MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, DECEMBER 6, 2024

8:33 A.M.

1215 0 STREET, 11TH FLOOR

CLIFFORD L. ALLENBY BUILDING

MEETING ROOM 1181

SACRAMENTO, CALIFORNIA 95814

AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Darcy Delgado, PsyD, Interim chair

Larry Dickey, MD, MPH, Vice Chair

Alicia Bazzano, MD, PhD (Via Zoom)

Maria Dinis, PhD, MSW (Via Zoom)

Catherine Hess, PhD

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS (Via Zoom)

Juan Ruiz, MD, Dr.PH, MPH (Via Zoom)

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna (Via Zoom)

ALSO PRESENT

CalHHS

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Jared Goldman, General Counsel (Via Zoom)

Maggie Schuster, Attorney

John Ohanian, Chief Data Officer

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Public

Agnes Balla, University of California Office of the President

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Dr. Chanita Hughes Halbert, University of Southern California, SPEC Lab, Norris Comprehensive Cancer Center

Dr. Trista Beard, University of Southern California

Dr. Evan Graboyes, Medical University of South Carolina

Dr. Matthew Cooperberg, University of California, San Francisco

Laura Allen, University of California, San Francisco

Dr. Ansu Shrestha, Cancer Registry of Greater California (CRGC)

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INTERIM CHAIR DELGADO: Good morning. Call to order the December 6th meeting of CPHS. And hope everyone had a fabulous Thanksgiving. And the same to members who are calling in and being on camera, we appreciate that.

I will start with Agenda Item A, which is Chair updates and welcome. I already appreciated folks turning on their camera. So, Sussan, could we do a roll call for a forum, please?

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

INTERIM CHAIR DELGADO: Present.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Present.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Present.

MS. ATIFEH: And Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Present.

MS. ATIFEH: And Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, the quorum is established.

INTERIM CHAIR DELGADO: Okay. Next on the agenda is to note that we found out this week that Dr. Bazzano has submitted her resignation from CPHS. And it is for very positive reasons because she is going to be doing amazing things with the federal government soon, maybe. Am I allowed to talk about that? I don't know. So maybe --

COMMITTEE MEMBER BAZZANO: I think it's okay. It's --

INTERIM CHAIR DELGADO: Tell us about what your next steps are?

COMMITTEE MEMBER BAZZANO: Sure, I'm happy to. I have accepted a tentative offer, pending clearance, to head Pediatric Ethics at the FDA. And that's across all of the FDA drugs, devices, biologics, vaccines, foods, et cetera. So, it's an incredibly exciting position. I'm so honored.

And I just want to take a moment to say thank you to all of you and how grateful I am to have been so privileged to do this work for the past 15 plus years. I know that this is the work that has actually contributed to my being able to do this work nationally.

And I can't tell you how much I've learned. How much I really, really appreciate having been spent -- having been able to spend the time with all of you, and how wonderful I think you all are. The work that you do is incredible. The impact is across the state, absolutely, but also many times across the nation and it really does make a difference for so many peoples' lives.

And so, I just want to say how grateful I am to have gotten to spend this time with you.

And I wish that I could stay on. If, for some reason, things don't work out in Washington, please, I hope I can say hello again at some point. So.

INTERIM CHAIR DELGADO: Well, we are so appreciative of you. I think I told you this, Alicia, you know, but I will repeat it. When I first joined the Committee ten years ago you were chair -- not chairing, but presenting one of the first projects. And the ability for you to balance protecting human subjects, meeting the needs of the researcher, you are obviously just brilliant. Anyone will know that the second you start talking.

And I just remember thinking, that first meeting I ever went to, just what a role model you are and were for me, and I just want to thank you for everything that you've done for this Committee. Like you said, 15 years is a really long time. Longer than my marriage.

(Laughter)

INTERIM CHAIR DELGADO: So, that's amazing. And thank you so much for all that you've done.

I saw Maria put something in the chat, as well. But if anybody else wants to say a few words or come off mutes, and tell Alicia how much we love her, that would be a new thing.

VICE CHAIR DICKEY: I'd like to.

INTERIM CHAIR DELGADO: Oh, go ahead. Dr. Ruiz is going to say something. Sorry, Dr. Dickey. I need more copy.

VICE CHAIR DICKEY: We're interchangeable.

I just want to thank you so much, Alicia. It's like, you know, can we consult with you in the future?

You're on mute.

COMMITTEE MEMBER BAZZANO: Oh. I would love to help out in any way that I can. Because of the overlap between, because we do CFCA trials at CPHS, and there's enough overlap that it's a potential conflict. But certainly, yes, in an unofficial capacity I'd be thrilled to

be able to contribute in any way that I can.

VICE CHAIR DICKEY: That's wonderful. And thank you so much.

COMMITTEE MEMBER BAZZANO: Everything that's going forward, because I know that honestly I -- California leads the way in so many areas, and here in particular I'm going to be taking this to Washington, as well, all the things that we've been doing and talking about. And I don't know that I can contribute but if I can, I'd be happy to. I think it goes the other way around that you guys have taught me so much. So, thank you.

COMMITTEE MEMBER DINIS: I just want to say that's going to be a big loss for us, but I'm very happy for you. And that's just wonderful, considering our new administration you'll be mentioning this.

COMMITTEE MEMBER BAZZANO: Right. We'll have to see how it goes, everything is in flux. I may be back very soon, so we'll see how it goes.

(Laughter)

COMMITTEE MEMBER LUND: Alicia, it's Laura. I just want to say thank you for your years of service on the Committee. I started at the same time Darci did. We started in the same cohort. And I was also so impressed with your intelligence, and your thoughtful reviews. I actually learned so much from you. So, thank you for that.

I echo Maria's sentiment that you will be missed here. But I also think our loss is the federal government's gain. And I'm so glad to hear that someone of your caliber will be working there and doing this work.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER BAZZANO: I'm really humbled. And it's been a true pleasure to work with you as well. I've learned from all of you so much.

INTERIM CHAIR DELGADO: Okay. Well, the door is always open for you and best of luck. And I'm just so excited that we can have you at least for this last meeting today. So, thank you again for everything. And make sure we all have your contact info so we can keep updated on all of the comings and goings at FDA.

COMMITTEE MEMBER BAZZANO: Absolutely, I will. I would have done -- I would have come in person and actually done this faster. I mean at a different piece I've been amazed and surprised at how quickly the clearance process is going. I think they're trying to speed up any new hires, you know, towards -- as quickly as possible.

So, I apologize. I had been originally told that it would be at least three months and it's gone very, very fast.

INTERIM CHAIR DELGADO: Well, you're with us today and appreciate you. And again, always come back. Door is

always opened.

Okay. Thank you all for that.

So, Agenda Item B is the nomination of the new CPHS Chair. So, I hand it over to John.

MR. OHANIAN: Thank you, Dr. Delgado. And I'm going to begin by thanking you for your service. A year ago, as we know, Darci stepped in as our Interim Chair, and we're grateful and continue to be very grateful for her leadership during this critical time for CPHS.

And as we move forward, I'd like to formally nominate Dr. Katie Hess for the CPHS Chair position. We've included her bio and CV in the meeting materials.

I want to share a couple key highlights of the bio, for the group here. For those of you that don't know, Dr. Hess received her doctorate from Boumemouth University in environmental anthropology. She has an extensive epidemiological background, including her work investigating how residential segregation impacted exposure to toxic metal pollution in urban (indiscernible) South Africa.

She was a post-doc fellow at both John Hopkins University, as well as UC Berkeley leading critical research in tobacco e-cigarette and alcohol use.

She's now serving as the Chief of the Epidemiology and Evaluation Unit in the Substance and Addiction Prevention Branch with the California Department of Public

Health, leading research focused on substance use, including tobacco cannabis, alcohol and opioids.

She has a deep expertise in research ethics and has been a member of the Committee since 2021. Meaning she meets all the selection criteria within CPHS Policies and Procedures, which must be a CalHHS or CalHHS Department employee, and been a member of CPHS for at least two years.

Dr. Hess has expressed interest to step into this role, which we're really grateful for. And the Department of Public Health has endorsed her nomination.

So, the next step is for the Committee to vote whether they endorse Dr. Hess' nomination.

So, do I call for that?

INTERIM CHAIR DELGADO: I do. Before we can vote, I think we have to ask for public comment. But before we open it up to public comment, I'll just say super excited for the potential for Dr. Hess to be the next Chair.

I truly feel like a rotating basis of this Chair position exposes you as a member to a lot of different aspects of the board, some of the other administrative functions, some of the decisions on purview, which has been a huge topic for the last year. And it gives you the opportunity to really expand your knowledge set in that space.

So, while Katy -- while Dr. Hess is going to have

that opportunity, hopefully, in the next -- after the vote, for the next chunk of time, I'll also say for other Board members that, hopefully, you will be open to that opportunity as well after Dr. Hess' tenure. Because, again, like the more that we're sharing this knowledge and understanding these different nuances, the stronger our Committee is as a whole. So, I think you're in (indiscernible) --

COMMITTEE MEMBER HESS: Thank you.

INTERIM CHAIR DELGADO: And excited. Any other thoughts before we open it up for public comments?

All right, hearing none, why don't we open it up for public comment. So, if you are downstairs in the Allenby Building, there should be somebody down there to help you make public comment. If you are virtual and online, there is a raise-your-hand function on the Zoom. You can raise your hand if you would like to make public comment.

DR. RYKACZEWSKA: All right. Nick, is there anybody in the room, maybe, who would like to make public comments?

MR. ZADROZNA: There is no public comments down here.

DR. RYKACZEWSKA: Perfect. And I am not seeing any hands on the Zoom.

INTERIM CHAIR DELGADO: Great. Okay, we will close public comment for this item.

And would somebody like to make a motion?

COMMITTEE MEMBER LUND: I'll make a motion. I move that the Committee accept the nomination of Dr. Hess as Chair.

VICE CHAIR DICKEY: I'll second it.

INTERIM CHAIR DELGADO: Great. So, we have a motion and a second.

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

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

INTERIM CHAIR DELGADO: Yay. We are thrilled with

your willingness to take this leadership role and are very excited.

COMMITTEE MEMBER HESS: Thank you. I'm excited.

VICE CHAIR DICKEY: Does that affect the meeting or --

COMMITTEE MEMBER HESS: I have to lead the meeting.

MR. OHANIAN: So, with this endorsement, CDII is going to submit your nomination to our Secretary Johnson for appointment. So, you're off.

INTERIM CHAIR DELGADO: So, you're off the hook for today?

MR. OHANIAN: Yes.

COMMITTEE MEMBER DINIS: Let me just say, Darci, that you were also a great Chair and I just want to also, you know, thank you for everything you did for the Committee.

COMMITTEE MEMBER LUND: Yes.

INTERIM CHAIR DELGADO: Thank you. It's always nice to come home. Just like Alicia, you can leave and come back. So, remember that, Alicia.

Okay, great. So, yes, the next step, as John mentioned, is to submit the recommendation to the Secretary and you will be sworn in, in the February meeting.

Okay, so moving on to Agenda Item C, Subcommittee

Updates. So, Laura, can I hand it over to you to to give updates from the November Subcommittee meetings?

COMMITTEE MEMBER LUND: Yes. So, the Subcommittee for the Development of Regulations to Support IPA Reviews met in November. And we went over -- it involved a document that was originally prepared by Dr. Schaeuble. We had input from our legal counsel. Jared is not here today.

INTERIM CHAIR DELGADO: He's online.

COMMITTEE MEMBER LUND: Oh, he's online. Okay, great.

And there was much Subcommittee discussion around some of the language. I'm wondering, can we put the motion up?

DR. RYKACZEWSKA: Oh, the motion or the --

COMMITTEE MEMBER LUND: Is it possible.

DR. RYKACZEWSKA: I will --

COMMITTEE MEMBER LUND: So, again, just so folks can know, one of the things that we talked about at the meeting that slowed us down a bit when we have our discussions, so that we can make it very clear to the public what we're actually discussing and the nature of the document.

So, the document that I'm referencing, that Agnieszka is putting up on the screen, is a supporting document that describes what's required in the IPA. And it

also describes in the second section the risks that the Committee is particularly concerned about in regard to some of the projects that come under our purview for the IRA -- of the IPA, I'm sorry. And we've discussed this before and we didn't make any changes to that section.

The third section, if you could scroll down just a little more. This is the section that talks about what we would like to be able to ask researchers when they're submitting their projects for IPA review. And this is the section in which we had a lot of discussion and language changes.

So, the motion on the right-hand side talks specifically about this particular section. So, it cleaned up some of the -- it wordsmiths a little bit to clean up the language around "it is available", because it's really redundant, we had that in here twice. So, it's really redundant.

The question came up about when to apply these criteria. And the Subcommittee was not able to resolve that question. We had a lot of discussion about it. We had a lot of issues and concerns.

So, we are bringing back these questions to this group for discussion and resolution by the full Committee. And in particular, the three questions that we had are do we want to restrict the request for additional information,

specifically the privacy practice documentation, to only those projects that propose to link to datasets?

That was brought up as being a special concern because linking to datasets from two different sources, especially if one data source is not a state data source, raises the level of risk. And we wanted to know about the information that had been available to people at the time their data was collected.

The second question is do we want to include requests for this documentation for all of the studies? So, instead of just looking at linked studies do we want to ask for it for all IPA reviews.

And the third option, the third question is do we want to have this additional documentation only for studies that exhibit the risk criteria that we enumerated in question two?

So, there were lots of -- obviously, as we couldn't come to a resolution as a Subcommittee, there were lots of different thoughts and opinions on this. And so, I'd like to open it up to the other Committee members, if you guys want to share your thoughts and where you sit on this?

COMMITTEE MEMBER KURTURAL: Sure.

COMMITTEE MEMBER LUND: Carrie, do you want to start?

COMMITTEE MEMBER KURTURAL: Yeah, I mean --

INTERIM CHAIR DELGADO: Before you start, can I ask a clarifying question?

COMMITTEE MEMBER KURTURAL: Sure.

INTERIM CHAIR DELGADO: Can you frame this discussion in the bigger picture of like the regulations process that would be necessary to make changes?

COMMITTEE MEMBER LUND: I can do that. Because we actually -- we had this conversation at the Subcommittee.

So, one of the things, once we have finalized what we want to do, the CDII legal team will then draft regulations language that turns our -- this is, again, supporting documentation and not regulations language in and of itself. I could say that again, for the minutes.

But they will take that and turn it into the required regulations language, which then has to go through a whole regulations process. There will be -- the regulations, once drafted, are posted for public comment. there's ample opportunity for public comment. I think it's 90-day public comment window, something like that. I don't know that for sure so, you know, don't hold me to that. But there's adequate time for public comment.

All the comments must be reviewed by the department and either incorporated or addressed. So, know the public comments are not just swept under the carpet.

They are, in fact, taken very seriously by the agency. And there's lots of opportunity for the public to comment and question on this as we move forward.

So, does that answer your --

INTERIM CHAIR DELGADO: Yes, thank you.

COMMITTEE MEMBER LUND: Agnieszka, do you --

DR. RYKACZEWSKA: One more addition, too. Once the regulations language is drafted, it will be brought back to this Committee first to endorse before we would submit it for --

COMMITTEE MEMBER LUND: Great. Thank you for that.

INTERIM CHAIR DELGADO: Got it. Yes, thank you for clarifying.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER LUND: So, this is the underlying policy to what direct we want to go in the regulation. So, as Committee Member Lund was explaining there's really kind of three different options.

One being the broadest that, you know, for any IPA reviews that, you know, do we need to ask for additional documentation.

If you want my opinion on it, I think it should be narrowed when we're asking for additional documentation. My concern with the higher risk projects is when there is a

research project taking State of California data and merging it with outside source data. And, you know, I think that it would be nice in application for those scenarios that have a higher risk to take a look at additional documentation and ask for that on -- with respect to outside sources.

So, I'll give you an example. You know, State of California, we have pretty much in agency a handle on the eligibility processes that the counties and the regional centers go through, and our notice of privacy practices.

I don't know if there's a project that comes forward and there's an outside source that's going to be connected with our data, I don't know necessarily anything as a reviewer about, you know, that other outside source. And anything related to that data being connected with ours. And so, additional information would be helpful.

I don't think for the projects that we see reviewing only State of California data, I'm the least concerned as a reviewer with that, personally.

And, you know, the question is what's being explained. Where we're going to ask the researchers to provide additional information in their application.

So, you know, that summarizes, I think summarizes my point of view.

COMMITTEE MEMBER LUND: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Okay. Well, my take

on this is a bit different. Using studies that involve linkage to other data as a threshold is, for me at least, not, I think, the best way to go. I see several outcomes from doing that, that I think are less than desirable.

Some of the projects that would be captured by that kind of threshold are studies in which the linkage to other data really does not cause any noticeable increase in risk because some of the linkages to other data are two variables, or in circumstances where the information is simply not all that sensitive.

So, in those instances I think we'd be asking for information where we really don't need to.

Not reviewing any studies or not asking for additional information for any studies that involve only state data would mean that some studies which, because of the particular variables they are working with, or the particular way in which they're working with them do raise the kinds of risks we've listed in the middle part of this document. Those studies would not be asked for additional information. And I think they should be. If those risks are really present in the way they are described, even if the study is only state data, then I think we should be trying to address those risks.

The third outcome that troubles me is trying to project what I would expect researchers to do under these

circumstances leads me to believe that researchers might very well choose to submit a project saying there was no linkage to state -- no linkage to other data and then, at a later time, come back with an amendment to actually add linkage to other data because the review process would be less burdensome initially, and quicker initially if they chose to say that there was not any linkage to other data.

And that would mean that our initial review would be done in a context where we had, really, incomplete information about the study as a whole, even a potentially misleading context to try to understand the study not knowing that there were later plans that were going to come along for us to consider.

So, those are three outcomes that seem, to me, not the best for our purposes.

I look at the process here as simply being an extension of what already happens when researchers submit various sorts of applications to us. They have to decide on a number of questions, whether the question applies to their particular study and, if so how it applies and how they need to respond and provide us with information.

It seems to me here that what we should want researchers to do is to look carefully at the risks we've identified as ones that we think are especially important, and to make their own determination about whether those

apply to their research. And, if so, to provide the information about how that risk applies in their study and how they are handling it to try to minimize -- and minimize the effects of it and provide us with the corresponding information in their application.

And if, for some reason, they miss something that we think they should have addressed, then as in any other review that we do we always have the option of going back to them and saying we think you should also consider such and such a risk that appears possible in your study, and address how you're handling it.

So, from my view, the third of the alternatives that are listed there on the screen is the one that makes sense to me. That we would focus on those studies that where some of the risks we've identified are actually present in the study, and not limiting ourselves to the one situation of linkage of data, but taking the more global approach to any of these risks exist and, if so, what's being done about them.

COMMITTEE MEMBER LUND: Dr. Dinis?

COMMITTEE MEMBER DINIS: Well, I agree with Dr. Schaeuble and I think that it needs to include the risks that we see. And, of course, we know that the data linkages are the -- the one that's, you know, obviously is more concerning than anything. But there's also other risks that

come up and we should be able to apply the regulations to those risks, whatever they may be. And, you know, and it's hard to even anticipate now what those may be, especially with AI and all those kinds things coming out it's just really difficult, you know.

So, I would like to be more inclusive than exclude, you know, certain things and only say it's only for one small area.

COMMITTEE MEMBER LUND: Great, thank you. And for me, I -- my personal feeling is that it's too restrictive to consider only data linkages. I think that we enumerated all these risks in our supporting document because these are the ones that we think are critical. That we want to ensure, go back to the language of the IPA, that there are sufficient procedures in place to ensure the data security and confidentiality. And that these areas be considered to be particularly risky and want to ensure that we do due diligence around our responsibilities under the IPA for that.

I think it's too burdensome for researchers to go with option number two. We get a lot of IPA studies. And if the study does not have one of the risks that we've identified in this document, I don't see any reason to ask researchers to do additional work to provide the NPP and other supporting documentation. I don't think it's

necessary.

So, I think I agree with Dr. Schaeuble and Dr. Dinis that number three, to me, appears to be the Goldilocks solution that we would want to ask for the NPP and additional documentation for those studies that have the risk factors that have been identified and the supporting documents.

I also wanted to say, in response to something Dr. Schaeuble said, that I think that the same rules are applied to projects that are amended under the IPA as applied to the original review. So, I'm not concerned if they tell us, initially, that they don't have plans to do linkage and then they come back later with an amendment that says they're going to do a linkage. Because that kind of happens all the time, they discover there's different data sources out there and they want to do it.

I would apply these same standards to requests for amendments that I would apply to the original protocol that was submitted. So, I'm not -- I don't share your concern about that particular outcome.

So, those are our thoughts as a Committee. As you can see, we couldn't come to a resolution. So, I would like to open it up to the larger group for your thoughts, and comments, and discussion.

VICE CHAIR DICKEY: So, this isn't a voting item,

it's a discussion.

COMMITTEE MEMBER LUND: Well, what we'd like to do, we didn't put in as -- I think we can vote on it. So, the next step, let me just talk a little bit about the next step.

This is something that we need to resolve to move forward. And we would like -- the way that we put it into our motion of the Committee is that we would like, I think, discussion and recommendations from the larger group.

Once we come -- this language, the way the CPHS wants it, this is what we will turn over to the legal team for the development of the regulations. So, we don't have -- after this outstanding work is complete, we don't have anything else that we need to do now, either as a board or a Subcommittee, until the legal team gets finished with their first draft of the regulation.

So, that's kind of where we are and what we're asking for. So --

COMMITTEE MEMBER SCHAEUBLE: Laura?

COMMITTEE MEMBER LUND: Yes.

COMMITTEE MEMBER SCHAEUBLE: Correct me if I'm wrong, but I think what we're looking for is for the full Committee to give us a decision among the three alternatives that we've just been discussing, with the outcome of that being that the Subcommittee, at its next meeting, would then

revise the language in this third part to correspond to whatever the full Committee's decision is.

COMMITTEE MEMBER LUND: Yes. So --

VICE CHAIR DICKEY: So, it sounds like you would like a motion or something, right?

COMMITTEE MEMBER SCHAEUBLE: I think as far as the alternatives we've been discussion, yes, that would be appropriate as a motion.

COMMITTEE MEMBER HESS: I mean, I'll go. From my perspective number three, the third option makes the most sense. Because looking at the list of risks it does include researchers who propose to link the requested data to information from other sources. So, that's already -- you know, if they're already going to do that, that's kind of some set up in the risk category, which would then trigger a need for the NPP. So, it's that encompasses option one, as well.

And I agree with Laura that requiring all of this documentation for all projects is just unfeasible for both us and for the researcher.

VICE CHAIR DICKEY: I'd just like to say between two and three there may not be much of a difference because the risk factors are so broad there's probably a majority of projects that are going to fall under those risk factors.

COMMITTEE MEMBER HESS: And it's going to

encompass a lot of them, yeah.

COMMITTEE MEMBER KURTURAL: And I can speak a little bit -- I'll be honest with you, I'm kind of stuck between going with the, what is it, number one and number three, myself. But my perspective on the number one is that it's just the ability to gain -- when you're talking about outside sources, I don't know what goes on outside of the State of California. You know, as a reviewer, like we have contracts with most of the departments, you know, and we know what our practices are when folks sign up for services.

It's one way of distinguishing it, you know, between everything.

The other option, on three, if we're concerned of just saying one of these risk factors, I mean could you do a weigh -- it would be tough with these gray areas because of the weighing of factors. That's where the problem is with three. It's the weighing of factors so that it tips the scale where the project is too risky. And I get it that there's several factors, as mentioned here, that elevate the risk.

COMMITTEE MEMBER VENTURA: Carrie, as a reviewer, would you not be obligated, but at least have to identify that risk factor that would trigger it for you as a reviewer, right, so that is clear to the researchers? It's not kind of like arbitrary, you know. It's this is why me,

personally, as a reviewer, why I think that requires that extra level?

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER HESS: I mean, that would be something, once we have the regulations, that we can point to and say, as a reviewer, like this project meets this criteria or --

COMMITTEE MEMBER KURTURAL: This risk factor, yeah.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER LUND: And we can -- we can try to make it as easy as possible for researchers, when there are regulations, by putting them on the website. That if your project, you know, falls into one of these areas, you know, provide the additional documentation -- (indiscernible) -- so it's not a -- you know, research can --

COMMITTEE MEMBER VENTURA: Right. Right. That's what I was concerned about is like researchers will, you know, say I'm getting picked on, or why is my project getting elevated. So, that would help, I think, a lot.

DR. RYKACZEWSKA: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Going back to part of what I said earlier, I think the first step on this would be for researchers to self-identify whether their project

involves any of the risks that are enumerated in this list.

So, as far as a reviewer having to call out a project for these additional questions, that would only happen is the researcher hasn't responded to something we think they should have responded to.

And in all of this, we have a reasonably long list of potential risks that we're concerned about, but presumably not all of them are going to apply in most of the studies we would see. So, researchers would only be asked to respond for those particular risks that are involved in their study. Their others they would be not trying to respond to because they aren't relevant.

Dr. Dickey mentioned that many of these are -- seem to cover pretty broad territory. And I can see that being true, but I also think that many of these have an aspect of them that is how intense is the risk, or to what degree are we talking about. Because a researcher could very well say, and we presumably would agree, that some of these risks can exist to a very small level that we are not especially concerned about. And, therefore, we wouldn't be expecting researchers to provide special information because it may be the case that the risk -- we can't say the risk does not exist at all, but exists at such a low level that it's not something that we're trying to pay special attention to.

And that's different from many of the places where these risks say, and give examples of, fairly extreme levels of those risks that we do want to know how the researcher is handling them.

It's a judgment call, I realize, and maybe not always an easy one for people to make, but I think they can certainly make a good faith effort to do that.

VICE CHAIR DICKEY: Well, the way the language is now it says, the reviewer will take (indiscernible) under submission. It doesn't say may, or they judge the severity of it, et cetera.

COMMITTEE MEMBER HESS: Where is it? Oh, I see, right here.

VICE CHAIR DICKEY: And as far --

COMMITTEE MEMBER SCHAEUBLE: Well, if it exists to the degree that's described there, though. So, I mean, looking just at the first item for example, many studies, most of them probably, have some information about physical health. Not all of them have such sensitive topics as the examples that are given there.

COMMITTEE MEMBER LUND: So, Dr. Dickey, our legal team wordsmithed this a bit, and I'm wondering if Jared would like to weigh in on the difference between "may" and "will", and whether that matters.

VICE CHAIR DICKEY: Yeah, sure. Great.

MR. GOLDMAN: I couldn't quite hear you. Could you repeat the question?

COMMITTEE MEMBER LUND: Yes. So, I know that the legal team wordsmithed this a bit, and I'm wondering, Dr. Dickey pointed out that this says "will" and wondered why "will" instead of "may". And I'm wondering if that makes a difference.

MR. GOLDMAN: It does. "Will" is mandatory language and "may" is permissive. So, if we include the "will", that means that the reviewer has to take the following risk criteria into consideration. Reviewers won't be able to pick and choose which risk criteria they want to look into.

So, to the extent any are applicable, they'll have to look at them.

COMMITTEE MEMBER LUND: Thank you. So, I'm just --

COMMITTEE MEMBER DINIS: Laura, couldn't we add something to that sentence that says when it applies, you know, in cases when it applies and maybe to kind of capture the spirit of what Dr. Schaeuble was saying that not all would apply. But in the case when it applies that you would want the reviewer to actually assess it.

COMMITTEE MEMBER LUND: Well, I think it's already -- that's already in there. That's what Jared was saying,

that when it says "will" it's mandatory. If it's present, then it has to be taken under consideration.

COMMITTEE MEMBER DINIS: Oh, I guess I misunderstood. I thought he said -- okay, I misunderstood. I thought it would have to apply to all of the cases there, every --

MR. GOLDMAN: I think it's implied that if it's inapplicable, there would be nothing to review. But I think Maria's proposal's not a bad idea. I think that clarification might be helpful for people to understand when something is or isn't reviewed.

COMMITTEE MEMBER LUND: Yes. So, my concern would be one of the reasons that we are developing these regulations is to take away the possible arbitrariness of review across, you know, projects, so that it's fair for everybody.

So, if the criteria exists that all projects that are submitted and meet that criteria review the same review, and if we say "may" instead of "will", it means we're back to it's a completely subjective decision, and you don't have to, if you don't want to.

And I think that that's not fair to the people who are submitted projects. That's my thought on "will" versus "may."

DR. RYKACZEWSKA: But could I ask a clarifying

question, that just looking at this again, popped into my mind. I'm looking and I'm realizing that there's two criteria here. One is about when we're going to be requiring a copy of the Notice of Privacy Practices, along with a description of the procedures.

The other one is information about these risks and the steps taken to minimize those risks.

And I just want to make sure that I'm following because I realized I wasn't necessarily, we're only talking about this first criteria and when that would apply. Regardless of when this first one would apply, the second one would still apply to all IPA reviews. Is that --

COMMITTEE MEMBER LUND: So, that's a good question and that's my understanding.

DR. RYKACZEWSKA: Yes, okay. I just wanted to double check. So, regardless whether they're linking or not linking, if they have one of these risks -- that their study meets one of these risk considerations, then they would have to still describe those risks and the steps they're taking to minimize them.

COMMITTEE MEMBER LUND: That's my understanding.

DR. RYKACZEWSKA: Okay, so it really is when do we ask for that Notice of Privacy Practices.

COMMITTEE MEMBER LUND: The official documentation, yeah.

COMMITTEE MEMBER KURTURAL: Yeah, it's the higher scrutiny. When does the higher scrutiny on the, you know, that we're requiring out of the submitter.

COMMITTEE MEMBER HESS: What are the criteria that we're looking for in the NPP? I mean, if the NPP does not include a statement that says "data may be used for research", we're looking at that, that would be relevant. Is that an automatic, like we're not going to approve this project?

COMMITTEE MEMBER LUND: No, I don't think we're planning that in the regulations.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER LUND: What we want is the additional information, so that then we can -- and it might have to come to full board in those cases.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER LUND: Or, you know, to say what should we do with this project. Just because it's silent, does that mean we shouldn't approve it.

COMMITTEE MEMBER HESS: Uh-hum.

COMMITTEE MEMBER LUND: And we might want to find out from the releasing entity what the laws are that govern their data and, you know, that kind of thing. So, that might trigger a request for additional information and a larger review process.

COMMITTEE MEMBER HESS: Uh-hum.

COMMITTEE MEMBER LUND: But I don't think we're talking in the regulations, and I want to say that for the record --

COMMITTEE MEMBER HESS: Yes.

COMMITTEE MEMBER LUND: -- about anything that automatically disqualifies a project.

COMMITTEE MEMBER HESS: Good.

COMMITTEE MEMBER KURTURAL: Then, I have a question for Dr. Dickey.

VICE CHAIR DICKEY: Uh-oh.

COMMITTEE MEMBER KURTURAL: Because you see most of the projects coming through to CPHS, as Vice Chair, and so do you, Darci, would we say that the IP -- currently, the IPA expedited reviews, nine times out of ten are they being -- is it an ask for state data to be connected with an outside source?

VICE CHAIR DICKEY: No. It's usually state data to be connected with other state data. That's more often.

COMMITTEE MEMBER KURTURAL: That's more often.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER KURTURAL: Okay.

COMMITTEE MEMBER LUND: And Kaiser. We see a lot of Kaiser.

COMMITTEE MEMBER KURTURAL: Yeah, that's what --

because I was thinking about Kaiser.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER KURTURAL: Because Kaiser --

VICE CHAIR DICKEY: You mean that Kaiser isn't the state.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER KURTURAL: That and the Cancer Registry projects, we get a lot of those.

VICE CHAIR DICKEY: The Cancer Registry.

COMMITTEE MEMBER LUND: That's state data. It's only when they want to link it to the EHRs, and Kaiser's got like a huge research division. So, I think we see a lot of those.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER KURTURAL: Yeah, and so that, I'm kind of like, all right, Kaiser's a healthcare provider, I have an idea that --

VICE CHAIR DICKEY: They always have patient authorization because of HIPAA.

COMMITTEE MEMBER KURTURAL: Exactly, because they're HIPAA covered. And, you know, they would have their Notice of Privacy. I'm less concerned about that when we're talking outside sources. And it is -- so, you know, that's why I'm stuck between one and three because -- but --

VICE CHAIR DICKEY: So, even on number one it just

says multiple data sources, it doesn't say including outside data sources.

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: So, that's --

COMMITTEE MEMBER KURTURAL: That's what we really mean.

VICE CHAIR DICKEY: So, that would apply to all of them.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER LUND: So, here's kind of my thought about the linkage and I think we may sit in two different places on this.

As a Committee, we really only have purview over the state data. So, if somebody has state data and they want to link it with an external data source --

COMMITTEE MEMBER KURTURAL: Uh-hum.

COMMITTEE MEMBER LUND: -- it's not really -- as long as the people, when they gave their information for the state data, have an appropriate NPP, and they're considering these other risk factors and so forth, when they gave their data to that other data source we can't be responsible about what they chose to do about their data with that data source. So, I don't think that we can be responsible for making sure that their documentation is correct, as long as people -- the documentation is correct and appropriate when

they gave their information to the state. Right. I just think that it goes beyond our purview as a Committee to consider what other people do when they're collecting the data under IPA.

I would feel differently if we were talking about that as a Common Rule study, but these are IPA studies. So, that's where I sit on this. So, we're on -- in two different places --

VICE CHAIR DICKEY: But are you saying that, then, we wouldn't have the authority to ask for outside data sources to provide the NPP?

COMMITTEE MEMBER LUND: No, I'm not saying that. I think that we can ask for information, right, but I don't think that we have the responsibility to consider how other data were collected under the IPA.

VICE CHAIR DICKEY: Well, then if we got the NPP and we didn't quite like the NPP that they're using, what authority would we have, then, to use that to turn the project --

COMMITTEE MEMBER LUND: Well, I think that we would have to have a discussion as a full board whether it would be appropriate to approve in those circumstances.

COMMITTEE MEMBER HESS: Yeah, I think it's based on -- it's so broad in the IPA, it's based on minimal risk. You know, what's minimal risk and what's not. And we would

have to clarify, you know, what that means in the IPA and this is our way of clarifying it. And if we want to delve into approaching this on number three, the problem is what you raised earlier that it's quite broad. It could be quite broad.

I'm thinking of like generative AI, for example, on some of these. I can't -- I don't know, I'm not smart enough, none of us are, to know if potentially what we think is de-identified data could be adequately masked, you know. I don't know what Stanford, and Berkeley, and everyone else is doing with generative AI to know -- to know that on that particular risk criteria.

So, that would encompass some of all the IPA process.

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

COMMITTEE MEMBER SCHAEUBLE: I guess, in all of this I keep coming back to what are we trying to protect. And I think it's the people who provided the state data originally. And in that regard, it seems to me it makes a difference whether people were given any relevant information when they're data was collected.

And it makes a difference to us, as reviewers, as to how we approach the way in which researchers are attempting to handle the potential risks in their project. It makes a difference whether, in effect, the data comes

from people who have some awareness of the uses to which their information will be put, and what the potential risks are of those uses, or that they have none, which may very well be the case in a lot of studies.

So, it's a vantage point or a perspective that I think we're trying to apply to our thinking processes as we look at what risks are involved in the study and how are the researchers handling that.

And I keep hearing, occasionally, comments about, well, when does that mean a project's going to be objected. I think the real focus here is on what are the researchers already planning to do to mitigate risks, and what else could they be doing to mitigate risks, particularly when we see these more intense kinds of risks that we've identified in the middle part of our document.

I know the public comments are very much focused on, well, my project's going to be rejected if you look at these things. And I've heard in our -- some comments here in the meeting today about, well, what does this mean as far as rejecting projects.

But I think that's not the major part of what we're trying to address here. I think rejecting is not expected to be any kind of what the frequent outcome is supposed to be is what, if anything else, needs to be done address and reduce risks. That's my thought on the matter.

VICE CHAIR DICKEY: These are projects -- these are not projects where it's easy to make up the past. We often, with the projects that are coming to us now, and human subjects, we often say do this to that, do this and that, we work out a way to fix it.

These projects the horse is out of the barn, the data's already been collected. Not what -- how are we going to mitigate? Because it's usually thousands of individuals or millions of individuals. And either they have an NPP or they don't. And how do you mitigate such a one?

COMMITTEE MEMBER SCHAEUBLE: One example would be to consider what particular variables are being included in the study and whether --

VICE CHAIR DICKEY: Well, the minimum necessary.

COMMITTEE MEMBER SCHAEUBLE: -- whether there are some that could be handled differently, or not used at all to reduce risk.

VICE CHAIR DICKEY: Right, but that's already in the IPA. It says we have to assure that the minimum necessary data is being provided.

COMMITTEE MEMBER SCHAEUBLE: Not necessarily addressed from the area that we're looking at here though.

VICE CHAIR DICKEY: I don't know. It seems that seems board enough, the issue of minimum necessary, to allow us to make judgments about whether certain data is necessary

or isn't necessary. I just think we have that ability already in the IPA.

COMMITTEE MEMBER SCHAEUBLE: And yet, we've had instances of projects where that has been an issue for the Committee, where we -- where there's been, I think, some disagreement about whether we could effectively say no to variables that were being proposed.

VICE CHAIR DICKEY: I don't remember that happened very often, other people do. But I'm thinking --

COMMITTEE MEMBER SCHAEUBLE: Well, I'm thinking of --

VICE CHAIR DICKEY: -- for example, we have some of these Cancer Registry projects where we may want to consider whether they need all the Cancer Registry.

I think often, traditionally, we've kind of not looked very closely at the minimum necessary aspect of things. That's just my experience.

COMMITTEE MEMBER KURTURAL: Just make sure they have a justification.

VICE CHAIR DICKEY: Right. And is the box filled out.

COMMITTEE MEMBER KURTURAL: Right. And, you know, they do -- everyone looks at demographics in their research projects, so that's the main clue for -- but the thing's that's the obvious is the thing like do you really need a

Social Security number, you know, in your research projects. Like I'll look at that stuff.

COMMITTEE MEMBER LUND: Or full date of birth when age will do. Right, yeah.

COMMITTEE MEMBER KURTURAL: Right, exactly. So that's, you know, kind of obvious. And researchers get that and don't ask for that, you know.

VICE CHAIR DICKEY: Exactly. And like with some of these Cancer Registry projects, they all want the information to contact subjects. But in the context to contact subjects this other data comes along with it.

COMMITTEE MEMBER LUND: Although, I think actually we have been, in those projects, ask for them to separate the --

VICE CHAIR DICKEY: We can, but sometimes we don't and sometimes we don't have to.

COMMITTEE MEMBER LUND: Yeah.

So, I'm wondering -- some of this sounds like the Subcommittee meeting.

(Laughter)

COMMITTEE MEMBER LUND: So, just in general we probably need to move forward. And has everybody who wanted to comment on this had the opportunity? Anybody on the phone who's got any other thoughts on this?

VICE CHAIR DICKEY: Does that include the public?

COMMITTEE MEMBER LUND: Not yet.

VICE CHAIR DICKEY: Oh.

(Laughter)

COMMITTEE MEMBER HESS: Can I just -- I'm going to follow up and recap for my own knowledge. So, in any application that demonstrates any of these risks that we've identified, we're expecting them to address those risks and discuss how they're going to mitigate them, et cetera.

The question is what's specifically the NPP. So, if it's -- at what point beyond that are we actually going to request the NPP?

COMMITTEE MEMBER KURTURAL: It's not necessarily just the NPP, it's also any other additional --

COMMITTEE MEMBER HESS: Any other additional documents.

COMMITTEE MEMBER LUND: Supporting documentation.

COMMITTEE MEMBER KURTURAL: Supporting documentation on --

COMMITTEE MEMBER LUND: These are the state administrative data.

COMMITTEE MEMBER HESS: The risks are kind of separate from the NPP, any other additional document request. Okay.

COMMITTEE MEMBER KURTURAL: Right.

VICE CHAIR DICKEY: Well, there will be in some

cases informed consent documents.

COMMITTEE MEMBER LUND: I mean, yeah, that's the kind of thing that would fall under the additional, the NPP and additional documentation. But if they had an NPP, they didn't have an informed consent.

COMMITTEE MEMBER SCHAEUBLE: There could be other ways in which privacy information was presented to people at the time data are collected, that would not be a formal Notice of Privacy Practices. Also, if so --

COMMITTEE MEMBER LUND: If it's state data, there will be. And by law, right, it's a requirement in law that they be notified. I don't know about if there are other data sources where it would be informal. I'm looking at Carrie because those are the ones that she's most concerned about.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Well, I'd have to assume from projects we've seen that the process is sometimes informal as far as other data sources are concerned.

COMMITTEE MEMBER KURTURAL: When it makes sense. Throwing out a suggestion. Because one of my primary concerns is generative AI. And the redisclosure of information, which you point out in a risk. When it makes sense to revise the risk criteria, and to put it more of a

-- instead of getting into the reidentification of de-identified data, and that risk, and change. Does the researcher plan to use generative AI tools.

COMMITTEE MEMBER KURTURAL: You're laughing at me.

VICE CHAIR DICKEY: Well, no, I don't know.

COMMITTEE MEMBER KURTURAL: Because if they do, you know, the problem is like Zoom, or whatever, they have generative AI in it and --

VICE CHAIR DICKEY: So does Google.

COMMITTEE MEMBER KURTURAL: Of course they do. But then, you know, who knows what those programs are doing. Right now, this meeting is public, but not, you know, confidential meetings you might not. With the other research participants over Zoom, who knows what happens. That's a higher risk. Right, if you're transcribing over Zoom and Zoom is using generative AI in its program.

I don't know all that information, but is there a possibility that we use that as a risk, because that's like an issue to me is that. I think that it should be a risk criteria because there are increasing partnerships between academia and, say, Google, and state and, say, Google, to identify risk factors for all sorts of things using huge datasets and AI.

I think it's fair enough for us to ask is this project in any way going to be fed into any generative AI

models, and to what extent, and for what purpose. Not, you know -- because the whole -- we only know, I mean just from a privacy perspective, if a researcher adequately says they're going to de-identify PHI or PII before they submit, you know, they publish. And the way they go about that, I look at that and I'm like, oh, well, this obviously is going to comply with HIPAA's high standard, you know, for de-identification.

I can't say the risk of whether something's going to be re-identified after they attempt to de-identify it. I have no idea. Because while a lot of times on these projects' characteristic data is being published, and demographic data, which isn't, you know, not address identifier. But take a generative AI system and put that with these projects and, to me, the risk is higher, you know, of something happening.

So, I don't know if we want to think about -- you know, I'm okay with three. If maybe we re-reframe some of the risk criteria.

COMMITTEE MEMBER LUND: So, I have a question for you.

COMMITTEE MEMBER KURTURAL: Yes.

COMMITTEE MEMBER LUND: Regulations live forever. And I want to make sure -- and we're doing what we -- and part of what we were doing with the IPA is that it was

written in a time where we didn't even conceive of the kind of technology that we have now.

So, I don't -- I'm concerned about writing regulations that are tied too closely to a current technology that may be very different 10 or 15 years from now.

So, that's why my concern is if we use these particular, very specific words that our regulations will be obsolete at some very -- point in the very near future.

COMMITTEE MEMBER KURTURAL: Well, and to respond to that, the devil's in the details and you would have a definition for generative AI and you would attempt to address it in the definitions. And you can always change regulations.

DR. RYKACZEWSKA: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: If it's not premature, I was going to try to suggest a possible motion for the Committee to consider that maybe incorporates some of these ideas for discussion on the --

COMMITTEE MEMBER LUND: We have to have public comment before we have a motion.

COMMITTEE MEMBER SCHAEUBLE: Okay.

COMMITTEE MEMBER LUND: So, that's why we should finish the discussion. And actually, if you would like to list the things you think should go in the motion, we could

be aware of that and then open it up for public discussion.

COMMITTEE MEMBER SCHAEUBLE: Okay, I can do that. I would suggest that that the motion not -- to include that the full Committee, as a general strategy, endorses the third alternative of the three listed here. Saying that the threshold for additional information is studies that involve any of the risk factors enumerated in the document. That would be one part of the motion.

Another part is that the Subcommittee would work with legal counsel to rephrase, reword as necessary the third section of this document.

And a third part would be to also work with legal counsel to incorporate, as an example of a concern, whether studies are planning to use or see a likelihood of using generative -- tools like generative AI.

So, in that part I'm saying maybe not to list it as a specific risk, but to use it as an example of a risk that we've already identified about the possibility of data being re-identified after identifiers have presumably been taken out.

Those would be the three things I would try to address in the motion.

COMMITTEE MEMBER LUND: Thoughts from the Committee?

INTERIM CHAIR DELGADO: I have one thought and

it's not specifically to the motion. But I do feel like it's really difficult to solve for a problem we don't fully understand. Like the AI, the gen AI issue. I feel that it is not, in this group's --

VICE CHAIR DICKEY: Scope of expertise.

INTERIM CHAIR DELGADO: -- scope of expertise to really understand. And so, I am hesitant to be making motions and decisions that are like specifically trying to solve for that when I don't feel like any of us have that subject matter expertise.

So, again, not speaking to any issues in the motion, but I also just feel like that might be something we want to explore more in the Subcommittee by asking for some subject matter expertise because I -- I don't know, it just feels uncomfortable to me.

Like I felt good with -- personally, as a board member, felt good with the kind of limited view that's represented in number one. And then, this whole discussion of gen AI has taken me to a point of uncertainty. So, I'll just leave it at that.

VICE CHAIR DICKEY: I mean, I've had the feeling that time has passed the IPA by and maybe it should be some Office of Technology, or whatever, that's vetting these things as opposed to us. It's going to have the expertise to understand.

COMMITTEE MEMBER LUND: I brought that up a long time ago. That we don't -- we don't have the expertise as board members to determine that.

VICE CHAIR DICKEY: Yeah. It was kind of a quick fix at the time. It's a problem. But (indiscernible) --

COMMITTEE MEMBER BAZZANO: I can speak up -- this is Alicia. Just before you -- some comment.

DR. RYKACZEWSKA: Dr. Bazzano, could you speak up a little bit louder? We're having a hard time hearing you.

COMMITTEE MEMBER BAZZANO: Yeah, yeah, sorry. You know, I would love to rely on technologists to be able to make ethical decisions. But I have to say, in my opinion, it seems to me that if there is an area that we aren't educated on well enough, that we should educate ourselves on it because we bring a different perspective from somebody who is in technology. Whether it's a data scientist, or a data security expert, those are different people from bio-emphasis.

And I think the conversation from our -- I would not rely solely on those experts rather than our own ethics. And if we need to bring in some educators or bio-emphasis to have expertise, or do learning ourselves in terms of AI. Yes, that's true, perhaps we haven't kept up, but I don't think that absolves us of the responsibility. Or, I don't think we shouldn't necessarily put all the responsibility on

people who don't have an ethics background.

And I'll just share with you from my personal experience, because I have spent time recently, you know, with people who are on the front end of AI in a number of capacities in healthcare. And they aren't thinking from an ethical lens. And they do need our expertise in being able to do that.

So, that's my take on it. I wouldn't shy away from it and defer to other people who don't have an ethics background, solely.

VICE CHAIR DICKEY: But the main thrust of the IPA is state security. Not to say that, you know, it's unique in that regard, it's different from the Common Rule. It doesn't explicitly specify it -- we're kind of deficient in the main topic. By trying to substitute our ethics ability for data security, it's a dangerous proposition.

COMMITTEE MEMBER KURTURAL: But the --

COMMITTEE MEMBER BAZZANO: I would hope that we would be able to bring our lens to data security. Because otherwise, I mean I would imagine that most data security experts would say they do need ethics involvement. And they're struggling with this, too. I think everybody is struggling.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: And it's data privacy

as well as data security, so there's actually two parts to this.

COMMITTEE MEMBER KURTURAL: Yeah, I would say it is -- is a review more on the privacy side. As in, you know, the onus is on the researcher to tell us how they're going to mitigate these risks. I think it's fine to say, you know, this is just going to be an additional risk. It is in our contracts for the State of California, in general, that if you have a vendor that is going to utilize generative AI or engage with a subcontractor that's utilizing it, and that's across the board.

So, it goes beyond technology. And I agree that more training needs to be done and all of that. But for purposes of the criteria, you know, I definitely think something should be considered.

And I'm looking on the specific risk factor her that the number and/or nature of the variables that will be able to be analyzed makes reidentification of the individual as a possible risk, despite researchers' efforts to remove identifiers or mask the data. Although risk heightens on that one as soon as you plug in generative AI.

And maybe we do use it as an example, as you mentioned, Dr. Schaeuble, and just add that in. Because if we leave that plain, you know, I don't know if we're going to have the answer to that.

VICE CHAIR DICKEY: And there are statisticians who probably have made this their lives work trying to figure this out.

COMMITTEE MEMBER KURTURAL: Right.

COMMITTEE MEMBER DINIS: I agree with what you're saying because the little I know about AI, the concern is it can, you know, tie things together and it has adapted in the background. And nobody knows exactly where that data is going to be stored and who's having access to it, you know.

So, there are some issues and I think that would be a good place to put it in there, you know, for them to consider what they're doing.

Because like, you know, even with the Zoom or AI transcripts, you know, we don't know exactly where all of that is going to go or who has access to it.

COMMITTEE MEMBER HESS: Is it -- I mean is it a possibility for the board to engage a subject matter expert in these matters. And then, you know, I would think that if we got any IPA applications that were proposing of AI that that would automatically go before the full board, and the discussion with a subject matter expert.

COMMITTEE MEMBER KURTURAL: Completely possible.

COMMITTEE MEMBER HESS: But I think that it's, you know, when you're reviewing the applications we need to know the threshold, are you going to be using these tools or not.

COMMITTEE MEMBER KURTURAL: Yeah. I need a yes or no, yeah.

COMMITTEE MEMBER HESS: Yeah, and if the --

COMMITTEE MEMBER SCHAEUBLE: If we ask the question first.

COMMITTEE MEMBER HESS: Yes.

COMMITTEE MEMBER KURTURAL: I mean, since the regulations is about asking the questions as part of the risk factors, and if they say yes, then, you know, we'll deal with it as a board from there.

COMMITTEE MEMBER HESS: Yeah, I think it should be just in IRB Manager, like are you going to use these tools.

COMMITTEE MEMBER KURTURAL: And that's really -- and I agree, you know, one hundred percent with when we get into sensitive information and everything that, you know, is listed, they're basically separate questions on an application, yes or no. And then, that heightens the risk.

I'm just saying a reframing could, you know, either support it as an example, or something of that nature, so we're not thinking all projects are going to fit in that bucket, you know. That's what I'm --

VICE CHAIR DICKEY: We've been asking for a data security person for a long time, even before AI, and haven't been able to get anybody.

COMMITTEE MEMBER KURTURAL: I think, you know,

there's been more of an effort of late to get out training for gen AI, and so I'm happy to help the Committee look into getting --

VICE CHAIR DICKEY: Getting a person.

COMMITTEE MEMBER KURTURAL: Yeah. Maybe internal with the State of California. So, I know we're working on a gen AI training.

COMMITTEE MEMBER LUND: So, what I'm hearing is that to take back to the Subcommittee -- just no motion. I just want to make sure I'm hearing kind of what the will of the board is. To add to this list of risks language around gen AI and the Subcommittee can wordsmith that. Take back all the comments here from the board and wordsmith that to make sure that we've captured what everybody's thinking. And that becomes another list.

Did I hear a resolution of our question about one, two or three? I heard some ones. I didn't hear any twos. So, I think really at this point we're on the fence between one and three, and I may have heard more threes than ones, but I don't know. So, if the board could just weigh in on that before we -- is it okay if we go with three, if we have gen AI listed as part of the risks?

COMMITTEE MEMBER KURTURAL: I think that is fine with me, but I want to hear from the board.

COMMITTEE MEMBER JOHNSON: I'm good with number

three.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER JOHNSON: I vote three.

COMMITTEE MEMBER LUND: So, since nobody would object --

VICE CHAIR DICKEY: (Indiscernible).

COMMITTEE MEMBER LUND: And then, so that is another thing to take back to the Subcommittee is the final wordsmithing around number three.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER LUND: And I believe, I just want to make sure we capture, as a board, everything that we had a discussion around. We had this discussion as "will" versus "may" for consideration of the risks. And I'm not sure if there was an objection to the "will" or if we need to consider "may" more.

I'm personally in favor of the "will" because I think that it makes it fairer across all researchers that reviewers don't have the discretion to arbitrarily decide. In some cases, the board will need to (indiscernible) --

Anybody else want to weigh in on that one?

COMMITTEE MEMBER HESS: I mean, I agree with it. Well, for the very reasons I heard.

COMMITTEE MEMBER LUND: Okay. So, having heard all of the discussion, I think at this point we're ready to

open it up for public comment. Would that be true?

INTERIM CHAIR DELGADO: Let's open it up for public comment.

COMMITTEE MEMBER LUND: So, if you would like to make a comment, any members of the public, please raise your virtual hands. If you are downstairs in the Allenby Building, there should be a staff member there who would be able to facilitate your public comment.

So, we'll hand it over over to Agnieszka to go through those. Who would like --

DR. RYKACZEWSKA: Let's start, Nick, is there any public comment in the room?

MR. ZADROZNA: No public comments in the room.

DR. RYKACZEWSKA: Thank you, Nick.

I see a public comment from Agnes Balla. Agnes.

MS. BALLA: Yes, thank you so much for having me. I work for the University of California Office of the President. I work in the Research Policy Office. And my role is I work broadly across our UC campuses with our research administrators on a range of issues.

And one of those is I work closely with the IRB directors at all of our campuses to make sure that we are on the same page about what the regulatory requirements are, talk about best practices, and shared experiences, and problem solve among the group.

One of the concerns that we, as a group, have been discussing as CPHS continues to roll out its framework is the concern that the role of CPHS is being muddled between its IRB hat and it's IPA hat with this expanded criteria being proposed.

And in listening to today's discussion, I have a lot more questions and concerns about that muddling of that role. You know, as I understand it, CPHS serves as the IRB for CalHHS for any studies that are supported or funded by them.

And then, separately, it has a role of being of a role that is designated under the IPA that talks about the need for making sure that state health data is handled appropriately, and that is the review of -- the review that CPHS conducts under the IPA role.

But much of the discussion that I heard today wasn't around that. Right. It wasn't around the IPA. It was, you know, as Dr. Schaeuble noted, about the protections of those whose data is being used, the ethical considerations.

And that is an IRB role. And the reason this brings me a lot of concern or at least more questions than anything else is because our researchers here at UC are going to be going to their own IRB to get review. And they're mandated to go to the CPHS to get an IP review. But

that is more sounding like an IRB review. So, this sounds very duplicative of those efforts.

And what happens in those cases, you know, there is a push on the federal end, particularly for federally-funded studies, to get a single IRB review. And how do we match up those requirements with now what seems like a duplicative IRB review?

And so, I have a lot of questions about how that's going to be managed if this effort really moves forward because it really just sounds like an IRB review. And if that's the case, then I think we need to be up front about that, right. Is that now all IPA studies are being pushed into an IRB review by CPHS.

And then, should we be coming up with, you know, reliance agreements or MOUs for all of these studies that now need to get an IRB review by the state, and perhaps not by our own campuses. So, a lot of questions on that.

The generative AI discussion that I heard today, I know we have been struggling with that quite a bit. And, you know, you said, you know, do you -- do you want an expert? I mean, I'm not an expert, but I can tell you about some of the experiences that we've had, and I'm happy to share those.

So, you know, just to give a very specific example, something that we've been working on is -- as some

of you might be familiar, NIH updated their certificate of confidentiality rules about what's required when getting a COC. And one of those is that we, as an institution, have to assure that any third-parties that we're working with do not further disclose information. That, you know, we are -- that might be available, right.

So, one of the things that we've been talking about is Zoom, for example, right. So, using Zoom in conducting interviews, how do we protect that information.

And so, there are actually things that we've implemented to meet our own obligation as the institution to protect that information according to the COC standards. And I'm happy to share what we've done, separately. I know my public speaking time is limited here, so I won't do that. But I can follow up, if that's helpful.

But I do want to be very careful about including generative AI in such a proposal because what is gen AI? You know, when I use Google, now we get that little summary of, you know, here is what the whole wide world, what is has to offer, and that's gen AI. So, if I'm using Google do I know -- is that something that's going to be part of the application consideration, right.

So, I do want to be very cautious about how this is brought forward. I will also just mention that the state has sort of other requirements. Including under Assembly

Bill 302, in a separate executive order that Newsom passed, around the use of gen AI. And, particularly, we all have to report that anytime that we get state funding. And I'm happy to provide information on some of those other requirements, in case the Committee is not familiar with them.

But again, I think one thing I do caution is not to create duplicative reviews, or duplicative requirements that already are in existence because I think that just provides a whole lot more confusion to everybody.

Thank you very much. I appreciate the opportunity to get to talk about this and I'm happy to provide my support in any way that would be helpful to the Committee.

DR. RYKACZEWSKA: Thank you so much.

INTERIM CHAIR DELGADO: Great. Thank you. We'll definitely reach out on the gen AI stuff.

DR. RYKACZEWSKA: Ms. Laura thinks that the more we can share information about that, the better, I think. It sounds like we're not the only ones struggling with it. And thank you for the full scope of your comments, appreciate it.

Others that would like to make public comments, please raise your virtual hands. Going once. Going twice. Okay, we've closed public comment.

COMMITTEE MEMBER LUND: Great. And I believe Dr.

Schaeuble had a motion.

COMMITTEE MEMBER SCHAEUBLE: Can we have the previous document back on the screen while I'm trying to make the motion?

DR. RYKACZEWSKA: Yes. Just one moment.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, let me try to do this as best I can.

For the first part of the motion, the full Committee endorses as a threshold for requesting additional information focusing on those studies which involve any of the risk criteria enumerated in the draft document.

For the second part, the Committee asks the Subcommittee to work with legal counsel to make any further revisions necessary of language in the document.

And as a third part, the full Committee asks the Subcommittee to work with legal counsel to find an appropriate way to include possible uses of generative AI or similar technology as an example of additional -- an additional risk factor in IPA studies.

Those would be the three parts of what I'm suggesting as the motion.

COMMITTEE MEMBER KURTURAL: I'll second.

COMMITTEE MEMBER SCHAEUBLE: And then, I'll say it as an aside, if the Committee wishes, on the previous parts of the draft I have reached out to Jared, trying to come up

with language for the Subcommittee to consider at its meeting. And I'm still willing to do that, if that's what the Committee wants.

INTERIM CHAIR DELGADO: Okay. So, we have a motion and a second.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Opposed. I don't believe any of this -- I believe all three criteria are too broad. I'm just giving you a reason for it.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Sorry. Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: I think Dr. Ruiz left.

And Dr. Bazzano has left.

Okay. Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, motion passed.

INTERIM CHAIR DELGADO: Okay, the motion passed.

And, Laura, do you want to talk about next steps for the Subcommittee?

COMMITTEE MEMBER LUND: Yeah, so the Subcommittee already has a meeting scheduled in January, I believe, but I don't remember the date. And we will take this back, this motion back and work again on this document so that, hopefully, we can present the revised version at the February CPHS meeting.

INTERIM CHAIR DELGADO: Got it. Okay. Thank you so much. Thank you, again, for the work of the Subcommittee for bringing this to the larger Committee, and thank you for the public comments.

And thank you for your work on this journey of, probably, a 30-step process. So, appreciate everyone's commitment.

Okay, we will now move to Agenda Item D. Noting for those who are calling in, we are now running 40 minutes behind, but we'll probably pick up 10 minutes right here, 10 or 15.

So, we will move to review and approve with the meeting minutes. Starting with the August 2, 2024 meeting minutes, I'd like to open it for public comment, if there's any on the August 2nd meeting minutes. Please raise your virtual hands.

MR. ZADROZNA: No public comments in person.

INTERIM CHAIR DELGADO: Okay. Any online, Agnieszka?

DR. RYKACZEWSKA: No.

INTERIM CHAIR DELGADO: Okay, no public comments, we'll close that.

Can I get a motion, please?

COMMITTEE MEMBER LUND: I move to approve.

INTERIM CHAIR DELGADO: Okay, we have a motion to approve the meeting minutes.

VICE CHAIR DICKEY: Second.

INTERIM CHAIR DELGADO: Seconded by Dr. Dickey.

Could we get a roll call, please, Sussan?

MS. ATIFEH: Sure. Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Abstain.

MS. ATIFEH: And Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Let me count. Okay. Yeah, the motion passed.

INTERIM CHAIR DELGADO: Great, thank you.

Now, let's move to the September 13, 2024 meeting minutes. Would ask if there's any public comment on the September 13, 2024 meeting minutes?

MR. ZADROZNA: No public comments in person.

INTERIM CHAIR DELGADO: Okay. Agnieszka, do we have any online? I see none online.

So, can we please have a motion?

COMMITTEE MEMBER LUND: I move to approve.

VICE CHAIR DICKEY: Second.

COMMITTEE MEMBER SCHAEUBLE: I'll second.

VICE CHAIR DICKEY: I beat you.

COMMITTEE MEMBER SCHAEUBLE: You beat me, okay.

INTERIM CHAIR DELGADO: Okay, so we have a motion by Ms. Lund, a second by Dr. Dickey. Could we please --

MS. ATIFEH: Dr. Dickey? Oh, okay.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Let me count. The motion passed.

INTERIM CHAIR DELGADO: Great. Thank you so much.

Okay, that motion is passed and we will now move on to projects, noting that we're only 30 minutes behind now.

So, I will hand it over to Dr. Johnson, who will be discussing Protocol 2024-149.

COMMITTEE MEMBER JOHNSON: Yes. I think I saw her before, but is Dr. Hughes Halbert on the line, still?

DR. HUGHES HALBERT: Yes. Good morning, everyone.

COMMITTEE MEMBER JOHNSON: Well, welcome. Yeah, if you'd first like to introduce yourself and any member of your team present, and then give a short overview of your study for the Committee.

DR. HUGHES HALBERT: Sure, thank you. So, again, greetings from Southern California, the University of Southern California. My name is Chanita Hughes Halbert. I am professor, and vice chair, and executive vice chair in

the Department of Population and Public Health Sciences, which is in the Keck School of Medicine.

I'm joined by my colleague, Dr. Trista Beard. And Dr. Lihua Liu.

And we're here to discuss our protocol, which is focused on understanding quality of life and social issues among African-American men who have a personal history of prostate cancer, and who've been treated with radical prostatectomy.

So, just as a way of background, we know that prostate cancer is one of the leading causes of morbidity and mortality, particularly among African-American men.

I'm a behavioral scientist. I've been doing work in this space, in cancer control. One of my roles here at the University of Southern California is Associate Director for Cancer Equity at the Norris Comprehensive Cancer Center.

And what we're interested in understanding is the ways in which social determinants of health, which include neighborhood depravation, experiences with social isolation, financial strain and perceived stress influence quality of life, specifically among African-American men with prostate cancer.

So, our primary research question are around, you know, the way the nature and distribution of social issues, social risk factors among this population. And then, what

are the associations between social background, social demographic characteristics, and clinical characteristics among these men as it relates to quality of life and social issues.

We would like to establish using an observational cohort, which would basically involve collecting self-reported data on social determinants of health, clinical experiences, and quality of life.

We would want to recruit them from the Los Angeles Cancer Surveillance Program. The eligibility criteria I think are pretty straight forward, and include African-American men who are self-identified, or identified using the Registry data, who have been diagnosed with prostate cancer and have completed a radical prostatectomy.

We propose to use our evidence-based recruitment strategies from my previous research to enrollment into the study. They would be asked to complete a structured survey, which would use validated instruments and questionnaires to measure quality of life, social isolation and perceived stress.

We also propose to extract clinical data using the CSP case report, which will be recorded in our study database. All of the databases -- rather, one database created for the study would only include de-identified information.

We'll use appropriate statistical analyses to address our study aims. And with respect to our study team, as I've mentioned I'm joined with -- by our colleague, Dr. Liu, who is also a faculty member in the department, and myself, and others who have considerable expertise in minority health and cancer health disparities research.

Thank you.

COMMITTEE MEMBER JOHNSON: Thank you for that summary. So, I'll just go then, actually, to the Committee since there were a lot of comments, and revisions, and back and forths with the application. And also, you know, like my gratitude to the research team for working with me, with making those modifications along the way.

So, just there were two main revisions in the most recent version that's in IRBManager. One was the removal of some items from the questionnaire that was regarding victimization. With the present submission these items have been removed. And I think that there is adequate mention and resources provided to participants if they do feel distressed from their acting in the study, and responding to some of those questions.

The other main revision was that originally the research team had included the modality of participants mailing back their questionnaire. And they were requesting a waiver of written informed consent.

They have since reduced the modality, so the mailer is no longer included. It's now just strictly phone. And participants that have -- for the modality on Redcap, they are going to be collecting consent, written consent from the participants. And they are still requesting a waiver of written consent for the phone modality.

So, given these modifications throughout the application, I feel fully satisfied with how the proposal appears. And I would also like to thank Sussan for assisting me in this review. And I will open it up to the Committee, now, for any additional concerns we've had.

COMMITTEE MEMBER VENTURA: I just have a clarifying question for the waiver of informed consent for phone. Is there -- they're still collecting a vocal consent?

COMMITTEE MEMBER JOHNSON: Yes.

DR. HUGHES HALBERT: Yes.

COMMITTEE MEMBER VENTURA: Thank you.

COMMITTEE MEMBER LUND: I think just a waiver of written, but it's not informed consent.

COMMITTEE MEMBER VENTURA: Yes. Thank you.

VICE CHAIR DICKEY: I had a couple of questions about how access to the Cancer Registry data is dealt with, and how the consent form in the letters.

I only noticed the one place where it was

mentioned that you're actually going to be accessing their data from the Cancer Registry, as opposed to using the contact information.

And maybe I'm wrong about this, but I'm just wondering if you could check. I think, does the consent form say anything about the Cancer Registry data will be accessed?

COMMITTEE MEMBER JOHNSON: I believe it does.

DR. HUGHES HALBERT: Trista, maybe you have that more easily accessible to answer that question?

DR. BEARD: Yes. Yeah, the informed consent form says that we will -- we will collect clinical variables from Cancer Registry. And the Cancer Registry brochure is going to be attached with the mailer so, you know, how people's information is collected, and why. So, yeah, it's in the informed consent.

COMMITTEE MEMBER JOHNSON: And just to outline the planned procedure, since it was relevant for our discussion earlier, is they first plan to have the Cancer Registry submit recruitment-related information.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER JOHNSON: They assign the ID to people who consent. And then, the Cancer Registry links that back up with that self-generated ID by the Cancer Registry to release the medical information.

So, there's not additional medical information being released --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER JOHNSON: -- for people who don't consent to be in the study.

VICE CHAIR DICKEY: Yeah. But just sometimes just including the Cancer Registry brochure is kind of not sufficient. It needs to be mentioned in the -- make sure it's in the consent form. So, if it is there, that's great.

DR. HUGHES HALBERT: It is there, as indicated. Thank you.

VICE CHAIR DICKEY: You also mentioned that they'll receive a gift card. I don't think it was specified exactly how they would get that. Is that an electronic card that's going to --

DR. BEARD: Yeah, at the end of the survey, at the end of the Redcap, this is our standard procedure is that we allow people to say, you know, please include your email. Your e-gift card can be sent to you. If you would prefer it be mailed, please give us your address and we will mail you a physical gift card.

COMMITTEE MEMBER JOHNSON: Okay.

VICE CHAIR DICKEY: I have nothing further.

COMMITTEE MEMBER HESS: Can I ask you a question of the annotated dataset that you mentioned. What exactly

does that final annotated dataset entail? Is it CCR data collated with the survey data that you're gathering?

DR. HUGHES HALBERT: So, it would be a de-identified dataset for data analysis. So, and that would include the self-reported data from our survey, along with the information on clinical characteristics obtained by -- from the Cancer Registry.

COMMITTEE MEMBER HESS: Okay.

COMMITTEE MEMBER JOHNSON: Okay. Given no other comments, I would make a motion for approval, minimal risk, one year.

COMMITTEE MEMBER LUND: Second.

MS. ATIFEH: Ms. Lund seconded.

Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis? Dr. Dinis?

COMMITTEE MEMBER HESS: I think she's gone, she signed off.

MS. ATIFEH: Oh, okay.

Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'll abstain.

MS. ATIFEH: Abstain?

MS. MUHAMMAD: Abstain.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, let me count. Yes, so the motion passed.

COMMITTEE MEMBER JOHNSON: Okay, great.

INTERIM CHAIR DELGADO: Okay. Well, thank you so much, Dr. Halbert to you, and your team, and to Dr. Johnson.

DR. HUGHES HALBERT: Thank you. And I just want to -- I was remiss in thanking the reviewers for Dr. Johnson and Ms. Lund for working with our team to, you know, ensure that we have the highest quality protocol that is consistent and compliant. So, thank you very much. And thank you to the Committee.

COMMITTEE MEMBER JOHNSON: Thank you.

INTERIM CHAIR DELGADO: Okay. So, you should be getting a letter confirming everything, the approval that we've talked about today, and great job. Have a great weekend.

DR. BEARD: Thank you.

DR. HUGHES HALBERT: Thanks.

INTERIM CHAIR DELGADO: Yeah, that really is a

great example of putting in a lot of effort and working with the research team behind the scenes to make the protocol's ready to go. So, thank you so much.

COMMITTEE MEMBER JOHNSON: Of course.

INTERIM CHAIR DELGADO: Okay, let's move to project 2024-183. Ms. Lund, we'll hand it over to you.

COMMITTEE MEMBER LUND: Yes. Is Dr. Graboyes on the line? Did I pronounce your last name correctly?

DR. GRABOYES: Hello, I'm here. It's Graboyes like color gender, but that's definitely close enough for the ballpark.

COMMITTEE MEMBER LUND: Okay.

(Laughter)

COMMITTEE MEMBER LUND: Great. So, if you don't mind, would you please introduce yourself and your team, and give the board, I think, an overview of your project. Let's say the method you plan to use for recruitment and so forth.

DR. GRABOYES: Sure. Thank you for the opportunity to be here and present. And just like Dr. Hughes Halbert said, we are very grateful for Ms. Lund's efforts in ensuring that the protocol was optimally prepared for you guys today.

I think we have one team member, our Research Coordinator Ella Starr is on the call. The MPI for the project, Dr. Deshmukh is not here due to a competing event,

but I'm happy to present. He and I prepared, so I can present on his behalf.

So, our project proposes to understand patient priorities and preferences for patients with human papilloma virus-related oropharyngeal carcinoma. For those of you who may be less familiar with this disease, most cases of having that cancer are now caused by human papilloma virus. And this is one of the fastest growing cancers in the adult male population in the United States.

In addition to becoming more frequent over time, there's been a shift towards, in the demography towards older adults who are having age (indiscernible) cancer which has rapid -- has forced us to evaluate how we think about survivorship or treatment in this patient population.

So, there have been a number of ongoing clinical trials that have looked at de-intensification, so trying to maintain how levels of cure with less morbidity, but older adults have been severely under-represented in those studies, and none were specifically designed for this patient population, nor have considered comorbidity evaluation and outcome evaluation.

Due to the challenges of trial infrastructures, it's unlikely that any will ever be done. And so, one of the most important things we can do is leverage other data sources to understand how older adults with oropharynx

cancer make tradeoffs between oncologic and non-oncologic outcomes to guide the optimal treatment in this patient population in the context of aging and comorbidity.

And so that's, I think, where our study is coming in. And the purpose of this study is to understand priorities and preferences of patients with age-related oropharynx cancer in relation to aging and comorbidity across the lifespan.

For this specific part of the project we are proposing to use CCR data for participant recruitment, and to collect demographic and clinical data about those participants to help us answer this question.

We propose intramural study methods to partner with CCR to help identify people who have age-related oropharynx cancer who have been treated in the last five years. And to reach out to those participants using approved methods.

First, sending them a letter describing the study, with appropriate CCR pamphlet and documentation explaining the study rationale and procedures, and then contacting them.

Secondarily, by telephone. After patients undergo written informed consent in a remote video teleconference fashion, study procedures involved completing two questionnaires. One is the standardized 12-item patient

priority scale. And the second is a standardized behavioral economics assessment called the Standard Gamble, that walks patients through tradeoffs between certain outcomes and what risks they would take with them.

Patients who complete this one-time study procedure, which takes approximately 30 minutes and is conducted by trained study staff, receive $50 in compensation for their time.

California is one of three registries across the United States through which we're recruiting. For the California-specific portion of the study, we are targeting 50 eligible participants and requesting 250 cases from CCR to achieve that, those 50 participants.

In addition to the recruitment, we are comprehensively characterizing our clinical sample with relevant demographic and clinical characteristics from the patient population. We included our statistical analysis plan and justification for those variables in our written procedure.

And I think with that I will pause, unless Ms. Lund thinks there's additional things that we should be addressing in this brief summary of the study.

COMMITTEE MEMBER LUND: No, Dr. Graboyes, thank you very much for that overview. There's a few things that I just wanted to make the board aware of.

So, as Dr. Graboyes mentioned, this is a multi-site study, so they are getting registry data from several different state cancer registries. And, of course, all state cancer registries are governed by different statutes.

So, originally, their application wasn't specific to CCR and I asked for revisions to make it clear for the board that they would be following the California protocol for the California folks, and they made those changes.

So, I think that that's -- their recruitment strategies are now specific to what's required in California for the Cancer Registry folks. So, thank you for making those changes.

It's also the case that this, because it's a multi-site project, the IRB with oversight over the whole project is the Institutional Review Board at MUSC, Dr. Graboyes institution. And I want to talk a little bit about that when we talk about the consent form.

Other changes that were made, the original notification letter was written at a little high grade level, and they made revisions. And I'm very comfortable with that notification letter, now.

They provided the full text of the script that they plan to use for the teleconference. And I didn't have any issues or concerns about the questionnaire.

They will not be audio and video reporting, so

there was no need for any additional recording information on the consent form.

And I think they addressed all of the concerns that I raised, so I don't have any other concerns, other than the consent form, and I want to talk to the board about that a little bit.

So, the initial version of the consent form that was submitted was a little confusing to me when I read it because it referred to health records, and they're not asking for any health records as part of the study. And it referred to MUSC, which is not applicable for the California folks. And I thought that this might be confusing for them. And there were a couple of other minor issues with the consent form that they plan to address.

But those are part of the standard template, as I understand it, for the MUSC consent form that Dr. Graboyes IRB requires.

So, he's agreed to work with his IRB to remove that language, especially around the MUSC health records that would not be applicable to the California folks. So, you do not have a final version of the consent form to consider.

What you have in the email that I sent, or I asked Sussan to send a couple days ago, is the proposed revisions that he will be requesting approval from his own IRB in

order to make.

So, when we discuss this project today, one of the things that I would like to recommend to the board is that I would hate for us to hold this project up if we get into a disagreement with the other IRB over the language that we, as a board, may not find appropriate for California.

And what I would like to say is that their strategy for consenting provides opportunity for folks, they will actually be talking to someone during the consent. Since this is not a self-administered consent form, there will be ample opportunity for the person to interact with a member of the research team, and have questions answered if something seems confusing to them. Like, why are you talking about my health records, when I thought you were just going to ask me questions and use my Cancer Registry data?

So, what I'd like to suggest is if Dr. Graboyes can't get approval from his IRB to change what is their standard language, that given the consenting process I think that participants are protected at least, you know, in regard to the confusion and what may or may not apply to them because of the way in which the consent will be administered.

So, board discussion, if we motion to approve this project, I would like to include deferred approval pending

Dr. Graboyes changes to the consent form, to the extent that those changes are going to be possible based on, you know, working with the other IRB.

So, that's all I have to say about the project. And I open it up to the board for questions and comments.

VICE CHAIR DICKEY: Before we go, what are the issues with the consent form that you have?

INTERIM CHAIR DELGADO: I think she said it's that it references health records, because that's regular consent language for MUSC, and just the fact it says MUSC.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: Oh.

COMMITTEE MEMBER LUND: Yeah, and because it talks about health records and we're going to use your health records, MUSC health records, it seems that might be confusing for somebody from California going what?

Yeah, so Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: So, there were some rather large parts that the researcher was trying to remove from the consent form because of it being so specific to his own institution.

Do we have any sense of your IRB there being willing to make the changes that you're proposing? Do we know anything about the likelihood of them doing that?

DR. GRABOYES: Yeah, that's a -- thank you for the

question. (Indiscernible) -- I would say, based on our experience with the IRB, they are incredibly accommodating and have been accommodating in many of our multi-institutional studies. I think the rationale that you guys have articulated for why this would be confusing to patients makes perfect sense to me, and would also make sense to other registries outside the (indiscernible) that we're working with. So, I don't have a specific number, but I am confident that they are reasonable people who are willing to work with investigators to make sure that human subjects are protected and that research can move forward.

So, I would be shocked if we had to come back to you and say we can't do this. I fully expect them to say, like, good point and we should not include parts of the consent that don't make sense.

I think the only tricky part would be if they said what happened if you had, by randomness, someone in your study who was an MUSC patient, who also was a Registry patient in some other states? And I think we would just say that we have no intention to look into anyone's medical records, so it really shouldn't be an issue. But I think that might be a little back and forth like we cannot promise them that no one will be an MUSC participant, because we don't exactly know the sample we're getting.

But I would say on the likelihood I think that

they would work with us just fine.

COMMITTEE MEMBER SCHAEUBLE: I'm glad for that reassurance. Because it seemed like a no-brainer, the kinds of changes you were asking for. And I was hoping that your second alternative here was not something that was probably going to happen.

DR. GRABOYES: No. And I think we -- yeah, we went back and forth for sort of like should we -- Ms. Lund was really nice to review this in time and I think we talked about whether we could get it back through our IRB to give you a clean version in advance of the meeting today. And I wasn't confident that we could get something turned around to you in time for today, which is how we wound up with this alternative.

But when she pointed it out, like, oh, yeah, this makes perfect sense, we should totally not have included that. And I don't think we thought it through all the way. So, it wasn't like we asked our IRB and they said no, and now we're going to back to them. This is just the first time, I think, we're going to have that discussion with them.

COMMITTEE MEMBER SCHAEUBLE: Thank you.

INTERIM CHAIR DELGADO: And I did think we've run into this so many times when there is -- it's a multi-site study, and agree, Ms. Lund, with your statement that

anything we can do to facilitate and move things along, and not be the holdup is a great approach.

COMMITTEE MEMBER LUND: Other comments, questions?

COMMITTEE MEMBER VENTURA: I had a clarifying question. Were the years of data being request from CCR clarified? I think that was one of your comments. I didn't see it in the revisions, but I might have missed it.

COMMITTEE MEMBER LUND: I think that all the data requests got clarified for me. I don't think I have any outstanding ones.

Some of those questions that you may have seen, there was some initial confusion on the first submission because there was a supporting document attached that had different information than what was actually in the protocol. And that had subsequently dropped.

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LUND: And removed. So, I think it's okay.

COMMITTEE MEMBER VENTURA: Okay.

DR. GRABOYES: And that's one hundred percent mine, and I was so -- when that was put out, I was so, so, so sorry. I'm sure you read that and you're like what is going on. The version you have since is a much more internally consistent and coherent document.

And I think the last part of that was that in

addition to integrating multiple pieces of Registry data, there's a whole separate part of the grant that takes the Registry data and would -- yes. Thank you, sorry, that was confusing. And the data procured is 2019 to present. With present being defined as whenever this makes it to CCR.

COMMITTEE MEMBER VENTURA: Yes, thank you.

VICE CHAIR DICKEY: Is there a central IRB involved in this? Again is --

COMMITTEE MEMBER LUND: Yeah, MUSC IRB.

VICE CHAIR DICKEY: So, they are the central IRB. But just it raises an interesting question between federal and state law. Federal law would say we need to defer to their central IRB. But we can't defer because of the Information Practices Act.

INTERIM CHAIR DELGADO: And CCR's statutory --

COMMITTEE MEMBER LUND: Yeah, CCR requires us to statutorily review CCR.

VICE CHAIR DICKEY: I think -- we looked at the regulation on research, so it's their IRB, using the word "their". I just think that it's something we need to (indiscernible).

I think the --

COMMITTEE MEMBER LUND: By "their" do you mean CCR's? Because first CCR's --

VICE CHAIR DICKEY: No, the research. But in any

case, we'd need to review it under the Information Practices Act.

COMMITTEE MEMBER LUND: Yes.

VICE CHAIR DICKEY: But the question is does it -- if it's Information Practices Act, does the extent of it looking at the consent form, and that sort of --

COMMITTEE MEMBER LUND: Right. But we are -- we are, today, working under the rules.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: And to your point, this is my -- if their IRB declines to make all these requested changes in the consent form, I don't want us to be the hold up in saying well, no, we won't approve it. So, that's why I think we should --

VICE CHAIR DICKEY: No.

COMMITTEE MEMBER LUND: -- defer to them on that, yeah.

Okay. Other questions or comments?

Okay, great. I think we're ready for a motion.

INTERIM CHAIR DELGADO: Great. Would you like to make a motion?

COMMITTEE MEMBER LUND: Yeah. So, deferred approval, minimal risk, one year, with the stipulation that the final version of the consent form will be attached to the protocol with a subcommittee of myself to review.

COMMITTEE MEMBER JOHNSON: I second.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

INTERIM CHAIR DELGADO: Great. Thank you so much, Dr. Graboyes for your project. Thank you, Ms. Lund for all of the -- again, all of the work that goes into pre-review to get this to a point where we can so rapidly approve it during the meeting.

(Whereupon, the Court Reporter interrupts for some spelling clarifications.)

DR. GRABOYES: Thank you, guys, for your attention to this protocol. You definitely made the science better through the process. So, Ms. Lund, thank you, we all appreciate it. And we'll be back in touch with our revised

consent document.

COMMITTEE MEMBER LUND: Great. Thank you.

DR. GRABOYES: Bye.

INTERIM CHAIR DELGADO: Bye.

VICE CHAIR DICKEY: Oh, well, shall we go on to the next project. Is Dr. Cooperman present or -- Cooperberg.

DR. COOPERBERG: Yes. Hi.

VICE CHAIR DICKEY: Hi. I'm Dr. Dickey. We communicated a little bit.

DR. COOPERBERG: Yes.

VICE CHAIR DICKEY: By email I think, I hope. Do we still have a quorum?

DR. RYKACZEWSKA: We might need to take a five-minute break because we do have less than seven in person right now, since they're stepping out.

VICE CHAIR DICKEY: Hold on.

DR. COOPERBERG: No worries.

VICE CHAIR DICKEY: So, we're taking a five-minute recess.

DR. RYKACZEWSKA: Yes, thank you.

(Off the record at 10:44 a.m.)

(On the record at 10:50 a.m.)

INTERIM CHAIR DELGADO: Okay, we are now going to restart the meeting. Court reporter, are we good to go?

Okay. We'll flag, for those on the call that are calling in, is that --

COURT REPORTER: I'm sorry, I just had a --

INTERIM CHAIR DELGADO: Did we spill our coffee on the laptop?

COURT REPORTER: Let's just go off the record again, just for a second.

INTERIM CHAIR DELGADO: We're going to restart this. Give us 60 seconds.

COURT REPORTER: Yeah.

INTERIM CHAIR DELGADO: While the -- am I unmuted?

(Off the record.)

INTERIM CHAIR DELGADO: Okay, we are now back on the record. We are -- got the green light from the court reporter that we are good to go. Shockingly, we are now only five minutes behind schedule, so we're recouping a lot of time.

So, we'll start with next the Project 2024-189, Dr. Dickey.

VICE CHAIR DICKEY: And Dr. Cooperberg. So, Dr. Cooperberg, would you briefly summarize your project. And I would ask you to emphasize the focus groups and the questionnaire, as opposed to the other components of the project which are not complete, yet. It's my understanding that what you want us to approve is the questionnaire and

the focus groups. Is that right?

DR. COOPERBERG: Yes, so we'll give you an overview of the proposal. So, thank you for your time first of all, and I hope everything is safe next door.

So, this grade group, low-grade prostate cancer has been a major public health concern for a long time. You know, we are increasingly clear that we save thousands of lives through the efforts screening and management of high-grade disease. The downside of which is we've had a tremendous amount of over treatment of low risk prostate cancer over many years. And there are multiple lines of evidence suggesting that low-grade, what we call grade group one prostate cancer is basically a normal feature of aging..

Half of all men we could find this in autopsy results if they live long enough and a growing number of molecular studies suggest that, you know, genetically it's actually not that different from adjacent normal tissue.

And the public health implications of over diagnosing and over treating have really hampered efforts to screen more effectively and to, in turn, address prostate cancer disparity.

So, there's a growing chorus of voices suggesting that we really should consider a change in nomenclature for grade group one prostate cancer. Not to call it normal, but to call it something else. There's a range of pre-cancerous

labels which have been proposed. And this idea has been out there for over a decade now, but it's starting to get more traction.

And I helped organize a symposium a year and a half ago, concurrent with the ASCO GU annual meeting. We had 50 participants from four different continents, very international, very multi-disciplinary with representatives from urology, (indiscernible) oncology, primary care, epidemiology, and patient advocates, as well to start discussing this idea a little bit more seriously. And there was a representative from the CDC at this meeting, as well.

And one of the concerns that came up, one of the, you know, potential objections is the question of whether patients would still take the diagnosis seriously if we changed the name.

So, to be clear, we've recommended for years, and all the guidelines are not consistent, that grade group one prostate cancer should be followed with active surveillance. We should not go straight to treatment. These men should be followed and we treat if we see the cancer looking more aggressive, within a window of opportunity that we think is typically measurable in years or even in decades. But there is a proportion of men, in patients in whom we will ultimately find higher grade cancer and they need treatment.

So, surveillance is very important. And active

surveillance has been rising over the years in terms of its uptake in community practice. We went from 25 percent a decade ago to about 60 percent now. That's still much too low. And there's still huge variations from practice to practice. There's still a lot of places, and a lot of urologists and (indiscernible) oncologists that pervasively over treat low grade disease.

But this question has been raised, if we don't give the patient the cancer diagnosis will they still follow up with the necessary PSA tests, biopsies, et cetera.

So, following this meeting there was an RFP from the CDC to put together a project exactly to ask patients how would you think differently about this diagnosis in the face of a different label?

So, we applied for an SIP grant through the CDC, which was just awarded about two months ago, to really go at this.

So, in our proposal there are two components of it. The first of which, in one is a qualitative -- a set of qualitative studies where we're going to recruit patients out of CCR, over-representing black and Hispanic patients. Black men, of course, as you heard from two presentations ago, they're a disproportionate burden of lethal prostate cancer. It's the highest disparity of any of the nature of cancers. Hispanic patients, as well, who have been

historically unrepresented in prostate cancer research in general.

And run a series of focus groups to really get at the questions of, you know, what -- you know, how they react. And this is recruiting men with low-risk disease, by the way, who are currently slated for surveillance, to really try to understand more deeply what the implications of relabeling might be. How their reaction to the diagnosis was, what their understanding of active surveillance is, what that entails. And start to get at questions of whether things might be different, whether they might think about either the diagnosis differently, the possible need for treatment, and the importance of active surveillance, how any of this might be different if they didn't have that word, "carcinoma", on the pathology report, the cancer diagnosis from a clinical stand point.

And we also want to collect feedback about the nature of the pathology report and just their understanding of the way the information is -- has been presented to them.

So, aim one is qualitative. There's a series of focus groups. And then, follow-up, more in-depth interviews which we're going to use to put together a questionnaire which we're going to use in aim two, where we're actually going to put a survey out online to a set of 525 patients. Again, recruited from CCR, to try to get a little bit more

quantitative about, again, anxiety levels, about preferences for surveillance versus treatment.

And also, to put in front of patients a sample of, you know, what an alternative pathology report might look like and see, you know, how this would potentially affect their decision making both at diagnosis, and at various decision points as they go down the surveillance journey.

So, that's the outline. This is all -- you know, none of this is sort of clinically oriented. This is all kind of focus groups and information gathering.

To briefly address your questions from the email yesterday, and I'm sorry I didn't get back to you in writing. I was in transit back from a meeting.

VICE CHAIR DICKEY: Just a minute, before you --

DR. COOPERBERG: Sorry. Right. Yeah, please.

VICE CHAIR DICKEY: Could you summarize the recruitment and the consent process?

DR. COOPERBERG: Yeah. So, the recruitment is going to be identifying patients through CCR for our group at UCSF, who have pretty substantial experience doing this in the past. Patients will be approach by -- you know, in writing or by phone.

To answer the question about call backs, up to three call backs. Based on their diagnosis with grade group one prostate cancer in CCR.

VICE CHAIR DICKEY: And how many do you think you're going to need to reach out to?

DR. COOPERBERG: For the qualitative, for the focus groups, the goal is to get six focus groups together with four to six participants per group. At least two of which the plans to do it in Spanish and the others in English.

VICE CHAIR DICKEY: And for the identifying the subjects for recruitment, you're getting contact information from the Cancer Registry, right?

DR. COOPERBERG: Yes.

VICE CHAIR DICKEY: Are you getting any more information from the Cancer Registry than those individuals?

DR. COOPERBERG: We will need basic clinical information about the cancer. We need to confirm the low grade diagnosis, of course. And we are hoping to get a few more details about the cancer to confirm the low risk status. So, the usual stage PSA and extensive biopsy core involvement to confirm eligibility.

VICE CHAIR DICKEY: So, that's beyond the contact information, but you feel like you need that information for yourself to determine that they meet the criteria for low grade?

DR. COOPERBERG: Yeah. Yeah.

VICE CHAIR DICKEY: All right. And then, how

about the consent process?

DR. COOPERBERG: So, the hope is a waiver of informed consent, as this is low -- a waiver of written consent as this is all low impact and meets all the criteria for low risk research, according to federal criterion.

So, our hope is for an approval of verbal consent.

VICE CHAIR DICKEY: And you've provided us with that document?

DR. COOPERBERG: Yeah.

VICE CHAIR DICKEY: The verbal consent document.

DR. COOPERBERG: I'm 90 percent sure. I will confirm with Laura Allen, who's been working on the submission with me.

VICE CHAIR DICKEY: I had a question. In your application there was a flyer that was provided. I don't think you're going to need that, right?

DR. COOPERBERG: We do not. I think that's based on a copy over from our -- our group at UCSF has done multiple similar studies in the past. I think that might have been a copy/paste from a previous similar consent, obviously. But, yes, this will be identification through the Registry.

VICE CHAIR DICKEY: And there is a questionnaire involved, in addition to the focus groups?

DR. COOPERBERG: Well, the questionnaire's going

to be developed through -- it's going to be refined through the focus group process. So, the questionnaire that we're going to -- the survey that's going to go out in aim two is going to be developed and refined based on the results from the focus groups and the interviews. So, yeah, we will --

VICE CHAIR DICKEY: I think there's -- I think there is a screening questionnaire before you get to the focus group that asks them about -- that asks certain information. Is that right?

DR. COOPERBERG: Yeah, we'll be getting this from the -- obviously, from the Registry. And the intent of the questionnaire is really just to validate, you know, the data that are in the Registry.

VICE CHAIR DICKEY: Right. But that occurs after you get the information from the Registry, before the focus group occurs, the questionnaire.

DR. COOPERBERG: Yeah.

VICE CHAIR DICKEY: And if there's nothing to rule them out then, then they go to the focus group.

DR. COOPERBERG: Correct.

VICE CHAIR DICKEY: And then, there is the consent. Okay.

And my only suggestion on the consent was, you know, maybe identify right up front that you're talking about low risk prostate cancer.

DR. COOPERBERG: Yeah, I saw that suggestion and we can actually do it. It's good points.

VICE CHAIR DICKEY: And these other aspects of the study for the long term, are the one-on-one interviews, and the more extensive questionnaire survey, you're going to be coming back to us for approval of those once you develop them. Is that correct?

DR. COOPERBERG: So, these -- for the aim two survey, yes. And the interviews are, you know, intended to be fairly open-ended based on the focus groups. So, you know, those are going to follow on really just to get a little bit more in-depth based on the responses from the focus group. So, I'm not sure that there's going to be a formal kind of written guide to those interviews. They're really just going to follow up on the content from the focus groups.

But the aim two questionnaire, yes, we'll be coming back for a revision.

VICE CHAIR DICKEY: Well, in general, even for a focus group or an informal interview, we'd sort of like something that these are the topics that are going to be discussed.

DR. COOPERBERG: Yeah, we can absolutely do that.

VICE CHAIR DICKEY: We don't need the exact questions sort of thing, but we need that --

MS. ALLEN: Sorry, this is Laura. I was attempting to interject on the phone and you weren't -- and I don't know why it wasn't hearing me.

But, yes, we fully intend to submit patient facing materials for the qualitative surveys, the one-on-one surveys that will be the iterative process following the focus group activities, which all -- you know, all of those patient facing materials we've submitted with this application.

And then, following those, that qualitative study, we would submit for the larger quantitative survey all of those patient facing materials as well.

And also, just to speak to the questionnaire component for the focus group participants, that's just a short demographics, basically, questionnaire. Like we included that as part of the study materials and that's the questionnaire that the focus group consent form is referring to.

VICE CHAIR DICKEY: Well, we have a copy of that in the materials.

MS. ALLEN: Yeah, it's attached.

VICE CHAIR DICKEY: Okay. I didn't have any further questions about this. I thought it's -- I think it's an important study of a male of a certain age. I appreciate the study. And I'll open it up to the rest of

the Committee for questions.

INTERIM CHAIR DELGADO: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I agree with your comments, by the way.

(Laughter)

DR. COOPERBERG: My word, this is exactly why we're excited about this. It's very timely and very important.

COMMITTEE MEMBER SCHAEUBLE: I was looking and I hope I'm not confusing studies here. I was looking at a list of data variables requested and what I saw was that the Registry had indicated, yes, they would release most everything on that list. But near the bottom of the list was Census tract information, which was flagged as, "we will release this if you can provide strong justification for doing so." And I was wondering why that information is needed at all and what the status of that is?

DR. COOPERBERG: It's honestly going to be more important for our second part, for aim two. The reason for that variable is so that we can geocode, you know, the patient's location and derive a series of parameters about social and structural determinants of health, which the UCSF group has a tremendous amount of experience doing.

So, you know, the focus groups, this is less critical because the number is small. But as we start to

look for predictors and determinants of different patterns and answers, and feelings of anxiety, and preferences, and all this we want to make sure, A, that we're representative, you know, of different geographic regions across the state.

And also, that if there are predictors, things like neighborhood factors and other structural determinants we can get at those. So, that's the reason for that.

But like I said, it's more critical for the second phase, than for the first.

COMMITTEE MEMBER SCHAEUBLE: So, how will those geocodes actually be used and what would -- what would they lead to as far as other information that might be acquired or related to the neighborhood of the person or what --

MS. ALLEN: So, if I may, we did provide additional justification for those variables. And the Census tract and block group numbers are required for a pending geospatially referenced data measuring structural and social drivers of health elements.

And these Census tract and block group information will not be disclosed outside of the study team authorized to examine that information.

So, it's in order to append geospatially referenced data measuring structural and social drivers of health elements. And we provided that for the justification to CCR, which I believe they agreed to them.

I thought I appended that to the application.

COMMITTEE MEMBER SCHAEUBLE: Maybe what I should be asking is does this imply some kind of linkage to other data in the future connected to the geographical information or the people?

DR. COOPERBERG: Yeah, so the group -- the (indiscernible) -- the group that consists of have basically developed and validated a few dozen different parameters related to neighborhoods. So, things like historical redlining, you know, access to high quality food. There's a whole range of these sort of structural and social determinants, which are pretty tightly pegged now to prostate cancer outcomes.

This is not patient level, not identified. These are factors that we know do affect both the diagnosis and the course of prostate cancer through variables that we're still trying to figure out at the biologic level.

We have other grant proposals pending, actually, to try to sift out what exactly those mechanisms are.

But we know that these are variables that do have a pretty profound impact on prostate cancer disparities, in particular.

But it's not -- the goal is not to -- we're using this to pull in other data sort of at neighborhood level, not at the patient level, if that's the questions.

COMMITTEE MEMBER SCHAEUBLE: Okay. I mean --

DR. COOPERBERG: I hope I'm answering that, if I'm getting your question right.

COMMITTEE MEMBER SCHAEUBLE: The reasons you're suggesting sound reasonable, I just hope they will be fleshed out before that part of the study takes place, so that we might know what additional variables you're actually proposing to work with there.

DR. COOPERBERG: Yeah, there's a set. And the group have a series of publications, actually, using exactly this methodology that I believe we reference in the -- well, it's referenced in the grant proposal. We can get those appended to the protocol as well, if you'd like.

COMMITTEE MEMBER SCHAEUBLE: That was all. Nothing more from me.

DR. COOPERBERG: Yeah.

VICE CHAIR DICKEY: Any questions out in ether land?

COURT REPORTER: The court reporter has a quick question. What was that group? What was the name of that group you just mentioned? It sounded like a bunch of names. Maybe -- you were talking redlining and the group that you're using or utilizing to --

DR. COOPERBERG: This is what we call the (indiscernible) that's Scarlett Lin Gomez's team in

epidemiology, and about six at UCSF. She is -- Scarlett Lin Gomez has been the lead on it. Anna Chang is probably the lead on most of the recent papers on this topic.

COURT REPORTER: The spelling of all those names is what I'm asking about.

DR. COOPERBERG: Oh, sure.

COURT REPORTER: Maybe an email.

DR. COOPERBERG: Yeah, sure. Sure.

COURT REPORTER: Beg your pardon. Thank you.

DR. COOPERBERG: Dr. Lin Gomez is on the protocol, she's on the current.

VICE CHAIR DICKEY: She's in the protocol. She's one of the researchers. Do you need to get that information?

COURT REPORTER: Yeah, I just -- for my purposes, thank you.

VICE CHAIR DICKEY: Any other questions? Any questions from the public? I'll make a motion.

INTERIM CHAIR DELGADO: Let's make a motion.

VICE CHAIR DICKEY: I'd like to approve this, but with the proviso that what we're approving right now is the focus groups and the questionnaire for the focus groups. And an amendment will be provided us for further development for the one-on-one interviews and the survey.

COMMITTEE MEMBER LUND: Second.

COMMITTEE MEMBER LUND: One year, minimal risk?

VICE CHAIR DICKEY: One year, minimal risk.

MS. ATIFEH: Okay. Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

INTERIM CHAIR DELGADO: Great. Well, your motion is passed, Dr. Cooperberg. Thank you for your work. Thank you to Dr. Dickey for the extensive work with Dr. Cooperberg's team. You'll receive a letter, an email that has the letter in the next week or so describing all of these details. And we look forward to continuing to work with you for the duration of your project. Thank you so much.

DR. COOPERBERG: Wonderful. Thank you so much.

INTERIM CHAIR DELGADO: Thank you very much. Even

though I'm not a person who identifies as a male over the age of 50.

VICE CHAIR DICKEY: But you may know some.

INTERIM CHAIR DELGADO: I do.

DR. COOPERBERG: It's 45 now, 45.

INTERIM CHAIR DELGADO: Forty-five, all right.

Okay, thank you so much.

DR. COOPERBERG: All right, thank you.

INTERIM CHAIR DELGADO: Okay, and last, but not least, four minutes ahead of schedule, we're going to -- two amendments on Project 2024-094. And I'll hand it over to interim -- no, not interim chair, Chair Elect, Dr. Hess.

COMMITTEE MEMBER HESS: Thank you. I see one member of the research team, Dr. Shrestha and Ms. Zhang.

So, just to give the board a little bit of background, this is an amendment to a previously approved project. I can't remember which board meeting we approved it.

This is a project looking at patient reported outcomes on individuals with metastatic colorectal cancer. It came to me as an amendment, but because it -- the amendment included some new human subjects data collection activities, I requested a full board review. And that is what we are considering today.

My -- I want to thank the research team for

providing clarification and explanation of an amendment to the way they are going to be identifying eligible cases. I still have some questions about that, so I would love it if you could explain both that and just give the board a quick rundown of the end-of-day assessments that you are proposing to add into the project.

DR. SHRESTHA: Certainly. Thank you, Dr. Hess, for this opportunity to give you some clarification.

So, in this study there are two main amendments that we applied for. The first part is how we are identifying eligible cancer cases for contact. And we were planning to use Registry data, a more refined form of Registry data.

However, during this process I learned that there's been some delay in reporting and I got -- we got concerned that we may not be able to identify enough eligible individuals for the study.

So, we decided to add another approach where, which still relies on Registry data, but instead of relying on already processed data we -- our plan is to work closely with Registry, cancer registrars of Cancer Registry of Greater California, to flag eligible patients already in the process.

So, in our Registry, doing cancer reporting we receive pathology reports first. So, and then that sits

there for many, many months before it gets processed. So, the change here is the study team are not going to be involved in that part. We'll be relying on our cancer registrars, who do this process, to prioritize certain, the colorectal cancer patients who could be potentially eligible for the study.

So, that part relies on -- so, when in the amendment, when we mentioned for pathology report that's what it was referring to. So, we are not collecting that data ourselves, for our study. It's we will still be relying on the Registry data.

And then, the second part of the amendment is after we -- after we enroll participants in the study, and they have completed first survey -- so, just a reminder, this is a longitudinal study where we are planning to collect data over 12 months period, once they're enrolled in the study.

So, after they complete the baseline survey, this new piece that we have, that we are introducing is to -- for those who opt for electronic method of contact for future surveys, we will be sending out this quick assessment measure.

And I do have -- if you need more details on that, I think I'll rely on the Co-PI of the study, who has, you know, who's leading this part of the effort.

But, basically, it's going to be, you know, a very brief, five-minute end -- five-minute end-of-day assessment and in a subset of participants.

And our goal at the Cancer Registry, here, is to select and collect data from up to 80 participants. I know in the amendment we say 160 participants, but the total number of participants we're hoping to get data overall in the study. But the study is a multi-site study and in California, within our catchment area we're planning to collect data from 80 participants.

COMMITTEE MEMBER HESS: Thank you. That would be one thing that we might want to amend is reporting the number of participants out of California.

I do have a couple of questions, still, about the Registry data. So, the data that we're talking about, these pathology reports, are data that are coming -- or reports that are coming into the cancer registrars, but have not yet been transmitted or processed to CCR, correct?

DR. SHRESTHA: No, they -- well, they are coming to the Registry and usually in our Registry process they are the first step. So, what happens is registrars screen those path reports and identify whether they're reportable or not reportable. And then, code it to a certain part. And if they determine they need additional materials, then they either look for other providers and whether they have

already provided the data, and then they consolidate all of the data.

So, it is -- it is within the Registry data. The difference, I guess, is when you mention CCR, you know, the regional registries, we process all the data and every year, at the end of the year during the big submission we submit that data, and that's what the CCR receives.

But this is technically still part of CCR database, it's just not -- it's in the upstream of the data processing.

COMMITTEE MEMBER HESS: Okay. I -- Laura, do you have any -- I've never encountered this before.

COMMITTEE MEMBER LUND: Yeah, so I just -- I have a question about this.

DR. SHRESTHA: Yes.

COMMITTEE MEMBER LUND: Because it goes to whether or not they have the authority in law to use these pathology reports. They have authority in law to use data, but abstracted from reports from various sources, because their authority is once it's abstracted it becomes part of the Cancer Registry database.

I'm not sure, and it might be worth requesting that they have a legal opinion on this from CCR. I am not sure, because the pathology report is technically part of the patient record.

DR. SHRESTHA: Yes.

COMMITTEE MEMBER LUND: It's protected health information. And it doesn't become CCR data until it's abstracted. So, I think that this is a gray area leaning towards black in regards to I'm not sure if this information can be used in the way that they are proposing to use it.

And so, before I could vote on this, I would really like to have a legal opinion from CCR on whether those pathology reports are truly CCR data in their pathology report zone, or whether they are still part of the patient record.

DR. SHRESTHA: May I make one more clarification here. So, the process of coding and flagging like the initial screening of pathology report by registrars is part of the process for CCR.

So, we -- as the researcher, we are not going to be using the path report, itself. But we will be relying on once they have finished the first couple of steps of data processing.

So, I don't know if that makes a difference in delineating whether, you know, it's Registry data or not.

COMMITTEE MEMBER HESS: I think the question is at that point is the data legal to release or does the data have to be fully ingested and processed into CCR before it becomes part of the data that they can legally release.

It's just -- well. Yeah, I realize that you're not using the pathology reports in research, but it's -- I think to speak to what Ms. Lund is saying, it's whether that release of that information is legal at that point.

COMMITTEE MEMBER LUND: Correct.

COMMITTEE MEMBER HESS: Prior to going to CCR. And that's what I think you would like clarification on.

COMMITTEE MEMBER LUND: Yeah. Or even to be fully -- because she's correct. It can be fully ingested into the local Registry and not yet reported to CCR. But at that point it's still considered to be CCR data, even though it hasn't, you know, technically made the electronic transfer.

COMMITTEE MEMBER HESS: Right.

COMMITTEE MEMBER LUND: So, I would want to know --

COMMITTEE MEMBER HESS: How does CCR feel about this.

COMMITTEE MEMBER LUND: Right. Right, and I would want to know whether it's legally releasable.

COMMITTEE MEMBER HESS: Yes.

DR. SHRESTHA: We definitely go through this and, you know, have this confirmation, that's definitely helpful. But I don't know if this helps or not, but we do -- at the Registry, you know, for patient contact studies we often use data that has been fully or partially processed in our

Registry. And especially for patient contact studies because we do not want to wait for two years of, you know -- so, there is a process for that. I don't know all the details, so I'm sure maybe the CCR's legal can help you clarify that better.

COMMITTEE MEMBER HESS: Yes. And I think that maybe we could just proceed with talking about any of the other aspects of the project, so we could get to a point where we feel comfortable approving pending a decision from CCR, so we don't have to come back to full Committee, but address all, any other concerns we have.

Correct, is that okay?

COMMITTEE MEMBER LUND: Right.

COMMITTEE MEMBER HESS: Okay, I agree with that.

INTERIM CHAIR DELGADO: Is that -- Dr. Dickey is in the --

VICE CHAIR DICKEY: I'm sitting over here so I don't cough.

INTERIM CHAIR DELGADO: Well, I feel like you're coughing because of the bagel you were eating, not because you have --

(Laughter)

VICE CHAIR DICKEY: It was a very good bagel.

A letter of support from CCR, as opposed to a legal, an actual legal document, you know, from legal, would

suffice.

COMMITTEE MEMBER HESS: I mean -- yeah, LOS does -- in the CCR LOS it does state that the data release is legal and meets -- does it not? And meets their required --

VICE CHAIR DICKEY: But was that with this? I don't --

INTERIM CHAIR DELGADO: Wouldn't that letter of support have been creating --

COMMITTEE MEMBER HESS: Yes. So, to your end, yes, a letter of support should be sufficient from CCR.

VICE CHAIR DICKEY: An amended one.

COMMITTEE MEMBER LUND: CCR won't submit -- that's been a problem in the past. CCR will not submit a letter of support for an amendment. So --

COMMITTEE MEMBER HESS: That's right.

COMMITTEE MEMBER LUND: So, you're going to have to ask them, or I would recommend --

VICE CHAIR DICKEY: Ask specifically.

COMMITTEE MEMBER LUND: -- ask specifically if this release of the data is legal.

COMMITTEE MEMBER HESS: Okay.

DR. SHRESTHA: The one thing, another thing I want to mention is thank you for bringing up letter of support. I had forgotten about that. When we request -- the original application we had requested, it was also planning on

relying on Registry data that have not been, you know, physically moved to CCR yet. It was partially processed. Like it's processed by the registrars, but there's always additional things that happens before we submit it to CCR.

So, whereas now, the second approval -- and we still want to use that approach and we will probably rely mainly on that, just because it's a little bit simpler for easier.

But if we have any -- we identify insufficient people through that approach, at least for this first six months or so, we would like to use, you know, a little bit upstream data, rather than the ones that we were initially planning.

INTERIM CHAIR DELGADO: Okay. Well, we'll reach out and maybe not a formal letter of support, but like even just ask for an opinion.

COMMITTEE MEMBER HESS: Yeah. I mean and there was no -- yeah, we would request kind of like that, the research team reach out and share the data method protocol with CCR, and ask for clarification on this. Because there's another component of the research team contacting the patient physicians, as well, in advance of contacting the patients.

DR. SHRESTHA: Yes. That's for the second approach because my understanding of our California State

law is if we -- so, this second approach is considered rapid case of certainment (phonetic) in the Registry world. And I was informed, I don't remember who, that in state -- California State they require, if we are using this approach for identifying eligible patients, then we need to notify physicians ahead of -- before we contact the participants. So, that's why we include it in -- you know, we're planning to incorporate that part as well.

So, I can definitely add these two and email them to CCR, CDPH. Do you -- would you like me to forward the email response, or how would you -- what is your expectation as far as like from us?

COMMITTEE MEMBER HESS: You can forward the response. You know, you're also free to cc me on the email request to CDPH, so that they see it. You know, if there's any questions or a push back on, you know, this, I can jump in and say that this was at the request of CPHS.

DR. SHRESTHA: That sounds good. Thank you.

COMMITTEE MEMBER HESS: Uh-huh.

As for the end-of-day assessment, I didn't see a lot of issues with that, outside of -- so, this is effectively a pilot study and not all of the participants in the main study will be eligible for the EODS, correct? It's only individuals -- EODA, sorry. It's only participants who opt in to be contacted electronically?

DR. SHRESTHA: That's our plan, yes.

COMMITTEE MEMBER HESS: Okay. I would ask if the board had any thoughts on that? No, okay.

In that case, I mean I'm satisfied with the amendment, outside of this CCR issue. So, I can make a motion.

So, I move for deferred approval, one year, minimal risk, provided that the research team share the amended protocol with CCR and provide the board with written confirmation that CCR supports the release and use of pathology reports from the registrars, and that is in fact legal.

Was that okay?

VICE CHAIR DICKEY: Is that a second?

COMMITTEE MEMBER LUND: Yes, second.

VICE CHAIR DICKEY: Okay, call the roll.

MS. ATIFEH: You seconded, right?

COMMITTEE MEMBER LUND: I did.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: I'm sorry, I forgot to ask Dr. Dickey.

Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: I seconded it.

COMMITTEE MEMBER HESS: I forgot to add a stipulation. Sorry.

MS. ATIFEH: Oh, okay.

COMMITTEE MEMBER HESS: Do I have to redo the whole motion?

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER HESS: Okay, I apologize, I forgot a stipulation. She can add the stipulation and I can second the whole thing.

VICE CHAIR DICKEY: However you guys want to.

COMMITTEE MEMBER HESS: Okay. Well, the second stipulation is just that they revise the number of participants to 80, which is the California portion for the end-of-day assessments.

COMMITTEE MEMBER LUND: I second the whole motion, including the stipulation. But before we vote, could we ask the public?

VICE CHAIR DICKEY: No.

(Laughter)

VICE CHAIR DICKEY: Any public comment? Anything, anybody got raised hands any place?

Okay.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: And Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: Okay. I guess we have -- can I see that list of --

DR. RYKACZEWSKA: We do need to address the other agenda items.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: So, this would be Agenda Item G.

COMMITTEE MEMBER HESS: We probably are sitting --

DR. RYKACZEWSKA: I'm sorry.

Your study is approved. You will be receiving -- well, it is a deferred approval, so you'll receive a letter that describes the stipulations as a deferred approval. And then, it's resubmitted.

DR. SHRESTHA: Thank you very much.

DR. RYKACZEWSKA: Thank you.

COMMITTEE MEMBER HESS: Sorry.

VICE CHAIR DICKEY: That's all right.

DR. RYKACZEWSKA: Questions for --

VICE CHAIR DICKEY: So, I have items I through O, any comments on those? Any questions from the public, as well as from the Committee?

MR. ZADROZNA: No public comments in person.

DR. RYKACZEWSKA: Thank you, Nick.

VICE CHAIR DICKEY: And then, we have some public comments that were submitted in writing. Just to note for the Committee, Carolina Reid and Rita Haman, regarding the amendment of the regulations.

And then, Margot Kushel and Asa Bradman regarding the fee issues.

Are any of those people on the phone or on the internet who would like to comment?

DR. RYKACZEWSKA: They are not on Zoom.

VICE CHAIR DICKEY: Okay. Does anybody want to comment on those before we go off?

COMMITTEE MEMBER HESS: Is there any update for the board on the fee?

DR. RYKACZEWSKA: Not at this time. We will bring that back in the spring. Sorry, we're still crunching

numbers.

VICE CHAIR DICKEY: Well, that's -- I think that's the ending, right?

DR. RYKACZEWSKA: Well, do we want to open it up for any further public comment?

VICE CHAIR DICKEY: Yes, we do. Any further public comments?

DR. RYKACZEWSKA: I'm not seeing any on the Zoom.

Nick, any in the room?

MR. ZADROZNA: None in the room.

DR. RYKACZEWSKA: Going once, going twice, that is it for public comments.

VICE CHAIR DICKEY: And if no more comments from the board, we will adjourn.

DR. RYKACZEWSKA: Okay, we are adjourning at 11:32. Thank you so much.

(Thereupon, the meeting was adjourned at 11:32 a.m.)

--oOo--

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

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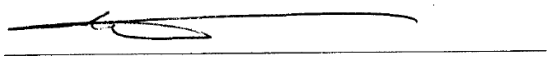

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