MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, JUNE 7, 2024

8:32 A.M.

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AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Darci Delgado, PsyD, Interim Chair

Larry Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD

Maria Dinis, PhD, MSW

Catherine Hess, PhD Dr.

Jonni Johnson, PhD

Carrie Kurtural, JD

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

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna

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Ann Hamilton, PhD, Keck School of Medicine, USC

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I n d e x

P R O C E E D I N G S

INTERIM CHAIR DELGADO: It's 9:32 a.m. Why don't we call this meeting to order.

Welcome all who are here in person, as well as those online, for the June 7th meeting for the Committee for the Protection of Human Subjects. Welcome everyone. So excited to see folks online, as well as in person.

Just a reminder to the board members who are Zooming in with us today, if you could please keep your camera on as part of the Bagley-Keene. I mean, my attorney is here, so I'm going to be like as on top of Bagley-Keene as I've ever been. If you could please try to stay on camera and engage during the meeting, that would be amazing.

So, good to see everybody. We're going to start. We have a lengthy agenda today, so why don't we just go ahead and jump into it.

We're going to start the meeting -- okay, we're going to start with an announcement first. And I'm going to try not to get emotional, but Lucila is going to be transitioning off of the CPHS team. We tore her back; we pulled her back into the mix after her first retirement to help with the transition of the board moving from HCAI over to agency.

She has been such an amazing resources and just a great

friend and colleague and has really helped Agnieszka with her transition on to being our full-time administrator. And just can never thank her enough for all that she gave to the board to start with, and then also coming out of retirement to help us with the transition.

So, just want to take a moment to say thank you. We will likely be having a going away lunch on her actual last day. But wanted to definitely acknowledge it in today's meeting and just open it up -- yeah, open it up for anybody who wants to say anything else, because I know a lot of us, Luci raised us as babies on this board.

(Laughter)

INTERIM CHAIR DELGADO: So, want to give space for anyone else that wants to express their appreciation for Lucila.

COMMITTEE MEMBER SCHAEUBLE: Thank you, thank you, thank you.

(Applause)

VICE CHAIR DICKEY: How long has it been?

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: How long has it been? It was only supposed to be a six-month --

VICE CHAIR DICKEY: I know, but I mean since you started way back when.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: I graduated. I

retired in 2021, I believe in December, and they waited about a year and a half to call me back.

VICE CHAIR DICKEY: No, but you've been with the Committee --

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Oh, with the state?

VICE CHAIR DICKEY: No, with this Committee for about 10 years, right?

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Since 2012. I've been with the state for 42 years. I walked out with 42 years.

(Collective Wow)

COMMITTEE MEMBER VENTURA: Congratulations.

MS. MUHAMMAD: Let me know when you're going on vacation.

(Laughter)

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: It's been a pleasure to work with all of you. I didn't get to -- Dr. Azizian, I knew him through research projects. Dr. Ventura, I just got to know her when I was bringing her on board, as well Carrie, and Catherine, I brought them on board. So, it's been a pleasure bringing you on board, and assigning mentors, and just getting to know you, and just moving your projects along. So, it's --

INTERIM CHAIR DELGADO: And providing us with tamales.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: And providing

you with tamales every Christmas.

INTERIM CHAIR DELGADO: Well, luckily we know you're just a text away. We won't bother you about work stuff, of course, because you will -- you will be off back in retirement land. But thank you so much.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Oh, you're welcome.

INTERIM CHAIR DELGADO: You will be missed.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Thank you.

INTERIM CHAIR DELGADO: Oh, I think, Dr. Dinis, are you trying to talk? Your audio isn't coming through, Maria.

Okay, so other folks can hear her. Okay, so just give us a moment, we'll fix our audio in the room.

MR. ZADROZNA: Maria, can you talk so we can test it?

COMMITTEE MEMBER DINIS: Oh, I can always talk, yeah.

(Laughter)

INTERIM CHAIR DELGADO: Oh, there you are.

COMMITTEE MEMBER DINIS: Does it work?

DR. RYKACZEWSKA: We can hear you, now.

COMMITTEE MEMBER DINIS: Is it working?

DR. RYKACZEWSKA: Yes.

INTERIM CHAIR DELGADO: Yes, perfect. Were you going to say something?

COMMITTEE MEMBER DINIS: All right. I was going to say, Lucila, thank you for all the years, and the amazing knowledge, and support that you had for us on the Committee. And even, personally, I've really appreciated you. So, thank you so much for everything. And we'll be in touch. You'll just be a text away, as they say.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Yeah, that's right. Whenever you go to the Azores, let me know, to Portugal.

COMMITTEE MEMBER DINIS: Right, right. I have to take you -- I have to take you there. Look at this background. See, that's one of the places I go to.

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Okay. I'm going to take you up on it.

COMMITTEE MEMBER DINIS: All right. That's my little house. Yeah, come to my little house.

INTERIM CHAIR DELGADO: Thank you. Thank you, Maria.

Okay, well, thank you all. Luci, thank you again, and for being here ---

OUTGOING INTERIM ADMINISTRATOR MARTINEZ: Thank you, Dr. Delgado.

INTERIM CHAIR DELGADO: -- in person today.

Let's see, Sussan, are you going to be doing roll call this morning?

MS. ATIFEH: Yes. Yes. Okay. I start with Dr. Dickey?

VICE CHAIR DICKEY: Here.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Here.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Here.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Here.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Here.

MS. ATIFEH: And Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Here.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Present.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, thank you. So, just for the record today we don't have Dr. Bazzano and Ms. Lund. They are not present at this meeting. But with the Committee members present a quorum

is established.

INTERIM CHAIR DELGADO: Wonderful. Thank you so much, Sussan.

MS. ATIFEH: No problem.

INTERIM CHAIR DELGADO: Okay, so we are going to start with some Chair updates. So, I'm going to start by talking about the cadence of the meetings. I should have waited to talk about this because it was a voting item. So, I know I had sent out an email asking for people's thoughts about meeting monthly versus every other month. But we're going to rehash that discussion here, so that we can have a formal vote with all folks present, and with the opportunity for public comment.

And so, what I had written in email was that there -- over the last few months we have really been trying to knock out a lot of policy issues. There were a lot of policy issues that had been outstanding that Agnieszka, and the administrative team, with the help of Lucila, have been working through. And we --

(Operator comment)

INTERIM CHAIR DELGADO: Thank you. And so, we had identified that the last meeting went fairly long and that there are many items to discuss. And so, we talked about doing a brief, six-months' transition. And there were two options.

The first was to maintain our cadence of meeting every

other month, but have full day meetings. For those old school folks who have been here, we used to have -- go straight through to four or five p.m. So, that was option one.

Option two was to move to a monthly cadence and meeting every month, and maintaining what we have come to have now, which our meetings get out around lunchtime.

And so, want to repeat that back to folks, open the space for any thoughts and comments from the board members. We will then open it up for public comment. And then, we will vote on whether or not we want to move to a monthly cadence for a six-month time period, or maintain every other month and extend ourselves to full day meetings.

COMMITTEE MEMBER SCHAEUBLE: Darci, would you clarify? Because I think your discussion of meeting every month was that protocols would be reviewed on the regular cycle, but the additional meetings would be for matters of procedures and --

INTERIM CHAIR DELGADO: Yes. Thank you so much for clarifying. We would not be changing the cadence of project submissions and project reviews because we know that a lot of researchers look out at that calendar and plan around it. So, we were not going to change that cadence.

And so, what we would do is move towards kind of an every other month. So, one meeting we would review only policy issues,

the next projects. Policy and kind of flip flop back and forth.

Of course, if there is like an expedited project or something that needs to be reviewed, or a special case that pops up, we would be flexible in doing that.

But, yes, thank you. The thought was that we would go policy items and then project items.

Okay, so opening it up for board members. Any thoughts about that? Many of you did reply over email. If you would please communicate your thoughts now, verbally, in this public meeting, that would be awesome.

COMMITTEE MEMBER DINIS: One question I had, Darci, was I think you had indicated, maybe, there would be a time limit that we will do this. You know, five months, six months, something like that. Is that what it was?

INTERIM CHAIR DELGADO: Yes.

COMMITTEE MEMBER DINIS: Okay.

INTERIM CHAIR DELGADO: I would think that it would only be for the remainder of this calendar year.

COMMITTEE MEMBER DINIS: Okay.

INTERIM CHAIR DELGADO: Because once we do knock the -- a lot of these are one-time policy issues. I mean today we're going to be talking about the Common Rule/IPA issue, which I know is going to take up a bunch of time. But like once we deal with that,

we're moving on. So, I do think a lot of the policy issues are time limited and this would only be for the rest of the calendar year.

COMMITTEE MEMBER DINIS: Thanks.

INTERIM CHAIR DELGADO: Okay, I'm going to start with Dr. Dickey and just go around the table to get peoples' thoughts and what their preference would be.

VICE CHAIR DICKEY: I'm in favor of either. I think having more time to talk about the policy issues is critical. I prefer the once a month.

INTERIM CHAIR DELGADO: Okay. Once a month, thank you.

COMMITTEE MEMBER VENTURA: I prefer once a month, as well.

INTERIM CHAIR DELGADO: Okay, thanks.

COMMITTEE MEMBER SCHAEUBLE: I would prefer once a month, yes.

INTERIM CHAIR DELGADO: Okay, thank you. Carrie?

COMMITTEE MEMBER KURTURAL: I would like once a month. I just have to make sure that it's on calendar. And the only other concern is like let's say we have to -- I mean, my preference is that, but we have to miss a meeting does that change the policy? Because the policy under the regs, under our policy book is we only have so much, right, that you can miss.

VICE CHAIR DICKEY: It says you can miss a third.

COMMITTEE MEMBER KURTURAL: Okay, yeah, that's plenty, I think.

VICE CHAIR DICKEY: So, it would keep the same ratio, I think.

COMMITTEE MEMBER KURTURAL: Yeah. Yeah, I mean I might have to miss like one, you know, between now and the end of the year.

INTERIM CHAIR DELGADO: Thanks.

COMMITTEE MEMBER HESS: I also prefer monthly.

INTERIM CHAIR DELGADO: Okay.

(Reporter comment)

INTERIM CHAIR DELGADO: Unless you want to do some karaoke, at which point we will take a break and then you can take a microphone and sing.

Okay, thank you, Dr. Hess.

Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: I'll go along with the majority at this point.

(Laughter)

INTERIM CHAIR DELGADO: It's okay to have differing opinions but, thank you.

COMMITTEE MEMBER JOHNSON: I was in favor of the monthly.

INTERIM CHAIR DELGADO: Okay, thanks, Jonni.

Dr. Ruiz, or Dr. Palacio, or Dr. Dinis, any thoughts or opinions?

COMMITTEE MEMBER PALACIO: Generally, I have no problems meeting once a month, providing I can continue meeting remotely. If that works, then I am happy to do that.

INTERIM CHAIR DELGADO: Okay, thank you, Dr. Palacio.

COMMITTEE MEMBER RUIZ: Meeting monthly for the next six months.

INTERIM CHAIR DELGADO: Okay, thank you.

Dr. Dinis, any thoughts?

COMMITTEE MEMBER DINIS: Yeah. No, I think that's fine. You know, once school starts I have class at noon. But, you know, I'll be here in the mornings.

INTERIM CHAIR DELGADO: Thank you. Okay, let's open it up for public comment. Any public comments, thoughts? We'll pause a second to see if anybody on Zoom raises their hand using the raise hand feature, or anyone in the room you can just raise your actual hands, if you have thoughts on this.

Nick, any hands raised?

Okay, we see no hands raised, no one in the room. Can we get a motion, please.

VICE CHAIR DICKEY: I move that we adopt the schedule of

once per month for the next six months.

INTERIM CHAIR DELGADO: Yes. Okay, so we have a motion on the table.

COMMITTEE MEMBER HESS: Second.

INTERIM CHAIR DELGADO: And Dr. Hess seconds.

Sussan, could we get a vote, please?

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Agree.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Agree.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Agree.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Agree.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Agree.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Agree.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Agree.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Agree.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Okay, great, thank you.

COMMITTEE MEMBER DINIS: So, before you go on, I have a question. So, next month, July 5th, is that the July holiday?

INTERIM CHAIR DELGADO: While some people may be dedicated to this board, I do believe July 5th would not be the best date to meet because of the state holiday the day before.

So, if -- we were looking at the Friday after that, which would be July 12th.

COMMITTEE MEMBER DINIS: Okay, got it. Thanks.

INTERIM CHAIR DELGADO: Okay, thank you.

Okay, moving through the agenda, let's move now to Item B. So, to frame today's conversation, this is not a decision-making item today. This item is up for discussion. We have a few folks, who are here, who are going to wow us with their legal knowledge, and opinions, and thoughts on this topic.

But again, just to frame the issue of the IPA and Common Rule. When a project comes to us an IPA, the decision to review it under the Common Rule or not has been quite a -- we've had quite a voluminous discussion about this, in this board, during the previous probably three meetings in discussing where the statutory guidelines fall.

We have had a lot of board member interest. We've also, thankfully, had a lot of interest from the public on this, as well.

I want to thank, and make sure that folks see, that in your packet we received -- you should have also received it over email. But just want to acknowledge that there was a letter written by a group of researchers that was received to our agency on May 6th, regarding just some of the issues that a group of researchers had and wanted to make sure their opinion was heard. So, want to bring that to your attention to make sure you saw it.

It's -- when it was emailed to you in the packet of information but also was distributed in paper copy for folks today.

And so, we have Jared Goldman and Maggie Schuster here today, who are both attorneys for CalHHS, who have reviewed and analyzed this issue. And so, really appreciate them both being here in person today.

And Jared and Maggie, if it's okay, we'd love to hand it over to you to walk us through your analysis.

MR. GOLDMAN: Great. I'm Jared. I'm the General Counsel of the agency. And Maggie is my colleague and I'm going to give a special thanks to Maggie for doing a lot of the heavy lifting on the (indiscernible) that came up as well.

I hope you all had a chance to read the memo. It's really sort of the underpinning of the discussion today. I'm going to go through it really quickly. But, really, I'd like for us to engage in conversation.

Despite Darci's claim that we're going to wow you --

(Laughter)

MR. GOLDMAN: -- we might not wow you. We're very good at reading books and writing memos, but we don't have the lived experience you all have with human subjects research. So, I'm really looking forward to hearing from you about your thoughts about the memo.

So, I'm going to start with the punch line, a really short overview of the conclusion, and then maybe we can go through the elements of the analysis piece by piece and talk about them one at a time. I think it's easier to eat the elephant one bite at a time.

So, the overall conclusion is that the Common Rule does not apply to everything we do by virtue of the fact of us being an IRB. Really, the Common Rule only applies to those research activities where the institution of the state is engaged in research itself.

I think that's probably one of the easier parts of the analysis.

The next question that flows from that is, well, if the Common Rule doesn't apply to everything we do, can the Common Rule apply on a discretionary basis to those other decisions where we don't have to apply it?

And the answer to that question is, is yes. So, the IPA has a list of criteria that we have to apply in every instance when we're doing an IPA analysis. And those criteria, those lists of criteria are nonexclusive lists. So, we can add to those criteria.

The thing is, is we can't willy-nilly add to it. So, anytime we are implementing a statute, or interpreting a statute, or embellishing on a statute we have to do it through regulations in most instances.

So, if we wanted to create a rule or a policy that we wanted to always apply the Common Rule or we only wanted to apply the Common Rule in some instances, we would probably have to do a regulation so that we didn't get sideways with the Administrative Procedure Act, and their prohibition against underground regulations.

So, that's the big picture. So, now, we're going to zoom in on the little pieces. So, we'll start with the Common Rule. Is everyone good? Okay? No one's had a heart attack, yet?

INTERIM CHAIR DELGADO: Can you -- not a heart attack, but can you just, for those of us that might not have as much knowledge on the state procedure, when you say regulations can you talk about regulations are?

MR. GOLDMAN: Sure. So, regulations are -- they're like mini statutes which we promulgate. We provide notice to the

public. We give the public an opportunity to review. The Office of Administrative Law then reviews the draft regulations and then they're promulgated, then they're adopted.

And once a regulation is final, it has the force of law. And so, it binds us, it binds the public. And they're used for, generally, not our own internal procedures, but those types of things where it impacts the rights of our beneficiaries, or the public, or people outside of the state.

So, makes sense?

INTERIM CHAIR DELGADO: Thank you.

MR. GOLDMAN: Uh-hum. So, the Common Rule. So, the Common Rule has to be used when research is supported by a federal agency, or the research activity is subject to the regulations of a federal agency. When the institution is engaged in the research, itself, when the research involves human subjects, and the project is not exempt.

I know at the last meeting where we discussed this there was also a lot of discussion about the impact of DFWA. And the way the FWA works is it's our voluntary agreement to apply the Common Rule without regard to us receiving funding from the federal government or having the research activity being regulated by the federal government in the outside world. It's our, basically, agreement to apply it.

That doesn't mean, then, that the Common Rule applies to everything we review. Because the Common -- the other rules of the Common Rule still apply. And, specifically, the rule that the institution itself has to be engaged in the research.

And so, you know, it means that any state research that we're involved in as a state is going to come under Common Rule review. It doesn't mean that everything that we do under the IPA will also come under the Common Rule.

Before I move on, are there questions about that piece of it? I know that was a big part of the last conversation. No. Okay, moving on, then.

Actually, did anyone have -- I didn't check to see if anyone had hands raised out in the virtual world.

MR. ZADROZNA: Nothing on the chat, either.

MR. GOLDMAN: All right, great. Moving on. So, maybe the more interesting piece is the piece about the discretionary application of the Common Rule. So, under the IPA we, of course, have to approve as a Committee any disclosures of PII used for the purpose of research.

And there are criteria that you -- and I'm sure you all know this, this is so basic for you. But just for the sake of organizing the discussion, there are criteria you have to apply in order to approve the release of the data.

There are two separate sets of criteria that you apply. There's one set, so the IPA rule that -- or the IPA statute that you apply is 1798.24, and then there's a subdivision (t), which applies to this Committee.

There are two sets of criteria. Criteria under (t)(1) is criteria that we always apply to every disclosure.

And then, there's another set of criteria under (t)(3) which applies when we are reviewing the disclosure of information from an agency database.

We don't have to get into specifically what the criteria are, but what's important to note is the language right before the enumeration of what the criteria say.

So, in (t)(1) it says that the criteria that you're supposed to include -- or, supposed to review, and this is in quotes now, "Shall include" and then it lists the criteria to be applied.

Now, in canons of statutory construction there is a presumption of a nonexclusive include. This is a fancy way of saying when we, as lawyers, see the word "include" in a statute before a list, we presume that list is nonexclusive. This is just a presumption that can be rebutted by other evidence in the statute, or other issues. But in general, it means the list is nonexclusive.

And we haven't seen anything that would include to the contrary, that this was supposed to be a nonexclusive list.

So, in (t)(3) the list says there's the criteria, and before that it enumerates all the things you have to apply, it says that you have to apply at a minimum, and this is in quotes, "At a minimum you apply the list that follows below." And the language, "at a minimum", we don't even have to apply a presumption. I mean, I think that language is clear on its face. When we say at a minimum we mean there's this and you can do more.

So, in sum that means that we can add to these lists. And then, we get into the issue of the Administrative Procedure Act and how we add to those lists. And I would say, in addition, we are constrained by one more thing, which is the purpose and intent of the IPA.

So, when we look at the very beginning of the IPA there's a statement by the legislature about the goals and the rights that the IPA is supposed to confer, and it's all focused on information privacy and security for the individuals whose information we're trying to protect.

And so, really, everything under the IPA is aimed at those purposes. And so, we think that any additional criteria that you might decide to add needs to be constrained by the purpose and intent of the IPA.

So, we couldn't decide, you know, to provide you a ridiculous example, that one of the criteria that has to go along with release and disclosures is all researchers have to wear purple socks and for us to authorize purple socks are cool. But that's not something that would likely fly if it was challenged.

INTERIM CHAIR DELGADO: Can you repeat that part, again, just for those of us who are under caffeinated?

(Laughter)

MR. GOLDMAN: The purple socks?

INTERIM CHAIR DELGADO: So, what I hear you saying, and I'm just going to repeat it back to clarify my understanding, is at a minimum -- the list does enumerate like at a minimum, meaning that it could be added to, but anything that could be added to is -- has to fall under the scope of the purpose of the IPA, which is for the purpose of --

MR. GOLDMAN: Information privacy, exactly.

INTERIM CHAIR DELGADO: -- information privacy. Okay, got it.

MR. GOLDMAN: And then, you know, the next constraint is, of course, sort of the more procedural aspect of it, is that we have to -- we would strongly recommend that you do it through a regulation. You are not strictly required to do it through a regulation. But if you decide to apply additional criteria without

there being a regulation, there's a material risk that you will run into challenges that the application of the additional criteria on a case-by-case basis is being applied to a researcher on a discriminatory basis, or in an arbitrary way.

Does that make sense?

INTERIM CHAIR DELGADO: Can I repeat back?

MR. GOLDMAN: You can. I love that.

INTERIM CHAIR DELGADO: This is like, this is how I confirm my understanding.

MR. GOLDMAN: I love the mirroring.

INTERIM CHAIR DELGADO: So, what I hear you saying is if you follow that list, the list that is enumerated as it's in black and white on paper, that's like option one.

Option two is if you want to go above and beyond, either on a case-by-case basis or broadly as a new policy approach it needs to go through regulations. Because you risk being seen as being discriminatory in how you're --

MR. GOLDMAN: Let me put a finer point on that.

INTERIM CHAIR DELGADO: Okay.

MR. GOLDMAN: So, you could apply additional criteria on an ad hoc, case-by-case basis. You can decide to add a criteria that's within the constraints of the IPA based on the particular facts presented to you in the research project.

So, you can say, this particular research project is so special, and it has such a weakness, or there's something so different about it --

INTERIM CHAIR DELGADO: The data is so sensitive.

MR. GOLDMAN: Right. -- and that it leads to the need for this particular kind of additional consideration of some other criteria. You could do that. I don't recommend that you do that because you're reviewing and approving so many different projects, and it's being done by so many different people as primary researchers it's going to be really hard for us to get a handle and apply this in a way that's fair, and that won't ultimately run into a challenge by someone who's saying, you know, this is all kind of arbitrary the way that you're doing this.

So, I think the better way to do it is to come up with a policy approach for how you would do it. Now, when you decide on a policy approach, a rule of general application about how you're going to apply these additional criteria, if you were to just put it into your policies and procedures that would be an underground regulation.

So, any rule of general application that is interpreting or implementing statute has to be done as a regulation.

So, if you decide to do a policy, it's not that you should just choose to do a regulation, you're going to have to do a

regulation if you decide to do a policy.

So, the decision point is are we going to do these on an ad hoc basis and expose ourselves to the risk of potentially doing this in an arbitrary and discriminatory way, or are we going to do a more thoughtful -- you can probably see where my bias is -- we're going to do this in a more thoughtful and planned approach, put together a policy and this policy is going to be implemented through the promulgation of a regulation.

VICE CHAIR DICKEY: Just to clarify so, but if you do it on an ad hoc basis you still need to stay within the bounds of data privacy and security.

MR. GOLDMAN: That's right.

INTERIM CHAIR DELGADO: No purple socks rule.

MR. GOLDMAN: No, well I'm -- yeah, that's right, no purple sock rule.

(Laughter)

MR. GOLDMAN: Yes?

COMMITTEE MEMBER SCHAEUBLE: I have two follow-up questions going back to what you've just been discussing and what you said earlier.

The policy manual, itself, seems to have implications for the rights of researchers as well, and I'm not clear on the distinction between needing a regulation in the circumstances we're

talking about versus information that exists in some form about a whole variety of issues in the policy manual.

MR. GOLDMAN: So, I'm not going to get into the specifics of your policies and procedures manual. I'm not super familiar with it. But I'll say this, that generally we adopt policies and procedures to govern the internal operations of an organization. And generally we adopt regulations that govern the rights of the public or our beneficiaries.

VICE CHAIR DICKEY: And we do have things in the policies and procedures that says, you know, you have to submit your application ten days ahead of time, that sort of stuff. But it's not binding. We deviate from it all the time, as needed. I would think that that would speak to the fact that those don't need to be in regulation.

MR. GOLDMAN: And I would encourage us to steer back into the conversation of the Common Rule and the IPA, and we'll leave the discussion --

VICE CHAIR DICKEY: Right.

MR. GOLDMAN: -- the broader discussion of your policies and procedures for another day.

COMMITTEE MEMBER SCHAEUBLE: A different question.

COMMITTEE MEMBER DINIS: Well, I also have a question. Oh, it seems like I'm having an echo, let's see.

INTERIM CHAIR DELGADO: Maria, can -- Dr. Schaeuble had a follow up. Can we do Dr. Schaeuble ahead of you?

COMMITTEE MEMBER DINIS: Oh, sure, of course.

INTERIM CHAIR DELGADO: Sorry.

COMMITTEE MEMBER DINIS: That's okay.

INTERIM CHAIR DELGADO: Thanks.

COMMITTEE MEMBER SCHAEUBLE: Different question. The desirability you're talking about of putting this into a regulation, I'm thinking that had there been an occasion several years ago to try to describe situations that might lead to additional factors being considered, what we would have said then may very well not have covered situations we've encountered in the past year or so that turned out to be, in fact, rather contentious.

And we have the benefit of hindsight now, where we could try to write something now that might cover the situations we've encountered. But again, won't be likely to cover some of the situations we may encounter in the future.

So, how is this dealt with if you're suggesting that it needs to be organized into a regulation?

MR. GOLDMAN: I would say this is a problem that is in the very marrow and bones of our statutes and regulations throughout state government. It is that we create rules, we apply them, we try to capture the most important things. We learn, after

we adopt statutes and regulations, through experience, and then we amend them to catch the situations that we've learned from.

But it's imperfect. But it is flexible. It's not as easy to change as, you know, a policy that we can change on a simple vote or a criteria we can add on an ad hoc basis. But it's the way we operate as a government.

COMMITTEE MEMBER SCHAEUBLE: So, if a situation is encountered that may not have been specifically stated in a regulation and, yet, is very troublesome as the Committee reviews, what's the --

MR. GOLDMAN: You could -- I mean, this is -- we're just spitballing now. But I can see a situation where you would draft a regulation similar to the way that your statute looks which is, I don't know, the CPHS will consider criteria that will include, but are not limited to. You will have specified additional criteria -- you could have specified additional criteria in your regulation that will be clearly articulated in ways that you could apply in a nondiscriminatory and a nonarbitrary way. But in an emergency you still might be able to apply additional criteria.

You know, all those same risks and things that I'm worried about would still apply by dropping in some new criteria on top of the regulations, but theoretically I think that's possible.

COMMITTEE MEMBER KURTURAL: I have a question.

INTERIM CHAIR DELGADO: Oh, sorry, Carrie, can we go to Maria next?

COMMITTEE MEMBER KURTURAL: Oh, yes, Maria, yes.

INTERIM CHAIR DELGADO: Maria, go ahead, and then Carrie.

COMMITTEE MEMBER DINIS: I'm here. Okay. So, I mean lots of things come to my mind, you know. So, this Committee existed way before the IPA and then the IPA came at some point in time afterwards. And, you know, I've always been told that the intent of the IPA was to be really on top of the CPHS or the intent of the Committee's rule, rather than something separate. And it seems like the understanding now is it's something almost separate.

The trouble I have with that is that, you know, when you look at, say, the federal regulations and you have personally identifiable data they become a human subject if you have this IPA -- I mean, this PII available to researchers.

And to me, we -- you know, what we've seen is then also researchers taking their state databases and merging with other databases, or at least that's what they want to do, that also have a ton of PII involved.

And I think that the question that comes to me, you know, is about, you know, data that's not been consented by human subjects, with personally identifiable data. You know, should that data be available to researchers, period? You know, that they

don't get consent because they're publically -- let's say, take the Cancer Registry. That's a mandatory database and people report there, and there's a bunch of PII that goes there. And you take another database, labor statistics, or something else that people never consented their data, you know.

And so, now, merge these datas and you can do all kinds of research and people have no idea that this is going on.

So, to me, you know, if this is allowed under the so-called state regulations, then we have to amend the IPA. I mean, I just don't see how this is actually a good idea. And eventually, this day and age, with AI and everything, the state is going to get in big trouble. I mean it's going to happen. Sooner or later there will be a major disaster with one of these cases because it's a lot of data going out there about people, people's lives, you know, very important things, and somebody's going to get pretty pissed off that the data is being used in the way that it is.

So, that's the concern I have in terms of how we're doing it, and maybe even our interpretation. Because at what point, you know, if the role of this Committee, and which the IPA says it comes back to -- they wanted this Committee to approve.

But you're saying we're not engaged, you know, we only approve, you know, the data release. Then why can't the state agencies approve the data release? Why does it have to come back

to an IRB? You know, to me it makes no sense because if it comes back to an IRB, then the IRB rules are going to apply. Otherwise, the state agencies could just release their own datasets.

MR. GOLDMAN: Well, I can't -- I don't -- I can't read the minds of the legislature. But I think that the reason why the IPA has this information and the decision to make it come back to you is to have a body, an objective body that is not a department, that has some distance from the decision and can do it in a more removed way and make the decision. I think you play an important role, even when you are not fulfilling the role as an IRB, for the purpose of an IPA release.

VICE CHAIR DICKEY: I just want to give it some background on the IPA, since I was the chair when it was put in place. The context was that Department of Social Services gave out some data they shouldn't have given out. And it was -- well, it didn't even go through their internal board and it was hacked at UC Berkeley. And the department ended up paying $750,000 to notify all the people.

And then, it became the question of, well, how do we keep this from happening again? And I think that somewhat CPHS was a convenient solution.

But we don't necessarily have the data security expertise that the IPA certainly implies we have. And that's why we've been

requesting some sort of additional researchers to help us do that data security work better.

COMMITTEE MEMBER KURTURAL: I hear Dr. Dinis' argument. And I'll give you a use case, so it's not as cryptic. But I believe that we had a few cases over the past year where, you know, one of them that I reviewed, for example, was a little concerning because it went through expedited review.

If you're not aware of expedited review, it's where it doesn't go through a full board decision. And, you know, we've -- a couple of the board members are assigned to take a look at it, review it, ask questions if need be, and then if it looks good, you know, and everything's buttoned up, it's approved.

But we got a couple of the things that -- and I can hear, Dr. Dinis, your concern because we received a data only review project that is connected with other financial and education data. And it's like, oh, if you cannot -- like CPHS data, or whatever it was, I don't even remember what it was, with, you know, the community college data. Which, community college was like, sure, you can do all of this, you know, and use all of our data. And they were very loosey goosey with it. And, you know, chancellor signed off on it.

And then, it gets a little concerning when you start to see, oh, my goodness, there is a connection here with -- it's not

just what we provide out, but there is a connection to this other financial and education data that it starts -- I think that's kind of like the new world we're living in, right.

So, in that particular case, which I did think we had under our discretion, I said, look, I'm going to kick this to full board review. Because I really feel that there needs to be a conversation before this is approved to maybe like limit the scope of the project, or at least get some justification for what's going on.

And I've always believed that, you know, that's in our discretion that if we get a data review project, and we feel it needs a full board review that, you know, we can go ahead and do that.

And maybe that has to be put in regulations. It's a more technical question I guess about the regulations if -- you know, it's kind of ad hoc, like you were saying, that decision. But rather than getting consent and going through the common law application, I thought that the best middle ground would be let's go kick it to full board review if it's something truly controversial that's mixing with other data. Which is better than nothing, right, because at least you get the opinions of everyone, and ideas flowing on, all right, how are we going to protect the human subjects in this case.

And in that particular case there was -- I believe there was another IRB that approved it, the project, who was engaging in research.

But anyways, just wanted to get your thoughts on that.

MR. GOLDMAN: That brings a question to mind for me. And I have all these experts in the room, so I might as well take advantage of it.

But when you are reviewing a data only review, and it's human subjects research, in every instance is there an IRB on the other side that's dealing with the researcher?

VICE CHAIR DICKEY: I think the federal rule is that if it is research it has to have an IRB reviewing it. But it's the institution that's receiving the data, it's their IRB that's reviewing it.

And I think a lot of our Committee members, and including me, think that sometimes the receiving institution doesn't have the motivation to find problems with it.

MR. GOLDMAN: I see.

VICE CHAIR DICKEY: Which -- but that's the way the federal law is written.

MR. GOLDMAN: Right. So, this is sort of like, you know, how you can drive on your California license everywhere in the United States. You don't have to retest your license in every

state you drive into. And maybe there's some driver's requirements in other states that might not really meet California standards, and there might be some out-of-state drivers on California roads that we're not too crazy about having.

COMMITTEE MEMBER KURTURAL: Everyone does something different.

MR. GOLDMAN: And it seems to me that's sort of analogous, but this is the situation we have.

MR. ZADROZNA: And then, Evan White raised his hand.

INTERIM CHAIR DELGADO: Yeah. We'll go to public comment.

MR. ZADROZNA: Oh.

INTERIM CHAIR DELGADO: Thank you so much. Noted that you want to make public comment. Want to hold space for other board members' questions and clarifications before we open it up to public comment. Thanks, Nick.

MR. GOLDMAN: Yes, please.

COMMITTEE MEMBER SCHAEUBLE: I guess two more follow-up questions. One, would you comment on what differences, if any, between trying to have a case-by-case decision on additional criteria versus a more general application of additional criteria. Which, by the way, I'll say for the public record I'm not advocating since I know that we have researchers trying to infer

things from what is said at the meetings.

But would you comment on difference in approach between those two situations?

Different question, following up on what Dr. Dickey was just observing about our experience with what seems to be happening as researchers' institutions review these kinds of projects.

What would be the situation if the Committee wanted to request information in connect with these preexisting data projects about what kind of consent, if any, was obtained when the data were originally acquired, before they were put into an agency database?

And what review, if any, did the researchers' IRB consider with regard to consent issues? Simply for the purpose of the Committee's longer term education as to what is actually occurring, not with the purpose of intending to apply that information in the research -- in the evaluation process for the research requests.

MR. GOLDMAN: Let's start with the second one.

COMMITTEE MEMBER SCHAEUBLE: Okay.

MR. GOLDMAN: And my sense is, is there's nothing that would preclude you for asking for someone to submit information in their application, if it's voluntary. That's the clear example.

Please, if you are willing, submit information about such and such. No problem at all.

I think the harder question is, is can you require, as a condition of approval of the project, information that's not tied specifically to an existing criteria.

That's a harder question and that's one I think I probably want to think about more before I answer it, if that's okay with you.

COMMITTEE MEMBER SCHAEUBLE: Uh-hum.

MR. GOLDMAN: I'm going to go back to the first question.

VICE CHAIR DICKEY: Okay.

MR. GOLDMAN: Which I'd like you to elaborate a little more on your first question about -- I don't quite understand your first question.

COMMITTEE MEMBER SCHAEUBLE: Oh. I wasn't sure whether there were nuances or not in your responses about what the Committee should do, was legally obligated to do in the situation of wanting to have the option to, on a case-by-case basis, apply some kind of additional criteria versus a situation where the Committee wanted to more generally apply additional criteria.

MR. GOLDMAN: So, I'll say this, I don't think you, as a body, should sort of adopt an invisible approach to how you're going to apply additional criteria. There shouldn't be some implicit policy that you're applying. I think you could potentially get sideways with the underground regulation

requirement.

I think that any -- any ad hoc application of an additional criterion really needs to be driven by the specific facts that are presented to you and the specific risks you're seeing with a particular project. And the criteria needs to be narrowly tailored to apply to the facts as you see them in front of you.

My preference, my recommendation as your lawyer, is that you minimize that approach. Just because the more you take that approach, the more you get into that territory I'm worried about, people making claims that you are apply these criterion in an arbitrary and discriminatory basis.

So, I'm -- that makes me nervous. You know, my Spidey sense is tingling. And so, my preference is that we ultimately engage in a rulemaking process if this is the kind of thing we ultimately want to do.

VICE CHAIR DICKEY: Just back to his second question. I think we probably could require them to submit a copy of their approval from their IRB because that is required in law, they need to have their IRB.

Now, we may not learn much from that because often it just says "exempt".

COMMITTEE MEMBER KURTURAL: Yeah, right.

COMMITTEE MEMBER SCHAEUBLE: Right, that's the problem.

VICE CHAIR DICKEY: But at least we're doing something.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: That wouldn't really answer the question I was trying to raise, though.

VICE CHAIR DICKEY: No, I don't know that it would answer many questions, but at least it would assure us that they have another IRB involved.

COMMITTEE MEMBER KURTURAL: Yeah. Another thought is I know that the departments contract direct with agency to utilize, basically -- like, for example, my department, DDS, utilizes CPHS as its IRB or privacy board. And we, you know, there's a small amount of money that's exchanged between the departments and that's for us to review.

But going back, Dr. Schaeuble, one of your points, was is the consumer on notice, right. Well, it depends. Because if you're a HIPAA covered entity and you're Healthcare Services, or you're DDS, they aren't getting a privacy notice on the front end when they sign up for services that says their data could be used for research purposes. Because we're HIPAA covered, we're required to do that under the law.

But there are other departments I'm thinking of, like Social Services, that might not have that. You know, if you're

worried about some kind of notice being provided.

And I -- you know, there are other departments that just aren't covered, like DOR, and some other departments like that. I don't know if they have a similar kind of privacy notice.

But one of the things that we could do is we could also address it in the contract, right, that -- possibly, that there has to be some kind of privacy notice.

MR. GOLDMAN: So, you have a -- so, tell me where are the contracts?

INTERIM CHAIR DELGADO: Like, you're saying the contract between the department and agency.

COMMITTEE MEMBER KURTURAL: Right. There's a basic contract between all the departments and agency on basically consenting for this board to be the IRB or privacy board, you know, for a HIPAA covered entity.

VICE CHAIR DICKEY: But the problem with that is that most of our data requests come outside of the agency. They -- it covers everything, even the Department of Motor Vehicles.

COMMITTEE MEMBER KURTURAL: Oh, they might not have a contract, is that what you're saying?

VICE CHAIR DICKEY: They don't have a contract.

COMMITTEE MEMBER KURTURAL: Oh, okay. Okay. Well, yeah.

INTERIM CHAIR DELGADO: But I think what Carrie is

saying, though, is that for those that are a HIPAA covered entity there are privacy notices.

VICE CHAIR DICKEY: It's required.

COMMITTEE MEMBER KURTURAL: Yeah.

INTERIM CHAIR DELGADO: I would actually even want to explore the DSS that there may be --

COMMITTEE MEMBER KURTURAL: Yeah, I don't know. Yeah, I'm just saying that's a question. I don't know, it's quite possible that the counties, hey, when you're signing up for social services benefits that there's some kind of notice that's provided to them upon eligibility.

INTERIM CHAIR DELGADO: That's a good question and something for us to explore. We're giving Jared a little bit of homework.

Maria, you --

MR. GOLDMAN: That sounded like your homework, not my homework.

(Laughter)

COMMITTEE MEMBER DINIS: I had on more thought, question because she just reminded me of something. Which is some of these projects also ask us for a HIPAA waiver or a waiver of informed consent. And that's what becomes difficult because you cannot do that if you're just doing IPA review. Then, you're going back to

having to use Common Rule. And so, that's -- you cannot separate the two and that's where it becomes very confusing for me. In this juncture, now, you're reviewing, you have to go back and be an IRB board in these circumstances.

And so, this is where to me this doesn't work. So, in this scenario you're just acting -- you know, you're just doing IPA, you know.

But here, you know, you can include all of the sudden, that's very strange to me.

MR. GOLDMAN: I would agree with your conclusion that you cannot -- you cannot approve a HIPAA waiver as an IRB for an entity for which you are not engaged in the research.

So, the HIPAA waiver is for the IRB that is overseeing the researcher. Not for us as the organization that's overseeing the data only disclosure under the IPA.

VICE CHAIR DICKEY: Which would mean that we would need to change our IRBManager because it gives everybody who applies for data the option of applying for a HIPAA waiver. And regardless of whether we're actually serving as their IRB.

As I think we have previously discussed, either that or we declare ourselves the privacy board for the entire state government.

COMMITTEE MEMBER DINIS: But what about the waiver of

informed consent?

MR. GOLDMAN: I think the waiver of informed consent should come from the IRB that's overseeing the -- should come from the IRB and the institution that is overseeing the researcher, not this body.

COMMITTEE MEMBER DINIS: But if it's from our own data, how can they do that?

MR. GOLDMAN: I'm sorry?

COMMITTEE MEMBER DINIS: If it's from our own data, our own database, how can the other side, let's say Berkeley or somewhere else, do a waiver of informed consent from data from the State of California?

MR. GOLDMAN: I mean, I think they would obtain the waiver of informed consent. It wouldn't bind us. It wouldn't compel us to disclose the information. But that IRB would do the analysis whether it was appropriate, under the facts of the research, to grant a waiver of consent.

COMMITTEE MEMBER DINIS: I mean, that's what they're trying to do now. They're trying to say that, hey, just give us all this authority, we'll be able to actually let you know better than you can, your IRB of the State of California, we will do this review for you.

But, of course, they don't have legal, you know, binding

to it. It's not their data that they have to worry about. But that seems to be the implication, at least on the other letter we got from the 10,000 researchers on that, that signed on.

MR. GOLDMAN: I mean, I think it would be fair for you to confirm if -- whether or not they had obtain a waiver of consent from their IRB or institution.

COMMITTEE MEMBER DINIS: But my point is, if we're granting a waiver of informed consent and we do that as well, we're acting now as an IRB.

MR. GOLDMAN: But what I'm suggesting is that you should not be doing that.

COMMITTEE MEMBER DINIS: So, then, this IRB doesn't exist except for IPA?

MR. GOLDMAN: No, the IRB exists for research in which the state is engaged.

COMMITTEE MEMBER DINIS: Yeah. I think you guys should split the Committee because it doesn't make any sense to me. Absolutely no sense.

COMMITTEE MEMBER HESS: Can I ask a question? What if there's an instance where we, say, disagree with another IRB's decision to waive informed consent and it's dealing with state data? We don't think that they've -- that they're granting it basically without all the facts.

MR. GOLDMAN: What you can do is you can look at the criteria that you have available to you under the IPA and make a determination if you feel like the concerns that you are able to take into consideration are met. And so, there may be some crossover there, where you could assert some authority based on the criteria that you already looked at to take into consideration.

INTERIM CHAIR DELGADO: And I also -- just sorry, just to add on, isn't that also a department decision?

VICE CHAIR DICKEY: Right.

INTERIM CHAIR DELGADO: That can a department not decide to not make it.

MR. GOLDMAN: Absolutely, a department can just decide not to disclose the information. Even though we approve it, they don't have to give it to them. That happens sometimes.

COMMITTEE MEMBER KURTURAL: It's sounding like we need regs.

INTERIM CHAIR DELGADO: I'm sorry, Carrie, did you have a question?

VICE CHAIR DICKEY: She said we need regs.

COMMITTEE MEMBER DINIS: I was just going to say that the IPA, though, does not even deal with issues of consent, it's just data and privacy issues. So, it's very outdated. It doesn't even include what's happening in these days with data issues and

computers. When it's written, everything was done in paper. You know, paper protocols, et cetera. It doesn't even address all the data online, on (indiscernible) -- things that are hacked. It doesn't deal with any of those issues, really.

VICE CHAIR DICKEY: One more comment. And, Jared, this has to do with stuff we've been talking about in the background. Which is that there does seems to be something where the federal government, you know, protection says that IRBs should be reviewing databases as they're established.

And part of that review can be the informed consent procedures. So that you can review the informed consent up front, but you're not reviewing every release. But there is a mechanism by which an IRB on these data releases, even though they're not engaged in the research, they are engaged in establishing the registry, which is considered research. And part of the establishment of that registry is the informed consent issues.

INTERIM CHAIR DELGADO: Lots to think about. Lots to think about.

Okay, before we move to public comment on this issue, want to see any board members that are online or in the room have any other questions, clarification points, use cases that we want to throw at Jared.

Dr. Palacio, I see you're off mute. Were you wanting to

say something?

COMMITTEE MEMBER PALACIO: No, I'm good.

INTERIM CHAIR DELGADO: Okay, thanks.

Okay, seeing no questions, why don't we now open it up for public comment. Should anyone in the room or virtually have a public comment, you can raise your hand.

Evan, you have been so patient, why don't we open up the floor to you.

MR. WHITE: Thanks, Darci. And thank you to Jared and Maggie for their work on the memo. I really appreciate your attention to the topic. I also wanted to thank the Committee for its obvious and considered engagement with these topics, which is an important one to myself as a researcher, and an important one to a lot of research that's done in this state.

I think, you know, one point that bears repeating is that the IPA's review under subsection (t) is focused on data security. And I don't think that the CPHS could adopt regulations that mimic the Common Rule in this case. The Common Rule covers a lot more topics than just data security.

And I heard some concerns from Committee members about data linkage. And I'm curious to hear what Jared thinks about another piece of the IPA, and one that was made very -- a change that was made very recently, is that the IPA was amended recently

to allow something called the Cradle to Career Data Set, which is a dataset that links together several state administrative datasets, including higher education data, K-12 data, workforce date, and also in the future, also data from Health and Human Services.

And, you know, I'll give Jared a chance to respond, but I'll just say my view, which is that the adoption of the Cradle to Career Data Set, and it's integration into the IPA, shows that the legislature is eager to allow data linkage between different administrative datasets. And has, in fact, done so in a pretty dramatic fashion recently.

And, you know, it may well be that folks on the Committee have a different policy judgment about whether or not that should be the case, and those policy judgments are entirely reasonable. But I don't think it allows this Committee to substitute their policy judgments for the legislature's. I think if you don't like the IPA, you can advocate to get the law changed, but I don't think that the Committee has the ability to basically take their own opinions and place them into the IPA, and make decisions on that basis.

So, I hope that's something that's taken away from the memo, which I thought was well done.

And I'll say one more thing, which is just like, you know, from my experience and, honestly, I've been submitting

projects to this Committee for several, several years.

And I often hear both on the researcher side and folks on the Committee sort of think of themselves as the state IRB. But in fact, this entity is not the state IRB, it is the CalHHS IRB. And it has authority over CalHHS departments and the research in which they're engaged.

And I just, I think it's a good reminder to the board that you're really not empowered to rule over all state research. And as frustrating as that might be, there are other, you know, entities in place. You may think less of those entities, that's perfectly fine. But I don't think you have the ability to then overrule them just because you think that your opinion is better.

So, I'll stop there.

INTERIM CHAIR DELGADO: Thank you so much, Mr. White. I -- Evan. Sorry, are you a doctor. Apologies if I'm -- Dr. White.

MR. WHITE: You can call me whatever you want.

INTERIM CHAIR DELGADO: Evan, thank you. Just in general, public comments don't want to get into like a back and forth. But I know Jared does have a response to the one pointed question that you had. Would encourage folks, if they do have specific questions, can email the board, can email myself or Jared for specific questions that you'd like answers to.

But Jared, thoughts on the pointed question that Dr.

White had.

MR. GOLDMAN: Sure. And first of all, hi, Evan, thanks for your participation and contributions to the discussion. Appreciate it, especially the memo that you spent a lot of time submitting. It was a helpful read.

On whether or not the CPHS is the state's IRB, I would clarify. I think we are the State of California's IRB, but we are not the entire state's IRB, if that's what you were implying. But I think the authority to act as an IRB extends beyond CalHHS. I'm seeing no -- a shake no head from Dr. Dickey. So, we'll say I'll have to hit the books on that one.

VICE CHAIR DICKEY: It's only the departments that are signed onto our FWA, for which we act as the IRB.

INTERIM CHAIR DELGADO: But departments do ask -- other agencies do ask us, too, as a courtesy.

VICE CHAIR DICKEY: And out of the goodness of our heart we review their things for them.

MR. GOLDMAN: Thank you, I appreciate your expertise.

On the question of whether -- whether there could be an additional criterion added to an IPA review related to consent, I don't think the IPA is limited to information security, only.

If you look at the very beginning of the IPA there's a statement by the legislature on the rights conferred by the IPA.

And, really, it's a statement of the value judgment that the legislature is making in the IPA. And it discusses both individuals' privacy and security.

And I think that when you look at the issue of privacy, and this is -- this is me spitballing here, again. I would ask -- I would first say to the Committee any -- I would hope that we'll work together on any criterion we will add, either through regulations or on an ad hoc basis. Before you do any of that, I think it would be -- it would make a lot of sense for us to get together and put our heads together, and make sure it's okay.

But I do not necessarily think that issues of consent are off the table. I think consent is an important part of privacy. For example, it looms large in the HIPAA privacy rule, consent is a very large issue there.

So, I'm not convinced that that issue's off the table, but we should look at it as the issues come up.

INTERIM CHAIR DELGADO: Great.

VICE CHAIR DICKEY: Can I ask a procedural question. We can't just, ourselves, create our regulations, right? We have to go through the agency and the agency --

INTERIM CHAIR DELGADO: The regulations process is quite --

MR. GOLDMAN: You would need our assistance.

(Laughter)

INTERIM CHAIR DELGADO: Yeah. And there is a public comment. There's a public comment piece of any regulation that's passed across the state. It is a complicated process that involves both agency, as well as the Office of Administrative Law.

MR. GOLDMAN: Yeah.

INTERIM CHAIR DELGADO: Am I right? Okay. Great, thank you.

Sidra, thanks for your patience. I see your hand raised. Do you want to come off mute for your comment.

DR. GOLDMAN-MELLOR: Thank you for allowing me to comment. Hi, everyone, I appreciate the work that you guys are doing here today.

I'm Sidra Goldman-Mellor, I'm a Professor of Public Health at University of California, Merced. I live in the valley.

And I have worked with Evan at California Policy Lab and for a while he -- CPL stores data that I have requested from you guys and gotten approval for on several occasions.

And I just -- I sort of just wanted to make a comment from a researcher's perspective, as someone who has spent the past ten years working with de-identified administrative data, including linked data from sort of a variety of sources at the state. That, I mean, there's no role in which I want to downplay the importance

of consent and privacy, and data security in any way. Those obviously take precedence over everything.

But there is a great deal of important research that can only be done by using large scale administrative linked data, of the kind that you guys oversee. And, you know, having -- sort of requiring individual level consent is sort of a foreign concept, you know, for researchers that are using these kinds of de-identified administrative datasets. And it would be completely prohibitive to, you know, these kinds of projects.

So, I do research on suicidal behavior and drug overdose among pregnant and postpartum women in this state. And, you know, that kind of research needs very large data because those outcomes are rare. And so, I really need to work, you know, with the sort of entire datasets. And it just is not possible to, you know, get informed consent.

So, I just wanted to say that it was -- you know, that I had concerns about this or worries that changing the regulations in this way on sort of an across the board sort of premise could be prohibitive and kind of shut down the work of researchers doing important work in the state.

But thank you all for your careful attention to all of these issues. I know that it is contentious and very complicated.

INTERIM CHAIR DELGADO: Thank you, Sidra. Thank you for

your comments. And also, thank you for the important research work that you do. Would echo your acknowledgement that any suicide research requires huge datasets because of the low base rates. So, totally hear where you're coming from, appreciate your comments, and really glad that you're calling in.

This is just my personal like comment in response to Evan White's letter that was cosigned by a number of researchers. One of the things that stood out to me, again just as a member of the board expressing my thoughts, is that the letter, to me as a reader, insinuated that the board was pushing for written informed consent for all administrative datasets. Which, to me, was generalizing the topic and issue in a way that was not representative of the nuanced discussion that we're having.

So, Sidra, super happy that you're here and kind of hearing first hand that the very narrow scope that we're trying to operate in, in a way that maybe better reflects the perspective and thoughts of the board members than what was written in the letter. So, thank you.

Other public comments? I see we've got about 30 people on Zoom. We have a number of people in the room. If folks want to just raise their virtual hand or, if you're in the room, raise your actual hands. Okay, I'm going to count to seven in my head to give folks a minute.

Okay, because we have more people than normal joining, we'll also remind folks that this is a volunteer board. And if you're interested at all in joining CPHS, we are always taking applications for research members to join our Committee. Especially in bringing the expertise that you all have. Feel free to reach out to me or to our Administrator, Agnieszka, we'd be happy to supply you with an application.

Okay, as I stated at the beginning, we are not making any decisions on this item today. It is such a weighty -- it's such a weighty, complicated concept that our goal for today I feel was met, which is to have Maggie and Jared kind of explain their analysis, give us all food for thought, and give the public an opportunity to comment on this topic as well.

My goal is that the next time we meet we come back to this topic with the hopes of having some kind of motion, should it be appropriate. A motion that we either continue to operate as is, with no regulation change, or an option to pursue the regulations process pursuant to what Jared described today. Not to bias one or the other, there may be other options out there or other avenues that we can address at the next meeting. But really, the goal for today was for us to deep dive into this topic, fully grasp and understand it so that we can come back in the July meeting with a potential action.

So, I'll pause for a second. Any closing comments or thoughts before we move on to the next agenda item?

COMMITTEE MEMBER JOHNSON: I have one. Could we get some extra information on what regulations would actually look like prior to the next meeting?

INTERIM CHAIR DELGADO: Sure. We can provide kind of a background of what regulations are, what the regulations process is. I've done it through other departments. It is -- there are many administrative hoops to jump through. Many kind of waiting periods. You submit them and then you wait for 90 days for the public to comment. It's a very state administrative process. But, yes, we'll that detailed out and out to the Committee members.

VICE CHAIR DICKEY: I had one, just if it's okay.

INTERIM CHAIR DELGADO: Yeah.

VICE CHAIR DICKEY: Just to sort of put this in context, there are other laws, other than the IPA, that have been written and specified that CPHS has to review and approve. We had one last session, where it was the SIDS research.

That was a law that was written, we were assigned -- we had to approve it, but it said that informed consent did not have to be required.

So, these laws are being written and they're not -- you know, the question is to what extent do we have stick to them in

the way they're written.

In this case, with the SIDS research, we approved it without informed consent and then the County of San Diego kicked it back and said, no, we won't do it unless you have informed consent. So, we went beyond our authority at that point. And to what extent can we do that with other laws.

And I don't think anybody knows all the laws. And I've been sort of like can we just at least get an accounting of all the laws that we're responsible for, you know, enforcing.

INTERIM CHAIR DELGADO: Well, if any of the professors that are online have a graduate student who's interested in doing a doctoral project on the comprehensive statutory laws and regulations that govern IRBs and research --

VICE CHAIR DICKEY: No, just over us.

INTERIM CHAIR DELGADO: Okay, just over us. We'd be happy to help support a doctoral student or an intern over the summer. It's a great project.

VICE CHAIR DICKEY: Maybe a law student.

INTERIM CHAIR DELGADO: A law student. Okay, Jared, hook us up.

(Laughter)

INTERIM CHAIR DELGADO: Okay, if there are no other comments, why don't we continue to move through the agenda. Jared

and Maggie, thank you both so much for your work on this, for your assistance. And we are in debt more than the chocolate chip cookie.

MR. GOLDMAN: Thank you, I appreciated it.

INTERIM CHAIR DELGADO: Okay, thank you.

MR. GOLDMAN: It was interesting and I appreciate the discussion.

INTERIM CHAIR DELGADO: Thank you.

Okay, moving on, so that was Item B on the calendar. Item C, we did end up having to scratch that item. It was going to be a follow-up presentation from last month, specific to the Health Care Payments Database. But we did have to scratch that item. So, we will come back to that at the July meeting that we voted on earlier. So, thank you, though, for those that helped pull together some of that information. Don't worry, it will come back around in a few weeks.

Okay, so moving on to Item D, a review and approval of the meeting minutes. So, it looks as though we have two meeting minutes' that we need to review and approve. The first are the meeting minutes from March 1st, and the second are the meeting minutes from April 5th.

So, why don't we start with the meeting minutes from March 1st, because we will need two separate motions to approve

these minutes. And so, starting with the March 1st, any edits, or comments on the March 1st meeting minutes?

COMMITTEE MEMBER SCHAEUBLE: Did we have minutes, as such, or I saw a transcript of a recording. What are we working with from March 1st?

DR. RYKACZEWSKA: The minutes, they got sent out, right?

MR. ZADROZNA: Yeah.

DR. RYKACZEWSKA: The got sent out in one of the packages ahead of the meeting.

COMMITTEE MEMBER SCHAEUBLE: Not in the attachments I saw. Maybe I missed something.

INTERIM CHAIR DELGADO: Okay, just give us a minute to go back and look.

COMMITTEE MEMBER SCHAEUBLE: I saw minutes for April.

MR. ZADROZNA: Yeah, we got your comments for that one. Let me just double check it was.

INTERIM CHAIR DELGADO: Sorry folks on Zoom, we're just double checking that those meeting minutes were sent out. If not, we'll just only be approving one, or motioning for one.

MR. ZADROZNA: Yep, you are correct. I guess it was just April on the thing, it didn't add March's.

INTERIM CHAIR DELGADO: Okay, that's okay, we're flexible. So, we will not be voting on the March minutes today.

We will only be voting on the April minutes. So, the April 5th meeting minutes were sent out. We did receive feedback from Dr. Schaeuble, in writing, suggesting the revision of a few just small typos.

Any other edits from Committee members on the April 5th meeting minutes?

MR. ZADROZNA: Do you want me to show them, okay.

INTERIM CHAIR DELGADO: Okay. And we'll show on the screen the revised -- the revisions that Dr. Schaeuble requested.

MR. ZADROZNA: Just those two.

INTERIM CHAIR DELGADO: Okay, great. So, what you see on the screen is just a -- the first was a grammatical edit. The second is a better description of what Dr. Schaeuble discussed in the meeting. So, those edits are up for approval, if we approve the motion, or if we get a motion for approval of these minutes.

Any other, any further edits from Committee members?

Okay, we'll open it up for public comment. Any public comment, as this is a motion and we always open it up for public comment.

Okay, hearing none, seeing no public comment, can I get a motion, please?

VICE CHAIR DICKEY: I approve that we -- a motion that we approve the minutes from the 5th of April.

INTERIM CHAIR DELGADO: Okay. So, Dr. Dickey has a motion for us to approve the April 5, 2024 meeting minutes.

Do we have a second?

COMMITTEE MEMBER VENTURA: Second.

INTERIM CHAIR DELGADO: Dr. Ventura seconded that.

Sussan, could we get a roll call, please.

MS. ATIFEH: Okay, Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: I have to abstain, I guess I didn't attend the April.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Thank you. And we will revisit the March meeting minutes at the next meeting. Okay, so that's Item D.

Let's move on into protocols. So, we'll first hand it over to Dr. Dickey, who is the primary reviewer for an amendment to Protocol 2023-123. Dr. Dickey.

VICE CHAIR DICKEY: Thank you. Is Dr. Hamilton on the phone?

DR. HAMILTON: Yes, I'm here.

VICE CHAIR DICKEY: Okay, great. Well, why don't you start out by first describing what the project was originally, and then what's being added to it. And then, we'll get into our specific discussions later.

DR. HAMILTON: Okay, thank you very much. So, I'm Ann Hamilton. I'm a professor at USC in the Keck School of Medicine. I'm the subcontract PI for a study that is called the SURVIVE CRC Study. The overall PI is Dr. Lauren Wallner at the University of Michigan.

This study had two aims. The first one did not involve patient contact. It involved review of path reports. This study is primarily focused on younger patients with colorectal cancer. That is those under the age of 50.

And the first aim had to do with review of path reports to identify instances of metastatic disease from a population-based perspective. So, that was strictly a path review. It did not involve any patient contact.

So, now we submitted aim two, which does involve patient contact and that's why it's being reviewed at this time. This is a survey of a sample of about a thousand cases. It involves case from Los Angeles County, who were diagnosed under the age of 50, between 2019 and 2023.

The primary protocol is that they're sent a survey in the mail to fill out when they are able to, or chose to. They receive $20 up front. An information sheet is included, which has the elements of an informed consent, a cover letter, as well as a postage-paid return envelope. They may also do the study online.

The survey primarily includes information about treatment that these young colorectal cancer patients have received, information on screening for recurrence that they have had. How their medical care has been coordinated. There are questions about side effects from the treatment and how that's affecting them.

There's also information about whether or not they've had genetic testing for cancer, and other information included in the survey.

Dr. Dickey reviewed the protocol and he had some

questions about how we were handling missing data. And we appreciate his input there. We had some inconsistencies in what we said in the information sheet and in the survey. And we want to make it clear that patients can skip any question they do not want answer. They can just leave it blank.

We have removed any instruction that they need to write "skip" next to a question because, of course, this doesn't apply in the online survey. The online survey does not have any restriction on going to the next question. They can skip any question they do not want to answer.

The only thing we are going to call back on, in some cases with these paper surveys people -- the pages stick together. They may turn two pages at once and leave complete pages blank, really just kind of by accident. So, in the past we have called back to ask them if they would be willing to answer those questions, and have done that on the phone. We've also, sometimes, mailed them back a paper copy of those pages with an envelope, and asked them to complete them, if they would wish.

Is there anything else that, Dr. Dickey, you would like me to discuss at this point?

VICE CHAIR DICKEY: No, I -- I'll just summarize what we discussed, which was that originally the survey did not have the language at the start of it that said you don't have to answer any

question. In fact, it said, answer every question.

DR. HAMILTON: Right, I took that out and changed it to the wording in the information sheet.

VICE CHAIR DICKEY: Exactly. So, now the wording that was in the information sheet or the consent form is now at the top of the questionnaire, which I think is great.

And then, there was this question about call backs for missing questions. And you've agreed that you would not do call backs for the questions that had to do with sensitive topics. And could you summarize those again for me, what those topics where?

DR. HAMILTON: Yes. Income, sexual orientation. I don't know, Denise, do you have those at the -- I know you provided some input on that with -- I don't have the list right in front of me, but I can get it, I can bring it up.

MS. MODJESKI: Right. We don't call back on sexual functioning, we don't call back on income, we don't call back on gender identity questions.

VICE CHAIR DICKEY: Right. So, even if it's something on a missing page, if it has that topics on it, you're not calling them back for it.

DR. HAMILTON: Right.

VICE CHAIR DICKEY: Great. And then, the other thing was if you're calling them back, we needed a call back script, which

you provided to me last night, I think, or yesterday afternoon. It hasn't been shared with the Committee, but it was very straight forward.

INTERIM CHAIR DELGADO: Oh, we got it on email.

VICE CHAIR DICKEY: Did you get it? Okay. So, other than that, I don't have any comments and I'll open it up to the full board.

INTERIM CHAIR DELGADO: Just a comment from me, just appreciate, Dr. Hamilton, your exchanges with Dr. Dickey and willingness to walk back the call backs specifically for the SOGI data. Thank you for that. I had no other problems with the protocol.

VICE CHAIR DICKEY: Hearing no questions, I'll make a motion that we approve the amendment as submitted, which includes the call back script.

Do I have a second?

COMMITTEE MEMBER RUIZ: I second the motion.

VICE CHAIR DICKEY: Okay.

INTERIM CHAIR DELGADO: Okay, we have a motion and a second. Sussan, can we please get a roll call.

MS. ATIFEH: Okay, Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: As always, thank you, Dr. Hamilton.

COMMITTEE MEMBER PALACIO: I approve, as well.

MS. ATIFEH: Oh, sorry. I thought you seconded. Who seconded that motion.

INTERIM CHAIR DELGADO: Dr. Ruiz seconded the motion.

MS. ATIFEH: Oh, okay, I'm sorry.

INTERIM CHAIR DELGADO: That's okay.

MS. ATIFEH: And thank you, Dr. Palacio.

INTERIM CHAIR DELGADO: Dr. Palacio's right on top of it

and he approves as well.

COMMITTEE MEMBER PALACIO: Yes.

INTERIM CHAIR DELGADO: So, thank you so much, Dr. Hamilton. Thank you to you and your team. You should be getting an email, with an attached approval letter, within the next seven to ten days.

DR. HAMILTON: Thank you so much.

MS. MODJESKI: Thank you.

DR. HAMILTON: Bye-bye.

INTERIM CHAIR DELGADO: Okay. Let's move on -- suddenly, we are nine minutes ahead of schedule, which is amazing. Okay. So, moving on to Project 2024-094. Dr. Hess was the primary reviewer, can I hand it over to you.

COMMITTEE MEMBER HESS: Yes. And I see Dr. Shrestha on. She just disappeared. There, okay. Hi, Dr. Shrestha.

If you want to take a minute to introduce the project, briefly, to the team.

DR. SHRESTHA: Sure. Sure, thank you. Hi, my name is Anshu Shrestha. I'm a research scientist at the Cancer Registry of Greater California, and a PI for this study called Tracking Health and Responses to Living with Cancer, or THRIVE Study.

We will be conducting a longitudinal survey study of individuals living with advanced colorectal cancer. So, this study

will involve recruitment of up to 900 cancer survivors from 48 counties within California, which are our catchment area.

And some surveys, there will be four surveys that would be sent out. First, the baseline survey, followed by three follow-up surveys in four months apart. So, each participant, if they're going to participate, will be followed up, up to 12-month period.

The overall PI of this study is Dr. Arnold Potosky, at Georgetown University.

All the sample selection, recruitment and data collection will happen within the registry. Initial contact of patients will be through mail. And in that mail, we'll include information sheet that have elements of informed consent, cover letter introducing the team and the study, and the survey with study ID attached to it, and the return envelope.

We'll also provide information about California Cancer Registry. And in the cover letter we'll also provide information about online survey, if any of them choose to participated through that.

And the return postage will not have any patient information and the survey would also not include any patient information. And so, that when it's returned the confidentiality is protected for all individuals who choose to participate.

Also, in the information sheet we will include

information about what's involved in the study. That it has four different surveys. And they can choose to participate in part or all of the surveys. And also, for each survey they can choose to not answer any question that they don't feel comfortable with.

And then, for their time for participating, we will provide $40 gift card for the baseline survey, which we anticipate to be longer. And then, the follow-up surveys are going to be more of a monitoring and shorter surveys, so they would -- for participating, we will provide $15 gift cards.

In addition, at the end of baseline if -- for people who choose to participate in baseline survey, we'll also ask them if they would be interested in or they would agree to participate in another component of the study, which involves use of their medical record regarding their cancer care. So, we would ask their permission to release medical records for their cancer-related care, so we can access those data.

And for that, if they agree to participate in that component, we will provide $15 gift cards for that.

Is there anything else, Dr. Hess, that you'd like me to speak about the study?

COMMITTEE MEMBER HESS: Yeah. I think I asked you a couple of questions about it over email. But I wanted to make, kind of clarify for the full board that all of the recruiting and

data collection, and correct me if I'm wrong, but this includes medical records if they authorize them, all of that is being undertaken by the Greater Cancer Registry of Greater California. And that the researchers at Georgetown are only receiving a de-identified analytical dataset. So, the researchers, there will not be the transmission of any identifiable data. Nothing identifiable is leaving the Cancer Registry, correct?

DR. SHRESTHA: That's correct, yes.

COMMITTEE MEMBER HESS: Okay, thank you. That had been one of my primary concerns reading the protocol, as that was not clear. But thank you for clarifying that request.

And I did also want to note, your protocol states that the survey that you have included is the draft survey.

DR. SHRESTHA: Yes.

COMMITTEE MEMBER HESS: That's not the final survey?

DR. SHRESTHA: No, we are still working on finalizing the English version of the draft survey. I forgot to mention, I think I mentioned it in the application, we are planning to have English and Spanish version, and we're still finalizing the English version. And once we have approval to use the data, we would like to field test that English survey and then do -- after, or based on the outcomes of that field test, we would like to then finalize and then translate them to Spanish translation.

COMMITTEE MEMBER HESS: Okay. If that's the case, we can approve the draft survey. But once we've approved the draft survey, no questions -- nothing can be changed without an amendment.

INTERIM CHAIR DELGADO: Yeah, or we could do like a modified approval. And then, when the finalized version comes in, it could be reviewed by just a subcommittee of you, Dr. Hess.

COMMITTEE MEMBER HESS: Right, but they want to test it. So, it would have to come back to us for an amendment, anyway.

INTERIM CHAIR DELGADO: Oh, oh, oh, oh, sorry.

COMMITTEE MEMBER HESS: So, we can approve the draft survey as it is, but, yes, then you could test it, but then the final, final version after testing would also need to come back to us with the Spanish translation as an amendment.

DR. SHRESTHA: Sure. I have one question. And I have another team member here who may also have (indiscernible) -- when we submitted this application survey, draft was a little bit older version, and we have an updated version. Should we submit that updated version to you, so we can use that update version for field test, and then do amendment later on for further, so that we're not using older version of survey?

COMMITTEE MEMBER HESS: Yes, please. And after this meeting, you will have access to your protocol again in IRBManager,

and you can upload the new -- the revised survey instrument. And that will be part of the current approval.

DR. SHRESTHA: That sounds good, thank you.

COMMITTEE MEMBER HESS: And also, your -- you are requesting data from VSAC, correct, you're requesting death certificate data?

DR. SHRESTHA: Yes, yes.

COMMITTEE MEMBER HESS: Okay.

DR. SHRESTHA: That's correct. And we have submitted our application already.

INTERIM CHAIR DELGADO: Perfect.

COMMITTEE MEMBER HESS: Okay. I did not have any further questions. I did flag the reading level of the information document and the cover letter. Thank you for making those changes. You got it down to about like a 10th grade level. And I understand part of that is because of required language from the CCR. So, I'm happy with that.

So, if -- does anyone else on the board have any comments, questions?

COMMITTEE MEMBER VENTURA: I do.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER VENTURA: In your description of recruitment and consenting of participants, so you give them an

information sheet and you say that completion of the baseline survey constitutes enrollment in the study.

DR. SHRESTHA: Uh-hum.

COMMITTEE MEMBER VENTURA: Did I miss -- is there any room for the potential participant to ask clarifying questions about the consent? I might have missed that.

DR. SHRESTHA: Yes.

COMMITTEE MEMBER VENTURA: And do they have a contact information?

DR. SHRESTHA: We do provide contact information in information sheet and the cover letter. So, if they have any concern about, or question about anything, they can contact us and ask us.

We also, if we don't receive any response for, let's say, about two or three weeks after we mail, we also plan to call them. And if they -- you know, that would be another opportunity for them to ask questions.

COMMITTEE MEMBER VENTURA: Okay. And then, another question I had was for the subset of individuals who, out of the survey completers, you will ask for their access to medical records, did you specify -- it's a small subset, so I just wanted to clarify how many individuals are you expecting to request that medical information about. I'm just -- I'm worried about such a

small subset that it could potentially be identifiable.

DR. SHRESTHA: Our goal is to receive agreement from up to 400 participants. However, we're not sure if we'll be able to reach that many people. We plan to send out request, out of the 900 we're expecting to recruit for baseline survey. And also, we will be focusing mainly on under 65 age group, so that we can obtain their additional treatment-related information, which we often can't get for under 65. Whereas with 65, you know, there may be other possibilities in the future.

And we haven't had a chance -- our recruitment plan is recruiting early case certain cases. Meaning individuals who are diagnosed with cancer within two to seven months. And we can look back in our data and I don't -- we have, at some point, looked at the data, but I don't have it off the top of my head to see what the distribution is, if you'd like us to share that.

COMMITTEE MEMBER VENTURA: Okay. And then, just one final small point. On the protection against small cell sizes, I believe Cal data de-identification requires it to be cells under 11, less than 11. So, in your protocol submission you have under 5 cases will be suppressed in publications. Can that be changed to less than 11?

DR. SHRESTHA: Yes, definitely.

COMMITTEE MEMBER VENTURA: Just to match with Cal --

DR. SHRESTHA: We use the typical suppression number that we use in the Cancer Registry, but we are happy to suppress it to larger.

COMMITTEE MEMBER VENTURA: Thank you. That's all.

VICE CHAIR DICKEY: Good.

INTERIM CHAIR DELGADO: Good catch.

COMMITTEE MEMBER VENTURA: Yeah.

INTERIM CHAIR DELGADO: Any other questions from board members on Zoom, or in the room?

Okay, Dr. Hess, do you want to make a motion?

COMMITTEE MEMBER HESS: Yes. I move to issue deferred approval -- deferred approval, pending the following changes. First that you will change the small cell size, minimum cell size to 11 per the DHCS guidelines. And I can actually send those guidelines to you.

The second is that you upload the most current version of the draft survey. I think that was it.

And I also want to point out that any subsequent survey, follow-up surveys would also need to come back to us for an amendment. Both for any testing and final version.

So, with that I make my motion.

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

COMMITTEE MEMBER SCHAEUBLE: I'll second it.

INTERIM CHAIR DELGADO: Dr. Schaeuble seconds the motion.

Dr. Ventura was going to second it, but she was eating her bagel, for those that aren't in the room.

(Laughter)

INTERIM CHAIR DELGADO: Okay, Sussan, could we get a roll call, please.

MS. ATIFEH: Sure. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dinis?

INTERIM CHAIR DELGADO: Maybe we lost Dr. Dinis. We can keep going.

MS. ATIFEH: Okay. Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Thank you.

COMMITTEE MEMBER HESS: Thank you, team.

DR. SHRESTHA: Thank you very much.

INTERIM CHAIR DELGADO: Thank you, team. Thank you for your work and your collaboration with Dr. Hess. You should get a deferred approval letter in seven to ten days. Have a great weekend.

DR. SHRESTHA: Thank you. You, too. Bye.

INTERIM CHAIR DELGADO: Thanks.

Okay, moving along to the next project, Project 2024-095. We'll had it over to Dr. Schaeuble to introduce this project.

INTERIM CHAIR DELGADO: Good morning, Dr. John, I see you on the screen there.

DR. JOHN: Yes, good morning everybody.

COMMITTEE MEMBER SCHAEUBLE: And are there any others with you today?

DR. JOHN: No, I'm here by myself to discuss the project.

COMMITTEE MEMBER SCHAEUBLE: Okay, just fine. May be to avoid confusion, I'll ask, your last name is the same as my first name, do you mind if I call you Esther?

DR. JOHN: No, that's totally fine. Thank you, Dr.

Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, we've engaged for several weeks over your project. And can you give the Committee an overview of what all is being done?

DR. JOHN: Yes, I'd be happy to. So, I'm Esther John. I'm a cancer epidemiologist and professor at Stanford University.

And this is a complex project. It is for the Northern California Breast Cancer Family Registry, which is one of six international sites that are participating in the Breast Cancer Family Registry that was established in 1995. So, it's a cohort that's been followed for 30 years.

The California site, and I'm the PI on that, we enrolled about 4,000 women with breast cancer, as well as family members and population-based controls. So, that is what we've done in the past.

And now, we have continued funding from NCI, the National Cancer Institute, and we're funded to expand the cohort with young women diagnosed with breast cancer, under age 45, and their family members as well.

And so, here at the California site we will enroll about 200 families over the next four years, and the California site is located at Stanford University.

The protocol that is in front of you has two parts. So,

part one is the recruitment of 200 young women with breast cancer to collect baseline data via specimens for them. And also collect, in future follow ups, additional data via specimens.

And the second part of the protocol is data sharing required by NIH. And these data that are shared, or will be shared, include data we collected from the women by them filling out questionnaires, but they also include select coded California Registry via vital status variables.

So, I will first just very briefly touch upon part one, the recruitment of new families. I can answer questions at that time. And then, I'll move to the second part that talks about the sharing. And there's a lot of detail to this. It's all described in extensive detail in the protocol. So, I will not go into details now because I don't think I'm being given the time to do so.

So, the CPHS approval, we will request case listings from the Greater Bay Area Cancer Registry so that we can invite young women with breast cancer to join the study.

The protocol we submitted was reviewed by Dr. Schaeuble. And he had requested that we also include all the study materials for CPHS review. And we were able to provide those by May 31st. So, we submitted the invitation letters, the screening questionnaire, the consent form, the baseline epidemiology and

family history questionnaires.

We also, based on Dr. Schaeuble's questions, the comments he had, we modified the protocol and we elaborated on specific issues, and a lot more descriptions and text, as he requested.

And then, three days ago we received additional feedback from Dr. Schaeuble and we integrated his suggestions into the study documents. They're ready now, so we can upload them as soon as we can do so in the CPHS system.

There is one issue that he brought up that we've been working on, and that's a complex issue. It relates to the revision of the consent form we had submitted. Dr. Schaeuble asked that we reduce the reading level. He felt it was too high. And in my opinion, it's probably the most challenging aspect of this new recruitment because we have a number of paragraphs from the Stanford IRB that have to be included in the consent form verbatim, and cannot be changed.

And then, we also have a number of concepts from the Breast Cancer Family Registry consent form template that need to be included, that relate to the data sharing.

So, we're working on another revision of the consent form, and we will work very hard in trying, you know, to lower the reading level for the sections that we can modify. And my hope is that by next week we'll have that ready and we can upload it to

CPHS.

So, I guess at this point I'd like to ask are there questions about this part one that deals with new recruitment of women with breast cancer? At this time would you have any more questions that I can answer, or anyone on the Committee?

COMMITTEE MEMBER SCHAEUBLE: I think I'll -- there are a couple of things that I will bring up, but I think I will wait until you've finished your summary, and then we can cover the few things that I had on my list.

DR. JOHN: Okay, very good. So, now, I'll just briefly talk about the second part, data sharing required by NIH.

So, as I said, the Breast Cancer Family Registry has been funded by the National Cancer Institute since 1995, and it also included funding for a central database. The central database maintains all coded data collected at the six study sites. And the data are assembled, they're cleaned, variables are prepared so that these data can be used for joint statistical analyses and collaborative research.

Now, in order to share select coded CCR and vital status variables with the central database we were advised that we needed to expand the research team to include all the PIs from the other Family Registry sites.

So, we started that process back in December, more than

six months ago. We asked each PI of the Family Registry to submit the CCR appendix 3 confidentiality agreement, and the IPSR agreement, with institutional signatures.

This has been a challenging process. I think in California institutions are used to signing these forms for the CPR and the IPSR form, but outside or internationally institutions are not used to that.

So, we have now received the signed documents with institutional signatures for all sites, except one site, a U.S. site. And that U.S. site is still in negotiation with the CCR lawyers about changing some of the language in the appendix 3.

And then, the plan is also that any individuals at the six Family Registry sites, we will analyze select coded CCR and Vital Status variables that they will be asked to sign the CCR appendix 2. Similar to what my staff does, because they have all the data at Stanford University.

And we will also collect the appendix 3, the IPSR agreements, and the appendix 2 from investigators external to the Breast Cancer Family Registry, who wish to analyze the coded data.

We, per NIH requirements, we also have to share data with an NIH database, such as dbGaP. That is the database that the Breast Cancer Family Registry has selected for data submission. And such data sharing will also be required for the new families.

Now, the data in dbGaP are much less extensive than what we keep in the central database. And it includes fewer variables and also just a few CCR variables.

So, that concludes my brief presentation of that second part, on data sharing. And I'm happy to answer any questions or expand on topics, as preferred.

COMMITTEE MEMBER SCHAEUBLE: So, thank you very much. And I appreciate you going through the two parts of the application so carefully with the Committee.

There were three areas, I think, that I wanted to bring up first, before asking for any other questions or comments from the Committee.

I'll thank you that you've responded so quickly. In many of the small requests for changes in various documents you've already taken care of in the information you sent to me, in the last day or so here. So, really don't need to look at those.

You did talk about the reading level in the consent forms, which we're in agreement that there's a difficulty there with the consent forms overall being at a 14th grade reading level, which just is awfully high. And even the summary at the beginning, which should be -- is intended to be a very easy to read summary of activities for participants, even that part was at a 13th grade level. So, I appreciate that you're already committed to doing

what you can to reduce the reading levels. And we'll certainly look at what you are able to bring back on that.

I could mention, along with that, I knew before that the standard text was information that you would not be able to change, but you did mention in your most recent message that you thought you could make some adjustments to text that comes from the consortium for the central database.

And I don't know how you will find this will work out for you, but it seemed to me that there was some considerable redundancy as a result of text from that source with other information that you had at various places in the consent form.

So, if you could look at any opportunities to reduce redundancy at the same time you're trying to reduce the reading level, that would be certainly greatly appreciated by us, and by your participants, obviously.

DR. JOHN: Yes. Yes.

COMMITTEE MEMBER SCHAEUBLE: So that --

DR. JOHN: I will definitely take a close look at that and see how we can reduce redundancies, yes.

COMMITTEE MEMBER SCHAEUBLE: Okay.

DR. JOHN: Thank you very much for your suggestion.

COMMITTEE MEMBER SCHAEUBLE: And that was -- that was my only comment in that regard.

The second area, I am either misunderstanding or there is something that just doesn't quite make sense to me with regard to one question that I brought up for you to consider.

In the interviewer version of the screening questionnaire, it seems very logical to me, people who answer some of the questions along the way that clearly indicate they would not be eligible according to your screening criteria are directed to a response at the end that says, you really would not be eligible. We thank you for your interest, but we can see from your responses that for this particular study you would not be eligible.

As opposed to those who work their way through all of the screening questions and end up with a response that says, we will contact you further regarding eligibility for the study.

The self-administered version of the screening questionnaire doesn't have that two-prong approach. And the oddity for me is that people can say at the beginning I'm -- I'm not a woman, I'm a man. Or, I don't agree that I would be willing to answer questions and provide samples.

And the screening questionnaire says, if you've answered in this way go to the end of the screening questionnaire, skipping over everything else. But the end of the questionnaire says, we'll review your responses and get back to you about whether you're eligible or not.

Well, it seems to me you already know they're not eligible at that point. It seems like there should be a kind of part A at the end of the screening questionnaire for people who arrive at the end in normal fashion, part A that says, thanks for your responses, please send them back to us, we'll review them and let you know about your eligibility for the study.

But these responses I've identified where people are sent to the end, without answering a whole bunch of questions, would see something that says, based on your responses, it appears you're not eligible for the study. Maybe, please look back at them to be sure you answered them the way you intended to. If that's the case, we'd like to have the screening questionnaire mailed back to us, so we can confirm that you're not eligible in our records, but we won't be contacting you again.

So, to me that seemed like the logical way of handling this and it's not the way that it turned out. So, I'm asking that am I missing something that makes that not an appropriate way of doing things, or what's going on here?

DR. JOHN: No, I think what you're suggesting makes sense, makes sense to me. And two days ago, you know, we made some modifications to the self-administered screening questionnaire. And so, we'll just go back and look at both of them.

So, we have a screening questionnaire that can be

completed online, if the women wish, and there's a screening questionnaire that will be provided in paper, so that's the self-administrative one that's on paper, that has to be mailed back.

So, I'll make sure that on both versions we -- you know, once we find out they're not eligible that they're informed they're not eligible, and we'll not further contact them. And the other group will be reviewed and they will then be invited to participate in the study.

So, I just -- we have to complete those two questionnaires, addressing your comments.

COMMITTEE MEMBER SCHAEUBLE: That's fine. I just wanted to be sure that what seems sensible to me was something that, in fact, would be workable for you, and that you'd be able to do it. So, that's fine, we can go ahead on that basis.

Third area, and this is something that I simply want to bring to the attention of the Committee members here for any questions you may have about the project, and about how the data will be obtained and used.

This is, of course, a very complex study overall, and for the information we're seeing now involving approximately 400 new women who would be participating, we have the new materials about how they would be recruited and what they would be asked.

And, of course, for these 400 women there is built into

the current consent forms information about how data will be shared and how it will be used by various researchers.

For the other part of the study that Dr. John was also describing we have, I think, about 10,000 women who have participated in the past, going back several decades. And, of course, for those women there's not an opportunity to directly reach back to them.

And there is a request, as part of this application, for a waiver of consent regarding the sharing of data that has been taking place and would continue to take place. That's part of what we're looking at here.

The data, I hope you realize, and I'm sure Dr. John will correct me if I'm misstating any of this, but as I understand it there are three sort of places where data may be obtained and used. What's being collected at Stanford, of course, may be used by researchers there, or by researchers who apply to Stanford for access to that particular data.

Then, there's the consortium, the six sites that contribute to this central database that has a huge volume of information to which researchers may apply for access.

And I don't know whether you had an opportunity to look carefully at the dictionary for that database, but it's extraordinarily large. The spreadsheet for it had some, I think,

20 or so individual pages of spreadsheet information. I tried to do a rough count across those pages and came up with something like 2,400 plus variables across the entire file.

So, this is a lot of data that is potentially accumulated about women over a period of time.

I don't think I saw any actual listing of variables that might be eventually transferred to the federal database. Dr. John has described that as the much smaller set of variables. But there will be access the researchers will have to that data source, as well.

So, if you have any questions for her, or concerns about the total package here, information that would be utilized by various people accessing the different sources, this would be the time to ask those questions, or any others that you have about the project.

So, I'm opening it up to the floor here for whatever may be needed in that regard.

INTERIM CHAIR DELGADO: Okay, opening it up. Dr. Schaeuble, do you want to give space for Dr. John to respond, or just open it up to the board?

COMMITTEE MEMBER SCHAEUBLE: Oh, if Dr. John has anything else to say, that's fine. I don't think I specifically asked her for comments, other than if I was misstating something. But I mean

if there are not any other comments here, I guess I will try to craft an appropriate motion.

COMMITTEE MEMBER HESS: I had a -- I had a question, if I could.

COMMITTEE MEMBER SCHAEUBLE: Sure.

COMMITTEE MEMBER HESS: About the -- on the informed consent. I understand that as a part of this research you are collecting genetic information and doing genetic screening. And you do a good job of describing the possible effects on the patient or the participant for the genetic screening.

I'm just curious what -- you offer the participants the opportunity to be contacted if anything shows up in their genetic screening that could be relevant to their health. And it just says, "You will be contacted if potentially clinically useful results are found in your biospecimen sample."

My two questions are, first, is that sort of boiler plate language that you're required to have, because some of this is a little clinical and I'm not sure that it really -- I'm not sure if like the language around clinically useful is clear enough to a potential participant that this could be something that's very important to her health.

And beyond that, what does contact actually look like? Is it a full report? Is it genetic counseling? Is it information

shared with their provider, their healthcare provider? I'm just curious as to what that looks like.

DR. JOHN: Yes, thank you for your question. The (indiscernible), you know, it's defined clinically useful information. This is -- this is, you know, a piece of language that's really coined by our physicians that are a part of the Breast Cancer Family Registry. We have several breast oncologists who are part of the Breast Cancer Family Registry, and they wanted to use that information. Because our genetic research, you know, we find a lot of genetic alterations but many of them, we don't know what they actually mean in terms of breast cancer risk, you know, what can be done in a clinic about them.

So, we had, last year, a project as part of our other linkage protocol and we submitted, you know, the materials to CPHS. We notified women, who had a clinically useful result. Now, we cannot send actual results to study participants because there's always a possibility of sample mix up or other, you know, laboratory errors.

So, all we can do is say in a letter that we found some information that might be clinically useful. We recommend that they discuss that with their healthcare provider or pursue genetic testing. And we actually gave a brochure with multiple places they can contact for genetic testing.

We also give contact information for the genetics clinic at Stanford University, which is headed by Dr. Allison Kurian. She's the director of that unit. And she's actually a co-investigator in the Breast Cancer Family Registry here, at the Stanford site.

And we had actually then learned that several women, after they received our notification letter, they contacted the Stanford Genetics Clinic and they got evaluated.

And that typically requires to give another blood sample or a saliva sample that is then being tested for, you know, a number of genes that we laid out in our notification letter. And that is done to make sure there's no sample mix up in the research study. You know, where we collect thousands of specimen samples, it could very easily happen that, you know a specimen is labeled the wrong way.

So, it's the clinical genetic testing always involves collecting another biospecimen sample and that is being used for the clinical testing. And it also requires genetic counseling and that happens before the woman receives her clinical testing, to make sure she understands what it means, what it could mean for the family, for other family members.

So, that's the procedure we have used in the family registry and we implemented that last year at our California site.

COMMITTEE MEMBER HESS: Okay. So --

DR. JOHN: Does that answer your questions?

COMMITTEE MEMBER HESS: Yeah, it does. So, they receive, effectively, a letter stating that we --

DR. JOHN: Yes.

COMMITTEE MEMBER HESS: -- found something in your genetic -- in your genetic screening that is potentially clinically relevant.

DR. JOHN: Right.

COMMITTEE MEMBER HESS: Okay. Yeah, that -- yeah, I appreciate that, just understanding a little bit more about that process, because that can be a very distressing component of cancer diagnosis is genetic testing. So, I wanted to make sure that there was enough information and support being given to the participants about potentially what these mean, and where they can go to get more information.

DR. JOHN: And we also have in the consent form that section where it says, when it's clinically results are found, I would like to be contacted or, no, I don't want to be contacted.

COMMITTEE MEMBER HESS: Uh-hum.

DR. JOHN: Because there are individuals who don't want to hear about it and they say, no, and we respect that. And we also have that section right below where we say in case -- I

forget, now, the exact working. In case you're deceased -- we probably don't say it that way. You know, would you like for us to contact a family member and share the results, yes/no.

COMMITTEE MEMBER HESS: Yeah.

DR. JOHN: And then, there's the opportunity to give a family member's name. And it's very interesting, a lot of participants -- I mean, I don't know the proportion but, you know, there's a number of participants who actually don't want anyone in the family to be contacted with such a notification.

And again, we respect that. We have to respect it.

COMMITTEE MEMBER HESS: Yes. Okay. No, that, thank you for clarifying that, I really -- I appreciate it, thank you.

COMMITTEE MEMBER SCHAEUBLE: Dr. Hess, when you first asked here, you were initially asking about the phrase "clinically useful" --

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Would you like Dr. John to try to think about alternatives to that phrase? I'm not sure offhand what they would be, but maybe something like results that could impact your health, or whatever she might come up with.

COMMITTEE MEMBER HESS: Yeah, that would -- that would actually be something that I would find helpful. You know, just a little definition somewhere of when you're referring clinically

useful what, exactly, you mean by that.

DR. JOHN: Okay. Yeah, because we can certainly do that. And Dr. Schaeuble just, you know, gave a nice description of it.

COMMITTEE MEMBER HESS: Yeah.

DR. JOHN: So, we will integrate that.

COMMITTEE MEMBER HESS: Thank you.

VICE CHAIR DICKEY: Thank you. Can I ask a question. Do you monitor your database that when some new discovery comes up regarding a particular genetic ailment that might in the past not have been clinically useful, but now is, to notify people? I mean, I'm not judging, you, I'm just asking you whether you do that.

DR. JOHN: Yeah, you know, it's -- the genetic data we have is really very much a function of the research studies, you know, the collaborators who do genetic analyses as part of their research. And genetic data, it is supposed to come back to the central database, so we have those data there.

And as, you know, new findings are made, we can certainly identify individuals who, let's say, have a particular alteration that is now found to be clinically useful and, you know, should be reported back. Or, you know, the notification should be sent back to individuals. So, we can definitely do that.

And because we have several oncologists who work in the area of genetics, you know, they are actually very much informed

about new findings that are clinically relevant. We have Dr. Kurian and we have Dr. Mary Daly, who are PIs, or co-investigators, who actually are on national committees that, you know, develop the guidelines for clinical testing.

So, they're the ones who really, you know, have that information right there. They're always up to date on newest information on that.

And Dr. Kurian also has her own patients, you know, she does genetic counseling with her team. So, again, they're very much informed about new findings from the research side that is actually relevant for the clinic.

So, I feel very fortunate that I have a resource like that, like Dr. Allison Kurian, because I'm a -- I mean, I'm not a physician, I'm a PhD. And so, whenever we have questions where we need a clinical perspective, you know, we have multiple members, you know, our team that can help us non-clinicians.

COMMITTEE MEMBER SCHAEUBLE: Do we have any other questions or comments?

COMMITTEE MEMBER KURTURAL: I think I had one.

COMMITTEE MEMBER SCHAEUBLE: Okay.

COMMITTEE MEMBER KURTURAL: And that my lens is always on the data. But just making sure, I know you're going to protect against small cells by doing statistical aggregate data in your

publication. And if -- just want to hear more about like the specific statistical methodology you would use to de-identify it. The data that your team will publish.

DR. JOHN: Yeah. Because we have such a huge dataset, with so many participants, I don't think we have ever run into any issues of having, you know, small sample sizes of less than 5 or less than 11 in our publications. I mean, we have published widely.

You know, we have over 15,000 families in the Breast Family Cancer Registry. We have data for over 40,000 participants. And even when we just analyze a subset of participants, we always have large numbers. So, we never, we never actually have an issue with small numbers.

COMMITTEE MEMBER SCHAEUBLE: Could you explain for Carrie some of the kinds of identifiers that are removed and some of the kinds of transformations of variables intended to disguise a portion of the information. That might help for, I think, what she was asking about.

COMMITTEE MEMBER KURTURAL: Thank you.

DR. JOHN: Yeah. Yeah. So, in the past and going forward, when women enroll in the Breast Cancer Family Registry they're assigned a study ID number, so that's like a 10-digit code.

And so, whenever in the protocol, and today when I talk

about coded data it means data that we collected for individuals, but they always use that study ID to link the data to that person.

And we never disclose any of the PHI identifiers to anybody. That information always stays at Stanford, in a protected database, and only select staff have access to this database. I don't even have access to that because I have no reason, as the PI, to look at names and addresses. So, I've never had access to that database. But two of my staff have access to that.

So, whenever we send data to the central database, or to pick up, or collaborators, those data are always identified by the study ID.

But we even go further, when data are being submitted to dbGaP, they actually are assigned a new ID. So, anybody in dbGaP who has access to those data would never be able to link the information to, let's say, another dataset they have received in the past.

COMMITTEE MEMBER KURTURAL: I see.

DR. JOHN: And we do the same thing in the central database. The central database has the study ID, that's the same study ID that we use at our sites, and each site has their own study IDs. But the datasets that are being shared for statistical analyses, they always have another, new study ID.

So, we -- I think these two procedures really help that

if somebody, you know, has data they cannot link it across different datasets. Because somebody could come back once or twice and get a dataset for analysis. And if there were a common study, I think they could potentially link them, right. So, we avoid that, by that.

COMMITTEE MEMBER KURTURAL: So, hearing all of the --

DR. JOHN: So --

COMMITTEE MEMBER KURTURAL: Sorry to interrupt you. But hearing all of this and that the denominator of the subject matter is only so large, you know, you mentioned 15,000, everything, could we -- and the fact that your aggregate data that will be published will likely be larger than 11, at this point would you feel comfortable saying that -- assuring the board that anything under 11 will be masked in a publication?

Because the concern is not -- is there is a catchall characteristic data, which could include -- you know, I don't know if you're like gender, I mean, obviously breast cancer primarily would be female. But there's other like -- I don't know exactly the elements.

But do you feel comfortable at this time that your research results will likely be masked under 11?

DR. JOHN: Yeah, I mean, you know, I can discuss that with the central database and ask them whether that is a condition

that can be written into like a data use agreement that, you know, they are not allowed to publish, you know, any counts of less than 11. That will be part of a data use agreement. So, any investigator who gets a coded dataset from the central database, there has to be a data use agreement in place between Columbia University, where the --

COMMITTEE MEMBER KURTURAL: Right.

DR. JOHN: -- central database is located, and the recipient institutions. And I can -- I will talk with the central database folks and ask them if they can put that condition into a data use agreement or at least for California. But it's actually, probably a good -- a good precaution for all the data, not just California data.

So, I would be happy to explore that with them.

COMMITTEE MEMBER KURTURAL: That would be great.

VICE CHAIR DICKEY: I guess I'm Chair right now. Do you want to make a motion?

COMMITTEE MEMBER SCHAEUBLE: I shall try. Okay, I will suggest as a motion here deferred approval for one year, at minimal risk, with the following conditions.

First, work on reducing the reading level and redundancy in the consent forms and resubmit those revisions.

Second, change the paper version of the screening

questionnaire to handle ineligible participants in a way similar to the online version.

Third, consider alternative words for the phrase "clinically useful" when asking participants about contacting them with genetic information.

Fourth, consult with the central database about including a requirement in data use agreements that cell sizes smaller than 11 will not be reported.

And fifth, finish making other changes noted by reviewer comments that you've already started to address.

Does that sound like it covers everything, people?

VICE CHAIR DICKEY: By a subcommittee of?

COMMITTEE MEMBER SCHAEUBLE: I suppose I can do it myself.

VICE CHAIR DICKEY: Do we have a second?

INTERIM CHAIR DELGADO: That's a great motion. Do we have a second?

COMMITTEE MEMBER KURTURAL: I'll second it.

INTERIM CHAIR DELGADO: Carrie, thank you, Carrie for seconding the motion.

Sussan, could we have a vote, please.

MS. ATIFEH: Sure. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Well, thank you so much, Dr. John, and Dr. John Schaeuble, for the very thorough review for your great back and forth communication on such an important project. Appreciate your time in being here and good luck in the -- good luck in your study.

DR. JOHN: Good. Thank you very much to the Committee and a special thank you to Dr. Schaeuble? His feedback has been incredible useful and helpful. And we will implement these things.

I hope that we can resubmit next week, because we do want to move forward with this. This application has been, you know, in the hopper since mid-December. So, it's just been taking a very, very long time to get to this point, which is a little problematic because we need to, you know, get our research done.

So, we will hurry up on our end and submit very soon. Thank you very much.

INTERIM CHAIR DELGADO: Wonderful. Thank you so much for your patience and your time, and I'm glad that we are moving this project forward. And please be in communication if we can help with anything else. Thanks so much, Dr. John.

DR. JOHN: Thank you. Bye-bye.

INTERIM CHAIR DELGADO: Bye.

Okay, we are moving right along. So, Agenda Items J through O are generally just reviewed and approved after today's meeting, but I'll pause for a second. Are there any questions about Agenda Items J through O? That would be new projects, projects requiring continuing review, amendments, reliance agreements, exemptions and final reports.

Okay, seeing none, we'll open it up for a final public comment before we wrap up. If you are on Zoom, I don't know how many people are still on Zoom, or in the room any public comment? You can raise your virtual hand or raise your hands.

Okay, seeing none, hearing none, we will now move towards adjournment. Based on our vote earlier, the next meeting will be July 12th, 2024. Just as a reminder, please come to the July meeting with lots of thoughts and questions, and follow up on the IPA/Common Rule, so we can move a motion on that item.

And just for -- just planting a seed, we'll also hope to talk about the Health Care Payments Database at the July meeting, with a little bit more specificity on the statutes and regulations around the Health Care Payments Database, and what the role of CPHS is in the process.

Thanks everybody for being here. I move to adjourn. Do we have to vote to adjourn? Nope. Okay. Great, thank you all so much. Thank you to everybody on Zoom. Thank you to the admin support staff for running the meeting flawlessly. Appreciate it.

(Thereupon, the meeting was adjourned at 11:13 a.m.)

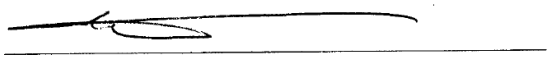
--oOo--

REPORTER'S CERTIFICATE

I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were reported by me, a certified electronic court reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting.

And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 12th day of July, 2025.



PETER PETTY CER**D-493

TRANSCRIBER'S CERTIFICATE

I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber. And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.
IN WITNESS WHEREOF, I have hereunto set my hand this 12th day of July, 2025.

Barbara Little Certified Transcriber AAERT No. CET**D-520