MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Darci Delgado, PsyD, Interim Chair

Larry Dickey, MD, MPH, Vice Chair

Alicia Bazzano, MD, PhD (Via Zoom)

Maria Dinis, PhD, MSW (Via Zoom)

Catherine Hess, PhD Dr.

Jonni Johnson, PhD

Laura Lund, MA

Carrie Kurtural, JD

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

CDII

John Ohanian, Director

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Maggie Schuster, Legal Counsel

ALSO PRESENT

PUBLIC

Satish Kumar, Suparna Health, AI, LLC

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Ms. Aamna Akhtar, City of Hope

Dr. Justin Harty, Arizona State University

Dr. Wendy Cozen, University of California, Irvine (UCI)

Ms. Mallory Bernstein, UCI

Ms. Danielle Shores, City of Hope

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P R O C E E D I N G S

INTERIM CHAIR DELGADO: So, we will call this meeting to order.

Sussan.

MS. ATIFEH: Yes.

INTERIM CHAIR DELGADO: Hi.

MS. ATIFEH: Hi.

INTERIM CHAIR DELGADO: Would you call roll for us, please.

MS. ATIFEH: Sure. Okay, let's do a roll call to see who's present in this meeting.

Actually, I start with Dr. Delgado?

INTERIM CHAIR DELGADO: Present.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Bazzano?

DR. RYKACZEWSKA: I'm not seeing her online.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Present.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER PALACIO: I'm not sure if you can hear me.

MS. ATIFEH: Yes.

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Okay, good.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: So, a quorum is established, thank you.

INTERIM CHAIR DELGADO: Wonderful. Thanks.

Okay, so I will start with a few Chair updates. Okay, so the first, I would like to remind everyone that I am serving as an interim chair, meaning others have the opportunity to step into the chair role.

And I wanted to remind folks of the requirements to serve as chair or vice chair, per our policies and procedures. So, the chair must be a current CalHHS or a CalHHS department employee. So, CDPH, DDS, DHS, a current

employee. Not looking at anyone specifically. And must have been a member of CPHS for at least two years.

To be -- serve as vice chair, you must have been a member of CPHS for at least one year but does not have to be a current CalHHS employee.

So, just reminding folks of my interim status and hoping to address this maybe in January of 2025, to see if we can't transition to a new, permanent chair, that doesn't have the interim title, like mine. So, wanted to put that out there as one of my updates.

Second update is a reminder about, what was it, Maggie, like two months ago that Jared sent out -- two months ago Jared Goldman, who is not present today, but serves as general counsel for CalHHS, along with Maggie, sent out a document that gave us a description of Bagley-Keene.

So, I just want to remind folks of the Bagley-Keene document. Specifically, that when we need to have a subcommittee, it includes when three members come together. Also, serial communication is -- reread that part in the document, as well, because it's a bit more complicated.

But just want to take a moment to remind everyone of those. And we can refresh that in your email box, if that would be helpful.

Okay, I think that's -- oh, and also a chair

update, there is more than just bagels today, more than just coffee and bagels. So, sorry to those on Zoom, you cannot partake in the feast we have. But please, everybody, make sure you get some food.

Okay, that's my Chair update. I'll hand it over to Agnieszka for her admin update.

DR. RYKACZEWSKA: Thank you so much, Darci. So, I have two that I'll be doing today. The first is a presentation I will be giving on some draft regulations we're proposing to the board on potential CPHS fees.

And so, let me just share screen here. And there we go. Okay, perfect.

So, first, let me start a little bit with the statutory authority. So, the California Health and Safety Code, Provision 109, is the section of the Health and Safety Code that created CDII, and also the various roles, responsibilities of CDII.

One of the pieces there is, of course, its role as a support and administration of CPHS. And a component of that says that "The center may collect fee-for-service payments from a non-state entity for services provided by the State Committee for the Protection of Human Subjects." So, this Committee.

Essentially, this has been a long-standing question of we provide a lot of services to non-state

entities in terms of reviews of studies. And this enables CPHS to charge for that. We would not be the only one out there, many others do, and I'll get a little bit into what we've looked at there.

But essentially, this gives the statutory authority for the charging of fees.

Now, as you can tell, that's the extent of what the statute says. There's no detail in terms of what fees, what does that look like, or anything like that. And so --

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

DR. RYKACZEWSKA: Yes.

INTERIM CHAIR DELGADO: Just as a reminder, so like all of our departments -- I didn't know this until I was Chair. But all of our departments pay a yearly fee to CDII/CPHS to pay for administrative fees, to pay for the recordings, to pay for our staff time.

And so, each of our departments, based on the number of applications that we reviewed from those departments, pay into the fees.

So, what this is really targeting more are outside researchers that are not directly affiliated with one of our departments but are using our IRB as their IRB and the services associated with it.

So, I just want to be clear that it's not for our

state departments, this is only for non-state entities.

DR. RYKACZEWSKA: Correct.

MS. EVANS-DEAN: So, that's the agency departments?

INTERIM CHAIR DELGADO: Agency departments, correct.

DR. RYKACZEWSKA: So, I bring this partially up because last month we had a really great presentation from Jared Goldman on the regulation process. And one of the things that he was sharing is that we pass regulations in part to either interpret statute or to make them more specific.

And given that the statute doesn't establish the fee schedule, doesn't get into that level of detail, we would need to pass regulations to determine what are those fees, and when we would charge them, who they would be charged. All of those kinds of details would need to go through regulations.

And just as a reminder, I took this directly, steps directly from Jared's presentation. These are the steps of actually passing regulations. And we are at the very, very beginning of that in the preliminary rulemaking activities, where we do a lot of research, and exploration, and kind of drafting, thinking about what the potential could be before we would even publish any notices of

proposed actions.

And I think that's really important because, for me, the most important piece is to get feedback from this Committee. So, some of the preliminary rulemaking activities that I'll cover in a moment, we did do some initial market research. And I'm going to put that with a lower case "m" and a lower case "r", because it is really more of information gathering, not any stringent research. But we wanted to get some sense of what's out there to be able to propose something.

We did get preliminary feedback from the chairs, and I'll cover a little bit about what that was.

And now, we're coming to this Committee to get your thoughts and feedback on it, and we'll make refinements based off of that feedback. And we will not move forward to the next step of the regulations process until the proposed regulations have been endorsed by this Committee. So, just want to be really clear about that process. We want to do this together and as part of these preliminary rulemaking activities.

And so, let me talk a little bit about the market research that we did. Like I said, this wasn't a rigorous research study by any means. This was really information gathering to give us a sense of what could a fee structure look like, what could those fees be.

And we researched ten IRB's fee structures that are listed here. These were publicly posted on the internet, which made them a little bit easier for us to access and be able to see what they did.

And the way we used the information from these is that the number one thing they informed was the categories. What would be the structure, the fee structure, what are the categories, the types of things that IRBs typically charge for.

And then, the second thing was the actual fee amount. What's the typical charge for the types of reviews.

Now, in terms of the IRBs that we looked at, we tried to have a little bit of -- at least one example of private industry. We tried to have a mix of California-based and non-California-based to kind of just broadly understand what the typical structures would be.

But again, not a rigorous study, but really information gathering and at least giving us a starting point.

In addition to that, we recognize that -- oh, I'm sorry. I'm getting ahead of myself.

So, the proposed fee structure is included here. So, let me start by the review types. They're divided by initial submission, continuing review, amendments, and then our closure and adverse events.

And then, we also are taking account the kind of intensity of the review is. Is it a full board review? Is this an expedited review? Is it not research? And tried to differentiate based off of that, as well.

And so, the fees are essentially averages of what we saw across those ten, with some refinement, but all in all about an average.

And so, the most expensive, most intensive would be the initial review of a study that would require a full board review. So, like the ones we will be discussing today, there's a couple of them we'll be discussing today, and on average that's been about $3,500 from what we saw.

In addition, for an expedited review, a slightly lower cost of $2,100, and for a not research or an exempt application that would be about $500.

For continuing reviews about half that cost, a little under half that cost, $1,200 for a full board continuing review. Now, those tend to be pretty rare. And then, for an expedited review about a thousand.

And then, finally, we have our amendments. So, an amendment that would require full board review, we have, I think, a couple of those today as examples, that would be a $1,400 charge.

For major changes that are expedited, that would be a $1,200 charge. And then, for minor changes, and that's

things like updating your research personnel, or like small changes that isn't really substantial that would be, of course, free.

Now, closure reports would be free, as well. We, of course, that's a small review.

And then, we also want to ensure that we're not charging for adverse events because we definitely don't want to discourage anyone or block anyone from -- financially, from reporting an adverse event, so those would be free.

Now, at the -- the note at the bottom, we also recognize that something might initially be submitted for expedited review, but as the reviewer is going through it, they may determine that it actually needs full board review.

What we would do in that case would be to essentially, initially charge for the expedited and then charge for the difference when it gets put up for the full board review so that they're not being double charged.

So, I'm going to keep going, but happy to answer any questions. Please feel free to stop me at any time.

INTERIM CHAIR DELGADO: Actually, could you go back? Sorry.

DR. RYKACZEWSKA: Absolutely.

INTERIM CHAIR DELGADO: So, the proposed fees in the right-hand column are based on your review of the ten other IRBs, like kind of the average plus or minus?

DR. RYKACZEWSKA: Yes.

INTERIM CHAIR DELGADO: Okay, thank you.

DR. RYKACZEWSKA: And I will say there wasn't a huge amount of variation in these fees. These were pretty typical of what we saw. So, I know sometimes an average can hide a wide range. These were pretty close to about these fees.

So, we were curious, if these were the fees we would be going with, what kind of revenue would be generated for CPHS to use by that.

And so, to estimate that we went through our 2023 studies and identified the ones that were non-state entities, to the extent that we could, to determine what would be -- have been the revenue generated, had we been using those fees.

And, of course, the numbers are there. We had a total of about 931 different submissions that were by non-state entities, which would have generated just over a million dollars of revenue.

Now, that is a slight overestimate because our IRBManager system right now does not enable us to differentiate state and non-state entities within that. So, that is an overestimate. But roughly a million dollars of revenue there.

Before we get too excited, we also had to do a

workload analysis because there is cost associated with processing fees, as well. So, that includes having staff that can do the financial tracking, making sure that invoices are generated, making sure that we've tracked whether that invoice got paid, that the money had actually transferred. It also includes things like third-party billing company fees, if we wanted to, for example, allow researchers to pay online, or to have some kind of other way to actually submit the payments to us. All of those things would have some costs associated with it.

And so, we did a workload analysis and we estimate that the costs are close to about $600,000 based off of the number of applications we would anticipate needing to have fees processed, based off of the 2023 numbers, and trying to understand what would be the steps that would be needed, and how much staff time that would be associated with that.

So, all in all, with just a little over a million projected revenues and about $600,000 costs, we would have a remaining just under $500,000 for CPHS's use.

In your materials I did send through a document where we drafted some proposed regulations for your review. Again, this is for feedback. We just wanted something for your reaction to be able to gather your thoughts and feedback.

So, just to cover kind of the key points that were

in there, again reinforcing that this is for non-state entities that would still meet the criteria for CPHS review. So, this is not just anybody out there, they still have to fall under our purview.

And we're proposing that these fees would start on January 1, 2026. Now, that is assuming, of course, that the regulations would pass by then should we pursue that.

There were a few other key points. One is the piece about escalation. So, should an expedited review need to escalate to a full board review, the researcher would pay that difference in the fees.

There's a point about continuing reviews that if a project would expire due to Committee inaction, so let's say they got their continuing review application in time, but it didn't get approved in time, they wouldn't be subject to additional fees where they would have to resubmit for an initial study or anything like that. That we would just process their continuing review fee.

The point about only substantial changes within amendments would be fees -- would be charged. Minor changes would not.

There's a point in there, as well, that payment must be made prior to the decision by the Committee. So, this isn't a guarantee of approval. The Committee, of course, would still have the right to deny studies. This is

for the processing of that application. And so, the payment would have to be made before the decision by the Committee.

And, finally, changing the fees. There would be a process where, by Committee votes every three years, fees could be changed.

And then, how can we then use the funds that would be generated through this? So, the exact statement in the proposed regulations is that the fees can only be used to administer, manage, and support the Committee.

So, examples of that would be things like operational costs, getting admin staff, translation services, those types of fees, those types of costs.

It could also be used to get expert consultation. So, if say we would want a privacy expert, or anything like that, we could get -- we could contract and have expert consultation provided.

And then, of course, I think we've identified many needs within our IRBManager platform for improvements and they often have costs associated with them. So, that's also something that we could use some of this funding for, to build out, customize, and so on and so forth any platform that we decide to use.

And then, my final slide here is on the initial feedback that was received. We haven't had a chance to incorporate this into the actual write up of the

regulations, but I wanted to bring it up so that you know that we're looking into it and would love your thoughts on this as well.

One idea is to have a potential fee waiver for graduate students, recognizing that oftentimes graduate students don't have a lot of funding for their research. And so, a consideration of that.

We're going to see if our IRBManager, we can work with that system to generate a report of, well, how many graduate students do we have and what kind of impact that would have. But that is one idea.

And then, another piece of feedback that we've gotten is around grandfathering in the currently active studies, kind of recognizing that they didn't necessarily plan, when they were doing their initial budgeting, for these studies to have these kinds of fees. And so, starting the fee structure with any new, initial studies that would be starting in January of 2026. And slowly moving those fees in, but grandfathering in the ones that have already been approved prior to that date.

And that is, that is it. So, I'm happy to answer any questions and I'd love your thoughts and feedback on any of this. Again, this is something that I'm hoping to do with you.

COMMITTEE MEMBER KURTURAL: So, I'm thinking of

our public universities in California, whether it's CSU or UC, and would they qualify as being part of the state or not?

DR. RYKACZEWSKA: So, I believe that is a question probably for our legal team to look into.

COMMITTEE MEMBER KURTURAL: The reason why I'm mentioning that is because there's a lot of collaboration with different universities. So, if you have like an out-of-state, you know, a professor at Yale collaborating with a professor at UC Davis or something, and they're like, oh, let's go through UC Davis professors to get the fee waiver.

DR. RYKACZEWSKA: That's a fair point. I will say that in our analysis we did include the California public university. So, those -- the estimates that were generated did include them.

COMMITTEE MEMBER KURTURAL: And it might be you have to clarify it, right.

DR. RYKACZEWSKA: Right.

INTERIM CHAIR DELGADO: In some ways I kind of put CDCR into that same category, right, because CDCR is a state entity, a state agency or department for which we review their projects. And at least on the Common Rule side they're actual not in our purview, they're not part of our FWA. And we do not charge them. If anybody has been on this board long enough knows, that that's something I've

fixated on for almost a decade, is we have on and off served as their IRB without any financial contribution from their agency, the way we ask our departments to do. And there have been years where CDCR -- the number of CDCR projects has been higher than our own departments.

And so, as an example, with that state department I have been initiating some outreach with them to say, hey, if you would like us to continue to serve as your IRB of record for Common Rule projects, then you need to engage in an interagency agreement to start paying us for those services.

COMMITTEE MEMBER KURTURAL: Right.

INTERIM CHAIR DELGADO: So, I don't know if like the UCs and the CSUs are in the same boat. Again, like would defer to legal. But per our FWA, we have purview, again Common Rule, we have purview over projects that involve CalHHS and that's it.

And the same thing for the, again, like historical, we sometimes get projects -- we've gotten projects from like DMV and --

VICE CHAIR DICKEY: Yeah.

INTERIM CHAIR DELGADO: -- what are some others?

VICE CHAIR DICKEY: Yeah, Air Resources Board.

INTERIM CHAIR DELGADO: Air Resources Board, stuff like that.

VICE CHAIR DICKEY: We even got one from Cal Fire.

COMMITTEE MEMBER KURTURAL: Interesting. Oh, wow. Yeah, that makes sense. I mean it's one thing if you have the -- our department, with our contracts paying, you know, thousands a year to the board.

INTERIM CHAIR DELGADO: Yeah, but it's really good question. And probably, the bucket that you described is larger than the Cal Fire bucket or the DMV bucket. So, it's a good point, thanks.

COMMITTEE MEMBER HESS: One way that we could kind of deal with that, though, because you're right, I mean you do have a researcher at Berkeley working with a researcher at Stanford. You know, one way to do that is to have them submit to us who is -- which university has -- like is home to the PI, and which university is administering the grant funds. Because even if they're on an NIH fund and they're collaborating, but one university is administrating the funds, they'll be the sort of university of record. That, I would say, then, would be the university that needs to submit the IRB application. Wherever the PI is, wherever the money is actually going initially, before it's being funneled to a Co-I or something like that.

INTERIM CHAIR DELGADO: I like that.

COMMITTEE MEMBER HESS: It would be more administrative work on our end, but relatively simple for

them to demonstrate to us. Like, I'm the PI on this grant, you know, my co-investigators are at these universities, but yeah.

INTERIM CHAIR DELGADO: And they're already submitting budgets.

COMMITTEE MEMBER HESS: Yeah, so --

INTERIM CHAIR DELGADO: That makes sense. Thanks guys. Other thoughts?

COMMITTEE MEMBER LUND: This is Laura. I'd like to see this notion of fee reimbursed for graduate students refined a little bit. In theory that sounds fine. In practice, it's a bit nebulous. Certainly, if the research being done is for the dissertation thesis, I would say that that would justify a fee waiver. But I'm not sure whether all research done by graduate students justifies waiving fees for them, especially since many of these are often more time consuming, frankly, than reviewing some studies by more experiences researchers.

So, that's just my two cents.

INTERIM CHAIR DELGADO: Thank you.

MS. ATIFEH: Oh, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Well, I might add to that. I think we have had some instances of graduate students submitting applications where it was pretty clear that the sponsoring faculty member was also engaged in the

research and may be the one who had funding that made the research possible. So, not an instance where the graduate student is working with limited funds for a dissertation or something of that sort.

DR. RYKACZEWSKA: Maybe it might be like a fee waiver based on Committee approval and it would be based off of the circumstances of financial hardship that we would be able to assess, where the graduate student would have to submit kind of a justification of their circumstances and how it would create financial hardship.

COMMITTEE MEMBER SCHAEUBLE: Okay. Sure.

DR. RYKACZEWSKA: Dr. Dickey?

VICE CHAIR DICKEY: I was going to say, on the issue of grandfathering in studies, do you have any projection of what that would mean, though, in terms of financial viability?

DR. RYKACZEWSKA: I will have to pull up -- we did, actually, a scenario testing of that, but I don't have the numbers on the tip of my fingertips.

Essentially what it would mean is that it would delay getting to that revenue.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: So, the first couple years would be much smaller numbers, especially since the majority of the funds would be coming from continuing review, when you

look back at that estimate. And that's partially because there's just the most of them.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: And so, since they accumulate year after year.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: And so, it just would mean that we'd have less funds in the first couple years.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: In that regard, I might wonder if grandfathering for a specific period of time, however many years that might be, would make more sense. Because I'm thinking about projects that go on for decades sometimes, and so we really want to say that we're grandfathering 10, 20 years into the future? Maybe not.

DR. RYKACZEWSKA: That's a good point. That's certainly something we can incorporate.

Other thoughts?

MR. OHANIAN: As I -- first of all, I just want to wish Agnieszka a happy birthday. Second, thank her.

(Collective happy birthday)

MR. OHANIAN: Second, thank her for this leadership of this group and support of this group. It's great to see this work that's been done by you and the team.

I'm curious, and I've always been curious, when we

start charging fees what kind of -- is it going to dissuade some researchers. And I'm curious in these areas that you've researched have they been charging fees all the time, and when they moved to charging fees what impact did it happen -- happened.

The other part is I know that in studies that we've done half of the folks that come for data never -- never apply. The other half maybe apply but never finish. And I'm just curious if in any of that work, if there's anything we can do. Is it anything on our part to make the process more streamlined, whatnot, or we know why those things happen.

And then, the last part I'm curious about is just streamlining the operational costs. Because to generate a million dollars and to spend 600, is there a way that we can look at -- it sounds like it's not something that can necessarily be automated that much because it looks like there's going to be some real handholding. But maybe we can look at it, as much as we can do on that as well. But great job, thank you.

DR. RYKACZEWSKA: Absolutely.

We didn't look into the how long the IRBs were charging fees, but we are wanting to -- we have been slowly reaching out to different IRBs on other work related to the common app. And that's certainly, I think, a question we

can start bringing up of what has there been -- what they're experiences have been, did they see drops in applications, and things like that. Because the intention is certainly not to dissuade researchers by any means --

MR. OHANIAN: Sure.

DR. RYKACZEWSKA: -- just recognizing the cost that it takes to run.

MR. OHANIAN: Yeah.

COMMITTEE MEMBER HESS: Kind of along the same vein, like what -- would we have a definition for what constitutes a major change with an amendment? You know, amendments can run the gambit. And it can be just submitting, you know, Spanish language surveys, or changing survey questions. Again, we don't want to dissuade researchers from submitting amendments when they need to.

And I can imagine there would be some researchers out there who are like, oh, it's just some changes to the survey instrument, we don't need to submit -- you know, pay $1,200 to submit an amendment. Not that many of them would do that, but it is sort of an impediment to them coming to the board with changes. Especially some projects have multiple amendments, right. You know, I just -- I would like to see us have like a definition of like a more -- so the researchers know what to expect, as well. You know, how much is this going to cost them, and we'd have a sense of

that as well.

INTERIM CHAIR DELGADO: And this is just a thought, but kind of working off what you're thinking is that I think when -- like we are -- we are putting our thoughts into this, but when it starts to move through the regulation process there will likely be areas where we don't have discretion, i.e. the grandfathering, grandpersoning in.

Again, it's quite possible through the regulations process that we will be told by the Office of Administrative Law you cannot request fees for something, for an event that occurred five years ago or, you know, or you must. I don't know what the rules are.

But to the same extent like they may ask for a degree of specificity that we will -- that we must do as part of the regulation process. So, also want to acknowledge that this is kind of like our first conversation, but also some of this may be outside of our -- outside of our scope when it comes to developing the regulations themselves.

DR. RYKACZEWSKA: Absolutely. And, yes, I meant to actually start with that. This is the first conversation. As I said, I'll take this feedback -- if you have more feedback after this meeting, too, please feel free to email it to me.

My intention is to come back either next month or

the month after, depending on how much of that feedback we're able to incorporate or how quickly we're able to incorporate it, to review, here's all of the feedback that was given by the board. And here's how we're incorporating it. And here's where we are. To ultimately get to a place where we're ready to endorse.

So, this is the first of probably a few presentations on this topic, because I want to give you time to reflect on it, too. I recognize this is the first time you're seeing it.

INTERIM CHAIR DELGADO: And I'll also put out there --

COMMITTEE MEMBER BAZZANO: Yeah, this is --

INTERIM CHAIR DELGADO: Oh, Alicia, is that you?

COMMITTEE MEMBER BAZZANO: Yeah it is, yes.

INTERIM CHAIR DELGADO: Go for it.

COMMITTEE MEMBER BAZZANO: I don't want to take up a ton of time but, yes, since I'm trying to reflect and understand this as well, a couple of pretty vague questions come to my mind as well.

The first is I was surprised about the revenue recovery fee. In my experience, they've been much closer to, you know, 6 percent, 10, 20 percent, maybe 25. I've never seen a 60 percent revenue recovery fee. And maybe I'm not understanding whether that includes all of the work that

goes into the actual -- the evaluating of the protocols. Or is it solely the act of obtaining the revenue. Just because I've never heard of that amount, paying for the time to get the revenue.

And then, the second part to that is if these estimates are off, say that they're off by -- you know, and we the cost earlier was mentioned that this could reduce the -- reduce the market. You know, when you put fees on something the demand, inflation go down.

So, knowing that, say it isn't, you know, a million, the high estimate as you already said, but say it's only $700,000 or, you know, a 20, 30 percent reduction and the fees are still the same -- sorry, the revenue collection is still the same, you know, in the $600,000 range, then we're really getting more to an even -- you know, a much more balanced price that we're looking at here.

And then, concerning as to whether it would be -- you know, whether there's a business case for doing this in the first place.

Because, on the other hand, there's also concerns when there can be scrutiny, certainly, for IRBs, although most of them do use -- do have fees. But it also raises concerns of conflict when those who you're regulating are also paying for the dollars, the upgrades, and so forth.

So, I'm throwing that out there. I don't -- I

mean, maybe it sounds like I'm being the devil's advocate here. It's my intention, I think this is interesting, I think it's a good thing for us to explore. I do think that we do need to think about all the different kinds of scenarios that are possible.

And if I could understand a little bit better, particularly that $600,000, that would help for me to be able to absorb and get a better understanding of whether I can support this or not.

DR. RYKACZEWSKA: Absolutely. And I can definitely, I'm going to say, in a future presentation give more background into what went into that number. I will say it is taking the number of studies into account. So, if there were fewer studies, we wouldn't need as many staff to process that. And so, the cost does go up in relationship to the number of fees that would need to be processed.

And so, we were basing it off of the numbers in 2023, but if it was number -- the number was lower, the cost for processing those fees would be lower, and vice-versa. It's directly tied to the number of fees that need to be processed.

And we tried to be pretty comprehensive in trying to estimate those costs, too. It doesn't include the cost of the review, itself, but the processing of the fees. But we were recognizing that it would take staff within CPHS,

who would have knowledge of financial -- how to do financial tracking. It also would mean collaborating with our colleagues at CDSS, which CDII works closely with them for any processing of funds and things like that.

And any -- as I said, any kind of third-party platforms that we would want to do. We don't have to do third-party platforms. We can say send us a check, and things like that.

So, there are, I think, ways to reduce those costs and streamline them. But it would also result in fewer options for researchers to actually send that payment to us, as well. But happy to provide more information on how we got to that number in a future presentation, as well.

COMMITTEE MEMBER BAZZANO: Okay, sounds good.

MR. OHANIAN: That's good.

INTERIM CHAIR DELGADO: Thank you, Alicia.

Other thoughts or comments from board members?

Okay, thank you for the administrative update. For those --

DR. RYKACZEWSKA: Oh --

INTERIM CHAIR DELGADO: Oh, sorry.

DR. RYKACZEWSKA: I do have a second item.

VICE CHAIR DICKEY: Oh. I was just going to ask any thought as to how this would interact with IRBManager, or the common app?

DR. RYKACZEWSKA: We would need to incorporate into it. And we did some preliminary looks into what that would take. It is possible. There are better ways of doing it and ways that are a little bit harder on the staff, but a little easier to implement in IRBManager.

So, I think we first wanted to make sure that we got the structure right, so that then we can really examine what would that look like in IRBManager.

One of the key things that I was thinking about is could IRBManager, based off of the responses that they provide, at least give an estimate at the front end for the researcher of --

MR. OHANIAN: Yeah.

DR. RYKACZEWSKA: -- this will need to be confirmed but based off of the type of research that you're requesting that has human subjects, that that would be an automatic full board review.

VICE CHAIR DICKEY: Direct contact.

DR. RYKACZEWSKA: Or excuse me, direct contact with human subjects.

It could help estimate from the front end so that the researcher kind of goes in with eyes wide open as to what the fees might be. So, those are some of the things we were exploring.

INTERIM CHAIR DELGADO: Okay, thanks. More to

come for those.

I see a few members of the public on the call. We'll also acknowledge that we're going to take public comment in a second. But also please know that the regulation -- if you're not familiar with the state regulations process, there are many future opportunities to also opine. There are mandated public comment periods that last anywhere from 30 to 45 days. And, as always, we welcome communication to our administrative staff, or to the chair and vice chair should you have any thoughts on this topic.

DR. RYKACZEWSKA: All right. And then, the second item that I have I hope will be pretty quick, but it is scheduling our September meeting. So, September 6th is the first Friday of September. But I'm going to note that Labor Day is that preceding Monday and I recognize that folks may be traveling and things like that.

So, I wanted to see if anyone would have objections to September 6th or we could also do September 13th for our next meeting. Any thoughts or preferences?

MR. OHANIAN: Do you have a preference?

INTERIM CHAIR DELGADO: I'd prefer the 13th to protect the Labor Day holiday. But others?

VICE CHAIR DICKEY: It might be safer to do the 13th.

MR. OHANIAN: Friday, the 13th is safer?

(Laughter)

DR. RYKACZEWSKA: And I will note we will need to do a vote on this to officially announce the next meeting.

INTERIM CHAIR DELGADO: Anybody on Zoom have a strong preference one way or the other?

COMMITTEE MEMBER DINIS: Either one is fine.

COMMITTEE MEMBER RUIZ: I'm also -- I'm also fine with both days.

INTERIM CHAIR DELGADO: Well, if people want to do this.

COMMITTEE MEMBER PALACIO: Me too, I have no problem either way.

INTERIM CHAIR DELGADO: Well, now I feel like the jerk saying I had a preference.

COMMITTEE MEMBER KURTURAL: No, I think I -- I would want to do the 13th because of other things going on.

INTERIM CHAIR DELGADO: Got it. Okay, so hearing at least two of us expressing a preference, others saying no preference. Because we are going to be voting on this, we will open it up for public comment.

Any public comment on the decision to have our next board meeting on the 6th or the 13th?

DR. RYKACZEWSKA: I'm not seeing any online.

INTERIM CHAIR DELGADO: Okay, seeing none, can we

-- can someone please make a motion?

COMMITTEE MEMBER KURTURAL: I'll make a motion for the September 6th meeting to be moved to September 13th.

INTERIM CHAIR DELGADO: Do we have a second?

COMMITTEE MEMBER VENTURA: Second.

INTERIM CHAIR DELGADO: Dr. Ventura seconds. Great.

Sussan, if we could have a vote, please.

MS. ATIFEH: Sure. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: I'm sorry, but I didn't hear what --

INTERIM CHAIR DELGADO: The motion was to have the meeting -- move the September meeting to Friday, the 13th.

COMMITTEE MEMBER RUIZ: Okay. Approve.

MS. ATIFEH: Okay, thank you.

Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

DR. RYKACZEWSKA: All right, September 13th, then. Thank you so much for the feedback and the thoughts and looking forward to more on this.

INTERIM CHAIR DELGADO: Great. Okay, moving right along, only ten minutes behind.

Oh, Laura, go ahead.

COMMITTEE MEMBER LUND: Yeah, I just wanted to follow up on your chair updates, Dr. Delgado, I had a question. We talked about what the requirements were for qualifications for chair and vice-chair. But could you go over what our process is for selecting a chair and vice-chair? I'm not sure that anybody is really clear on how we do that.

INTERIM CHAIR DELGADO: Yes. And I have that information right in front of me. Thank you for asking.

COMMITTEE MEMBER LUND: Great.

INTERIM CHAIR DELGADO: Okay. So, for -- per our policies and procedures -- I'm just going to read on my

document. So, the chair, as I mentioned, must be a CalHHS or CalHHS department employee, and have been a member of CPHS for at least two years.

They're then nominated by CDII Director John Ohanion, but voted on by the CPHS board, and then approved by the secretary.

So, it seems as though it's kind of three steps. The first is a nomination by Director Ohanion. The second is that it then comes to a board meeting, where it has to be voted on by the board. And then, approved via a secretary action request. That's for the chair.

And then, for the vice-chair it does not go through a nomination process with the director. It is, instead, chosen by the CPHS chair and then approved by the secretary. Again, per our policies and procedures.

COMMITTEE MEMBER LUND: So, the board doesn't get to vote on the vice-chair, only the chair?

INTERIM CHAIR DELGADO: I believe so, but I can double check. Actually, yeah.

COMMITTEE MEMBER LUND: Thank you.

INTERIM CHAIR DELGADO: Let me -- I'm actually going to pull up the policies and procedures just to double check that question.

Yeah, so the regulation -- or the policies and procedures around the vice-chair are much less descript in

our policies and procedures. For example, the tenure, it's just the vice-chair serves at the discretion of the chair. Whereas the chair has three years of service at chair.

Not to intimidate anybody because you can always choose less.

But the chair is then eligible for an additional three years' terms of service based on reappointment by the secretary.

But in looking at our policies and procedures, there's many more details related to the chair's selection, service, tenure and duties, as opposed to the vice-chair.

But if you happen to have the policies and procedures in front of you, it's page 13 through 15.

VICE CHAIR DICKEY: I just want to bring up, the 10 and 20 percent time has been taken out, right? The policies and procedures used to say the chair would get 20 percent time protected to be the chair, and the vice-chair would be 10 percent, I believe. And Committee members are 10 percent. But those percentages were taken out.

INTERIM CHAIR DELGADO: Thank you for noting that.

Any other questions about that topic?

Again, not to put anybody on the spot, but also asked our admin staff to pull up all current members' length of terms to see who might or might not be eligible. I'm looking at everyone in the room, not anyone in particular.

Okay, thank you, Laura. Any other questions?

Okay, moving right along. So, on to Item C on the agenda, which is a follow up on the IPA and Common Rule discussion.

So, just to summarize where we are at, this is now the third meeting that we're talking about the IPA and Common Rule discussion, which is great. Because from the get go the goal was to not move fast, but move in a manner where everyone feels comfortable, everyone feels like their voices are heard, and ensure that we all have enough time to digest the information that we are discussing.

And so, if you do remember, two meetings ago we started the conversation about IPA and Common Rule. And I will try to summarize but, Maggie, feel free to jump in if I'm misrepresenting anything.

For those who are only in the Zoom room, Maggie Schuster is here, legal counsel for CalHHS, who's been working hand-in-hand with Jared on this topic.

So, in the first meeting we reviewed a memo that Jared and Maggie provided, that talked about statutorily and legally the role of CPHS and this issue of when things fall under the IPA, when things fall under the Common Rule.

And as part of that memo there was a very clear recommendation that there are various paths what we, as a board, could take.

The first path is if we continue to remain very strict to the IPA definition, very strict to the Common Rule, do not deviate based on other variables that could be considered. That we could do that and continue operations as normal with a stringent definition that we are interpreting of the IPA and Common Rule.

On the other end of the spectrum if we, as part of the language in the IPA, there is kind of a gray area when it comes to potential variables that could also be considered.

And that, I think, was the crux of the discussion, such that the recommendation from legal -- again, we haven't made any final decisions on this. This has all been deliberative. But that if we decide to want to examine other variables, that we would need to clearly define what those variables are and would recommend pursuing through regulations to define what our process is. Such that there was no -- such that everything was clear. And so that researchers wouldn't feel discriminated against based on their project. My project was reviewed differently from others because it was not clearly defined in statutory language.

A regulations process would clearly define that, would clearly define our process.

Last meeting, so the July meeting, we discussed

again, and Jared and Agnieszka asked if anyone would be willing to contribute some thoughts into documents, to help operationalize what this might look like, to please submit those to our admin team so that we could discuss them today.

And that is our goal for today. I know we had a couple of submissions and probably folks have a lot of thoughts about maybe the documents that were submitted, or your own thoughts about what you've been stewing on for the past month.

So, our goal today is to review, as a group, the documents that were submitted and also, potentially, reach a consensus on what next steps should be. Whether that is to pursue regulations with any portion of the documents that we will be reviewing today, or to opt not to pursue that avenue. But then, with the understanding that our reviews would have to be really boxed in to what is clearly statutorily defined in the IPA.

Maggie, did I say that right? What am I missing.

MS. SCHUSTER: That was great, yeah. The only thing I'll add is the part of the discussion about the additional criteria that might or might not be added to the IPA, we are operating within the constraint of the spirit of the IPA, which is really geared towards data privacy and security, and trusted issues.

So, when we're thinking about what type of

regulations we might want to make, additional criteria, it's good to be thinking about them within kind of -- I don't want to say the confines but the, you know, the structure of what the IPA is really meant to do, and just to protect, you know, data privacy and security.

INTERIM CHAIR DELGADO: So, don't introduce a variable like hair color --

MS. SCHUSTER: Exactly.

INTERIM CHAIR DELGADO: -- or color of shoes, or anything like that.

Okay, great. So, thank you, Maggie, for helping define what we are talking about today.

And so, what we'll move now to, maybe Carrie, if you don't mind, we start with you, and talking about what you submitted.

COMMITTEE MEMBER KURTURAL: Sure.

INTERIM CHAIR DELGADO: And then, Dr. Schaeuble, with you and talk about what you submitted.

Since we have those concrete items, hopefully folks had a chance to review before today's meeting, why don't we start with those two and then open it up to a broader discussion.

COMMITTEE MEMBER KURTURAL: Sure. I didn't formalize anything. I don't have draft regulations for you all.

(Laughter)

COMMITTEE MEMBER KURTURAL: But I do feel that the sticking point, really with these data-only reviews for me, has been whenever we get a project where they want to take our state data and mix it with some sort of third-party data. To me, when I get a project like that, I feel like that needs more of an in-depth, full board review. And that, to me that's kind of the segregation of what would go through expedited review versus a full board review.

And I think that as far as -- I didn't go in-depth to the IPA and think of additional criteria we'd consider. And I figured we could discuss that in detail later, as a group.

But if I were drafting the regs on this and, you know, I think we have to somehow figure out, you know, what's okay if it goes through expedited review or full board review. And, you know, if they're just looking at state data, I don't see a problem with going through expedited review at all, and what we have been doing for years.

I don't -- you know, if someone's looking at Health and Human Service data, and in a way, I don't mind if someone looks at Developmental Service data with Health Care Services data, as long as it meets the criteria of the actual IPA I'm find with that. Expedited review is fine.

If the department signed off and approved that, that's fine. There's a data use agreement.

But where it gets murky for me is when you're taking the state data and you're mixing it with other -- with other data, whether it's financial, college data, or something like that.

And so, I would -- I would kind of encourage it like some sort of like two-tiered approach, or a hybrid approach to prevent any criticisms about, or discrimination from the review process. But that's just my two cents.

You know, and I think we discussed last time, by the way, that there is -- I don't know if we're asking for it now in the applications, you'll have to correct me if I'm wrong. But when a researcher is doing a project and they have approval letters from our state departments to get our data, and then they want to mix it with another entity's data there should be another IRB approval out there, right, from that entity for it.

And so, you know, perhaps that could be some of the things we can start to acquire is I want to see your IRB approval, you know, as more of the certain things, or the stricter criteria that we will get as a board.

And, actually, I think as well with your proposed fees. Looking in the direction of the proposed fees and we're distinguishing, you know, what gets an expedited fee

versus a full board fee. I mean it is a hassle, kind of a more in-depth review if you want to connect data with third party institutions. So, you know.

INTERIM CHAIR DELGADO: Awesome. So, what I hear you saying, just to kind of summarize, is that your suggestion is that there is a -- there is some kind of delineation that when state data is being merged with sensitive data from outside of our agency, you know, the examples you gave were student financial aid, any financial data.

What was the second one you gave?

COMMITTEE MEMBER KURTURAL: Yeah, I mean it could be anything. We could just draw the line like as soon as you want to merge State of California data with a different dataset.

INTERIM CHAIR DELGADO: Okay, so any dataset --

COMMITTEE MEMBER KURTURAL: Outside -- outside of the state.

INTERIM CHAIR DELGADO: -- it doesn't have to be sensitive. Merging it with any other dataset.

COMMITTEE MEMBER KURTURAL: We could draw the line straight. And go ahead, I see Dr. Dickey.

VICE CHAIR DICKEY: No, I just wondered, but the distinction that would be full review versus expedited. But still, the full board would still be using the same criteria

as in the IPA, right.

COMMITTEE MEMBER KURTURAL: Well, I said that's the question is that I do think that for the expedited that we can just continue to use IPA criteria. But we would have to discuss that, right. You know, what, would it be any different. I'm open, if we need to be looking at additional criteria.

I will say that getting individual consents and adding that on to these more in-depth reviews is probably not going to be feasible, in my view. But I think we can add on additional criteria like I need to see your IRB board approval. And then, if there's murkiness on what does minimal risk mean under the IPA, we can kind of explain that. So, we'll have to think about that and get as a group.

INTERIM CHAIR DELGADO: Okay. Thank you for that.

Anybody have any questions on what you see on the screen with Carrie's suggestions or emails? No one expected you to write regs, okay.

COMMITTEE MEMBER LUND: So, I --

INTERIM CHAIR DELGADO: Okay. Go ahead, Laura.

COMMITTEE MEMBER LUND: This is -- this is Laura. I just would really like to request that we stop referring to these things as data-only projects. Because while all IPA reviews will be data-only projects, there are data-only

projects that fall under the Common Rule. So, when we talk about things as data only, I think that we are obfuscating some of the underlying issues. And I'm wondering, this is just a request, if we could change the nomenclature to IPA only, rather than data only to avoid the confusion. So, thank you.

INTERIM CHAIR DELGADO: Can you expand a little more, give us an example to make sure that we're all tracking?

COMMITTEE MEMBER LUND: Yeah. So, under the Common Rule there are -- the Common Rule divides projects into research that involve direct or indirect contact with actual human subjects.

So, for example, things that would be you're going to interview people, or you're going to go and pull medical records and extract information from the medical records, that's considered indirect contact, i.e., you need people's permission to do that.

But data-only projects fall under the Common Rule when they contain personally identifying information. So, for example, if a researcher were using birth certificate data and requesting fields from the confidential portion of the certificate, including names and other personally identifying information, and the researcher falls under our purview, for example it's a research that is in a government

agency, one of our government agencies, or collaborating, or providing funding to, for example, UC Berkeley to conduct this study, that would fall under the Common Rule, but it would be data only. Secondary data source, you're not going to interface with people, you don't need a HIPAA waiver, you don't need informed consent, but it does fall under the Common Rule.

So, that's a data-only project that is not an IPA-only project. So, an IPA-only project, my understanding and lawyers can say this again, but I believe this is what I've heard them say, a data-only project involves a project where we are not the IRB of record, we are not reviewing under the Common Rule, but we are reviewing under the IPA when a state agency falls in our purview, who is releasing the data for a researcher for the purposes of doing research.

So, if we're calling all data-only projects -- if we're calling projects data only and binning them into the IPA-only bin, we're ignoring all those projects that we should be applying Common Rule criteria to. So, that's my point.

INTERIM CHAIR DELGADO: Got it. Before we --

COMMITTEE MEMBER LUND: So, I mean --

INTERIM CHAIR DELGADO: No, super helpful, Laura, thank you. Before we go to Dr. Dickey, Maggie, anything you want to agree, disagree, clarify with what Laura said?

MS. SCHUSTER: No, I agree with all of that. That's accurate.

INTERIM CHAIR DELGADO: Awesome. She said that's accurate. So, Laura, you earned your JD in the last 30 seconds.

Dr. Dickey.

VICE CHAIR DICKEY: Well, I'm going to get my JD, now.

INTERIM CHAIR DELGADO: We're just passing them out today.

VICE CHAIR DICKEY: So, when -- I think we went through this in detail that data coming from an agency department, if it doesn't involve human subjects contact, it's not covered by the Common Rule. The receiving institution's IRB has to get the Common Rule approval.

In those circumstances, we are only approving the release of the data under the IPA.

DR. RYKACZEWSKA: Just I think the distinction, though, is that, for example, one of the CalHHS departments, and I'm just picking one at random, CDSS, has their own researchers.

VICE CHAIR DICKEY: Oh, yeah.

DR. RYKACZEWSKA: And they're researchers might be --

VICE CHAIR DICKEY: No, that's true, sure.

DR. RYKACZEWSKA: -- using, and that's where the data-only piece, because it's CalHHS engaging in the researcher and, therefore, it is under Common Rule purview of this board because it's CalHHS engaging in it, using only data.

VICE CHAIR DICKEY: Yeah, or if they're using their data -- we get very few where they're just analyzing their own data because they have access to it, anyway.

DR. RYKACZEWSKA: Right. But I think the intention is just to be clear that there are circumstances, potentially, where CalHHS is engaging in research and doing a data-only project. And so, distinguishing that from a truly IPA-only project, where it's an external group doing the research, there's no CalHHS staff funding, or involvement of subjects under CalHHS care.

And in those cases, it is truly an IPA-only project.

VICE CHAIR DICKEY: Right. And there's one other instance, which is where a department is receiving data and doing research on it, then that falls under the Common Rule and we have to review that under the Common Rule. Even though it's a data-only project, we have to review it under the Common Rule.

DR. RYKACZEWSKA: Yeah.

VICE CHAIR DICKEY: So, I think the distinction,

Common Rule versus IPA, is important to make. It's just -- I agree that just saying data only doesn't capture the nuance.

INTERIM CHAIR DELGADO: Got it. Thank you, Laura. I saw you came off mute, was there something else to add?

COMMITTEE MEMBER LUND: No, no, I'm good. Thank you.

INTERIM CHAIR DELGADO: Okay, got it. Dr. Schaeuble, can we hand it over to you to talk about your documents?

COMMITTEE MEMBER SCHAEUBLE: Okay. Can you go past that to the one that says suggested framework, the other document.

MS. ATIFEH: Oh, sure. Yes.

COMMITTEE MEMBER SCHAEUBLE: That's, I think, the one that we want to be looking at.

So, as you can tell, I tried to approach this from a broader viewpoint, I think, than what we've been discussing so far. And tried to pull together a number of ideas that have come up in our discussions in recent months.

And I'll try to walk you through some of the thinking of the different parts of this and then see where Committee members want to go as far as discussing it.

The first section here reiterates the minimum criteria that are specified in the Information Practices

Act. And you can see those are directly quoted from the text of that law.

And then, after that the next section goes on to talk about -- go back up. Yeah, stop right there. A list that begins in this section of some attributes or situations that seem to create a heightened risk of privacy and I'm saying should be taken into consideration when reviews are done of the -- of what the researchers have proposed.

If you look at the first four items on this list, you might scroll down just a tiny bit so we can see all of the four. There, that's good. I think these are sort of a cluster talking about some kinds of variables and some kinds of populations that would raise particular concern as far as privacy.

Now, of course in any of these areas, take physical health for example, certainly there are variables that are personal information, but not maybe considered extraordinarily sensitive by most people and might not be cause for extra attention.

But clearly, there are some variables that seem particularly troublesome. I've tried to give several examples for each of these four items.

In the first one here, we know that, for example, abortion and gender affirming care that are two topics that are highly politicized, and data that might be relatively

protected in California may not be relatively protected when somebody in another state is working with the data, or people from California move to another state and their information is potentially exposed.

So, these are the kinds of things that led me to try to choose what I hoped would be clear cut examples for each of these four topics. Physical health, psychological health, social economic, or legal information, and vulnerable populations. About four examples in each instance of things that I thought should be considered as part of the review process.

If you go down farther to the next two items, I think those are sort of a cluster themselves. Talking about how the data that the researchers are requesting might be expanded in some way in the future, perhaps there are plans to gather additional data over a period of years about individuals. Perhaps there is information researchers want to add from other sources. And particularly, if data coming from other sources would fall in the categories, the four categories above that -- for identifying especially sensitive information.

So, both of these two are looking at what may be requested beyond simply the data that the researchers are asking to receive from a state agency, or the initial set of information they are asking to receive.

COMMITTEE MEMBER VENTURA: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. RYKACZEWSKA: Can I ask a clarifying question? So, when you say the researchers propose or will later propose, I'm trying to think about a concrete example of what that might look like. And I just want to check whether my thinking is aligned with what you're intending.

So, sometimes the researchers will, for example, say like this is phase one of a three-phrase study where in future phases we're going to do X, Y and Z. That's what -- I'm just checking, is that the intention behind the -- like, they're letting us know that they're later going to propose something else with this data?

COMMITTEE MEMBER SCHAEUBLE: Yes, it is. I think very often they say we only have the resources to do X amount of work in the next year or two, but we, for the purposes of the researcher questions we are trying to ask we would want to do Z in the future.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: And that will involve, for example, linking to other data at some future point when we have the funds to do that, or have finished the initial stages and can go on to later stages of the researcher, whatever the reasoning might be.

DR. RYKACZEWSKA: Okay, good. Okay, just wanted

to make sure I understood. Okay.

COMMITTEE MEMBER SCHAEUBLE: So, I guess we can go on from there to the next two items. I think the next two items are both looking at issues related to data being re-identified, possibly from the total number or nature of the variables available in the data, which may have enough unique or specific information about individuals that re-identification is possible, despite what researchers do to remove identifiers or mask the data in some way.

And also, it's fairly common for researchers to remove identifiers but to keep them and store them separately, in a file that is still linked to the analysis file that doesn't have identifiers present. So, that creates another opportunity for data to potentially be re-identified.

So, these two statements are with regard to that topic.

The next two talk about making data available to other researchers or even just other people. Frequently, this is to place data in some other kind of database that will be accessible to other individuals, where once the information is in that other database any limits on how the data would be used, or other stipulations that might exist within our project approval likely will not apply to that other database.

And as we've seen, even taking out all of the identifiers listed under HIPAA, in some instances of projects we've looked at does not turn out to really be sufficient to rule out the possibility that individuals could be re-identified.

So, those two statements talk about that aspect.

COMMITTEE MEMBER VENTURA: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Yes.

COMMITTEE MEMBER VENTURA: Is an example of that the requirement of some NIA -- or some manuscripts -- or, journals, excuse me, to upload data to a shared public database?

COMMITTEE MEMBER SCHAEUBLE: Yes, that would fall under the

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER SCHAEUBLE: -- first of the two statements here.

COMMITTEE MEMBER VENTURA: Okay, just making sure I understand.

COMMITTEE MEMBER SCHAEUBLE: Sometimes, we've had some projects where researchers have been working in some kind of a consortium where they are sharing data with other universities or other places where the research is going on, and making a database through that kind of arrangement.

We certainly have had, as you were talking about,

what are often grant requirements to place data in some kind of repository that will be available in some way to other people.

And then, if we can scroll down just a bit more, there are three items here related to what disclosure or consent was obtained at the time the data were originally collected. I should emphasize here, by the way, we sometimes get stuck on the idea that of course it's not reasonable for researchers acquiring data to go back and obtain consent from individuals that they have no ability to contact, and the volume of information in any case is much too great for that to be a practical possibility.

But that -- I don't think that's where the issue is. I think the issue is -- goes back to what individuals were told at the time that the information was collected from them in the first place and how does that relate to anything that researchers might want to be doing with the data.

So, the first item here talks about whether individuals were told at that initial time that their information would be used for research.

And the next two items ask for an assessment, would individuals not expect, from any knowledge they have, that the data collected about them might be used for research. And if they knew about the kinds of privacy

procedures in the research that's being proposed, would they object to having their information used.

So, all of these items in this section are intended as considerations for reviewers to take into account as to whether there is a heightened risk to privacy that should be part of the review process.

The final section, much shorter, talks about additional criteria that then would be considered in those circumstances.

And the first one deals with if there was a consent when the data were originally collected, did that consent sufficiently describe purposes for the proposed research.

INTERIM CHAIR DELGADO: Could I ask a question on that data point. So, what -- what would the process then be for like many of the projects that we get, where folks are asking for a waiver of written informed consent, how would that play into what we see here?

COMMITTEE MEMBER SCHAEUBLE: So, two possibilities. We could ask them to obtain from the agency releasing the data whatever information there is about consent at the time the data were collected, instead of simply asking for a waiver of consent. I think that would be one reasonable kind of thing to do.

If they cannot or don't provide that sort of

information, then I think we would have to conclude for our purposes we can't tell that any consent was ever obtained at the time the data were collected, and we'd have to review with that as the assumption we're working with about the data.

INTERIM CHAIR DELGADO: Got it. So, that, I mean this is where in my mind some of the flags are raised. Because with the bulk of our dataset -- well, I shouldn't say the bulk. I mean, I think of multiple datasets related to state hospitals, the data that I'm most familiar with, or social services, or probably DDS, it is a very broad consent that's obtained, if at all. And that the consent obtained prior to services being received, for example with DSS, is a -- like, your data could be used for research purposes in the future per, you know, the IPA or whatever.

It would never -- like, I can't think of circumstance where in an administrative dataset there would be consent that per this definition sufficiently describes the purpose of the proposed research.

So, that's where in my mind I worry about that line item specifically, that that would then by default eliminate a ton of projects that we review.

COMMITTEE MEMBER SCHAEUBLE: I think that language probably could be changed a little bit to make it clearer that the intention was did the consent at all describe

situations similar to what the researchers propose to do, or not. And again, this is a --

COMMITTEE MEMBER LUND: This is Laura.

COMMITTEE MEMBER SCHAEUBLE: This is a criterion to be considered. And I don't think one has to argue that if the -- if the consent was not there at all, if it is so broad as you were describing that a person would not really construe that as being like the research that the researcher wants to do.

I don't think that should be taken as an automatic rejection. I think it should be taken as this is a, certainly a negative factor to be considered in the review process.

And now, again, the question is what's the -- the remaining question is what's the nature of the information that the researchers want to work with and is the research still reasonable to do in the absence of what might otherwise be considered a meaningful consent. Or, are we in fact talking about data that raise so many red flags, plus --

INTERIM CHAIR DELGADO: Plus the consent, yep.

COMMITTEE MEMBER SCHAEUBLE: -- there wasn't any consent to begin with, then I think we really have to say -- well, what's left here. Can the researchers make changes to alter the situation in a way that deals with the problems

we've identified or is this a project that we simply aren't able to approve given the total set of circumstances.

There are always multiple things --

INTERIM CHAIR DELGADO: Right.

COMMITTEE MEMBER SCHAEUBLE: -- that the committee can attempt to do in these situations.

INTERIM CHAIR DELGADO: Thanks. Laura, go ahead.

COMMITTEE MEMBER LUND: I just wanted to respond to your comment, Dr. Delgado, there's a couple things. First, I think that consent might not be the correct word and that we could consider what the correct wording would be. Because, typically, in the state databases that I'm familiar with, people have the right to be told how they're data could potentially be used. The state basically collects these data, birth certificate data, CCR, so on and so forth, so people don't have the option to consent to having it collected. But they are told that it may be used for X, Y or Z purposes in the future, and who might use it.

So, I would think that in lieu of a consent, we might want to consider language that gets to the point that people have been told that their data would be used for research in the future. That they're aware and that they're told the kind of purposes for which the research could be used.

I agree with Dr. Schaeuble that these are -- I

think that the point here is not that each of these items is a make or break, although if the reviewer's looking at this and say, oh, no, no, there wasn't, you know, sufficient information provided at the time the information were originally collected that's a factor to consider, based on other circumstances surrounding the research. Not necessarily a deal breaker in and of itself.

I think the point is to be able to give the Committee tools to be able to consider some of the really -- some of the ethical considerations around research that are not currently described completely in the IPA.

So, I think this is being offered as things to be able to consider, but not necessarily each and every one a deal breaker in and of itself.

So, those are my comments.

INTERIM CHAIR DELGADO: Got it.

COMMITTEE MEMBER LUND: Thank you for letting me interrupt.

INTERIM CHAIR DELGADO: No, you didn't interrupt, and thanks. I think that the word "consent", like I have such a formal definition of that in my head, what you just described helps tremendously. Thanks.

Go ahead, Carrie.

COMMITTEE MEMBER KURTURAL: I think I understand the idea behind this, but the workability could be a problem

because researchers are going to have no idea if the 58 counties or the 21 regional centers, who are basically executing the services, or the boots on the ground, right, that sign people up for services. And it's the county who is -- you know, does Medi-Cal for Health Care Services, and we have the regional centers to sign people up to get services through DDS.

And once they're signed up, upon eligibility, they should -- yes, they should be given that notice of privacy practices, not consent, but the same concept, right, that where it says your information can be used for research purposes.

My issue is a researcher's not going to know that. It is a 58 counties, and nonprofit regional centers that by law, like my department doesn't have control over -- over that at all. I mean, I have a contract with them that says you, 21 regional centers, need to get out a notice of privacy practices, and it should look sufficiently similar to ours, which has a little blurb on research in it that says your information can be used for research purposes.

But as far as a researcher being from the outside, coming in and saying IPA only project, you know, and then having by regulation a criteria that says, okay, well, what -- how do you know that they know they can use their data for research purposes. They won't know.

And when we get, you know, we're asked, so, who provides the information. When we're asked to approve a research project at the department level, we will take a look at it, obviously, and we also use -- will take a look at, you know, is it minimal risk, and all of that, to the department, on our side, for preapproval purposes. And, you know, the department will also look at the security and all of that, they have that.

But the department does not likely, I can't speak for Health Care Services, but I can speak for DDS, you know, we don't collect that information. That information is with the nonprofit regional centers. So, the department, itself, wouldn't be able to say that.

I just don't think it's going to be workable because I don't know where the information would come from. You know, if there's not going to be informed consent because it's not human subjects research, that's the part that's stuck.

But I just want to make a comment that I really do like some of the factors that you laid out, Dr. Schaeuble, and I think that those would go hand-in-hand in the front-end factors of what to consider for what's minimal risk. And, you know, to have a here are some of the things you can consider in a regulation. You know, when you're reviewing your projects, some of that information would be great.

But that's my problem with the first point here. So.

COMMITTEE MEMBER SCHAEUBLE: So, I guess if I can try to respond a bit. I think you're absolutely right that in a number of instances researchers would really have to say we don't have the information about what people were told when data were collected. And given the entities we're working with, we don't see an easy way of acquiring that information, either.

And I understand that, and I'm perfectly willing to work with that as what may be a very frequent outcome of trying to raise this question in the first place.

There are, I think, as we've seen in some of our projects, agencies that collect data and have some kind of statement to the individuals at the time that they are collecting the information. One that I think comes to mind is regarding the student financial aid, where people applying, even if it's a very imperfect kind of disclosure, are given some information that the agency says this is how your information may be used. Which, in fact, goes beyond just how it will be used for student aid, but other ways it may be used as well.

COMMITTEE MEMBER KURTURAL: I see.

COMMITTEE MEMBER SCHAEUBLE: Now, if that's the case, then the researcher may not have that immediately

available, but probably could get it from the agency without a great deal of difficulty. Certainly, the entity supplying the data in that instance should be able to provide it, I would think.

VICE CHAIR DICKEY: Can I --

COMMITTEE MEMBER SCHAEUBLE: Go ahead.

VICE CHAIR DICKEY: I'm going to bring this up again. There is something that the Common Rule says that the IRB for a releasing agency can do, which is when databases are established for researcher, the IRB can review the consent processes, and the policies and procedures of -- being used for the database and set parameters as to what that data can be used for.

And, in fact, if you read the regulations on the OHRP website, it says that IRBs should do this. And the expectation is that they will. But we haven't been doing that.

So, we don't have that, as an IRB, that ability to sort of review the consent process before the database is established. And then, we get these projects and we're like we don't know what was the consent process, so we don't want to approve them.

So, I would just urge, in terms of consent, we look at that process and what should be our role in terms of approving and reviewing databases.

COMMITTEE MEMBER SCHAEUBLE: And I certainly agree that that is a place that we likely should be involved in, in what's happening. Unfortunately, I don't think it addresses the situation of what do we do with the research applications we are receiving and will continue to review because we --

VICE CHAIR DICKEY: We haven't been doing it.

COMMITTEE MEMBER SCHAEUBLE: We haven't been doing it. Even if we started doing it, we would not be able to cover all of the entities that are supply data.

VICE CHAIR DICKEY: It would be a long catch up process.

COMMITTEE MEMBER SCHAEUBLE: Yes. So, I --

COMMITTEE MEMBER LUND: So, Dr. Dickey, I'd like to respond to that. This is Laura.

According to OHRP, that IRB review of database applications only applies when an agency is creating a specific --

VICE CHAIR DICKEY: A research database.

COMMITTEE MEMBER LUND: If it's for data files that the agency creates as part of its normal business that are then being requested for research and used, then that oversight of creating the database doesn't come into play.

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER LUND: And I think a lot of the

databases that we have reviewed as IPA-only projects, for example, the financial aid data that the Committee reviewed six or eight months ago. That would not be a database that we would review for the creation and the consent procedures in advance because that database was not created for the purposes of research. It was just data collected in the course of business.

VICE CHAIR DICKEY: Understood. But there is a lot of databases that are established for research that we haven't reviewed, such as the Cancer Registry, and it will go on and on. And I'm not saying that's a solution, but I think it's part of the solution.

INTERIM CHAIR DELGADO: Thank you. Others that we have not yet heard from, thoughts on either Carrie or John's documents that we've been reviewing. Dr. Palacio, Dr. Ruiz, Dr. Denis, Dr. Ventura, would love to get others' thoughts.

COMMITTEE MEMBER DINIS: Well, I can add -- I can add something. A lot of our problems would be solved, in my view, if we looked and saw that anytime you collect data with personal identifiers, the personal identifiers under the -- under OHRP, they become a human subject review. And we have not been able to do that, somehow, and some of us don't think that that's true. But it's clearly a regulation, it says right there.

And so, that would change this whole thing, this

whole conversation if we just saw that anytime they're collecting personal identifiers it becomes a human subject. And at that point then this whole thing -- you know, then it's reviewed under the Common Rule, as well. If they're not collecting personal identifiers, that's a different matter.

But I like what John, you know, that's what he is pushing.

INTERIM CHAIR DELGADO: Thank you. Others?

Maggie, not to put you on the spot, but I know that there were -- as we can see on the document that's shown, Jared, even though he's not here today, did get a chance to look at Dr. Schaeuble's documents, made some edits to it. Which just as a reminder for Bagley-Keene, is actually totally kosher because he is not a board member.

But that being said, Jared did delete some points that Dr. Schaeuble noted in the document but then kept them in the document. And so, even though Jared's not here, Maggie, I don't know if you could speak to just your thoughts on why it was suggested that those items not be included. So, at least we can have that awareness for the board and give folks a chance to respond.

MS. SCHUSTER: Yeah, definitely.

COMMITTEE MEMBER SCHAEUBLE: Actually, I should add one thing to that, also. Part of what Jared said in his

comments back to me, I had earlier used a phrase referring to what a reasonable person might think. And he, in particular, was not happy with that choice of words. So, we'll see what Maggie says here in a moment.

I tried to reword those particular items to avoid the language that he was especially objecting to. But I don't know his thoughts about the content otherwise, and that's why I felt I needed to flag the items as ones that he had marked in that way.

MS. SCHUSTER: Yeah, so reasonable person is kind of like a legal term of art that's used specifically in different contexts. And I think we probably just didn't want to bring that kind of legal terminology that has this kind of specific definition into the regulations because it's probably not exactly what we were intending to do here.

I think the -- if you could scroll up just a little bit to look at the three bullet points on the second section. Yeah, down a little bit.

So, yeah, so the two at the bottom that Jared raised a question about. I think the general kind of thought process that we had is these two bullet points are kind of asking the Committee to like use a subjective interpretation of what people might be thinking.

So, the first one that he flagged, it asked for what individuals would expect or not expect. That's

something that we would be kind of having to step into the shoes of, you know, these individuals to make an assumption, to some extent, about what they might have expected or not expected. But that's not something that we would know for sure.

The same one -- the same with the second one, you know, that they would object to having their information used if they had a specific piece of information. That's, again, a subjective interpretation that could be kind of hard to apply because we would be assuming that if they were aware of this information then we think that they would object. But that's not something that we would be able to know for sure.

So, like the bullet point right above, where the individuals were not told that their information would be used for research. That's objective. We can ask, specifically, did you, yes or no, tell the individuals if their individuals would be used for research, and then we would have a concrete answer to that.

These two, not necessarily that we can't, you know, try to apply a criteria in this way, I think the application would just be a little bit more difficult to defend because we are kind of stepping into the role of these individuals to like determine what they might have been thinking, or would be thinking if they had, you know,

X, Y, Z information, which is just a little bit like squishier, if that makes sense. So, I think that's kind of the flags there.

COMMITTEE MEMBER SCHAEUBLE: Maggie, can I ask in that regard. Certainly understandable that the two points do call for reviewers to try to assess or make an inference there. Is that different in some meaningful way from other places where reviewers are also, according to this write up, being asked to assess are the variables in the research especially sensitive information, as opposed to less sensitive information about physical health, or psychological health, et cetera.

It seems to me there are a number of places that judgment of some sort is called for as part of the review process, regardless of how we go about doing it.

Is there something unique about these two that makes them different from other places where judgment is called for?

MS. SCHUSTER: Yeah, and that's a good point. I think here it's more just the fact that by making this determination we're kind of being asked, or the researchers are being asked to step into the minds of these individuals to kind of make a determination about what they might be thinking in the specific situation. And people might have different thoughts, as well. So, maybe some individuals

would expect their data collected to be for research, and some wouldn't. But it's just, it's that really kind of like asking to step into the minds of the individuals to try to decide what they might have been thinking.

Which I think is a little bit different than deciding -- like there are subjective questions throughout this process, of course. Is this -- you know, is this data particularly sensitive or not, but there are -- there can be kind of guidelines, ways to think about those questions that apply broadly, so that we have ideas of what is sensitive and not sensitive data. And that's a discussion that the Committee can have without having to necessarily trying to put on the hat of a specific individual and decide like I think that they would think, if they had this information, this is the mindset that they would have and the expectations that they would have. I think it's just a little bit more subjective, if that makes sense.

So, again, not saying that we can't use these types of criteria, it's just something to think about in terms of kind of the application. Is it something that would be easy to apply? Can we apply across the board? Will people have different inferences or assumptions about, you know, what folks might be thinking in any situation.

COMMITTEE MEMBER SCHAEUBLE: If the Committee chooses to go ahead and try to engage in establishing

regulations, is this a kind of thing that could be discussed further down the line as to whether it's best to leave it in or not to leave it in?

MS. SCHUSTER: Yeah, absolutely. This is starting, so this has probably many discussions and a very long process, which involves public comment and all that, as well.

So, this is just my initial thoughts, and we can certainly discuss more, and Jared will be able determine as well. And, you know, folks in the public might have opinions they want to share on this topic as well, but this is just initial thoughts on this. So, certainly something we can leave in and keep discussing.

COMMITTEE MEMBER SCHAEUBLE: Did you have any other thoughts you wanted to share with the Committee about any other parts of the document.

MS. SCHUSTER: No, I think that the restructuring that you worked through Jared makes a lot of sense. It's really just the -- whatever final version of the regulations that we come up with, we'll want to make sure that it's something that when researchers read the document, they'll want to be able to know how to apply it.

So, if there's certain additional pieces of information that we want them to give us in order to evaluate these new factors, that's something that we'll want

to take into consideration. But, yeah, I think this structure makes sense. And there will be, I'm sure, many iterations of this before we get to a final product.

INTERIM CHAIR DELGADO: I think I said this earlier with the fee structure, but I think it also applies for this, which is, you know, as part of the regulations process if that is the avenue that we pursue, or decide to pursue with solidifying these criteria that we will be addressing, that it is a lengthy process. Right.

Like even if today we decide that, yes, we're going to pursue regulations with some iteration of what we have been reviewing, that there is Office of Administrative Law review, public comment time periods, and other aspects that, as Maggie describes, would allow for chances to tweak.

Laura, going back to the issue that I had mentioned about not -- or, about really getting hung up on the word "consent", is there other language that you could suggest that might better describe -- that might better reflect what you described, as opposed to using the word "consent" in the -- if we could scroll down on the screen, those few bullet points.

COMMITTEE MEMBER SCHAEUBLE: Darci, I've been thinking, too, and I may have some words to suggest as well.

INTERIM CHAIR DELGADO: Please, please.

COMMITTEE MEMBER SCHAEUBLE: Given what we've

talked about.

INTERIM CHAIR DELGADO: Anybody who has thoughts on that.

COMMITTEE MEMBER LUND: Yeah, I would defer to John on that. I think he's done a great job of putting this together.

INTERIM CHAIR DELGADO: Thanks. Because I'll just tell you, John, from my perspective, I feel like if someone were to make a motion that -- that next step being, you know, initiating the regulations process to reflect an examination of these criteria, I would feel really good with that up until we get to these three data points that are on the bottom, that talk about the consent.

But if that were softened a bit to reflect that dynamic that Laura and you described earlier, I would feel solid with that next step.

COMMITTEE MEMBER SCHAEUBLE: Well, what I would suggest, actually only the first of those three items uses the word "consent", so I don't think we have the problem in the other two.

But I might to pull from the language used in previous section discussing risks and maybe change that first item to say something like if individuals whose data will be used were told at the time the data was collected that their information might be used for research, that

information was -- what do I want to say.

Well, let me try this again. And I don't know, do we have the ability to try to put words on the screen in that document or is that document not editable?

DR. RYKACZEWSKA: That was a .pdf and not editable, I don't think.

COMMITTEE MEMBER SCHAEUBLE: Okay, so I need --

INTERIM CHAIR DELGADO: Can we just like open a text box.

COMMITTEE MEMBER VENTURA: Can I make a suggestion? Maybe if individuals were notified or informed that their data, their information can be used, if we use that wording instead of consent.

COMMITTEE MEMBER SCHAEUBLE: Right. That's what I was trying to say.

COMMITTEE MEMBER LUND: So, yeah, could I make a suggestion here because I think -- I think it was Carrie that made this point, and it was a good point.

In the case of information that belongs to a state agency, often that's collected by satellite organizations, whether those are counties or whether they're nonprofits, that then have to report to the state, or hospitals, or whatever.

So, it may be an unfair burden to require that each individual actually saw the information. Right. I

think that's kind of a fair criticism.

But I do think that we want to ensure that the institution releasing the data has policies, procedures in place to ensure that individuals receive the appropriate information regarding the use of their data, and that that information contains, you know, the statement that this will be used for research or may be used for research in the future.

So, I'm wondering if we could just shift this a tiny bit to make the statement that the agency collecting the data can confirm that there are policies and procedures in place for ensuring that the individuals, whose data were obtained, received appropriate information that the data might be used for research in the future, or words to that effect.

Because I know, speaking from the CDPH side, for both Vital Records and for CCR, that's what happens is that the state has requirements, whether those are embedded in the statute or whether they are in contract, which can be legally enforced, that the entity that is collecting the information must tell the person. Must give the person a privacy statement saying, you know, here's what your data -- here's what will happen to your data. It might be shared with X, Y or Z for A, B or C purpose.

And I think, as a board, my opinion would be that

if we concede that that's what the agency does and we can't be, you know, police. We can't go out and make sure that in every single case it was done. I think that's an unfair burden.

But to know that with due diligence the agency tried to ensure that this information was shared with perspective research, that would be kind of what I would suggest. I don't know.

COMMITTEE MEMBER SCHAEUBLE: I think the direction I was heading was trying to work off of how Jared had rephrased an earlier statement that said when the data were originally collected, the individuals were not told that their information would be used for research.

And if we could say in this criteria section, something like if individuals were told when the data were originally collected that their information could be used for research, that description is consistent with the purposes of the proposed research.

That would get away from the words "consent" and still give us the opportunity to ask what were people told, if we can find out at all, what were they told and is it at all consistent with what the researchers are proposing to do.

So, I'll ask if that sounds any better to you than what's there now.

INTERIM CHAIR DELGADO: It does, thank you.

MR. ZADROZNA: Can you repeat it one more time?

DR. RYKACZEWSKA: Nick, I think I got it.

MR. ZADROZNA: Oh.

DR. RYKACZEWSKA: If you let me share.

MR. ZADROZNA: Yeah.

DR. RYKACZEWSKA: Thank you.

VICE CHAIR DICKEY: Can I -- on a different issue.

COMMITTEE MEMBER SCHAEUBLE: Oh, okay.

VICE CHAIR DICKEY: Can you show the --

DR. RYKACZEWSKA: Oh, can we just confirm that I captured it?

VICE CHAIR DICKEY: Oh, no, you can get that.

DR. RYKACZEWSKA: I'm sorry.

VICE CHAIR DICKEY: No, no, go ahead.

INTERIM CHAIR DELGADO: Dr. Schaeuble, do you feel like that's a good reflection of what we're saying?

COMMITTEE MEMBER SCHAEUBLE: Just one question. Used for research or used for purposes consistent with the proposed research, I'm asking?

DR. RYKACZEWSKA: I'm just making sure I'm even -- so, it would be --

COMMITTEE MEMBER SCHAEUBLE: How does that look to you?

COMMITTEE MEMBER HESS: Can I ask how -- how are

we defining purposes consistent with proposed research? Because in some of these cases individuals who are -- whose data are being collected are simply told their personal information or their information may be used for research, which could mean anything.

And an example of this that I'll bring up is I've recently come across some research that looked at cancer patients in a large cancer registry, and they tied that to consumer credit data. And the conclusion that was ultimately drawn, you know, was that financially cancer patients suffer. But the conclusion was ultimately that cancer patients are a credit risk.

Now, you can reasonably assume that someone who's in CCR, who knows that their research is being -- their information is being used for research, assumes that their information is being assumed -- you know, is being used to drive forward cancer research. Not to be used for what effectively comes down to like financial services research.

But that would never have been spelled out to those individuals in the CCR. It's just, you know, researchers may be able to use your data.

So, I wonder, like, do we have any leeway to look at that sort of thing and go, yes, you may be ticking all the boxes with, you know, with privacy here, but the research you want to do is not really consistent with what

an individual who is in this dataset might reasonably assume their data is going to be used for.

COMMITTEE MEMBER SCHAEUBLE: I agree with your concern, and I guess I would hope that in that instance we conclude that the information provided really was not specific enough to cover the kind of search purpose that ended up being the case.

COMMITTEE MEMBER KURTURAL: I have a question on this. So, is this intended to be for just the third-party data, the outside source data sources, or is this kind of criteria supposed to be for Health and Human Services data?

The reason why I say this is because of the problem I mentioned before that, you know, the counties -- everyone has their own notice of privacy practices procedures and, you know, it's not the state directly that holds that information. It's the counties and the regional centers.

But, also, that might be able to be dealt with in the contract, the annual contract. And that we have the annual contracts, when they become due. Unfortunately, you know, like we just signed off on a three-year, so it's not going to be due for another three years.

But the idea of putting in there that some kind of acknowledgement that the department, you know, has notices of privacy practices that it gets out, that allows research

projects or something of this nature, you know, like we have written up here.

And then, that gets dealt with, with the state data side, and then maybe this criteria could be for other sources of data. Have you thought about that?

COMMITTEE MEMBER SCHAEUBLE: Truthfully, no. I'm not sure exactly how to work with that.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Trying to think off the top of my head.

COMMITTEE MEMBER KURTURAL: I mean, well, I guess --

INTERIM CHAIR DELGADO: I feel like it eventually gets us to a point of making a recommendation to all of our departments. This is like kind of inside CPHS purview, but also a recommendation we make to all of our departments saying --

COMMITTEE MEMBER KURTURAL: Yeah.

INTERIM CHAIR DELGADO: -- hey, for the purposes of privacy protection related to research, related to the data requests, the data requests that end up coming through us, we highly recommend all of your legal offices review with, you know, local contracts to ensure --

COMMITTEE MEMBER KURTURAL: And we could even do an internal. I don't mean to like blow up this issue, but

it is a big issue, right. Because I'll tell you right now, I'm looking at our privacy practices for Development Services, it says, basically has a laundry list of when we may share someone's confidential health information. And it goes through all the exceptions. You know, there could be public health, whatever.

And then at the end it says, "For research, when approved by an IRB, to ensure the privacy of your protected health information." That's it.

And so, most of these privacy notices are very like it's not going to get into these nitty-gritty details of are you connecting this with third-party data or whatnot.

So, we can take a look at that. And then, does there need to be some sort of collaboration for compliance purposes, you know, across, and deal with that in a contract.

And then, for the regulations maybe this applies more to the outside sources of data. Because I just don't know --

COMMITTEE MEMBER LUND: So --

COMMITTEE MEMBER KURTURAL: Go ahead.

COMMITTEE MEMBER LUND: I was going to say we're just talking about IPA-only.

COMMITTEE MEMBER KURTURAL: Right.

COMMITTEE MEMBER LUND: And our purview with IPA

data that are held by state agencies.

VICE CHAIR DICKEY: But the concern is that that data is then matched with other data --

COMMITTEE MEMBER KURTURAL: Correct.

VICE CHAIR DICKEY: -- that we don't have the control over. And that's really where the rub is right?

COMMITTEE MEMBER LUND: So, this -- so --

COMMITTEE MEMBER KURTURAL: Yeah, I mean I think that's where, Dr. Schaeuble, you're coming from, right, because you're talking about the financial data from other sources, which is kind of the reason behind this.

COMMITTEE MEMBER SCHAEUBLE: That's certainly one good example, yes. It's not the only one but --

COMMITTEE MEMBER KURTURAL: Yeah. It's just an idea. Because it's going to be very difficult. I mean, the researcher -- I mean, imagine that this is put in regulation, right. So, we've got to update IRBManager. And then, we update -- I mean, the question's going to be on the application for IPA-only, and then it will say, tell me, you know, individuals were informed their data were used for these specific research purposes, or for research purposes, whatever we decide. I don't think the researcher is going to know.

I think they could, you know, if they're connecting with other sources they might be able to get us

something.

But for actual, the source of the state data, I mean, it's going to be difficult. I think there might be another way to address the concern outside of regs.

VICE CHAIR DICKEY: For the state data.

COMMITTEE MEMBER KURTURAL: For the state side.

VICE CHAIR DICKEY: Yeah, it's the outside data that's the problem.

COMMITTEE MEMBER KURTURAL: Yeah, it's the outside that -- because I understand like some of these research projects trying to connect with outside FAFSA, you know, like I don't know what they -- what you sign off on when you apply for student financial aid. And that would be useful for us to see that map, if they have that. But on the state side it might be more difficult.

DR. RYKACZEWSKA: Carrie, can I just make sure I'm understanding. So, when you're saying kind of addressing it through a contract, it would be something where the recommendation would be to include language so it doesn't just it might be used in research, but it gives a little more detail. Like it could include things where your datasets are merged with other datasets, and --

COMMITTEE MEMBER KURTURAL: We can look into that. Whether we can make, and we have authority as an IRB board to make everyone go change their notice of privacy

practices, you know, that's another thing. It would have to be a collaboration with the departments if we want it to be beefed up.

COMMITTEE MEMBER SCHAEUBLE: I guess I am wondering how something like this, and again it does depend on whether the Committee is prepared to try to go ahead with the process of developing regulations. But it seems like you're raising a very good question that I don't know exactly how to try to resolve today.

And it seems like one of the things that might need to be discuss as that process proceeded, rather than attempting to come up with something that totally fits with what you're talking about. Because off the top of my head, I don't know how to do that at the moment, frankly.

COMMITTEE MEMBER KURTURAL: Yeah. I just would think that for this point, that if we could get to the point of actually getting it into regulations, that I'm more on board if it only applies for outside data sources. And it's like a do-you-have-this type of question on an application. It's not like an absolutely requirement, it's a criteria, you know, if we set it up like that, of a factor to consider in the analysis. And it applies to outside data sources. I'm a little more on board, then.

COMMITTEE MEMBER SCHAEUBLE: So, what would you ask of the state agencies as far as when it's being told to

individuals at the time those agencies are collecting data? What would you expect from them or want from them?

COMMITTEE MEMBER KURTURAL: We have -- you know, each department has a privacy officer, and we do have a group where sometimes we discuss issues like this that may impact us. And CDII takes the role of doing that.

And it would be -- it has to start with the departments' notice of privacy practices, because what it is, is then they contract with the counties, who says, all right, you guys have to have a notice of privacy practices and this is what it has to say, you know, when you're signing someone up for services.

So, it starts with fixing our stuff at the state level and kind of getting on the same page. And it could be a compliance check, too, like CDII could put all the departments on the, you know, on the spot. But, you know, CDII also focuses on different areas.

And this might be an area of focus, next for CDII, with the departments. And go from there.

VICE CHAIR DICKEY: Could you see recommending, this Committee recommending language for the information -- for the departments to use?

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: To be more specific about what kind of research.

COMMITTEE MEMBER KURTURAL: Absolutely. I mean, we can always submit recommendations. And to be honest, we haven't looked at that as an agency in a while, notice of privacy practices. And, you know, it might be a good thing to look into.

But I think that it would be a discussion, and it usually starts with privacy or security, you know, and we huddle as a group sometimes. And we would discuss moving forward.

But, yeah, I don't think it's -- it's not uniform.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER KURTURAL: I'll tell you right now. Looking at me. And I'm looking at ours and I'm like it would be nice to sub privacy board or mention a one-liner about outside research or something like that, but it doesn't say that. It's just very --

VICE CHAIR DICKEY: What about just changing it such it says research for health and welfare purposes, something like that, so that it eliminates the financial and these other things that we find objectionable.

COMMITTEE MEMBER KURTURAL: I think that we're going to have to think about what the recommendation would be as a board. I know that for us it's very loose because we want to encourage research. But at the same time, we have to protect, you know, our job is to protect human

subjects as a board. So, it's going to be something to consider and think about doing a recommendation later.

I mean we could start by pulling each department's notice of privacy practices and take a look, because I don't know what Social Services has, or Health Care Services, or DOR, or any of that.

So, yeah, that raises a good point with the other departments that aren't contracted with us. I mean, how else are you going to get assurances on this. But with a contract with departments.

VICE CHAIR DICKEY: Yeah, that's true.

COMMITTEE MEMBER KURTURAL: So, you know, CDCR probably should contract with us.

COMMITTEE MEMBER SCHAEUBLE: So, this is all very challenging stuff --

COMMITTEE MEMBER KURTURAL: It is.

COMMITTEE MEMBER SCHAEUBLE: -- as far as trying to think from a policy angle as what agencies might do that -- the difficulty I'm having in my head is that trying to carve out what exists for state agencies as opposed to other data sources still leaves me very uncertain about what individuals are actually being told when the data's collected.

I mean, I'm thinking of all those different ways that we interact with entities.

COMMITTEE MEMBER KURTURAL: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: I've heard driver's license; I've sent in my tax return.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: What is told to individuals anywhere along the way in that process that would be a meaningful disclosure saying your information is going to be used for more than just processing your tax return, or more than just maintaining your driver's record, but might also be used for something else in addition. I don't know what's being said or if anything is being said.

COMMITTEE MEMBER KURTURAL: I can --

COMMITTEE MEMBER SCHAEUBLE: And I don't see the question there as being different for state agencies compared to other agencies, the process or procedures that we might use to approach it, I suppose they might be different. But I don't see the question about the information that's being given to the people, that that question is really different.

COMMITTEE MEMBER KURTURAL: It's a form that they're handed to, you know, that they sign off on. I don't think there is a conversation. I mean, you know, speaks personal experience, my son is a consumer of Development Services. I had to apply for him to get services. And, you know, there's no conversation about it, you fill out the

paperwork. And if you apply for benefits, whether it's Social Services or whatnot, you're applying online.

COMMITTEE MEMBER SCHAEUBLE: Sure.

COMMITTEE MEMBER KURTURAL: They have an online portal. It's actually really easy, it's great because it connects services with Social Services and Medi-Cal, I believe, and all the Medicaid services.

And so, you'd be looking at that, possibly, too, making sure privacy practices are on there. But it's going to pop up on the computer or, if you're still using paper like, unfortunately, we are, it's going to be in a paper application mailed.

INTERIM CHAIR DELGADO: But I do like the -- I mean, I'm seeing -- because I was reminded, I can't make a motion. But if I were, part of what I would see developing is kind of, you know, a regs approach to some of the variables that we agree with, that we find consensus on, on Dr. Schaeuble's form. And, in addition, a different lane of work that asks CDII, at large, not like you, specifically, but CDII at large to bring together the privacy officers from each of the group -- each of the departments. And saying, hey, here's the issue we're running into with our research reviews. Would -- you know, here's where we're moving towards, would love to get you on board to ensure your privacy notices for your consumers include something to

the effect of what we see on the screen.

And be pursuing that avenue in addition to a regs process.

COMMITTEE MEMBER JOHNSON: Could we ask them what, if any, privacy statement they use and if they can supply it, and what years that was kind of going out.

Because I think as we move forward and we have, maybe, potential longitudinal studies, and if people had different privacy things either provided to them or not, or a change, we would need to take that into consideration.

INTERIM CHAIR DELGADO: Yeah, it would be nice to get a kind of like an as-is snapshot. Like, when were they last developed, what is the mode of delivery in obtaining paper versus electronics, what are the details of what that privacy notice says and, you know, any implications it might have one on our research.

VICE CHAIR DICKEY: So, that would be for every state department.

INTERIM CHAIR DELGADO: For every -- I mean, for every department under our agency.

VICE CHAIR DICKEY: Well, no, under the IPA we have every state department.

INTERIM CHAIR DELGADO: We could put it out to them as something to consider, as we are the IRB for the State of California.

But legitimately, we only have control over our own departments. Which is better than nothing at this point, given where we're at.

COMMITTEE MEMBER KURTURAL: Yeah, you always start with us and then, you know, once we have our stuff figured out, for outside departments we can say, guess what, you guys contract with us.

VICE CHAIR DICKEY: I mean, the control we have for outside departments is we just won't to approve releasing their data unless they give us their privacy statements. Right. I mean it's -- it's a lot of work.

COMMITTEE MEMBER KURTURAL: It's a lot of work, but it would give us assurances without having to put this in regs for our data sources.

INTERIM CHAIR DELGADO: And, frankly, it should be done.

COMMITTEE MEMBER KURTURAL: Yeah. Right, like we probably need a compliance check to make sure that we're doing things appropriately.

INTERIM CHAIR DELGADO: Well, and in the long run it makes our work easier. Right.

COMMITTEE MEMBER KURTURAL: Yes.

INTERIM CHAIR DELGADO: So, it is a lot of work up front, but long term it clears up a lot of gray areas, I think.

COMMITTEE MEMBER KURTURAL: Right, and it's like, you know, when the contract's up or whatever we can add in some sort of acknowledgement, or maybe make the departments attach their privacy statements, right, their notice of privacy practices to the contract. Why not?

And then, we have assurances as a board, where we know as a base, we're good to go with Health and Human Services, you know, without having to worry about it.

VICE CHAIR DICKEY: Yeah. Some of the most problematic projects have been for data outside the agency. I think this one with the --

COMMITTEE MEMBER KURTURAL: I agree.

VICE CHAIR DICKEY: -- it was the state colleges, I think.

COMMITTEE MEMBER KURTURAL: Yeah, right. I agree, there was a few on FAFSA, and community colleges, and other things. But, you know, we can --

COMMITTEE MEMBER LUND: So --

COMMITTEE MEMBER KURTURAL: Go ahead.

INTERIM CHAIR DELGADO: Go ahead, Laura.

COMMITTEE MEMBER LUND: I think -- yeah, thank you. I think that the point of the list of criteria here is so that when projects come to us, we can consider whether people receive sufficient information. And if we're concerned about the nature of the project, the uses to which

the data will be put, and possible re-identification on top of the fact that this agency may not have informed people that this is something that would be done with their information, that that can be a basis for us to, you know, deny a request for approval of their research.

So, I think -- I think I would disagree with some of the conversation. Under the IPA, we are only responsible for approving the release of state data for a research project. And I think one of the considerations that John's put into this document that we want to be able to consider is whether those state data will be linked with other data. But I don't think we can control the other data.

Whatever IRB -- because this is where IPA-only, we're not the Common Rule IRB. So, whatever IRB approved the release of those other data sources, they're not under our control.

I think that these considerations about information about how the data will be used are really something that we can only apply to the state data over which we have purview that we're being asked to make a judgment about in the IPA, for release.

So, those are my thoughts. And it includes all state agencies. So, the FAFSA data actually came to us because it has IPA implications.

VICE CHAIR DICKEY: Right. But if the other IRB

for the -- say, for the other datasets is outside ours, shouldn't they be looking at consent. Do we not trust them to look at --

COMMITTEE MEMBER LUND: They should be. But we can't control them, right. They're the IRB. They're responsible under the Common Rule for making sure that all aspects of the Common Rule, including sufficient informed consent, are in place.

But we, if we're IPA-only, can't -- in my opinion can't be concerned with how other data, non-state data, were collected and what people told. That needs to be the Common Rule IRB.

If we're Common Rule IRB, I'm totally on board with us doing that research. But if we're IPA-only, then we can only look at the state data that we have purview over.

VICE CHAIR DICKEY: But that would seem to undercut what Dr. Schaeuble is saying.

COMMITTEE MEMBER LUND: No, I don't believe so. And, you know, Dr. Schaeuble might want to correct me on that. But I think the concern about other data sources is when you link the state data with the other data sources you have a much larger dataset, with many more data fields than were originally intended.

So, the individuals whose data were obtained by the state may never have been aware that that might happen

to their data. That is the perspective that I'm coming from, you know, is that were the state individuals told that their state data, that this is what might happen to it, right. Or could they reasonably expect from, you know, the information they were given at the time this data was collected that, you know, it was going to go and be linked to all of these other sources.

How they handle providing their information to the other sources is up to another IRB. We're concerned with how their state data are used and whether they expected that their state data would be used in this way, in my opinion.

VICE CHAIR DICKEY: So, if we changed the form that said for research, which may include linking with other databases.

COMMITTEE MEMBER KURTURAL: The devil's in the details. I mean, you know.

COMMITTEE MEMBER LUND: Yeah, so -- so, for example, when the birth certificate data, the privacy statement that goes with the birth certificate data tells them that their birth certificate data will only be used -- because it cites the actual state law that authorizes the release of birth certificate information for research. So, it actually tells them that their data will be used in accordance with, you know, Health and Safety Code Section 102.30, which specifically states for health-related

research.

So, their birth certificate data can't be used to link with, you know, economic data to do an economic study, unless those people can demonstrate that that's health-related research.

So, and I'm not familiar with all the privacy statements for all of the agencies. I do believe that the CCR, the code that enables research using CCR data, I do believe that it states that it has to be related to cancer in some way, treatment, cause, longevity. I'd have to look that up.

So, some of these data sources are already handled in regard to what people can do and how far you can stretch it. So, but a lot of state databases are not regulated in that way.

I think that that would be my concern here is that people giving their data have no idea that it was going to be not only used for research, but linked with these other, you know, datasets, so that it becomes, you know, far more powerful and far more dangerous from a privacy perspective.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: And I think that last point is the most important part. The linkage to other data may greatly increase the potential privacy risk to the individuals involved.

VICE CHAIR DICKEY: So, I'm just saying it's --

COMMITTEE MEMBER SCHAEUBLE: Through state that's being used.

VICE CHAIR DICKEY: -- is that something that we should say should be, you know, something along those lines put in these privacy statements. I mean, if we can't -- if the other databases have other IRBs that are looking at their consent issues, really what we're looking at is what's the risk due to the matching in just creating these larger databases.

COMMITTEE MEMBER DINIS: I think that is the issue. Because I think with the Berkeley one that came to us, they would have exempt from Berkeley because it was data that they got, you know, in Experian with the financial data.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER DINIS: And then, they came to us wanting the student load data. And at that point, then it was up to us to, you know, either give it to them or not, you know, kind of thing.

So, that's where I think it falls apart is at these places, at these universities they'll be considered exempt because it's data-only that comes to them in some kind of format, de-identified, with an algorithm, whatever. But it's the matching that I think we all have -- well, many

of us had concerns with was when they match and what would happen, particularly when the algorithm was the same between the two, the two datasets.

And so, that's what I have an issue to, myself, is when they match these datasets. And, you know, if you go to the Student Loan Commission website, they talk about how their data is going to be kept private, et cetera, et cetera. No place there do they ever say we're going to be matching your financial information with other datasets, you know, your credit report. It doesn't say any of that. It's not there.

COMMITTEE MEMBER KURTURAL: Right.

COMMITTEE MEMBER DINIS: And so, then there's no way a person applying for, let's say, financial aid would ever know that that was a possibility that that would happen to them.

COMMITTEE MEMBER KURTURAL: Would a resolution, in lieu of having this, just trying to fix it on our side with the contracts and the privacy statements and then requiring IRB approval letters on the outside sources' end. Would that be workable? I mean, I'm looking at Dr. Lund because --

COMMITTEE MEMBER SCHAEUBLE: As a practical matter I don't think so. And I'm reflecting on what we've seen from projects we've reviewed. And it's nice to say in

theory that the researchers' institution should be doing a review of everything that needs to be reviewed. But in practice what we find is that the researchers' institutions say, well, as far as we're concerned the data are all secondary data, people at our institution aren't collecting it. So, we don't have to review it.

VICE CHAIR DICKEY: Well, what they'll do is they say it's exempt.

COMMITTEE MEMBER SCHAEUBLE: They say it's exempt, which by definition says we don't have to review it. An exempt decision is a decision not to review because it doesn't fall under the criteria that require review.

So, in practice the considerations we're talking about don't get attention from the researchers' institution.

COMMITTEE MEMBER KURTURAL: Okay.

COMMITTEE MEMBER HESS: It's just a giant loop.

COMMITTEE MEMBER KURTURAL: It is.

COMMITTEE MEMBER SCHAEUBLE: So, if we -- if we don't work it into our thinking, then --

COMMITTEE MEMBER KURTURAL: Right.

COMMITTEE MEMBER SCHAEUBLE: -- it just doesn't happen.

INTERIM CHAIR DELGADO: It does make sense to me that we work it into our thinking right now, with the understanding that we'll have to think about it less and

less over the years as we engage in this second pathway of quality assurance over privacy statements.

COMMITTEE MEMBER SCHAEUBLE: Agree.

COMMITTEE MEMBER KURTURAL: Yeah, I mean I think that -- right, I don't think why we can't come up with a template or something like that. It's not rocket science. I mean, everyone has the same privacy exceptions, pretty much.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER KURTURAL: You know, across the board. So, I mean --

VICE CHAIR DICKEY: And we have the -- you know, as the IRB we have the authority to make recommendations about what it should say about research.

COMMITTEE MEMBER KURTURAL: Well, we have authority, if they want us reviewing under the contract.

VICE CHAIR DICKEY: Or under the -- or, if they want us reviewing it under the IPA.

COMMITTEE MEMBER KURTURAL: Yeah. If they -- I mean, you're their IRB so --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER KURTURAL: I mean, I think that -- I would probably, knowing the group, do a recommendation on language. That's what I think would need to happen and, you know, and gather thoughts and report back to the board.

INTERIM CHAIR DELGADO: Laura, I see you have your hand raised.

COMMITTEE MEMBER LUND: Yeah. So, I'm just wondering, I think that we're not going to be able to resolve all of the many details that need to be addressed, and getting into the weeds of, you know, what we can do with other agencies in the future and whatnot. I think it's really important and I think every -- all of the points that have been raised have been great. And that we should make sure to capture that.

What I am wondering is if we have accomplished the purpose today of what was on the agenda, which is to continue the discussion of the IPA. And the documents that have been submitted by Carrie and John, I think form a great foundation.

What I'm hearing -- I didn't hear any objections to regulations, and I heard a lot of interest in regulations. And I don't think we have to have the actual language resolved today.

What I'm thinking I'm hearing is that the Committee is generally in favor of moving forward with a regs package regarding the IPA, and that we might need a subcommittee, all official under Bagley-Keene, so that we're making sure that there's the opportunity for the public to hear those discussions and be part of it. So, we'll need to

calendar those.

But I would -- it sounds to me like maybe we're in favor of motioning to move forward with regulations and forming a subcommittee to draft language and bring that language to the board.

Is that what everybody's hearing?

VICE CHAIR DICKEY: I'm hearing --

INTERIM CHAIR DELGADO: I'm seeing some head --

Oh, go ahead Dr. Palacio.

VICE CHAIR DICKEY: I'm sorry.

INTERIM CHAIR DELGADO: Dr. Palacio, you have your hand raised.

VICE CHAIR DICKEY: You're on mute.

INTERIM CHAIR DELGADO: Maybe you were just waiving to us.

VICE CHAIR DICKEY: He's talking, so maybe somebody else.

INTERIM CHAIR DELGADO: Okay, Dr. Dickey.

VICE CHAIR DICKEY: I'm hearing two things. I'm hearing that there's an interest in pursuing a reg package and there's also an interest in pursuing standardized language for privacy statements for the agency, in terms of how research is dealt with.

So, I think it's a dual path is what we're hearing.

INTERIM CHAIR DELGADO: We're getting a lot of head nods, if anybody is --

Oh, John, don't throw a wrench, but go ahead.

MR. OHANIAN: No, no wrench. This is an "and" to it. It is just letting the group know and we're happy to come and bring folks to brief this group. But with respect to CDII and the work that we're doing with the Data Exchange Framework, which is legislation AB 133, which is tied to basically real-time information sharing among both health and social service providers.

Through that work, through that data exchange work on of the key areas is obviously ID management and consent. And so, consent is obviously being talked about at a national level. There's work happening, there's work happening with local pilots around consent. And we're taking that on from a statewide perspective to understand where the opportunities are.

And while that's different than what we're talking about here, it's actually related. Because when that consent to share among providers happens there's some underlining. So, I think this is a great opportunity for us to kind of have both, and at future meetings we can bring our group with some early findings, let you know what we're seeing things at.

But we know that over the next couple of year we

really need to address it statewide or else we're never going to have the type of information sharing we need with providers, as well.

COMMITTEE MEMBER KURTURAL: Yeah.

MR. OHANIAN: That can help inform.

COMMITTEE MEMBER KURTURAL: Might help with a template.

MR. OHANIAN: Yeah.

COMMITTEE MEMBER KURTURAL: Or something.

INTERIM CHAIR DELGADO: Dr. Schaeuble, yeah.

COMMITTEE MEMBER SCHAEUBLE: I guess I'm not sure exactly where we are with regard to part of this. I haven't, I don't think I've heard objections to the kinds of things that are in the document I was discussing with the Committee. And I guess I'm wondering if we're at a place that we could say that is a framework that the Committee will take as starting point to work with legal counsel towards developing regulations.

VICE CHAIR DICKEY: What about the idea of establishing a subcommittee?

COMMITTEE MEMBER SCHAEUBLE: I assume the subcommittee would be working with legal counsel.

VICE CHAIR DICKEY: Yeah, but this first step would be to establish a formal subcommittee under Bagley-Keene to work out the details of that.

COMMITTEE MEMBER SCHAEUBLE: But my questions is whether we are far enough along today to say that this is a beginning statement that the Committee is ready to start working from as a subcommittee, with legal counsel, to try to develop things.

INTERIM CHAIR DELGADO: I'll just say my perspective, but then others please feel free to chime in. I know this has been a long conversation, but I feel like there's really good progress because where I feel like the group consensus is at, but again please interrupt me if you disagree.

Going back to the Jared/Maggie conversation last meeting was you got to make a decision, group. Do you want to pursue regs to formalize how IPA review criteria should be considered or do you want to maintain as is.

And what I hear the group consensus being is that, yes, we would like -- we believe pursuing regulations is important to protect the sensitive data in the scenarios that we have described.

And we have a good starting point in the document that we discussed today. I do not think we have consensus as to all, every line of that document and every criteria. But then we are establishing a subcommittee that will go through, line by line, get to a like best version that they, the subcommittee, can then bring back to the full Committee,

that we can vote on. We can nitpick some of the words in our next meeting. But then, that we can vote on to be the criteria that we then hand over to the lawyers and the team that creates a regs package, to start that probably year-long process of pursuing regulations that reflect what the subcommittee brings to the full Committee.

VICE CHAIR DICKEY: But can there also be a motion to work on --

INTERIM CHAIR DELGADO: We're going to have two motions.

VICE CHAIR DICKEY: -- privacy statements.

INTERIM CHAIR DELGADO: So, that's motion one. Not that I'm asking anybody to make a motion. But if you were, that might be one to consider.

And then, a second motion to consider would be based on a lot of what Carrie was talking about, which is CDII and anyone, in fact no more than two board members so we don't have to Bagley-Keene it, who would be interested in pursuing this privacy notice discussion with our department to do an as is of, you know, what's happening in your privacy notice space.

And then, eventually getting us to the point where we can make a recommendation to all of our departments and state agencies at large.

COMMITTEE MEMBER DINIS: Would those be both at

the same time?

INTERIM CHAIR DELGADO: Yeah.

COMMITTEE MEMBER DINIS: I mean, the could exist, the subcommittees.

INTERIM CHAIR DELGADO: Yeah, I think so. Because I mean both of them are going to take a while.

COMMITTEE MEMBER DINIS: Important.

INTERIM CHAIR DELGADO: And they're incredibly important. And I think it's we're looking big picture, long term when we would expect these changes to be reflected.

COMMITTEE MEMBER KURTURAL: How big of a subcommittee are we looking at?

INTERIM CHAIR DELGADO: What was that?

COMMITTEE MEMBER KURTURAL: How many people on a subcommittee are we looking at?

INTERIM CHAIR DELGADO: Two.

VICE CHAIR DICKEY: You mean you and --

(Laughter)

VICE CHAIR DICKEY: -- how many others?

INTERIM CHAIR DELGADO: Let's start with a motion. Does anybody have a motion? Because we also have to --

COMMITTEE MEMBER LUND: I'll make a motion.

INTERIM CHAIR DELGADO: Okay, awesome.

COMMITTEE MEMBER KURTURAL: I'll make a motion for the first one.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER LUND: Motion number one. I move that the Committee move forward to create regulations regarding requirements for IPA-only project reviews. And that a subcommittee be established to draft language to bring to CDII legal and to this board.

INTERIM CHAIR DELGADO: Yes.

COMMITTEE MEMBER LUND: For regulations.

COMMITTEE MEMBER SCHAEUBLE: Laura, do you --

INTERIM CHAIR DELGADO: Great. Okay, so we have a motion. Let's look for a second and then we will open it up to public comment.

COMMITTEE MEMBER HESS: I'll second.

INTERIM CHAIR DELGADO: Okay, a second from Dr. Hess. Thanks.

So, you can see the motion up on the board. Let's pause -- before we go any further, let's open it up for public comment.

If you are in the public, either on Zoom or in person, and would like to make a public comment, please either raise your hand or raise your virtual hand so we can hear what you have to say.

COMMITTEE MEMBER SCHAEUBLE: Darci?

INTERIM CHAIR DELGADO: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Question. Question

for Laura. The motion, as I'm looking at it there, seems to imply starting from scratch to draft language. And I'm -- is that what you intended? Did you intend not to say anything about what we've been discussing today as far as the document the Committee has been looking at?

COMMITTEE MEMBER LUND: No, that was not my intent. By drafting language, I was intending to include everything that's been brought to the board so far, as well as anything that the Committee want to suggest to enhance that, as well as changes that CDII legal might make.

INTERIM CHAIR DELGADO: Thank you for the clarification.

Okay, so, Dr. Hess, do you still second that motion?

MS. MUHAMMAD: Dr. Delgado, Satish would like to speak.

INTERIM CHAIR DELGADO: Okay, thanks. We're just going to get a second to the motion before we open it up for public --

COMMITTEE MEMBER HESS: Yes. Yes.

INTERIM CHAIR DELGADO: Okay, yes, we have a second.

Okay, so we have one person in the room. And then, again, anyone on Zoom who would like to comment, please raise your virtual hands.

Go ahead. Oh, sorry, go ahead.

MR. KUMAR: Good morning, Chair, Dr. John and all the members. I want to make a comment regarding clarification of the purpose of research.

So, there are known research which can happen today. But there are many, many research like CDII linking the different datasets from Human Services and Health. And on top of that AI may link the data many, many different ways and different kind of research, which is not possible to imagine to what can happen next three years down the line, or next five years down the line.

But these datasets are going to last for like 10 years, or 20 years, any period of that. So, down the line a three years, or five years if this data used for research which is not possible today, or not envisioned today, and if that is used how can it be communicated to the people (indiscernible) -- is complicated.

Okay, one of the reasons (indiscernible) -- and list it down this is the kind of research we are doing; this is the research we are going to conduct. And these five years, only, or ten years (indiscernible) --

Second, the person this way -- sorry. That linking over there. So, now, the madam also told that if you link those datasets the information (indiscernible) -- it was to triangulate that information and come to know,

even if you remove PII, that where that person lives. Say, that's posted in a news article in the Sacramento Bee that they have 90-year-old person cancer is cured.

Now, it's very -- it's a very small people who are 90 years plus or 85 years plus. Those can be triangulated to immediately find out who that person is. And if you see there a case in the (indiscernible) -- that this had happened in real life. That they had been able to triangulate that kind of thing.

So, my -- the (indiscernible) of my point is for future research, which is not (indiscernible) -- because this Committee is going to set the standard for world, not only for California.

INTERIM CHAIR DELGADO: Okay, thank you.

Any virtual hands raised? Nick, do we see any virtual hands raised?

MR. ZADROZNA: Nope.

INTERIM CHAIR DELGADO: Okay, seeing no virtual hands raised, we have a motion up, we have a second.

So, Sussan, would you mind doing roll call.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER BAZZANO: Can you hear me?

MS. ATIFEH: Yes, yes.

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Okay, thank you.

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: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great, thank you.

Do we have a second motion? Go ahead, Carrie.

COMMITTEE MEMBER KURTURAL: I do. So, I would like to make a motion to request that CDII obtain from each CalHHS department their current notice of privacy practices and bring back to the board for review and consideration.

Let's just start there.

INTERIM CHAIR DELGADO: Great, thanks.

We have a motion; do we have a second?

COMMITTEE MEMBER VENTURA: I'll second.

VICE CHAIR DICKEY: I'll second.

INTERIM CHAIR DELGADO: Okay. Dr. Ventura just beat you to the buzzer for the second.

VICE CHAIR DICKEY: Wow.

INTERIM CHAIR DELGADO: Open it up for public comment. Any public comment on this issue, please raise your virtual hand, or in the room if you'd like to speak, please raise your hand.

Any virtual hands, Nick? Okay, great.

If we could do a roll call, Sussan?

MS. ATIFEH: Sure. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Okay, thank you.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Oh, I approve.

MS. ATIFEH: Okay, thank you.

And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Great. Thank you so much.

Just want to say thank you to the Committee. This has been multiple meetings. It's been a lot of work on the individual level, particularly with Dr. Schaeuble and Ms. Kurtural for sending in the documents. Just really appreciate everyone's commitment to this issue.

Also, thanks to the researchers that are on the call. I know, as the Chair, I'm way out of the time frames that you were given. Apologies. Thank you for sticking with us.

Also, just recognizing it's an incredibly important issue that we were discussing, so thank you for giving us the patience to bump you back.

Yeah, Laura.

COMMITTEE MEMBER LUND: You should probably name

the members of that subcommittee.

INTERIM CHAIR DELGADO: Oh, good call, we should name the members of the subcommittees.

So, for the first subcommittee, I think Dr. Schaeuble -- okay, wait, sorry. Would anybody like to nominate themselves before they get volunteered? Does anybody have any specific interest in serving on either of the -- or, excuse me, just the first subcommittee, that's the only one we identified.

And how many people do we have? Like, how many people do we put on a subcommittee?

VICE CHAIR DICKEY: It really depends.

INTERIM CHAIR DELGADO: Okay. So, a subcommittee, if there are only two people interested --

VICE CHAIR DICKEY: Well --

COMMITTEE MEMBER DINIS: I would like to be on the first committee, as well.

COMMITTEE MEMBER LUND: And I would, as well.

VICE CHAIR DICKEY: Well, we got three.

INTERIM CHAIR DELGADO: Okay, so then we -- if others are interested, then we will post them as public meetings.

COMMITTEE MEMBER LUND: I was thinking that committee would be important enough that we might want to have three or four people, really, to discuss the language.

I think the draft documents that we have are great, but we have not had the opportunity to actually have a discussion about those. So, I couldn't hear everything. I'm hoping that John volunteered to be on the subcommittee because he's really such a great source of the language so far. And I understand Bagley-Keene can sometimes be inconvenient, but I think --

INTERIM CHAIR DELGADO: Yeah. I think we need to have them be open meetings that will be noticed per Bagley-Keene, given the importance of this topic and the interest from the public.

So, John, how do you feel about it? Knowing that we don't want to overwhelm since you're literally on like every single subcommittee we have.

COMMITTEE MEMBER SCHAEUBLE: Yes. Burnout is a problem but, yes, I'll do it.

INTERIM CHAIR DELGADO: Okay. I feel bad. I understand that issue deeply.

So, Dr. Schaeuble, Ms. Lund, Dr. Dinis. Anybody else want to be on that subcommittee? Carrie's smiling, like a maybe.

COMMITTEE MEMBER KURTURAL: I'll do it.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER KURTURAL: Fridays are best, guys.

INTERIM CHAIR DELGADO: Okay.

COMMITTEE MEMBER KURTURAL: But --

INTERIM CHAIR DELGADO: Got it. Okay. Okay, so that's our subcommittee.

I do -- okay, so let's -- we are going to move on. I'm seeing like portions of --

COMMITTEE MEMBER SCHAEUBLE: Darci?

INTERIM CHAIR DELGADO: Yes?

COMMITTEE MEMBER SCHAEUBLE: Is legal counsel included on the subcommittee?

INTERIM CHAIR DELGADO: They can be. They don't have to be named. But I imagine Maggie and Jared are fully invested in this topic, so one of them will be happy to attend.

COMMITTEE MEMBER SCHAEUBLE: I think we're not going to get very far if they aren't involved.

MS. SCHUSTER: Yes, thanks for that.

INTERIM CHAIR DELGADO: I mean they -- they've been ride or die on this issue, like super supportive. So, I'm fully -- I don't think we need to name them officially, they'll be there.

MS. SCHUSTER: Yeah, we won't be official members, but we can provide counsel.

INTERIM CHAIR DELGADO: Awesome. Okay, thank you, Laura, for pointing that out.

So, I've been seeing some items pop up in the chat. Let's practice our flexibility. So, we have one amendment and two projects, right? Okay, one amendment and two projects.

So, we have Dr. Loretta, Dr. Justin and Dr. Wendy. And I see Dr. Wendy needs to potentially leave ASAP. Could Drs. Wendy, Loretta, and Justin come off mute and let us know if any of you have flexibility to get bumped later, so that Dr. Wendy could get moved up.

MS. AKHTAR: Hi, sorry, Dr. Loretta is not going to be joining. I'm going to be speaking on behalf of her lab. I just want to clarify, so getting bumped up today, right, was just at a later time?

INTERIM CHAIR DELGADO: Yes, just at a later time. So, Dr. Wendy's saying she has until 12:30. We are going to hear all three projects today, without a doubt. It's just a matter whether you're good going at 11:30, 12:00, 12:15 kind of thing.

MS. AKHTAR: Yeah, we have flexibility, so if someone needs to go before us, that's fine.

INTERIM CHAIR DELGADO: Awesome. What about you?

DR. HARTY: Yeah, me, too, I'm good.

INTERIM CHAIR DELGADO: Okay, great. So, why don't we go -- why don't we bump Dr. Wendy first, if Dr. Hess, you don't mind.

COMMITTEE MEMBER HESS: No, that's great.

INTERIM CHAIR DELGADO: Okay, so the order's going to be, then, Dr. Wendy will go first, then Dr. Loretta's project, and then Dr. Justin, thank you for your patience, and we'll hear you third.

Okay, so Dr. Wendy, thank you for joining us. Dr. Hess, I'll hand it over to you to introduce the new project and lead us off.

COMMITTEE MEMBER HESS: Okay. So, we have Dr. Wendy Cozen on the line and I don't know if you have any other project staff with you that you want to introduce.

DR. COZEN: Yes, Mallory Bernstein, Project Coordinator, Research Associate is on the call. Thanks.

COMMITTEE MEMBER HESS: Okay, thank you. So, this just --

DR. COZEN: Sorry about my background, I forgot to change my background.

COMMITTEE MEMBER HESS: It just makes you look like --

DR. COZEN: By the way, I can't see you. I can only -- I can't, you're not visible.

INTERIM CHAIR DELGADO: Apologies. We're in a different room than normal. Normally, we have this super fancy camera that like scans and goes to the person talking. But we're in a different room today, so apologies.

DR. COZEN: Okay, no problem.

COMMITTEE MEMBER HESS: So, this is a problem from UC Irvine called "Is There a Link Between Prostate Cancer and HPV?"

I have submitted some questions to Dr. Cozen in advance and she may have some -- she'll have responses to those, and we can go through them before the rest of the board chimes in.

Dr. Cozen, do you want to give a very brief description of your project to the board?

DR. COZEN: Yes. My husband, when we were at USC for 20 years, I just moved to UCI, had a twin registry and it was based on DMV and birth records of twins. And so, questionnaires were sent out. This was in the 2000's. And 50,000 people sent back a questionnaire.

So, periodically, for different proposals we have linked in CCR to get updated cancer information. And so, in this proposal we're using the original questionnaire and people were asked a bunch of conditions. Do you have this condition? Does your twin have the condition. So, both twins could answer.

And we had identified about 300 twins who said they had prostate cancer in this original questionnaire.

Now, what we want to do is we want to link with CCR to update that and see if anybody's deceased, so we

don't contact them, and see if there are any new cases.

And the purpose of the study, there's some evidence that goes both ways about whether HPV might be a risk factor for prostate cancer and before we go into tissue studies and other studies, I just thought we should determine whether there really is a link. And the very best way to do that is with twins because the twin of a case is the perfect control. They were in the same uterus; they have the same environmental factors.

So, what we plan to do is have a very simple questionnaire. But mostly this is a serology study where somebody will go to the house of both twins, take their blood, and measure HPV antibodies to measure exposure.

If we find out that the twin with prostate cancer has significantly -- there are significantly more of those twins that have positive antibodies to HPV, then we can say maybe there's possibly a link, and then go on to do other studies.

My -- we're proving a new hypothesis. My guess is there won't be. And so, you need the blood from both twins to prove that.

Now, the people who are doing the assay are the best in the world of doing this assay. It only takes a tiny, tiny amount of serum, I think it's 50, wasn't it, micro liters. Right, Mallory. And it's in Germany. It's

in the German Cancer Research Centers. The PI of the lab is Tim Waterboer, and he specializes in HPV. And on that tiny amount of serum, he can measure like 50 different antibodies of HPV. And has many publications.

So, we're -- I have two other studies with him. And we're sending the serum to them. They will do the assay. They don't get any information. It's all, for them, de-identified. Although, we'll ones that they won't. And they send back the antibody information.

So, that's -- it's a pretty simple study. It happens to be a pilot that was approved by our Cancer Center, so it's a Cancer Center pilot study which comes partially from UCI funding for the Cancer Center Core Grant, and partially from, you know, internal UCI Cancer Center money.

So, is that --

COMMITTEE MEMBER HESS: Thank you. That was a really --

DR. COZEN: -- how -- and the questions were good. Thank you for that, they were good questions.

COMMITTEE MEMBER HESS: Yeah, that was a really great introduction to the project. And so, I had a bunch of questions. They are submitted in IRBManager, you'll be able to see them afterwards.

And we can go through them. Some of them we don't

really need to discuss. Some of the bigger issues that I came -- that I saw was that, first, it wasn't clear to me whether you were requesting data from VSAC or that you would be obtaining data deaths from CCR. And --

DR. COZEN: I think we're -- yeah, I'm always confused about that. We're requesting data death and cause of deaths because that that will help if it was prostate cancer.

But we don't want to contact, it's very awkward to contact a twin and their twin dies, we don't -- that causes a lot of problems, so we don't want to do that. So, we want to find out if any of the cases are deceased.

And I think that CCR has that, those data. So, I think what we do is we have to submit an application to VSAC and then, if they approve it, CCR will give us that information. That's what I was thinking.

And by the way, we don't get it directly from California, we get it from USC, they do it for us.

COMMITTEE MEMBER HESS: Okay, so --

DR. COZEN: Because they're --

COMMITTEE MEMBER HESS: No, sorry, I didn't mean to interrupt.

DR. COZEN: It's okay. They're one of the regions; they're the other main region in California besides the database that (indiscernible) --

COMMITTEE MEMBER HESS: I'm sorry. Yeah, so I -- again, I'm just a little confused. You would need to apply directly to VSAC to get death certificate data, which is separate from CCR.

DR. COZEN: Right.

COMMITTEE MEMBER HESS: So, in your application there needs -- in your IRB application there needs to be an application specifically to VSAC, not just to CCR. Because VSAC verifies the death records from CCR, through death certificate data. So, they are separate entities. And we would need applications, basically, from both.

So, the VSAC application would need to be added here.

DR. COZEN: Yeah, I was confused about that, so I'm sorry that we put the wrong application in. Rita (phonetic) called me from CCR and told me that.

COMMITTEE MEMBER HESS: Okay. But she said first we get the CPHS approval because that's needed for the VSAC, and then we do the VSAC. We can upload it after, is that acceptable?

COMMITTEE MEMBER HESS: We need to see that, your application to VSAC. And what happens is VSAC will not release the data until CPHS approves.

INTERIM CHAIR DELGADO: Right. So, we can do -- if we eventually get to it, we can go a contingent -- what's

it called, not a contingent approval.

COMMITTEE MEMBER HESS: A deferred.

INTERIM CHAIR DELGADO: Deferred approval, awaiting you to submit the VSAC application. Once we just see the application, not their decision, we can ultimately push through our approval, which then triggers the domino effect of everybody else to approve.

But we get it, it is like so confusing. It's so confusing. So, don't ever hesitate --

DR. COZEN: I'm sorry.

INTERIM CHAIR DELGADO: No, no, you don't need to apologize, we do. But always feel free to shoot us questions like that. Dr. Hess can help you navigate that, as well.

DR. COZEN: So, you want us to -- what you want us to do is add the VSAC application to the CPHS application.

COMMITTEE MEMBER HESS: Yes.

DR. COZEN: Okay.

COMMITTEE MEMBER HESS: Yes.

DR. COZEN: Will do.

COMMITTEE MEMBER HESS: Yes.

DR. COZEN: I'm getting different messages like CCR said, oh, you don't have to, you can wait until CPHS (indiscernible) --

INTERIM CHAIR DELGADO: I know. We hear about a

lot.

DR. COZEN: But we will do that, thank you.

COMMITTEE MEMBER HESS: That was -- that was actually one of my biggest concerns about the application was it wasn't -- it didn't seem clear whether or not you were going to be obtaining information from VSAC. So, that's a pretty easy fix.

My other concerns were about privacy. So, the recruiting letter that are sent to the twin pairs states that participants may be receiving the letter because their twin had cancer. And I'm wondering if that constitutes a breach of privacy for the cancer-affected twin.

So, you know, is the assumption that the unaffected twin is aware of the cancer diagnosis of their sibling, if they're no longer in contact? I mean, this is --

DR. COZEN: Well, I think that way that we both thought that that raised a really good point. Now, when they did the baseline questionnaire, the way we ask all the questions is did you have cancer, did your twin have cancer. If they said yes, my twin had prostate cancer and they give a data, I think we can be sure that they know about it.

But if they didn't, for example if we do the linkage and we find new cases, and we don't know because we never asked them, then we just decided on the basis of your

comment that we will contact the case first, and then say, could you contact your twin. And, you know, see if your twin will participate.

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: And so, therefore, we won't send a letter unless we're sure that the twin knows on the basis of that original questionnaire. What do you think about that?

COMMITTEE MEMBER HESS: I think that's an absolutely perfect remedy to the issue.

DR. COZEN: Well, thanks for raising that.

COMMITTEE MEMBER HESS: Thank you.

DR. COZEN: We didn't think of that.

COMMITTEE MEMBER HESS: And my other question was about the REDCap survey. So, you'll be sending the twins a survey, a pretty lengthy survey. I don't have any issues with the survey, itself, but except for the fact that it also contains identifiable information like date of birth, sex, twin type, and some other demographic information.

I'm wondering why it's necessary to collect that information on the survey when you already have that data. It just seems like one more like node in the research where there could be privacy issues.

DR. COZEN: Well, usually we do it to make sure there weren't any errors. We check to just double check it's the right person.

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: And especially when there's twins, you can -- I mean, date of birth won't help, it's really just the name.

COMMITTEE MEMBER HESS: Uh-hum.

DR. COZEN: But that's flexible, probably. You know, it depends on how much of a risk it is, I guess. Usually we recollect it again, but we don't have to. We don't have to.

COMMITTEE MEMBER HESS: I mean, if you can just provide some additional justification for collecting that information in the survey and how that information will be stored and protected, that's fine. I just wanted to flag it as a potential kind of spot where things could go.

DR. COZEN: Okay. Okay.

COMMITTEE MEMBER HESS: Where you're collecting more identifiable information.

DR. COZEN: I mean, really, once we make sure it's the right person, we don't need that information, and we can delete it. Is that possible, Mallory, to delete it from the survey?

MS. BERNSTEIN: Yeah. We definitely could do that.

DR. COZEN: Okay.

COMMITTEE MEMBER HESS: Okay, so can you --

DR. COZEN: So, that's another option.

COMMITTEE MEMBER HESS: So, then you would be kind of purging from the survey any identifiable information, with the exception of a unique identifier code, which would be kept separate from their identity, correct.

DR. COZEN: Yeah.

COMMITTEE MEMBER HESS: Okay. That works.

DR. COZEN: Okay, good.

COMMITTEE MEMBER HESS: Yeah. If it's just being used for verification that's fine, you can delete and then -- and then have a more secure dataset.

And those were the main issues. I don't -- you know, I just asked you to elaborate on the recruiting process and add all the staff who will be handling the biospecimens. So, the German, researchers in Germany, just add them as named project personnel.

DR. COZEN: That, we don't know yet because these, you know, staff change. It's probably going to be at least six months before they get the samples. And so, I can give you the director of the lab and his lab manager.

COMMITTEE MEMBER HESS: Yeah, that --

DR. COZEN: I'll ask them, but I don't think they know, yet.

What we were going to do, as we've done before, is we're going to consent them verbally on the phone for the

questionnaire and, of course, it's implicit because they don't have to fill it in, they can just -- if they didn't want to do it, they don't do that. But we'll do that.

And then, when they do the blood, the in-person, written consent for the HPV assay will be done by the phlebotomist. And this company, we do have a co-PI who is an oncologist at UCI, Dr. Rasazday (phonetic), and he uses them for his clinical trials. So, they're very vetted at UCI and they go out and (indiscernible) -- for clinical trials, so they know how to do the consent. I've actually not used them before --

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: -- but all the oncologists use them.

COMMITTEE MEMBER HESS: Are they able to answer questions and concerns on site, if the participant has any questions or concerns, or do they just refer back to project staff.

DR. COZEN: I think -- I think so. And if not, I guess we can be made available, Mallory and I, for a phone call.

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: If anything comes up. But, yes, that's -- we'll have to train them about the study to answer questions.

COMMITTEE MEMBER HESS: Okay, that's fine. If you

could add that into a protocol that it, you know, specifically it's the phlebotomist that will be obtaining consent, that there is a process in place to answer questions --

DR. COZEN: Okay.

COMMITTEE MEMBER HESS: -- from project staff should the participant -- you know, it's the day of the blood draw and they have questions, there should be a way for them to get those questions answered with relative ease.

DR. COZEN: Okay.

COMMITTEE MEMBER HESS: So, just, yeah, making it clear who is actually obtaining consent for the blood draw and then, it's -- it wasn't clear to me, but it sounds now like you're waiving written -- you would like a waiver for written informed consent for the -- for the interview.

DR. COZEN: Yeah. I mean, we don't usually have it because we can put it on the first page of the survey that it's kind of implicit, and it's remote.

COMMITTEE MEMBER HESS: Uh-hum.

DR. COZEN: So, if somebody doesn't want to do it, then they just don't do it. But we're going to get -- we're going to get a waiver of written consent, but we're going to do verbal consent over the phone.

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: For the survey.

COMMITTEE MEMBER HESS: I didn't -- I may have missed it, so this could be on me. But I didn't see like a specific --

DR. COZEN: Well, I just thought -- after your questions, I just decided --

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: -- to add it.

COMMITTEE MEMBER HESS: Okay, that's fine.

DR. COZEN: If that's okay, if you want us to get -- it's not hard to send them an informed consent and have them sign it and send it back for the questionnaire, if you want to do that. I think the blood is better in person because questions might come up and it might not be, you know, they might send the -- do the questionnaire and then the blood might not be collected for a few weeks, and so by that time the consent is not up to date. So, I'd rather get them consented for the blood right when they're getting it.

COMMITTEE MEMBER HESS: I think written consent is preferable for a survey. I do recognize that sometimes that can make recruiting more difficult.

So, my suggestion is to start out asking for written consent and if it -- you know, if it's a huge barrier to recruiting, then you can always come back to us for an amendment and request that waiver of written consent and we can consider that then. If that's --

DR. COZEN: Okay. The only confusing part is they're going to have two consents. And so, we have to make it clear to them that that's just the consent for -- we don't -- in the past, with the twins, we have not done consents for the questionnaire. I think most of the cohorts don't do that because, again, they're already registered in the twin study, you know, and that sort of thing.

COMMITTEE MEMBER HESS: Uh-hum.

DR. COZEN: But we can do that, that's not a big deal. And it's only a matter of who will -- if they'll send it back, you know, because sometimes people don't. But that's no problem, we can do that.

We'd have to go back to our IRB, first, and right. And Mallory, do you have any comments?

MS. BERNSTEIN: I do. Would it be sufficient to add the consent form onto the very first page of the online survey?

DR. COZEN: That's what's usually -- that's what we usually do.

MS. BERNSTEIN: And that way they can sign and see the consent form before they take the survey.

COMMITTEE MEMBER HESS: Yes. Yeah, I think so.

MS. BERNSTEIN: And we can do, we can do that. I'll have that in.

DR. COZEN: But we have to -- we'll go back to our

IRB first, so it might not be immediate. Because we have to write it, they may have comments, and then we'll send it. I guess we upload a new questionnaire on our website for you to include that form.

COMMITTEE MEMBER HESS: Okay. Yes, I mean that works. I don't really want to create any additional undue burden, but I think the middle ground is to do online consent at the time of the survey.

DR. COZEN: It's fine. It's not a problem. I feel like with the twins they're pretty -- they're usually pretty interested in participating because they're twins and they (indiscernible) -- and, you know, it's not a problem at all.

COMMITTEE MEMBER HESS: Okay. That was all I had that was for to be discussed. I did have a couple of other questions for you, but we can talk about those offline. So, I will like open it up to the rest of the board now, if anyone has any additional questions or comments.

COMMITTEE MEMBER VENTURA: I did have a comment about another privacy issue. I was wondering under purpose --

DR. COZEN: You know what, I can't -- I can't hear you very well. If you can --

COMMITTEE MEMBER VENTURA: Okay. I have another question regarding privacy. Is that any better?

DR. COZEN: Yes.

COMMITTEE MEMBER VENTURA: So, under "purpose" you describe the location of the blood draws and say that home or workplace are potential -- you specify home or workplace.

I'm wondering if you can leave the location to the discretion of the individuals, so that as Dr. Hess' point earlier, you know, no one else might know about their cancer diagnosis. And I believe, you know, having it at a workplace, you know, might kind of compromise that.

So, I'm wondering if you can just make it consistent in under your purposes, as well as -- oh, sorry, my screen -- I think throughout your application, and under study procedures, if you can just make that blood draw location -- leave it to the preference of the individual.

DR. COZEN: Yes. That's kind of what I was trying to imply.

COMMITTEE MEMBER BAZZANO: Okay.

DR. COZEN: But I think it would be better to be explicit, thank you.

COMMITTEE MEMBER VENTURA: Okay, got it. Yeah. And then, I just wanted to clarify, just to make sure that the location of the study is USC and the Germany lab. Those are the two --

DR. COZEN: No, UCI.

COMMITTEE MEMBER VENTURA: I'm sorry. I'm sorry,

UCI, excuse me. That was my point.

DR. COZEN: Well, Germany is hard to -- I mean they're doing the assay and, yeah, we're trying to do a collaboration agreement right now for another study. They will only have an ID, they won't know who the case or control is, but they will be doing the assay, so they'll have the antibodies.

COMMITTEE MEMBER VENTURA: No problem.

DR. COZEN: They usually like to keep the antibodies, though, to use for other studies, just for like UC for quality control.

COMMITTEE MEMBER VENTURA: Okay.

DR. COZEN: But they won't be able to -- they don't know who the people are, and they don't know who is a case and who is a control.

COMMITTEE MEMBER VENTURA: Okay.

DR. COZEN: And then, they just send us back the results.

COMMITTEE MEMBER VENTURA: Okay.

DR. COZEN: And we're the ones who analyze it. So, the study's really taking place at UCI.

COMMITTEE MEMBER VENTURA: Okay. My point was on -- I think under password controls you still have USC, so I was confused on where they came into play. So, if you can correct --

DR. COZEN: Where do I have USC at?

COMMITTEE MEMBER VENTURA: Under password controls and kind of the USC servers, and things like that.

DR. COZEN: Oh.

COMMITTEE MEMBER VENTURA: So, if you can correct that to UCI, I just was confused on where USC played into this. And it makes sense, now, that was your previous --

DR. COZEN: Yeah, here's the situation.

COMMITTEE MEMBER VENTURA: Yeah.

DR. COZEN: The twin registry database is still at USC. I'm an adjunct at USC and we have access to all the servers.

COMMITTEE MEMBER VENTURA: Got it.

DR. COZEN: So, what I have to do, what I'm doing is I'm taking the twins -- we're going to have to copy the database and move it to UCI, and then (indiscernible) -- so, sorry, I just -- so, both -- and I think I talked to somebody and they said put both on it because USC will still have -- still have the twin database in their servers. And then, we're also going to have it. So, it's like a multi-ethnic cohort that's in Los Angeles and Hawaii, it's going to have two sites.

COMMITTEE MEMBER HESS: Got it.

COMMITTEE MEMBER VENTURA: Okay.

INTERIM CHAIR DELGADO: Sounds good, thank you.

DR. COZEN: So, they're not going to be involved in this study, per se, they're not going to know -- they're not going to have the updates, but they have the original database. And, in fact, we've got the names -- or the numbers, not the names, the numbers of the twins with prostate cancer from USC. So, how do I handle that?

COMMITTEE MEMBER VENTURA: Thank you.

COMMITTEE MEMBER HESS: Sorry, did you ask how do you handle that or -- I mean, if USC is just providing the data to you, I don't know does that mean --

DR. COZEN: Yeah, they're --

COMMITTEE MEMBER HESS: Oh. Go ahead.

DR. COZEN: Yes. Yeah, well, what we have to do, we can do it one of two ways. We can just link from USC to the CCR, but I think it's better if we copy the database and bring it to UCI and have a copy of the database. Which has to go through IRB and a data use agreement. So, there will be two sites, like there are with some other cohorts.

COMMITTEE MEMBER HESS: Got it.

DR. COZEN: There's going to be two sites that have the database. When we do the study and when we link, we're keeping the linkage and we're not sharing it with anybody else. It's just at UCI.

COMMITTEE MEMBER HESS: Okay. That works because otherwise you would have to have a data security letter from

USC. So, in this instance you do not have to have a data security letter from USC. But if you could provide a copy of the data use agreement in your application, that would be great just for recordkeeping.

DR. COZEN: Okay. We haven't done that yet, so just it might take a little bit. So, we'll get all these new materials to you, but it might take --

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: -- a couple months or something like that.

COMMITTEE MEMBER HESS: That's -- I mean that's fine. Okay, does anyone else have any --

COMMITTEE MEMBER SCHAEUBLE: I hate to be a sexist person, and I probably am when I say this, but this is a project about men with prostate cancer and the survey questions certainly include some sensitive information --

COMMITTEE MEMBER HESS: Uh-hum.

DR. COZEN: It does.

COMMITTEE MEMBER SCHAEUBLE: -- particularly at the end. Is it possible to have a male contact person available for questions, in addition to you?

COMMITTEE MEMBER HESS: Oh, great.

DR. COZEN: That's a good idea. One thing, we have two possibilities. We have our co-PI, Dr. Rasazday, and there's a fellow that's -- I don't know, Ahmed

(phonetic) wasn't named on the grant this time because he didn't get his username and everything from CPHS, but he has it now, so we'll add him. And he's a Fellow. So, those are two people.

But we were thinking that we were going to originally, we were going to hire a person to do the recruiting and answer questions, and we can -- we don't have that person, yet, but we can make sure that person is male. I think that's a good idea.

We do have, and we'll put this in the consent, and it's in the questionnaire, that any questions that are uncomfortable they can just skip.

COMMITTEE MEMBER HESS: Okay.

DR. COZEN: It's important because --

COMMITTEE MEMBER HESS: Yeah.

DR. COZEN: -- when HPV was first discovered to be linked to cervical, anal and other cancers, that I was -- I'm old enough that I still remember. And it was on the basis of epidemiology, you know, and the number of sexual partners, and that sort thing. So, those questions are important for trying to establish this link.

COMMITTEE MEMBER HESS: Got it.

DR. COZEN: And that's why we're asking those questions. But we're definitely going to say you can skip them.

COMMITTEE MEMBER HESS: Understood, thank you.

INTERIM CHAIR DELGADO: Thanks. Do we have a motion, Dr. Hess?

COMMITTEE MEMBER HESS: Yeah, if no one else has any comments, I have a motion.

INTERIM CHAIR DELGADO: Go for it.

COMMITTEE MEMBER HESS: Okay, so I motion for deferred approval, minimal risk, pending the following conditions.

The first is that in the IRB protocol you address in writing, wherever possible, the seven questions that I sent over email. And those will all be in IRBManager.

DR. COZEN: Uh-hum.

COMMITTEE MEMBER HESS: And that includes a VSAC application.

That you will amend the protocol to reflect that you will be contacting the twin with cancer first.

And that the location of the blood draw will be left to the discretion of the participants.

DR. COZEN: Okay.

COMMITTEE MEMBER HESS: That you'll submit a copy of the data use agreement between UCI and USC.

And that the contact person -- there will be, in some capacity, a male contact person for consent. Whether that's the recruiter or another male member of the study

staff.

DR. COZEN: Okay.

COMMITTEE MEMBER HESS: There will be -- there will be a male available.

DR. COZEN: Can --

COMMITTEE MEMBER HESS: Yeah.

DR. COZEN: Okay. My question, and we're going to add an informed consent on the first page of the survey.

COMMITTEE MEMBER HESS: Yes. Yes, thank you.

DR. COZEN: My question is about contacting the twins first. I was only going to do that if the -- if the other twin didn't know.

COMMITTEE MEMBER HESS: Correct.

DR. COZEN: So, in the original baseline, that's in there --

COMMITTEE MEMBER HESS: Correct.

DR. COZEN: -- if they say yes, the twin has to -- okay.

COMMITTEE MEMBER HESS: Yeah. Yeah, only if there's an unawareness of one twin. And if you could make that clear in the protocol, that would be great.

So, did --

MR. ZADROZNA: Agnieszka has her hand raised.

COMMITTEE MEMBER HESS: I'm sorry, I just raged through that. So, I need to make sure our note taker got

everything.

DR. RYKACZEWSKA: I think I missed the -- I missed the piece on USC, I'm sorry.

COMMITTEE MEMBER HESS: That they provide a copy of the data use agreement between UCI and USC for the twin registry data.

DR. COZEN: Thank you.

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

COMMITTEE MEMBER VENTURA: I second.

INTERIM CHAIR DELGADO: Dr. Ventura seconds.

Sussan, could we have roll call, please.

MS. ATIFEH: Yes. Sure. Okay, Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

DR. COZEN: Thank you. Oh, sorry.

INTERIM CHAIR DELGADO: We're just -- we're just voting. Just give us one more second.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Abstaining.

MS. ATIFEH: Dr. Palacio?

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

INTERIM CHAIR DELGADO: Okay. Your motion -- your deferred approval motion has passed. Dr. Wendy, thank you again for your patience. You will get a letter from us in the next week or two that describes all of these things that we discussed today. And we look forward to getting you a final approval letter. Thanks for your work in this space.

DR. COZEN: Thank you very much and thanks to the other PIs for letting us go first. I have a commitment. So, thank you very much.

INTERIM CHAIR DELGADO: Yes. Awesome.

DR. COZEN: Thanks everybody.

INTERIM CHAIR DELGADO: Thanks.

Okay, Laura, I'm going to hand it to you for your amendment on project 2022-004.

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

So, who is here representing this project?

MS. SHORES: Ms. Lund, it will be me and let me identify myself. I am Danielle Shores and Aamna is also on the line. We're both CRAs for Clinical Research Associates, for Dr. Erhunmwunsee.

COMMITTEE MEMBER LUND: Great, thank you. So, if you would -- what I'm going to have you do is introduce yourselves, give us a brief summary of -- this is an amendment.

So, for the board, you've heard this project in the past. We have approved this project in the past. This amendment, the reason that it's coming to the board today is the researchers have asked for some significant changes to the consenting process. It's very -- what they're proposing is very different than what was originally approved. So, we're really here for the board to consider the human subjects' aspects of this amendment.

So, what I'm -- what I'd like to ask you, Dr. Shores, to do, is introduce yourself and your team, give us a brief summary of the changes that you're requesting via the amendment. And perhaps how it's different than what was previously approved.

Then I have a few questions for you and then, I'll open it up to the full board. So, if you would proceed, please.

MS. SHORES: And would it be all right if I give a

short presentation to kind of clarify some aspects?

COMMITTEE MEMBER LUND: Sure.

MS. SHORES: Awesome, I'll pull that up. So, my name's Danielle Shores. I work at City of Hope for Dr. Erhunmwunsee, who wishes she could be here today, as well. But we do want to extend a big thank you to CPHS for approving our prior study, and for allowing us to get to the place where we are today with it.

And, yeah, I do want to note we were recently approved for an NIH grant, R37, and this study actually served as a pilot study. So, I'll go ahead and go over the presentation here. All right.

All right, so, yeah, we recently were approved for that grant. And we are basically -- sorry about that. I'm hoping (indiscernible) -- all right, there we go.

So, yes, so we (indiscernible) -- to expand the study for the purpose of that grant. And like I said, the previously-approved CPHS study is the pilot for that grant. So, with those expansions with are also trying to improve our design process as well, which I'll go right into.

Our project is the study, The Impact of Racism-Related Socio-Environmental Factors on African American Non-Small Cell Lung Cancer Mutational Signatures.

So, what this means is that we are investigating the impact of structural racism on very specific lung cancer

mutations in African American and black patients.

So, we do this by a multi-pronged approach. We have our first current study, which is our first study activity, which is a survey that addresses socio-demographic factors (indiscernible), as well as environmental factors, and discrimination risk.

And the way -- the second part, the second study activity is evaluating -- sorry -- is evaluating previously dissected longitudinal samples to see what those mutations are and to (indiscernible) -- sequencing on those. And then, going back and connecting it to the survey to evaluate what factors might cause an increased rate in lung cancer in black and African American populations.

Because as we've seen in previous literature, unfortunately, this group is very marginalized and has not been actively represented. And we've found that African American and black individuals have a higher rate of lung cancer, despite smoking less. So, there would have to be another factor that goes into this, and we believe that structural racism is one of those.

So, we want to know how factors, such as structural racism, differently impact genes in African American and black individuals, and kind of compare those to those of non-Hispanic white lung cancer patients.

So, yes, thank you for previously approving this

study. And we were very grateful to be able to get the NIH grant and expand our findings, expand our impact on this population.

Our original approval was 60 individuals for the African Americans and 20 non-Hispanic whites.

Next, a summary of the changes. We'll be expanding the (indiscernible) through R37. With that (indiscernible) an additional recruitment site in order to get to higher numbers.

And we're proposing amending our consent process to be a one-part consent and having an option for individuals to independently completing that consent form. And I'll go into the reasons why.

So, I think that (indiscernible) -- marginalized population and they have not been accurately represented across studies. We're trying to bridge this gap in bringing out literature that focuses on disparities and different factors that might make African American and black patients more predisposed to lung cancer, and also (indiscernible) --

So, with this, we know that this group has a significantly different experience in the research in this space due to this lack of inclusion. So, we're trying to adapt nontraditional methods that might be more inclusive for marginalized participants.

So, with this we've found, where we have the study

site that had successfully included and enrolled African American and black participants through a very specific consent process. So, we're using that study as a guide, and also patient feedback.

So, this site is Emory University. They're actually a part -- well, they're located in Georgia, and they're actually a part of our study. And they did this study called RESPOND, which was working with the same populations, also in the pool of tumor markers and different environmental factors on prostate cancer, right.

Our focus is on lung cancer. However, the design follows a very -- or it follows a very similar design to this study.

RESPOND had an increased response rate in the number of patients who completed the study at 50 percent of respondents completing the study.

So, our project currently has a 20 percent completion rate. This is significantly lower and so, we've looked at the reasons why we've had this lower response rate.

And this slide was in the consent form. So, we're using this study as a guide, like I said, and are proposing to adopt a similar recruitment strategy as RESPOND.

MS. AKHTAR: Sorry, I just wanted to add really quickly, and I think Danielle is going to say it here, as

well, but the R37 was granted to us originally to work in California. So, we're already doing it in the -- in the pilot study, in Southern California. But now, you know, we're hoping to be expanding to Northern California. And then, we were approved to do this work in both Georgia and Detroit. And at Detroit, it's (indiscernible) University who we're partnering with. And they were also part of the RESPOND Study and the study that Danielle was referring to. So, they're one of our partners for the R37 who previously participated in the RESPOND Study.

MS. SHORES: (Indiscernible) -- and, so, why we added the site. So, yeah, we're adding the RPHI site to a Public Health Institute to allow us to get to that increased number of 100 participants. And current we have those four sites, one in Georgia, a retrospective cohort in Detroit, and then the two in California, which would be us, and Public Health Institute.

So, changing or adding (indiscernible) -- by Public Health Institute, Health and Cancer Registry of Greater California. And we've added them or are proposing to add them to refer (indiscernible). They would be -- and in our currently approved CPHS study we're having LACR deliver LA participant contact information to us. We enroll patients in the study. We then send consent form and that's when we (indiscernible) to retrieve Southern California

tumor samples.

So, PHI would be doing a (indiscernible) with us, with the Northern California cohort. So, we're proposing to add them to deliver us participant information, contact information for eligible patients. We're going to enroll them in the study, send them a consent form and then (indiscernible) -- and then PHI would send us the tumor.

So, this follows the same process as LACR, as which has been currently approved.

And another change, so another change today would be a one-part consent process. Currently, we're doing a survey information sheet for the survey. When we call patients (indiscernible) -- send the information sheet and complete the survey with them. And another signed informed consent form for the tumor tissue and medical records requests.

So, between doing part one, which is the survey consent, and part two, which is the tumor tissue and medical record request consent, we've lost about 40 participants who did not complete part two.

And the feedback that we've gotten from patients, when we ask them why they're not going to continue the study is that they find that these two touch points are very extensive and very long. And we're worried about this undue burden on our already marginalized population.

So, we're proposing to amend by following the RESPOND model, where they offered a one-part consent. This was where tumor -- the survey, sorry, and the tumor and medical requests were under one phone consent form. Participants were able to sign that, be eligible to participate in the study, and then they were sent the gift card that was promised, and all study activities, study materials.

So, we would -- if approved, we would send one $75 gift card to participants after receiving all these forms and participating in the study. And this is covering the original cost, which we were sending one $25 gift card for a survey completion and one $50 gift card for completion of the medical release form.

MS. AKHTAR: Sorry, I just wanted to add, it was actually before, in the currently approved it was one $25 gift card for completing the survey and then a $25 gift card for completing the medical release form. And both from patient feedback and from the literature we found that, you know, $25 is not sufficient for the completion of the MRF, and so that's why we upped it to $50, totally to $75 for completion.

MS. SHORES: And, finally, our last change is to have the option, just an option for patients to independently complete the consent form. Our originally

process completing these forms was remotely consenting the participant and the study representative. And we received in patient comments, letting us know that, hey, I don't have time to complete this, two different consent forms for the study. Can I do this on my own time, where I understand the study information presented, and that's how it's been.

So, we have had participants also not continue participating in the study for this reason, after discovering that they have to do another consent form over the phone.

So, we want to note that this has been done in the past, where patients in the past have had the option for independently completely the consent as part of the RESPOND Study. So, that part of our study as the RESPOND, to have this independent consent form completion and we believe that is what led to their high accrual rate of 1,000 African American and black participants.

So, with this, we recognize that individuals might need, or do need a guide, and so we've included an informed consent video that guides patients through all aspects of the informed consent form, as well as a cover letter included for that. And this would be in the introductory packets that participants receive about being introduced to the study via mail.

They have options all throughout the packet to

contact the staff if they wish to undergo remote consenting. And they are actually encouraged to do so.

And if patients have not responded to the introductory packet, we will call them and follow up as needed. As we do know, want to emphasize that we are not revoking the option of study staff completing the informed consent with patients. We just want to have this option available for those patients who want to do the consent form on their own time and may not have questions.

And that's the end of my presentation. Aamna, do you have anything to add on it?

MS. AKHTAR: No, I don't.

MS. SHORES: All right. Thank you.

COMMITTEE MEMBER LUND: Great. Thank you so much for that. That was a really helpful and thorough presentation. I have a few follow-up questions that I'd like to ask you to address.

So, I'm going to talk first about the consent process. So, one of the things that's really different from your original protocol is that there will be only one consent, as opposed to two consents.

And that you are requesting to allow people to self-administer this consent as an option. So, they wouldn't actually interact with study staff.

Now, I have a couple of concerns. My first

concern is that the consent form is pretty long. It runs to 10 or 11 pages, and it's at a fairly high grade level. When I ran it through the word checker, I got a 12th grade reading level. And especially considering the sensitive nature of the study, and the data being collected, and the tumor samples being used I'm wondering if it would be -- I am concerned that there are going to be individuals who are going to look at that consent form, go to page 11, sign, and not really understand, even if they read through it, because of the reading level.

So, could you comment on that? That's -- one of my main concerns was to request for self-administration without any, you know, staff going over the form with them is that this packet you're sending them is very thick. There's a lot of stuff for them to read through. They read through, you know, Dr. Loretta's introductory letter. They read through a second introductory letter that's attached to the questionnaire. They have to read through this and, actually, it's 14 pages when you include the HIPAA authorization, the consent, and then there's the survey itself. That's an awful lot for the average person to do on their own.

So, if you could comment, please.

MS. SHORES: Yeah. Absolutely, yes. We have -- I noticed the comments about that. And when trying to address

this, we do know a lot of our language is coming from an IRB template that we use for the City of Hope. And going in and addressing it, we tried to make it a little bit more digestible.

However, the length is a little bit of a hard thing to mitigate since all of that information is essential for the participant to hear, or to know, sorry.

But absolutely, you know --

MS. AKHTAR: I also wanted to add where I totally hear you that, you know, it's long. I mean I think from even, you know, the perspective of like researchers who really do try to keep that minimal. But, you know, there is like IRB on the other end who's like, you know, this information needs to be included.

And I feel that we have gotten the opposite feedback from patients where they're kind of like, you know, like you're telling us everything about the study over the phone, that's good enough, I don't need to then go through this entire like packet, and a survey with you over the phone, when I have the capacity to kind of do it on my own. That's actually the feedback that we've gotten from the patients is that like going through it with us over the phone actually makes it longer for them and makes the process, you know -- like we've had patients who go through the survey with us and the verbal consent process for the

part one. And then, when they find out that they're probably going to have to do something similar, if not a little bit longer for part two, they're just like I don't have the capacity to do this with you over the phone. Can I just do it on my own.

And we have to be like, no, you know, like this is what's required, we have to go through it with you, and they don't want to continue.

That's why we're giving the option, right, for these patients who want to do it on their own, that they can, right. We're not revoking at all the aspect of us even like calling the patient. I just want to make not that's still a part of our recruitment strategy is that after we're mailing this to the patient, we're still calling them and being like, hey, did you get the information in the mail? I just wanted to quickly go over it with you and see if you have any questions, you have the option of completing it on your own or I can walk you through it. Whatever they're comfortable with.

And, you know, there are patients, again it's just an option, it's supposed to be like supplemental and provide patients with that -- with that option of doing the consent on their own, if they feel comfortable.

COMMITTEE MEMBER LUND: So, let me just follow up on that because I think you said something that's a little

different than what I read in your amendment.

You will be calling each of these people, who've received the packet, to talk to them about the study?

MS. AKHTAR: Yes.

COMMITTEE MEMBER LUND: So, that's not in your -- that's not in your protocol.

MS. AKHTAR: So, if we're sending the introductory packet and in two weeks, we don't hear anything from that patient, that patient gets a phone call.

Now, if they respond to the packet, as in like they send us something back in the mail, and it takes about two weeks to get back to us, at that point we're not in contact with the patient because they've -- you know, they've completed the forms, indicating that they're okay with this.

And I don't know if all of the documents were attached to the amendment, but even if our cover letter, you know, at every point it's like, hey, if this is confusing, here is our contact information. Give us a call and we will clarify it with you, so adding that.

But, yeah, if a patient doesn't reply to our introductory packet, they're most definitely getting a call from us.

COMMITTEE MEMBER LUND: Okay. But there will be people who will have to wade through all of these materials

on their own, or to choose to do so, and then send them back to you.

MS. AKHTAR: Yeah.

COMMITTEE MEMBER LUND: So, I understand your point when there were two consent processes, that when they found out there was a second consent they're sort of like, no way, this is just too much.

I'm not sure that that applies when there's just one consent because, you know, it's one and done. And you go over it with them and then they don't have to do a second consent process. Where a staff member would actually interact with them to make sure that they understand the consent.

That's my main concern here, it's written at a high level, people may not call you if they have questions. They might just go, oh, whatever, and sign. And if -- I think it does a disservice to the participant to not have a staff person walk them through such a long and complicated consent form.

And this is open for the Committee's discussion. After we go over some of my other questions, I'll open it up and the Committee can discuss.

So, my second question was one of the things in your materials was an option for DocuSign. So, when that happens, that only happens if they call you and say, can I

do this electronically, and then you give them some kind of a QR code, or a link, and they can log in and see the same consent form, and sign both the consent and the HIPAA authorization via DocuSign.

Okay. And will you be -- I think I read it in your materials, but I just wanted to make sure I understood. So, in addition to the mailed materials, if they choose to do the questionnaire either online or over the phone, they'll have the opportunity to do that, they can call you and say can I just give you this instead of having to fill it out all the way.

MS. SHORES: Absolutely. Yes, and that's what we're doing currently, too.

MS. AKHTAR: And I just wanted to add where both those -- those things are written in the introductory packet. So, on like the letter, so it says like, you know, if you wish to do this electronically, give us a call. If you wish to completely the survey over the phone or electronically, give us a call.

COMMITTEE MEMBER LUND: Okay. So, one of the things I don't think I saw clearly, and this may just be me, they'll return -- if they return the written survey, they will return the physical, signed, informed consent and the HIPAA authorization, and they'll have those three things together.

If they do the survey over the phone, how will you obtain informed consent prior to doing the survey?

MS. AKHTAR: Yeah, so -- and this is how it stands right now. So, if the patient calls up, they're like, oh, I want to do the survey, we would want to first check if we have their informed consent with us on file. And if we don't, we'll let them know that, hey, did you get a chance to complete this? And if they say, like, oh, I've completed it, like it will come to you in the mail, we tell the patient that we need to see that you've completed the informed consent in order to do the survey. So, we schedule a time to call them back.

Or, if they haven't completed the informed consent form at that time, then we tell them that, you know, we have to complete this with you or you can do it independently, in order for you to do the survey.

COMMITTEE MEMBER LUND: Okay, great. If you could just clarify that in your (indiscernible) -- because that was super clear that that was your plan. Thank you.

MS. AKHTAR: Yeah.

COMMITTEE MEMBER LUND: And then, I wasn't sure what you were asking for. You talked about retaining the address information after the end of the survey for in perpetuity. Can you tell me why that is?

MS. AKHTAR: So, the address history that we are

using to conduct the geospatial assessment, which is going to, hopefully, see what factors are associated with different tumor markers. This study could be extended -- well, actually, it could -- we could use this data in the future for secondary findings. So, that's the only reason why we keep it, and I believe that's in the HIPAA authorization, and then also in the -- in the consent form that we're keeping their information.

But I did want to note -- I did want to note that that information, it's stored with us, like the study staff. But when we -- even to like our biostatisticians, or other folks, it's always de-identified as the actual (indiscernible) -- census block. So, it's given like a value. But the addresses are not shared or given that way to any of our staff.

COMMITTEE MEMBER LUND: Good. Great, thank you.

And the final thing that I wanted to ask about -- well, there's two things. First, I want to note that the original version of your amendment talked about website outreach. And I believe that you've taken that out. So, that if you are going to choose to do that, you'll submit an amendment.

So, we're -- the version of the amendment that we're considering doesn't include website outreach, it's just the changes to the consent, and the increase in sample

size, and that kind of thing.

I wanted to talk about the role of PHI. So, in California PHI is basically CCR, they do the work for CCR. So, the way that California works for cancer registries, and the way we have the state CCR, and all of the satellite registries are under the auspices of CCR.

So, even though you're doing two different cancer regions, you're actually doing all CCR data. So, you don't need -- if all PHI is doing for your study is providing you with the data that CCR would provide, then you just need to include them under as a research partner.

And it's kind of unusual, your request was very unusual because people don't usually -- PHI does some research, but in regard to the cancer registry they're really just the operators of the cancer registry.

If they are, in fact, a research partner for your study, you need to specifically identify the staff who are going to be working with this data, that are associated with this study. And I didn't see that anywhere in your amendment. You talked about adding PHI as a research partner, but you didn't -- I couldn't see that you identified any staff. And we would need a data security letter from them.

My recommendation would be that you check with them. Because usually what happens in California is that

you apply to CCR for your study. And I didn't see that you had a new letter of work, so I'm assuming that CCR has seen the changes that you've proposed to make, and they've approved adding the second registry site as part of your study.

So, and then CCR, the big CCR, tells the sites that they can release the data to you. So, that's where PHI would come in and they're actually the operators.

So, I would clarify with them. If that's they're only role in this study, then you could modify the protocol to take them out as a research partner because it just makes it more complicated for you if they're listed that way.

And if they are, in fact, a research partner, then we will need a data security letter and the names of the PHI staff that are associated.

MS. AKHTAR: Got it. The only thing that I was going to ask for is that they have these separate tumor repositories. So, for all of our Southern California, like L.A. cohort, the repository -- the tumor repository is through USC. So, like they have their own separate system. And then, PHI has their own tumor repository.

So, the tumors will be coming from two different places. I think that's why we had listed them that way.

Danielle, correct me if I'm wrong.

But if you feel that, you know, we should just

maybe keep it uniform and like remove them and -- or, if we can talk to their staff and see if they want -- if they're okay being listed this way at --

COMMITTEE MEMBER LUND: No, I think that's fine. I think everything I read was that all of the work that you're asking them to do is under the auspices of CCR.

MS. AKHTAR: Okay.

COMMITTEE MEMBER LUND: Including the tumor repository information. So, in my opinion, having read through it, they're not really your research partner, they're acting as a CCR contractor. So, it's up to you, if you do choose to keep them as your research partner, but it makes it simpler for you if they're just a data provider.

MS. AKHTAR: Okay, sounds good. We'll talk to them about that, and we'll update it in the portal.

COMMITTEE MEMBER LUND: Okay, great. Thank you.

So, with that, I'd like to open it up to the Committee. And I'd especially like input on this notion of doing a self-administered consent.

COMMITTEE MEMBER VENTURA: I did -- this is Maria. I agree, I think the consent form for me was confusing, reading through it. And I think all study material, including the cover letter should all be simplified and made to be at the eighth grade reading level. Especially if we are considering the self-administered consent form process,

all of the material I think needs to be simplified. So, just wanted to make that comment. I don't know if I have a suggestion for this self-administered consent.

MS. SHORES: May I ask a quick follow up regarding that communication?

COMMITTEE MEMBER VENTURA: Uh-hum. Yes.

MS. SHORES: Okay. I was just wondering, for the cover -- or the introductory letter, the one with Dr. Erhunmwunsee on there, I know there was a lot of effort put into simplifying that language. Is that still something -- was that something that's still of concern when you were looking through the packet, that also the introductory letter was (indiscernible) -- should it also be simplified?

COMMITTEE MEMBER VENTURA: I believe so. The cover letter that I read, and I don't know if that -- I hope that's the most updated version. But it was still registering at 12th grade level. And so, I think there still needs to be further simplification of the language.

MS. SHORES: Okay, thank you.

MS. AKHTAR: So, would the Committee like to see maybe like our updated cover letter and consent form to, you know, maybe like an eighth-grade level in order for it to be considered for independent consenting?

INTERIM CHAIR DELGADO: Laura, do you think that --

COMMITTEE MEMBER LUND: I, personally, would be more comfortable with that. But I'd like to hear from other Committee members. I think that eighth grade, that's sort a general population can read and understand the materials. If you guys can do that, I would be personally much more comfortable with it.

INTERIM CHAIR DELGADO: Go ahead, Dr. Schaeuble.

MS. SHORES: Yeah, I agree with that.

INTERIM CHAIR DELGADO: Got it, thanks. We've got another question in the room.

COMMITTEE MEMBER SCHAEUBLE: Laura, this project raises some concerns that I've experienced with some other protocols in the past. Let me sort of run through them.

Sending genetic data to an NIH database, I saw this mentioned only under a HIPAA waiver and not elsewhere in the protocol. Didn't see anything about the risks of doing that being discussed in the protocol.

The consent form also says tissue samples may be made available to other researchers through a Biobank. And it seems to me it's one thing for people to agree to participate in the research, but it's quite another to agree for information to be shared in those particular ways with other entities.

And I would think there ought to be a separate permission asked within the consent form for that kind of

data sharing. I mean, ideally, I would say that people ought to have an option of agreeing or refusing. But even if the researchers consider it to be mandatory, I think they should asked separately to affirm that they agree to the data sharing in addition to affirming that they agree to be in the project.

Going a bit farther on that, I'm looking at everything I'm seeing here in the study, which includes survey data, geolocation from 20 years of addresses, medical records, DNA extracted from tissue samples, with genome sequencing and genetic ancestry. It's not at all clear to me, from reading the consent form, whether every single piece of information that is ever obtained about these individuals is potentially to be shared in the ways the researchers talk about, or only certain portions of the information.

I don't think the consent form is at all clear on the extent of the data that might possibly be shared with others in some way. And I think that needs to be addressed, too.

COMMITTEE MEMBER LUND: Thank you, Dr. Schaeuble. Anything else?

COMMITTEE MEMBER SCHAEUBLE: No, that's -- that's really it.

MS. AKHTAR: As far as the secondary use or, you

know, the biobanking, we can definitely talk to our IRB for giving patients the option of either opting into that or opting out whether they are okay with us biobanking their specimen.

I think we have an option with like a question like that for the incidental findings. So, I'm sure that the IRB will accommodate that, and we can definitely add that there.

And then, as far as the risk for genetic data sharing with NIH, and everything, we can definitely add that to the protocol. I think we actually missed that. I apologize, but it is in our larger grant and also in our protocol at City of Hope. So, we can definitely add that there.

And then, as far as the data sharing of the patients' goes, I think I mentioned this about we're (indiscernible) spatial data, as well. But we don't plan to share it. We don't plan to share any type of identifiable data in the future. And even for this study, that's -- that identifiable dataset is very limited in terms of who can access it. But we can definitely clarify in the consent form with what the sharing would look like, if it were to happen for the -- in the future. And maybe even would specify that it will be de-identified and typically cannot be like traced back to the patient without the identifiable

codes.

COMMITTEE MEMBER LUND: Dr. Schaeuble, does that address your question, your concern?

COMMITTEE MEMBER SCHAEUBLE: Mostly, yes. I think the most important part as far as the information in the consent is to be very clear about what information might be shared. I mean it's nice to reassure people that you expect it to be de-identified and protected in that way, but I think the people need to know what information of theirs is potentially at risk, however it is protected or not protected within the procedures of the research.

MS. AKHTAR: Absolutely. I completely understand and I agree, as well, that we can make that more clear in terms of what data of theirs is at risk, as well as the way that it will be shared, and what will be shared if, in the future.

COMMITTEE MEMBER LUND: Anyone else? Any other comments?

INTERIM CHAIR DELGADO: None in the room, Laura.

COMMITTEE MEMBER LUND: None in the room. Okay, great. I don't see anybody on the call.

So, I think we're ready for a motion. I move deferred approval, minimal risk -- I don't think I have to say a time period because it's an amendment, so it's linked to whatever the time the protocol was approved for. With

the following stipulations.

The reading level for all of the material that the participants will receive, including the introductory letter, the cover letter, and the consent form, and HIPAA authorization will be modified to achieve an eighth grade reading level as closely as possible. I think that that would help considerably.

The consent form will separately list biobanking the tissue, as a thing that's going to happen, an option. And there will be -- the researchers will confirm with the other IRB that there can be an opt-in or opt-out option for that, for people.

The consent form will more clearly describe what information about the participants will be shared.

The role of PHI in this study will be clarified either to include more information about them as a research partner or to remove them completely as a research partner.

And the risk associated with the sharing of genetic materials, information on genetic materials will be included in the consent form.

I think that captured what you said, Dr. Schaeuble.

Those are the only stipulations that I had. Did I get everything?

COMMITTEE MEMBER SCHAEUBLE: Sounds good to me.

INTERIM CHAIR DELGADO: Very, very thorough. Thank you for the motion.

Do we have a second?

DR. RYKACZEWSKA: I just want to also make sure that we actually captured all of it.

INTERIM CHAIR DELGADO: And, Laura, if you see anything on the screen that we missed, let us know.

COMMITTEE MEMBER LUND: Let me take just a second. Yeah, I think that's everything.

DR. RYKACZEWSKA: Okay, great.

MS. AKHTAR: Sorry, I just wanted to a thing. For number five, it was in the consent form and in the protocol, so probably somewhere in the application.

COMMITTEE MEMBER LUND: Okay, yeah, in the consent form -- yeah, in the protocol. Great, thank you. Thank you for that.

INTERIM CHAIR DELGADO: Okay, do we have a second?

COMMITTEE MEMBER HESS: I second.

COMMITTEE MEMBER RUIZ: Second.

INTERIM CHAIR DELGADO: Thank you.

And Sussan, if we could have a roll call.

MS. ATIFEH: Okay, who seconded?

INTERIM CHAIR DELGADO: Doctor -- we'll say Dr. Ruiz seconded.

MS. ATIFEH: Dr. Ruiz, okay.

Okay, Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Oh, good.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Mr. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

MR. ZADROZNA: He nodded.

MS. ATIFEH: Oh, okay, good.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

INTERIM CHAIR DELGADO: And Dr. Dickey.

MS. ATIFEH: Dr. Dickey?

COMMITTEE MEMBER SCHAEUBLE: He left.

INTERIM CHAIR DELGADO: No, he's on the phone.

MR. ZADROZNA: Dr. Dickey, you're on mute.

INTERIM CHAIR DELGADO: Can you unmute him from your end?

DR. RYKACZEWSKA: I'm trying.

MR. ZADROZNA: I can only ask.

DR. RYKACZEWSKA: We can only ask on here.

INTERIM CHAIR DELGADO: Dr. Dickey, if you can hear us, you might have to press --

VICE CHAIR DICKEY: This is Dr. Dickey. I approve.

INTERIM CHAIR DELGADO: Thank you.

MS. ATIFEH: Okay, thank you.

Yeah, the motion passed.

INTERIM CHAIR DELGADO: And the motion passes. Great.

Thank you so much, Laura, for your review, and Danielle and Aamna for meeting with us today. You'll receive a letter with all these details in about a week. And please reach out to Ms. Lund should you have any follow-up questions or concerns.

MS. AKHTAR: Awesome. Thank you so much, everyone for your time. We appreciate it so much, thank you.

COMMITTEE MEMBER LUND: Thanks for your patience in waiting. You've been on for a long time.

MS. AKHTAR: It's all good. Thanks so much, everyone. Have a nice day.

INTERIM CHAIR DELGADO: Thanks. And the same shout out to Dr. Justin Harty, for whom we will now move to

your project.

Also, just noting for Bagley-Keene purposes, Dr. Dickey is now on the phone. He had a medical appointment, which under the new rules of Bagley-Keene he can call in and still be counted as a quorum. So, we can continue with the last project review.

Okay, so Carrie, if we can pass it to you and introduce the project.

COMMITTEE MEMBER KURTURAL: Sure.

INTERIM CHAIR DELGADO: And Dr. Harty, are you still with us?

DR. HARTY: I still am, yes.

INTERIM CHAIR DELGADO: Amazing. Really appreciate your patience and willingness to move in the schedule.

Go ahead, Carrie.

COMMITTEE MEMBER KURTURAL: All right.

DR. HARTY: All good.

COMMITTEE MEMBER KURTURAL: So, this is a new project. And thank you for joining us, Dr. Harty. It's on Expectant and Parenting Youth in Foster Care.

It does involve, if anyone is questioning, adults, over the age of 18, not minors.

So, Dr. Harty, if you can kind of give an overview of the project, and also if you could touch a little bit on

the recruitment process so we have clarity there, that would be great.

DR. HARTY: Sure. And I am (indiscernible) -- so, if there's anything else you want to know about the study that you want me to share, just let me know.

So, this is part of a larger study on Expectant and Parenting on (indiscernible) dependents in California Foster Care. So, these are parenting and youth between the ages of 18 to 21.

It's a qualitative study. I did a quantitative analysis using the Cal Youth data, which is part of a (indiscernible) from this study. This is a qualitative component of it.

And so, what I'm asking youth, parenting youth in care to do is to participate in interviews and/or focus group interviews through a recruitment process.

And the recruitment process, I'm not directly recruiting through CDSS. These youth already have a number of people in their lives, in the system, that they have to interact with. I don't want to add another one.

I should disclose that I was in the Child Welfare System and got frequent calls about studies and it did not make me feel good. And so, I want to avoid that by recruiting directly through workers. Also, I also interact with a number of foster care advocacy groups that do -- they

collaborate with youth in care. And also, youth advisory boards that are led by youth that are in care.

So, my recruitment would be through that. So, I'm not requesting any information from CDSS. I have relationships through CDSS and CWDA through the work I've done on the Cal Youth Study. I'll be going through them directly and asking them to distribute recruitment materials directly to any that they've identified on their caseload.

And for me, it's also that's a more practical approach than using CDSS data because oftentimes expectant parents aren't yet flagged in the system, their worker wouldn't know or be aware of that.

Also, young fathers in care, sometimes they're reluctant to report they're fathers. And so, CDSS data is not also a great source of information on young males that are parenting.

I think that's an overview. Please let me know if you have any other questions.

COMMITTEE MEMBER KURTURAL: Thank you for that, Dr. Harty. And you are clarifying, already, a question I had with whether you were seeking data to doing opt-in/opt-out. Great, you're not.

So, what I'm hearing is that you're going to have recruitment flyers and you're going to recruit from the county system. And then, you're hoping to get participants

for your project to come direct to you. Right?

DR. HARTY: Yes. And so, I used a similar approach for my dissertation study, and it is a little more work, it does take more time. But again, you know, these youth have been through a lot and a lot of people float in and out of their lives. And the last thing I want is having some random person contact them. So, I figure they already have relationships with people, I would like the recruitment to be through them.

COMMITTEE MEMBER KURTURAL: Thank you. The last kind of -- and I saw that you updated the recruitment letter. One of the things with these interviews is I was reading the questions and the interviews, and they were very open ended, which would allow any participant in focus groups, or interviews to kind of be prompted to obviously explain their personal circumstances of what it's like to be an expectant parent.

And I understand, you know, the logic there and you want a broad brush of whatever information you can get out of this focus group to move along the research project.

So, I saw that you did update, and thank you for responding to that, the recruitment flyer to add the risk of it's possible that, you know, when you're in these interviews or focus groups that others could obtain your personal information. And we can't control other people in

the focus groups. I appreciate that.

I think the one part that's missing for me is the informed consent. So, I'm a little confused about the informed consent. I see that you want it to be electronic.

DR. HARTY: Uh-hum.

COMMITTEE MEMBER KURTURAL: And I also don't see many of the elements in there. And I'm confused if you're doing informed consent for interviews and focus groups or only focus groups. So, can you please explain more there?

DR. HARTY: Yeah. If you look at form 2.1, that is the consent -- those are the elements that we will be seeking consent for. And so, in that, in 2.1 it has -- it is asking them to consent. They have the ability to consent to an interview, focus group interview, if they're in the focus group they can consent, or not consent, to having it recorded.

And then, we ask their preference, if they do want to do a focus group, which focus group that they want to participate in.

COMMITTEE MEMBER KURTURAL: Okay. Okay. I think, and I know that a lot of this information might already be in your recruitment file, but to be in compliance with the Common Rule there has to be more information in your informed consent. There's a number of factors, and you might even feel like this is repetitive from your

recruitment flyer, but it's not. And so, you're in compliance with the Common Rule.

But it's that description of reasonable foreseeable risks, statement of the project, again, needs to be in there. A description of benefits. And the big thing here is that, you know, they are going to be participating in these groups, so you're going to be disclosing a lot of personal information in there. So, there is a risk.

And there's a number of other factors that go into what's in an informed consent. And so, that is one flag I will see.

I think I did on the recruitment flyer, so everyone knows, I did kind of test it on readability and it was a sixth grade. So, if we can keep that, you know, a revised informed consent at that sixth grade to eighth grade range level, that would be better.

DR. HARTY: And I'm sorry, was your -- your comment you just made, is that in response to my consent form, form 2?

COMMITTEE MEMBER KURTURAL: Yes. I'm looking at your form 2.1. It basically --

DR. HARTY: So, there's -- there's two forms. There's form 2.

COMMITTEE MEMBER KURTURAL: Uh-huh.

DR. HARTY: That's the informed consent form. And

form 2.1 is after they read through that is what will be displayed in Qualtrics. And so, in the recruitment material it will be printed out consecutively. So, they will get the consent form and then what they would -- what will be displayed in Qualtrics.

And so, the recruitment flyer, I basically took my consent form and just rephrased it a little bit, so it's actually the recruitment letter.

COMMITTEE MEMBER KURTURAL: Okay, I'm popping it up, now.

COMMITTEE MEMBER HESS: So, 2.1 is basically just the signature page of --

COMMITTEE MEMBER KURTURAL: Oh, okay.

COMMITTEE MEMBER HESS: -- form 2, correct? That they will see on Qualtrics after they've read form 2, then on Qualtrics will pop up -- basically, form 2.1 will populate and that's really just for signatures, correct?

DR. HARTY: That's correct.

COMMITTEE MEMBER HESS: Okay.

DR. HARTY: So, basically, in Qualtrics it detects where they're at and where they're at on the page. And so, once they've scrolled down to the end of what prints out is form 2, form 2.1 will be displayed next.

COMMITTEE MEMBER KURTURAL: Uh-hum.

DR. HARTY: And so, my consent form is really form

2 and form 2.1 combined.

COMMITTEE MEMBER KURTURAL: Okay. I see this. All right. So, I think that it would probably be better -- I don't know if it's possible to combine these forms or how to resolve that.

DR. HARTY: Yeah, I can just copy and paste --

COMMITTEE MEMBER KURTURAL: Yeah. Right, right, right.

DR. HARTY: -- the text from 2.1.

COMMITTEE MEMBER KURTURAL: Just because we want to make sure whatever the participant is signing off on, that they understand they're signing off on the informed consent. Because when it's separate from that, it gets -- I mean, if I was confused, I can imagine, you know, them being confused.

And then, is this going to be electronic signature or how -- can you explain that one more time?

DR. HARTY: Yeah, so with Qualtrics it will. I mean, it's an electronic signature that they provide. And so, in Qualtrics, if they're on a computer, they can use their mouse or track pad. If they're on a phone, they can do -- a little box will come up where they will scribble -- like they'll use their finger. So, it's electronic, but it's not where they have to check a box, or they can put in, like type in their name. It will require an actual for them

to sign it.

COMMITTEE MEMBER KURTURAL: Yeah. And, okay, so we could probably fix this. The language on the risks I want to talk about, because we can easily combine, like I said. But the language on the risks, we have a sentence in here that we will also remove all private information that would allow someone to easily identify you as a study participant.

DR. HARTY: Uh-hum.

COMMITTEE MEMBER KURTURAL: So, I think that's going to -- I think that's a little bit misleading is like my take on it, because you're in this -- whether it's in the interview or focus group, you're in it, and you are going to be explaining very personal information. Who knows what they're going to say. But they're going to say something personal.

And you're going to try to protect identities as much as you can, I'm sure, as you mentioned by deleting, you know, the names or whatnot when you go to publish.

But there could be a risk that someone's characteristic information might be disclosed.

So, I think we need to do like a better job of kind of explaining the tail end of that. It's the very end of the risks and discomforts of being in the study.

DR. HARTY: Okay, I can do that.

COMMITTEE MEMBER KURTURAL: Taking a look at that, because that sounds like, oh, you know, you don't know right now until you start getting into the -- what's going to happen. But you can very well, you know -- someone could be seven foot tall, you know. I don't know what, exactly, you're going to do. That describes the specific scenario that say it was a crime that was in the news. I don't know what's going to happen.

So, I just think it's going to be hard to say all your private information.

DR. HARTY: So, if -- yeah, I can easily do that. So, in the recruitment form I've put in there, saying that, you know, based on the information you provide it -- someone may be able to determine that you are a participant in the study. So, we'll make efforts to --

COMMITTEE MEMBER KURTURAL: Right.

DR. HARTY: -- you know, use an alias, or a fake name. If you provide an agency, we will hold it back. If you provide specific information about an event, we will rephrase it. And so, I've done that in the recruitment letter, but I don't think it -- I didn't do that in the consent form. So, I can certainly just adopt --

COMMITTEE MEMBER KURTURAL: Okay.

DR. HARTY: -- the language from the recruitment form into the consent form.

COMMITTEE MEMBER KURTURAL: Okay, thank you.

COMMITTEE MEMBER HESS: I also have a comment on that. Can I --

COMMITTEE MEMBER KURTURAL: Oh, go ahead, yeah.

COMMITTEE MEMBER HESS: Yeah, I also had a bit of a hang up with that particular sentence. And I think it was over the phrase "private information", because identifiable information and private information are not the same. Like these are interviews that are divulging private information and that's part of the data that you want. You're not actually getting rid of that.

But what you want to convey is that you will do your best to remove all information that could identify the participant.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER HESS: Not necessarily get rid of the private information that you're collecting.

COMMITTEE MEMBER KURTURAL: That's a good point.

COMMITTEE MEMBER HESS: Thank you, Carrie.

DR. HARTY: I can certainly change that language.

COMMITTEE MEMBER HESS: Thank you.

COMMITTEE MEMBER KURTURAL: Sorry, I had one more comment and it was on the protection of small sizes. You did a great job of describing everything that you're going to do in detail with each of them. But under -- I don't

want you to think I'm being difficult, but it's taking a needle in a haystack. But my background is in privacy law so, and it says here to protect the people.

DR. HARTY: My -- my wife's an attorney, so --

(Laughter)

DR. HARTY: -- it's part of my life.

COMMITTEE MEMBER KURTURAL: The fourth point you have on aggregate reporting. So, when report findings and data ultimately will be presented, that you'll aggregate whenever possible.

So, there is a way to do statistical de-identification that I highly, highly recommend, or masking under a certain cell size. So, you know, some researchers go I'm going to mask anything under 11. Other researchers, to protect confidentiality, we actually have agency, California Health and Human Services de-identification guidelines that I highly recommend as a method for de-identifying.

So, if you could clarify what method you're going to utilize in that aggregate reporting as well.

DR. HARTY: Sure.

COMMITTEE MEMBER KURTURAL: And I'm --

DR. HARTY: So, on the -- in the Cal Youth Study we (indiscernible) -- in California. You know, we have it, because it's survey data, and we say that any youth in the

county under 10, we won't report that data. And so, I'm happy to look at the qualitative version of that, but I'm not sure if there's going to be a specific sample size.

So, do you want me to look into that and --

COMMITTEE MEMBER KURTURAL: Yeah, I'm --

DR. HARTY: -- provide a qualitative version of that or do you want me to use the quantitative requirements of that?

COMMITTEE MEMBER KURTURAL: It would be across the board with whatever data you're using. What I can do after this is I'm happy to email you our agency de-identification guidelines so you can take a look and --

DR. HARTY: Great.

COMMITTEE MEMBER KURTURAL: -- see just here's how we go about de-identifying to ensure that aggregate data doesn't have such small numbers. You might not know now, until then, but you'll be able to revise your protocol to have a specific method to de-identify.

DR. HARTY: Cool, I appreciate that. That will be really helpful.

COMMITTEE MEMBER HESS: I actually -- sorry. I actually don't think that our agency guidelines address qualitative de-I, which could be a problem. Because he's not -- what you're dealing with is not like cell sizes, correct, and for the interview stuff it's that qualitative

data. And qualitative data sample sizes are naturally, just by virtue of the type of research, extremely small.

So, I think maybe the best way to do it is to just look into best practices for preventing, you know, or for protecting confidentiality in very sensitive circumstances like this.

Like, you know, if you're reporting it out, generally when you report out a quote from, say, a participant, you would say, you know, female aged 18, right. Maybe you don't report that, or you just say, you know, female participant or a participant. There are ways to deal with qualitative data. And I would just say look into best practices, but I don't think there's any hard and fast cell size considerations for qualitative data.

DR. HARTY: Uh-hum.

COMMITTEE MEMBER KURTURAL: Yeah, there isn't under the guidelines, either.

DR. HARTY: Yeah, you know --

COMMITTEE MEMBER KURTURAL: I'm still going to forward it to you, just as a way -- I'm not telling you, you have to do it, but what I'd like you to do is update, just tell us what type of method you're going to use to de-identify your aggregate data in the protocol, whatever it's going to be.

DR. HARTY: Yeah, absolutely, we'd be happy to

make those changes.

COMMITTEE MEMBER KURTURAL: Yeah. Okay, I'm going to open it up to the group if there's any further comments or questions.

COMMITTEE MEMBER SCHAEUBLE: Carrie, just to confirm, I think it's been clarified in everything that's been said here, but the consent process will be the same for the interviews and the focus groups. Because you had asked at one point why there was something about verbal consent for interviews and written for the focus groups.

COMMITTEE MEMBER KURTURAL: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: And it's all going to be written, now, or electronic.

COMMITTEE MEMBER KURTURAL: That was my understanding. Can you answer it?

COMMITTEE MEMBER SCHAEUBLE: Is that correct?

DR. HARTY: Yes. Sorry, if I said verbal. No consent will be verbal.

COMMITTEE MEMBER SCHAEUBLE: Okay.

DR. HARTY: It will all be -- in the consent form they have to sign next to everything that they consent for.

COMMITTEE MEMBER SCHAEUBLE: Okay.

DR. HARTY: So, if they consent to a phone-in interview, they'll sign that. If it's an interview and a focus group, they'll have to sign in two places.

COMMITTEE MEMBER SCHAEUBLE: Okay.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Thank you, that's what I thought you were saying.

COMMITTEE MEMBER KURTURAL: I think he clarified it.

COMMITTEE MEMBER SCHAEUBLE: But just wanted to know.

DR. HARTY: Okay.

COMMITTEE MEMBER SCHAEUBLE: The only other thing I saw, at one point you indicate that you'd like to be able to recontact people. And I think that should be offered as an option, are you willing to be recontacted, rather than just assuming they are if the sign the consent form otherwise.

So, I'd suggest you make that a separate kind of line to agree to be recontacted.

DR. HARTY: Yeah, thank you. I'll certainly clarify that. And we would only recontact people that consented to an interview and a focus group. And so, I think when they consent to both, to them it would be implicit that we would contact them again because they agreed to do both.

But I'll look at that language and certainly make that more clear --

COMMITTEE MEMBER SCHAEUBLE: So, so --

DR. HARTY: -- after the conclusion of the study, I will be --

COMMITTEE MEMBER SCHAEUBLE: Am I missing -- am I misunderstanding, was there some desire to recontact after the interview and focus groups, or only for the purpose of scheduling, say, a focus group after they've done the interview, something like that?

DR. HARTY: That's correct. So --

COMMITTEE MEMBER SCHAEUBLE: All right.

DR. HARTY: -- we don't intend -- or I don't want to contact them after the study. And if they've only agreed to do a survey or a focus group --

COMMITTEE MEMBER SCHAEUBLE: Fine.

DR. HARTY: -- I don't want to contact them afterwards. It would only be if they agreed to do both, then I'll --

COMMITTEE MEMBER SCHAEUBLE: Okay. I apologize, then, that was my misunderstanding because I thought it was referring to contact you for some future purpose, other than the interviews and focus groups. But if that's not the case, then not to worry.

DR. HARTY: Well, no, I appreciate that. And I'll -- I mean, I'll look at that language because if that's what you perceived, I don't want youth to think that I could

potentially contact them after.

So, I'll revisit that language, still, and make sure that it's clear.

COMMITTEE MEMBER SCHAEUBLE: Okay.

DR. HARTY: That it will only be for scheduling purpose.

COMMITTEE MEMBER SCHAEUBLE: Okay. Good. Good.

DR. HARTY: Thanks.

INTERIM CHAIR DELGADO: I just have one comment, Dr. Harty. This is Darci Delgado. Just want to say thank you for sharing your lived experience and the importance of what it brings to this project. It's great to be reviewing projects when, from our role, trying to protect human subjects, with you bringing your lived experience in that space is really heartening, and just appreciate the work that you're doing. So, thank you.

DR. HARTY: Thank you. I appreciate that. And I should say this is a really fun group to work with, these youth, they're a lot of fun. They're very opinionated and it's exciting to see them in their trajectory out of care and in their early adulthood, with a lot of promise, and excitement.

COMMITTEE MEMBER KURTURAL: Yeah, that's awesome.

INTERIM CHAIR DELGADO: Okay, do we have a motion, Carrie?

COMMITTEE MEMBER KURTURAL: Yes, I'm ready. So, motion for minimal risk, deferred approval, for a year, contingent on noting in your protocol your de-identification methodology for when you publish aggregate data.

Combining the informed consent with the signature page. So, that would be combining form 2 with 2.1.

And taking a look at revising the risk section of your informed consent to adequately describe the risk of participants who may disclose personal identifiable information.

DR. HARTY: Okay.

COMMITTEE MEMBER KURTURAL: And that's it.

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

COMMITTEE MEMBER VENTURA: I second.

COMMITTEE MEMBER RUIZ: Second.

INTERIM CHAIR DELGADO: Second from -- oh, Dr. Ventura beat you, Dr. Ruiz.

COMMITTEE MEMBER RUIZ: That's fine.

INTERIM CHAIR DELGADO: So, we have a second.

Sussan, could we do a roll call?

MS. ATIFEH: Okay, sure.

DR. RYKACZEWSKA: I just also want to make sure that I captured it correctly. Apologies, it is getting late, and I feel like I'm typing wrong a lot. So, did I

capture it right?

INTERIM CHAIR DELGADO: Is that good, Carrie.

COMMITTEE MEMBER SCHAEUBLE: Two, I think is combining --

COMMITTEE MEMBER KURTURAL: Yeah, noting and -- yep, combining, not coming.

INTERIM CHAIR DELGADO: Okay, so we have a motion and a second. Sussan, if you could roll call it, please.

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

COMMITTEE MEMBER RUIZ: Approve.

INTERIM CHAIR DELGADO: He said approve.

MS. ATIFEH: Okay. Dr. Dickey?

INTERIM CHAIR DELGADO: Dr. Dickey, we can see that you're calling.

MR. ZADROZNA: He's unmuted.

INTERIM CHAIR DELGADO: You're unmuted. We'll try to come back to you.

MS. ATIFEH: Yes. Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

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

MR. ZADROZNA: Thumbs up.

MS. ATIFEH: Yes, okay, approve.

INTERIM CHAIR DELGADO: Approve from Dr. Palacio, thank you.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, I'm going to come back to Dr. Dickey. Dr. Dickey?

MR. ZADROZNA: He unmuted himself; I think it's just a delay. Dr. Dickey, can you hear us?

INTERIM CHAIR DELGADO: It's okay, we still are good on the vote.

MS. ATIFEH: Yes, the motion passed.

INTERIM CHAIR DELGADO: Okay, your motion is passed, Dr. Harty. Thank you again so much for your patience with us, for giving up your spot in line earlier. With this deferred approval letter, you will receive it in the next week or two, but please don't hesitate to reach out to Carrie should you have any logistics questions. And thank you so much.

DR. HARTY: All right. Thank you all for your time, I appreciate you for being here and providing the good

feedback.

INTERIM CHAIR DELGADO: Thanks. Have a good day.

Okay, board members, don't hang up yet, board members. I forgot to get the meeting minutes approved from June 7th. So, last week CPHS staff emailed a copy of the June 7 meeting minutes, no revisions were requested by members.

Would like to see if there's any edits or any public comment? Seeing none, if I could get a motion to approve those minutes, please.

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

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

Do we have -- Carrie is giving a second.

COMMITTEE MEMBER KURTURAL: I'll second.

INTERIM CHAIR DELGADO: Sussan, if we could do a roll call, please?

MS. ATIFEH: Sure. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Dickey? Okay, I'm gonna come back.

Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Okay, thank you.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Abstain, I wasn't at the June meeting.

COMMITTEE MEMBER HESS: Oh, I'm sorry. I was also not at the June meeting, so I have to revise that to abstain. I thought we were -- my brain. I apologize.

MS. ATIFEH: Oh, okay.

Dr. Palacio?

INTERIM CHAIR DELGADO: He said approve.

MS. ATIFEH: Approve, okay.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, so let me come to -- oh, let me come back to --

MR. ZADROZNA: Dr. Dickey's offline.

MS. ATIFEH: Off the line. Okay.

INTERIM CHAIR DELGADO: So, that passes?

MS. ATIFEH: Yes, the motion passed.

INTERIM CHAIR DELGADO: Perfect. Okay, the other

items will -- I missed a lot of items today. For Item E, just want to make note for the record there were no adverse events or unanticipated problems needing full board discussion.

Any questions from board members on Items I through O? Seeing none.

Any public comments? Seeing none.

I will remind everyone that based on the earlier Committee vote, our next meeting is scheduled for Friday, September 13th.

I will now adjourn the meeting. Thank you, everybody, for hanging in there and for the great work. Appreciate everybody. Have a great weekend.

(Thereupon, the meeting was adjourned at 1:13 p.m.)

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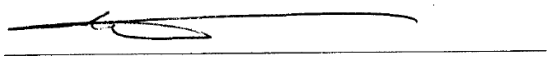
REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of August 2025.



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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 transcribed by me, a certified transcriber. And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.
IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of August 2025.

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