes, that participant went through the consent process if they didn't sign? You know, the protection is both for the participant, but it's also for you. Just to think about that, maybe. It's an unlikely possibility, especially since you're removing their data, you know, there's no identifying data, they won't come back to you afterwards.

So, I'm just wondering, then, you know, how do you -- and if a dispute occurs, how do you prove that they actually did consent and it wasn't just her team signing, you know.

DR. LARIBI: That's a good question. I'll ask Dr. Hyland how she -- what was the rationale behind and what was proposed by UC Berkeley IRB. But I don't have the answer to that.

COMMITTEE MEMBER BAZZANO: I don't think it's a reason not to approve this study. I just do bring it up. And if you can -- you know, if there are any -- I guess this

is for you all, for the rest of the team to think about whether that -- you know, just this is a piece of information to have.

INTERIM CHAIR DELGADO: I agree. Thank you so much, Dr. Bazzano.

Dr. Dickey.

VICE CHAIR DICKEY: I just want to say that one of the explicit reasons for waiving written informed consent in the final rule is if the only way a person would be identified is through having signed the consent form, and they might suffer damage for that reason.

I mean, we could pull up that section to look at it, but that's probably their rationale.

Another thing I wanted to bring up, though, is this might be a case where a certificate of confidentiality from NIH might be a good idea because it would help prevent you having to reveal any information in court or otherwise.

Are you aware of that certificate of confidentiality?

DR. LARIBI: No, I am not. But I will look it up.

VICE CHAIR DICKEY: Okay. Yeah, it's through NIH. After you have an approval from an IRB, you can go to NIH and ask them for a certificate of confidentiality.

DR. LARIBI: Okay.

INTERIM CHAIR DELGADO: Thank you, Dr. Dickey, great suggestion.

Others that have comments or questions? Dr. Ventura.

COMMITTEE MEMBER VENTURA: Hi, Dr. Laribi. In the -- in the risks section of your proposal, you state that there are no significant mental or physical health effects anticipated. However, if there are unanticipated effects, you've outlined a step that you'll take as far as reporting.

But I wonder if you should also include resources for the participants if they feel any distress during the interview, discussing exposure to pesticides or losing employment because of it, or even the distress of possibly having retaliation from their employer for just participating. I wonder if there are any resources that you can provide to them at the end of the interview if they experience that. So, that was just one point.

And then, in the English consent form, I don't know about the Spanish consent form, but the reading level for that, for the English consent form looked too high. And in my assessment it was at the 12th grade level and I think it needs to be simplified. The language is too advanced.

INTERIM CHAIR DELGADO: Okay, thank you, Dr.

Ventura. Dr. Laribi, any comments in response to that?

DR. LARIBI: So, the first one, we tell this to the participants. We can definitely add the information. We worked closely with lots community-based organizations across the state, so we have lots of contacts that we can send people to. And we also have material that we commonly give. So, that's not something that's a problem. Also, legal organizations for retaliation.

For the 12th grade level I agree. I mean, we have asked our health educator to go back to the consent form. And I think Dr. Azizian mentioned it. So, she will look into it and make it more accessible.

INTERIM CHAIR DELGADO: Great. Thank you so much, Dr. Laribi.

Others? Ms. Lund.

COMMITTEE MEMBER LUND: So, I just had a -- just a couple of questions. At one point on your data access you stated that only the PIs and Nancy Villasenor would have access to the data. But you have other research staff listed. So, can you clarify for me who's going to have access to the data?

DR. LARIBI: The people that we have here, we have actually two PIs, so myself and Carly. And then, Nancy Villasenor, our health educator, will be doing the interview. But we are asking another person to attend the interview, so that the interviewer will need time, so other people will kind of be around to just take notes. And so, we identified those people who might be involved. So, we couldn't really give a -- so, that's the only place that they would have access to kind of information.

And then the data, itself, will only be with Carly and myself.

COMMITTEE MEMBER LUND: So, the list of people is because only one of those people will be present, but you don't know which one, yet?

DR. LARIBI: We --

COMMITTEE MEMBER LUND: Because I think you have several listed.

DR. LARIBI: Yeah, we have --

COMMITTEE MEMBER LUND: Under other research staff.

DR. LARIBI: -- we have listed. They won't have access to the recordings or access to the -- to the form, where they ask about their gender and age. But we -- they will have access to the script of the information. So, they will part of this study.

And I could -- I didn't -- and in doing the -- we will have -- we will need them for at least helping out in

the interview, and like in the sense of -- and I think I mentioned that in the protocol that Nancy will be -- will have somebody else with her. So, hope that helps.

COMMITTEE MEMBER LUND: Great, thank you. I just wanted to make sure that I understood why there seems to be two different statements. So, the people that you have listed here don't have access to the collective data, but they might have access to the actual interviews, themselves?

DR. LARIBI: Yes. Sorry.

COMMITTEE MEMBER LUND: Okay, great. I just wanted to make sure I understood.

DR. LARIBI: Yeah.

COMMITTEE MEMBER LUND: And then, I noticed you have a data security letter from OEHHA. Some of your study staff have Berkeley emails. Will the data only be stored and accessed at OEHHA or will they -- will the data also be available at Berkeley?

DR. LARIBI: So, only Dr. Hyland is -- from Berkeley, is -- doesn't have an OEHHA address. She's the co-PI in this project. The others are OEHHA staff. So, Carly will not have access to the raw data.

COMMITTEE MEMBER LUND: Okay. So, I guess my question is will any of the data under the transcripts of the interviews, or any data filed be available at Berkeley, or will all of the information from your study only be available at OEHHA?

DR. LARIBI: Only at our Oakland Office in OEHHA.

COMMITTEE MEMBER LUND: Okay, great. Thank you. Okay, those are my only questions.

INTERIM CHAIR DELGADO: Thank you.

Other questions? Okay, seeing none, no hands raised, nobody in the room.

So, I'm going to go ahead and make a motion for deferred approval -- what was that?

Minimum risk, deferred approval, one year, with the following suggest -- or following action items. The first is just a suggestion, not a requirement.

DR. RYKACZEWSKA: Oh, just to clarify, as Chair you can't make the motion.

INTERIM CHAIR DELGADO: Oh, never mind. Okay, I can't make the motion as Chair. Thank you for those who better understand the rules than I.

I'm just going to comment, then, about if I were to make a motion what it might include, and then maybe somebody else can make the motion.

COMMITTEE MEMBER HESS: I can make the motion and then you can read off the requirements.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER HESS: Is that -- can we do that?

DR. RYKACZEWSKA: Yes, you can say I move what she says.

COMMITTEE MEMBER HESS: Okay. I'll move -- you say everything and then I'll move to accept what you say.

INTERIM CHAIR DELGADO: Okay, got it. So, my first is just a suggestion for Dr. Laribi, not a requirement, but just suggest you explore doing an IRB reliance agreement between CPHS and UC Berkeley, so that you don't have to do this back and forth.

Berkeley generally approves relying on us as the state IRB. So, therefore, they would just accept any decisions that we make. So, as an example, for your informed consent you wouldn't have to go back and forth, and back and forth. So, just something to think about. The form's available on our website.

The second part of my non-motion is, again, exploration to look into a certificate of confidentiality, as Dr. Dickey described, available via NIH.

To -- these are requests, not recommendations. To go back to the consent form to decrease the reading level. I think that was actually it.

COMMITTEE MEMBER VENTURA: Adding resources for --

INTERIM CHAIR DELGADO: Oh, and recommend that you add resources to distribute to participants specific to mental health resources, legal, employment, retaliatory info.

DR. LARIBI: May I ask one thing? Is this something that you want me to add into the protocol, those resources, the details or --

INTERIM CHAIR DELGADO: Yes. And so, what will happen after today is that the -- after we have a motion and we move through the vote, you will have the opportunity to make adjustments to your protocol. And, for example, update the new script that takes off the immigration question. Sorry, I should have added that, too. To ensure that the scripts are up to date.

Yes, you'll have the opportunity to just make these changes right in the IRBManager.

DR. LARIBI: Uh-hum.

INTERIM CHAIR DELGADO: Yes. And so, the final version of the script and consent form, also as part of the non-motion.

COMMITTEE MEMBER HESS: Okay. So, I move to grant -- or deferred approval, one year, minimal risk pending revisions A through D, as outlined by Dr. Delgado.

INTERIM CHAIR DELGADO: Okay, great.
DR. RYKACZEWSKA: E should be uploaded -- uploads.
COMMITTEE MEMBER HESS: A through E, and E should be uploaded the revised consent form and script.
INTERIM CHAIR DELGADO: Okay, thank you. We have a motion. Do we have a second?
COMMITTEE MEMBER LUND: I'll second.
INTERIM CHAIR DELGADO: Ms. Lund seconded.
DR. LARIBI: I think I need to do -- actually, add another one. Sorry to be -- but I think I'm supposed to upload the new questionnaire with the --
INTERIM CHAIR DELGADO: Okay.
MR. ZADROZNA: Was there something for us or --
INTERIM CHAIR DELGADO: No. Well, hold on one sec.
COMMITTEE MEMBER HESS: I think the questionnaire script might suffice. That's what we mean by the uploaded. Upload the revised consent form and the questionnaire script.
MR. ZADROZNA: Could you just repeat that one more time?
INTERIM CHAIR DELGADO: Okay.
COMMITTEE MEMBER HESS: That's it.
MR. ZADROZNA: Oh, okay.
COMMITTEE MEMBER HESS: Okay, seconded by Ms. Lund.
MS. ATIFEH: Laura.
Okay, so I start with Dr. Dickey?
VICE CHAIR DICKEY: Approve.
MS. ATIFEH: Dr. Ruiz?
COMMITTEE MEMBER RUIZ: Approve.
MS. ATIFEH: Dr. Bazzano?
COMMITTEE MEMBER BAZZANO: Approve.
MS. ATIFEH: Thank you.
Dr. Palacio?
COMMITTEE MEMBER PALACIO: Approve.
MS. ATIFEH: Dr. Schaeuble?
COMMITTEE MEMBER SCHAEUBLE: Approve.
MS. ATIFEH: Dr. Ventura?
COMMITTEE MEMBER VENTURA: Approve.
MS. ATIFEH: Dr. Johnson?
COMMITTEE MEMBER JOHNSON: Approve.
MS. ATIFEH: The motion passed.
INTERIM CHAIR DELGADO: Okay. Dr. Laribi, thank you so much for your time and your work on this project. You're going to receive a letter that describes these A through F, A through E. And Dr. Azizian can be your main point of contact. I know that you two have been communicating regularly. So, we'll let him know about this

deferred approval. And if you have any follow-up questions, just shoot him a quick email and you should be good to go.

DR. LARIBI: Great, thank you so much.

INTERIM CHAIR DELGADO: Thank you. Have a great weekend.

DR. LARIBI: Thank you. Bye.

INTERIM CHAIR DELGADO: Bye.

Okay, we're close ya'll. Those are all of the new projects.

On Agenda Items M through R, which are expedited reviews, continuing reviews, amendments through expedited review, IRB reliances, exemptions and final reports, any questions or concerns on any of those items?

Hearing and seeing none, we will now open up for public comments. For those who are calling in or those in person, if anyone is interested in making a public comment, please let us know.

Okay, hearing none, seeing none, we will now close public comment.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Oh, Dr. Schaeuble has one.

INTERIM CHAIR DELGADO: Oh, sorry.

COMMITTEE MEMBER SCHAEUBLE: I don't know that it comes under public comments, but if you could indulge me for just a second. I'd like to follow up on two things that came up earlier in the meeting.

One with regard to what we talked about for people who abstain or oppose providing a reason. I see what's in the policies and procedures, and recognize that. And I fully agree with Dr. Dickey that it's often helpful to understand those reasons.

I still have a bit of concern having it in the policies and procedures that this is something mandated for people to do. I don't think people should be put in an awkward position of having to say something that they may not want to say. I think most people would explain why they are voting that particular way. But I was glad to see that nobody challenged Dr. Johnson, of her saying that she had personal reasons for her vote, and didn't -- we didn't ask for any further explanation of that, which is as it should be.

So, my hope is that the policies and procedures might more clearly say that those reasons are requested if members are willing to provide them, something to that effect. Just a thought for future consideration.

INTERIM CHAIR DELGADO: That's great. And maybe the way that we, quite quickly today, reviewed the edits

that Dr. Dickey suggested for the policies and procedures, if maybe you can work with admin staff to make some suggested language change that we can vote on next meeting to that effect.

I see lots of heads nodding in agreement.

COMMITTEE MEMBER SCHAEUBLE: Okay.

INTERIM CHAIR DELGADO: Sorry. See, you comment and then you just get work to do.

COMMITTEE MEMBER SCHAEUBLE: I've got a new job --

INTERIM CHAIR DELGADO: You got a new job, that's what happens.

COMMITTEE MEMBER SCHAEUBLE: All right, not a problem.

INTERIM CHAIR DELGADO: Thank you.

COMMITTEE MEMBER SCHAEUBLE: Not a problem.

The other thing, just as a bit of information that I thought might be helpful to the Committee, I mentioned sending a research article to Dr. Zickafoose, when we were discussing his amendment.

I've been reading several things recently about the effects of haphazard, or casual, or non-attentive kinds of responding to surveys and questionnaires, and what the impact of that is and how to handle it.

The interesting thing that came up to me, in the particular article that I glommed onto and passed along, traditionally, from a statistical point of view we've sort of assumed that if we have some kind of haphazard responding that that's simply going to add to the error variability in the data and make it harder to find significant findings against the noise from that haphazard responding.

But this study did an analysis of the situations and showed numerically that what really can take place is that results can appear to be more significant than they actually are. That, for example, correlations can be increased in size by the presence of additional randomness in the responding, rather than being decreased. Which, I think, most of us would have expected otherwise.

So, this suggested to me that this is even a bigger issue than what we might have otherwise thought. And, of course, it can happen with any kind of survey or questionnaire, but particularly with these online panels where people are being paid, and encouraged to basically respond very quickly in order to get through the survey and get their points, or payment, whatever it is. Especially a difficult situation to deal with there.

So, for what it's worth, I'm passing the essence of that article along for you to think about.

INTERIM CHAIR DELGADO: If you have the article, just if you could send it to admin staff to distribute, I'd be interested in reading it.

COMMITTEE MEMBER SCHAEUBLE: Oh, I'd be glad to. I sent it to him, so I can easily send it to you.

INTERIM CHAIR DELGADO: Thank you.

Dr. Dickey, did you write that article?

VICE CHAIR DICKEY: Yeah, I just --

INTERIM CHAIR DELGADO: No, just -- sorry, just kidding.

VICE CHAIR DICKEY: I'm sorry?

INTERIM CHAIR DELGADO: Ignore me. Go ahead.

VICE CHAIR DICKEY: No, what I was going to say is it -- I'm sure you guys know, but it's very hard to hear some people. Like I could hear virtually nothing that Dr. Schaeuble was saying, unfortunately.

I don't know what the solution is, but it makes it very difficult for some of us. And it's almost having to appear in person but --

INTERIM CHAIR DELGADO: Well, the good -- the good thing is that Dr. Schaeuble was discussing an article that will be distributed out to the group. So, more to come on the topic that he just discussed.

And also, we suggested and asked Dr. Schaeuble to propose language regarding abstentions, and providing reasonings. So, that will be something that we will expect to talk about in the next meeting.

VICE CHAIR DICKEY: All right. Thank you for letting me know that.

INTERIM CHAIR DELGADO: Yeah. Okay, our next meeting will be Friday, June 7, 2024.

Thank you, as always, to board members, to admin staff, to the public calling in. But just, again, a shout out to all the board members for their continued work on top of everything else that they're doing. Appreciate everyone's time. And have a great weekend.

And I think I need to officially adjourn.

DR. RYKACZEWSKA: Yes. We have someone here, too.

INTERIM CHAIR DELGADO: Oh, he didn't want to talk in public comment.

Okay, we'll adjourn the meeting. Thank you.

(Thereupon, the meeting was adjourned at 12:25 p.m.)

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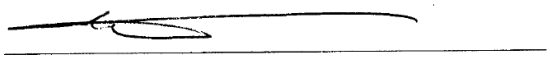

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