MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY (HHS)

DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION (HCAI)

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, MARCH 1, 2024

9:00 A.M.

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AND

ZOOM ONLINE MEETING PLATFORM

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Allen Azizian, PhD

Alicia Bazzano, MD, PhD

Larry Dickey, MD, MPH

Maria Dinis, PhD, MSW

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

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I n d e x

P R O C E E D I N G S

CHAIR DELGADO: Okay. I'm going to go ahead and open up the meeting. Sussan, if you wouldn't mind calling roll so we can go ahead and get started.

MS. ATIFEH: Sure. Darcy Delgado.

CHAIR DELGADO: Present.

MS. ATIFEH: Dr. Ruiz.

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Dickey.

COMMITTEE MEMBER DICKEY: Present.

MS. ATIFEH: Dr. Dinis.

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Ms. Lund

COMMITTEE MEMBER LUND: Present

MS. ATIFEH: Ms. Kurtural.

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Dr. Palacio.

COMMITTEE MEMBER PALACIO: I'm here.

MS. ATIFEH: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: Here.

MS. ATIFEH: Dr. Ventura.

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: And Dr. Johnson.

COMMITTEE MEMBER JOHNSON: Present.

MS. ATIFEH: So, the quorum is established.

CHAIR DELGADO: Wonderful. Just a kind of housekeeping item is that our court reporter was originally on Zoom and was going to do all of his court reporting duties through Zoom, but was having so many technical issues that he is coming in. So, he will be coming in probably in the next 20 to 30 minutes and setting up the material. We do have recording devices going, as well as the Zoom being recorded, so that we can still transcribe the meeting, but I will also say that we have to make – have extra caution with not talking over each other because generally the court reporter can manage a bit of the multiple voices at once when he is here present and hearing it live, but given that we will be working off of the recording devices for the first 30 minutes until he's fully set up, just something for us to be mindful of.

Any questions or concerns about the process?

MS. ATIFEH: Just one. Dr. Bazzano is also joining us.

CHAIR DELGADO: So, Dr. Bazzano will be joining us as well.

COMMITTEE MEMBER BAZZANO: Oh, I'm here.

CHAIR DELGADO: Hi, Alicia. It's good to see you

or hear you.

COMMITTEE MEMBER BAZZANO: Hi there. I'm trying to get on the Zoom, bur right now I'm on the phone but I'm here.

CHAIR DELGADO: Wonderful. Good to see you -- hear you.

Just two quick chair updates before we jump into the meat of the discussion for today. One, just wanted to express my extra appreciation for everyone to add onto their work duties and volunteer by being here today, especially those who showed up in person after some nudging from Lucila and I and Nieszka so that we could establish a quorum, so just extra special thanks to everyone. We know that on a stormy Friday getting into the office is not the first thing on our list of things we want to get done today, or for those on Zoom, calling in and spending a few hours with us this morning, so, just want to express extra appreciation for all of the board members and staff.

The second thing, just as an update, we talked about this at the last meeting, but our admin. team has been pulling together the CITI training. Thank you to Nicholas who actually culled through probably 80 different trainings to find out what might be the best for our team, and, so, he did identify six trainings. Not all of them will be required, but actually some of them look super interesting,

and I'm really excited to get into them. So, I think we're still purchasing the package, and, so, there is no imminent need for us to get it. We're not going to be able to get it done before the next meeting, but maybe just stay tuned because that purchase will be made soon and those trainings will be available to everybody.

So, thank you to Nieszka and Lucy and Sussan and all of the admin. staff for that. Super exciting.

Okay. So, that's just the housekeeping I wanted to go over. So, we have no projects to review today. We are here to give all of our time and attention to the issue on the Common Rule and the IPA regulations and the application.

We're thankful that we don't have to shove this in to a conversation where we're also reviewing projects, so, again, thank you for the extra meeting.

But what I'm going to do is first hand it over to Jennifer Schwartz. I know most of you know her. She is the Chief Legal Counsel, to, first, kind of introduce and give us a bit of a history on this topic, and after we hold questions until all of the materials have been presented that Jennifer is going to present, but then, also, many board members have sent in documents related to this topic. You should have received most of them a few days ago, maybe last week, but there was some updated information also sent

this morning, so if you haven't had a chance to look at it, Dr. Dinis, hopefully you can walk us through it, since I don't know if everyone has checked their emails this morning, to make sure that we all have the most updated information, so, my hope is that we can kind of go through, start with Jennifer and then present all of the documents, to give everyone a chance to express their perspective before we jump into any kind of questions and discussions.

Oh, and there's Dr. Bazzano's beautiful face. Good to see you.

Okay, with that, Jennifer, I will hand it over to you.

CHIEF COUNSEL SCHWARTZ: Fantastic. Thank you. Can folks hear me?

CHAIR DELGADO: Yup.

CHIEF COUNSEL SCHWARTZ: Great. Thank you. So, delightfully, my internet has been less than stellar, so I might have to ask you to repeat something if you break up a little bit on my end. Just so folks are aware, I don't always catch everything because sometimes things go in and out. So, please be patient with me as we walk through this.

What I would like to do is I'd like to pull up a flow chart that was created by our fantastic and wonderful CPHS administration staff to sort of explain the legal authority of the CPHS, but also to assist both the Board,

both the CPHS staff, as well as researchers in understanding what kind of review should take place for what kind of project.

So, what I'm going to do is I'm going to go ahead and share my screen, and can folks see this?

CHAIR DELGADO: Yes.

CHIEF COUNSEL SCHWARTZ: Thank you. I'm going to move your beautiful faces to the side, so I will no longer be able to see you, so that I can see the screen. What that means is I'm going to need you to verbally say something as opposed to raising a hand or making gestures because I won't be able to see them, so forgive me for that.

Okay. So, what is this? This is a flow chart, as I mentioned, to sort of explain the different reviews of the CPHS for different kinds of projects, but it's a little bit more than that. This flow chart is really explaining the legal authority, which is often called jurisdiction, of the CPHS.

So, the Committee for Protection of Human Subjects was established in law and essentially established in contract. There are two pieces of its jurisdiction, its legal authority. One is through the Federal-Wide Assurance with the Federal Government that talks about the establishments and rules over the IRB activities of the CPHS under the Common Rule, and the second piece is its

establishment as a committee to review requests for state data in the Information Practices Act and sort of let's call that -- that was where it was established first, and then recently when CDII became an entity in CalHHS, there is also an introduction of a new statute that sort of talks about the CPHS as well, and Dr. Dinis sent that statute this morning, so to give some background for that.

So, let's talk a little bit about the three different pieces. So, the CPHS has jurisdiction under the Information Practices Act to review requests for state data under the Information Practices Act criteria, and we're going to call that the IPA, and that's in the Civil Code section. I'm going to try and highlight that. Can you that highlighted? Can folks see that?

COMMITTEE MEMBER DICKEY: Yes.

CHIEF COUNSEL SCHWARTZ: Okay, great. Thank you. Sorry about that. I'll just keep irritating you by repeating unless I hear you. Sorry for that.

So, that's in the Civil Code Section 1798.24, and specifically in Subdivision (t).

So, there are requests for State data, just for requests for State data. Then there are times when the CPHS is acting as an institutional review board under the Common Rule and under the agreement of the Federal-Wide Assurance with the Federal Government. And that is when they're

reviewing projects for – that involve human subjects, or human subject participants, or contacting human subjects. And those pieces of authority are over here under the 45 CFR section. I've highlighted them here. I'm hoping you can see those.

If I'm going too fast, somebody should say something to let me know.

The third kind of review is when a project involves human subjects and State data, and that's when the Common Rule and the IPA both would be involved and the CPHS would review under both those criteria.

So, let's kind of walk through the flow charts to sort of help folks see how the paths work and sort of the three different pieces. There is one more piece which is, of course, that the CPHS has no purview at all. It's not involving State data. It's not involving a Common Rule project and, so, there's no purview whatsoever. In other words, there's no legal authority to review the project. The CPHS only has legal authority over those different things that I just mentioned.

So, let's go through. So, let's start with the question, which is kind of the easiest question, which is, is there any request for State data from a State department. And if the answer is yes, then the next question is does your project involve human subjects, human subject

participants, contact with human subjects, and do you plan or do you plan on using the requested data to contact human subjects? If the answer is yes, yes to State data and yes to human subjects, then we go to this box right here on the very far right, and I am going to -- can I use -- I can, okay. So, I can actually highlight things, so let's do that.

Then we go to this, this "yes" piece. The IPA review is required because the project is asking for State data, and then we have to go to the next piece. The next piece of course is -- maybe it wasn't a good idea to do highlight. Well, let's hope everyone can see this. I apologize. So, once we have the -- there we go -- once we have the fact that this is IPA review required, then we have to see does this actually mean that the project which does involve human subjects is an optional project, meaning that the CPHS can but is not required to review it, or is the project something that is required to be reviewed.

The analysis for whether the CPHS is required to review it is that the project is funded by CalHHS funds, it involves CalHHS staff, or the project, itself, involves human subjects that are within the custodial care of one of our CalHHS departments. Those are the pieces that are noted within the Federal Registers and within our policy documents. And if the answer to that is yes, one of those

pieces are in existence, then the CPHS is required to review the project under the Common Rule.

So, this piece here would be yes to the IPA review and, yes, the CPHS is required to review the project under the Common Rule. Those are all yeses.

However, if the project does not meet one of these different criteria, it's not funded by CalHHS, the human subjects are not part of the custodial care of a CalHHS department, and the project does not involve CalHHS departmental staff, then the review under the Common Rule is optional. It is not required. It is optional. CPHS can choose to take it or can choose not to take it.

However, regardless of whether it's optional or required, the IPA review is required because this project is involving State data.

Let's go to the next phase. We go back up to the top where we have a project that does involve State data. So, we're still in the yes branch. And then we go back to this question, does your project involve human subjects? Do you plan on using State data to contact human subjects? And if the answer is no, then this project is just an IPA review project, and the IPA review by CPHS is required.

So, we have one branch where, yes, there is state data, one piece is Common Rule applies and IPA applies. The other branch is just IPA review, not Common Rule.

So, the next branch, if we go back up to the top, is the no branch. There is no State data. There is no request for State data. So, if that's the case, we go down the no flow, and then the next question would be does your project have any direct or indirect contact with human subjects. And if the answer is no, then the CPHS does not have purview, meaning that the CPHS does not have any legal authority to review the project at all.

If the answer to yes, human subject interaction, even if indirect is yes, then we go to this next branch under the yes piece right here. I'm trying to highlight it so you can see that.

And then we ask the question, the same criteria that's in the Federal-Wide Assurance and in our policy and procedures document which is, is the project funded by CalHHS in some way? Is the project involving CalHHS staff? Is the project involving human subjects from State custodial care? And if the answer to that is yes, then there's a required review by the CPHS under the Common Rule.

This particular project does not involve an IPA review. It's just a human subject review under the Common Rule.

If the answer is, no, yes we're still dealing with human subjects but the project is not funded by a CalHHS department, it is not involving staff from CalHHS, the

project does not involve subjects -- human subjects from CalHHS custodial care or State custodial care, then the full board review is optional. It is not required. So, the board could choose to review the project under the Common Rule, but does not have to choose to do that. This would be Common Rule only because there is no request for State data. So, this would be just IRB activity.

So, I want to stop here and ask folks if there are any questions at this point.

COMMITTEE MEMBER DINIS: I have one. On our FWA we check the box, which means we choose to review or check the box and you will review all research, whether it qualifies or not under the guidelines for the Feds, so how does that play into this chart that you just said yes and no to?

CHIEF COUNSEL SCHWARTZ: So, what I heard you say is -- can you repeat that question, you check the box --

COMMITTEE MEMBER DINIS: Yes. When the State filled out a Federal-Wide Assurance, they also did a thing what they would call "check the box" which means that they tell the Feds that they're going to review all research according to the Common Rule whether it's required by the Feds or not. That's what that box meant -- means. And so, I wonder under this criteria how does this apply here?

COMMITTEE MEMBER DICKEY: Maybe you can pull up

the FWA. I think that box may have been taken off, out of it.

COMMITTEE MEMBER DINIS: No, it's not the --

COMMITTEE MEMBER DICKEY: I wanted to see our current --

COMMITTEE MEMBER DINIS: No, I think you've got to check, yeah, absolutely.

CHIEF COUNSEL SCHWARTZ: So, I don't have that easily accessible. Let me see. I would have to ask staff to pull that up.

CHAIR DELGADO: So, staff is working to pull up, and, Ms. Schwartz, I'm going to say it out loud, the most recent signed to FWDA. So, for those who don't know the FWDA -- the FWA is the Federal-Wide Assurance that our committee submits to Federal HHS to provide the ability to perform as the state IRB, for those who don't know what FWA is.

So, Jennifer, we're going to look for that and pull up and come to Maria's -- to Dr. Dinis's question. Let's pause and open up for other questions.

COMMITTEE MEMBER LUND: Hi, Jennifer, it's Laura. I have a question. Title 45, in addition to data being used either collected from human subjects or being used to contact human subjects, there are research projects that are recognized as research projects that are data-only projects

in which the data obtained contains confidential, private information, and the OHRP guidance document that I sent out actually has that as one of the criteria for projects being subject to Common Rule review. I don't see where that falls in on the decision chart.

CHIEF COUNSEL SCHWARTZ: So, that is a great question. I actually don't have those materials.

COMMITTEE MEMBER LUND: Okay. Maybe Sussan could put that -- using the chart one up on the screen and Jennifer would be able to take a look at that.

MS. ATIFEH: (Indiscernible) the charts.

CHAIR DELGADO: Yes, if you could please -- in Laura's documents that were submitted.

COMMITTEE MEMBER LUND: Yeah, I pulled my documents. She's holding it up.

CHAIR DELGADO: Which is very helpful for Jennifer. Jennifer, Sussan is going to be pulling up the document that Laura is referring to.

CHIEF COUNSEL SCHWARZ: Thank you. So, while Sussan is doing that, are there other documents that were submitted that I should take a look at?

COMMITTEE MEMBER LUND: Probably all of them.

CHAIR DELGADO: Yes, probably about a hundred pages of documents. Maybe not a hundred. I'm being sarcastic.

COMMITTEE MEMBER KURTURAL: Jennifer, this is Carrie. I pulled what was just like, you know, the practical law and the research, but I have to do a deeper dive, myself, to understand if a carve out needs to be made to the chart, but it seems that the problem that I've seen, and that Laura might have seen that, is when they take our State data, data-only projects and then they mix it with like something else that's clinical in nature or, you know, involve -- it gets -- where it gets complicated for me is when they take it and they mix it with another data set that somebody else has. And then I'm kind of like -- it makes me pause like is this board review, you know, and it came in as an expedited, and so those are the tricky ones for me and Laura.

COMMITTEE MEMBER LUND: Yeah, and it can be expedited if it's data only. It's just that the Common Rule has to be applied in the review, so that's where it gets a little bit complicated.

So, Jennifer, Sussan has this up on the screen. The source of this document is the OHRP website. As our guidance agency as a committee, we rely on them for a lot of the interpretations of Title 45 and Common Rule.

So, it's consistent, so we walk through here. We first determine that it's research, and let's just assume for purposes of argument in this particular situation it is

research, so we're going to go down to where it says activity is research, and then a decision is a yes, no question, does it involve a living individual about whom an investigator obtains information or biospecimens through intervention. So, this is the "human subjects" box, yes or no.

CHIEF COUNSEL SCHWARZ: Can you scroll down, please, so I can see the -- thank you. Can you continue?

MS. LUND: Yeah.

CHIEF COUNSEL SCHWARZ: Go ahead and continue. Just give me a good space here. Thank you.

MS. LUND: Okay, great. Thank you, Sussan. All right. So, we have this yes, no box, does it involve contact. And if it says no, then there's a subsequent question, does the research involve a living individual about whom an investigator conducting research obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

So, in this case the researcher is not contacting the human subject, so there is no human subject contact, however, they are obtaining information that contains identifiable private information, and many, if not most, of our State data bases that involve research would say yes to this question, and, therefore, that is considered an activity involving human subjects, even though there's no

human subjects contact, and I don't see in your decision tree where that's been accounted for.

COMMITTEE MEMBER DICKEY: Jennifer, can I jump in here?

CHIEF COUNSEL SCHWARTZ: Go ahead. I actually need to look at this a little bit more in detail. I'm sorry, this just came up now so I would like to take a look at it, but go ahead, Doctor.

COMMITTEE MEMBER DICKEY: Yeah. I think that this is saying that -- well, and you'll see on the materials that I sent that if you're obtaining data and it has to be reviewed by the IRB as the institution of the researcher obtaining the data. So, yes, data is considered to be even subjects. But if you go down to the bottom of your chart there's a box that says that it's -- Common Rule review is optional and that if they're not going to take advantage of our Common Rule, they need to submit a copy of the approval from IRB.

COMMITTEE MEMBER LUND: So, Doctor --

COMMITTEE MEMBER DICKEY: That's the approval of that.

COMMITTEE MEMBER LUND: Right. Dr. Dickey, I think that's a separate question. I don't disagree with you, but in some cases we are the IRB, and so we need to have a place in this decision tree to cover that for the

cases where we are the IRB, and I don't see that represented here.

COMMITTEE MEMBER DICKEY: Well, it's hard to talk about the chart without having the decision chart up, but there is a box where we are the IRB is what we find it if there is staff involved or if there's, you know, (indiscernible) we are protecting.

COMMITTEE MEMBER LUND: Right, but not for data-only studies. That's what my question here is.

COMMITTEE MEMBER DICKEY: Well --

CHIEF COUNSEL SCHWARTZ: Can I ask a question? Because what I'm looking at -- okay, I want to make sure I'm following where we are in this discussion because I don't think I am. But if we look at the box that says does the research involve a living individual about through an investigator investing research obtained information or biospecimens through intervention or interaction with the individual, then that would be human subject research because the subject is being directly contacted.

COMMITTEE MEMBER LUND: Right, but we don't -- I'm looking at your decision tree and I don't see an option for human subject when the subject is not being directly contacted, and that's what this other box on that OHRP --

CHIEF COUNSEL SCHWARTZ: Can you stop sharing the screen real quick. Just give me one second. I'm sorry.

Maybe I can clarify. Can you stop sharing the screen. I'm going to share for a moment. Somebody stop sharing. Thank you. I'm going to share real quick then go back to the -- and there is actually a box for indirect, so let me see if I can -- can you see this? Let me see if I can -- all right. So, there is a box that talks about direct and indirect interaction, but I'm not seeing direct action. And my understanding, and correct me, Laura --

COMMITTEE MEMBER LUND: No, because your box, and I'm going to read it, it clarifies that direct, indirect interaction by saying, "for example, e.g., any contacts or interactions with human subjects, whether in person, by mail, phone, text message, cellphone app., online survey interview, focus groups, et cetera, or by third party working for your project." It does not allow for data that has been previously collected and are not being obtained through an interaction, right? So, if I were a person, for example, getting birth data and hospital record data to link for my research study I would say no, my project doesn't involve any interactions with human subjects. All that data already exists.

CHIEF COUNSEL SCHWARTZ: That's an existing data set.

COMMITTEE MEMBER LUND: Right. That's what I'm saying, and that's what that OHRP guidance says, is that

existing data sets count if they have private identifiable information. It does not --

CHIEF COUNSEL SCHWARTZ: Can we blow up the chart real quick for a moment? Sussan, can you put that back up because I'm not sure that's what that says. What that says is -- I think that there is a question about what the chart says. The way that I learned that was is that the research is involving information that has been collected directly from the individual, and -- okay, right there. Thank you. Thank you. And, so, I'm not sure that it necessarily indicates -- I would actually have to go to the sites themselves, and I apologize, Laura, I did not see this before right now, so, unfortunately, I'm not as prepared as I should be for this, but from my reading of this, this appears to be something that they received it through intervention or interaction that's direct, not necessarily indirect.

COMMITTEE MEMBER LUND: Actually your --

CHIEF COUNSEL SCHWARTZ: Indirect is listing data sites and then you use a different rule for that, but I have to go back and look at the regulations of both to be able to actually answer the questions accurately at this moment and I apologize for that.

CHAIR DELGADO: Can you point out what box you are talking about because you lost me.

COMMITTEE MEMBER LUND: In the middle of the page where it says "no." Does the research involve a living individual by -- yes, that box is correct.

So, Jennifer, what I'm going to say is also Maria has had several email exchanges with OHRP about this which have also been shared, and maybe you haven't had the opportunity to take a look at those either. And OHRP has been very clear, and I would direct you to their responses to her as well as this note -- not that box, other box --

CHIEF COUNSEL SCHWARTZ: This is not the right one?

COMMITTEE MEMBER LUND: That's not the correct one.

CHIEF COUNSEL SCHWARTZ: I highlighted the one I thought we were talking about.

COMMITTEE MEMBER LUND: No, we are talking about where -- to the right. So, the box to the right involves data that have already been collected, so they don't involve a direct interaction by the researcher with a subject. They are existing databases, but those databases contain identifiable private information.

For example, in the guidance on the OHRP website even cites biobank as an example. It's not being collected through direct -- by the researcher through direct or indirect interaction with a subject it has been collected

previously, perhaps years previously and is being used. So, when data sets exist and are being obtained, that's this word "obtained" by the researcher, they collect and they have identifiable private information, they are then subject to Common Rule review.

So, if we are the IRB and we are reviewing research projects that use these data, then we need to review those projects under the Common Rule as well as the IPA, and I don't see that in your decision tree.

CHIEF COUNSEL SCHWARTZ: So, that doesn't make any sense to me, Laura, and the reason it doesn't make any sense to me, and again, I would need to go back to the regulations, is that it makes the same data set is identifiable information.

COMMITTEE MEMBER KURTURAL: Can I chime in here? I --

COMMITTEE MEMBER DICKEY: Can I jump in?

CHAIR DELGADO: Hold on one sec. Carrie was talking.

COMMITTEE MEMBER KURTURAL: I looked up the regulations before this and it is kind of confusing because if you see the last portion of the box, Laura, what you're saying it says, "Generate identifiable private information or identifiable biospecimens," right.

CHIEF COUNSEL SCHWARTZ: Right.

COMMITTEE MEMBER KURTURAL: I think that this is referring specifically to clinical biospecimens, that private information portion of that statute, but here's the thing. We can't solve that without going back to the Federal Register and seeing what were the comments then specific to this regulation, and that is information we do not have attached to this meeting. I think that -- and it's going to take too long for me to pull it, and I'm not even going to do it right now. But I --

CHIEF COUNSEL SCHWARTZ: That needs to be done separately from this meeting because it's going to take a while to go through. Yeah.

COMMITTEE MEMBER KURTURAL: I do think the confusing part of this is the way the statute is worded, because what I pulled off of "West Law," it looks to me like it's the data only, the existing data stats only that's tied to clinical research, so that would be the situation of pulling the birth data that you were saying and tying it to like biospecimen stuff that Kaiser, whatever, you know, the project is.

COMMITTEE MEMBER LUND: So, the guidance we have gotten from OHRP does not make that distinction,

COMMITTEE MEMBER KURTURAL: Well, that's why it would be helpful. Just because you talk to somebody at the Federal -- you know, some staff at, you know, the Federal

office does not necessarily mean that's what Congress intended, right. You know, we have to go back to see what the comments were on this particular regulation, and if we could find that it was narrowly tailored to mean to tie to clinical research, then, yeah, then we can update the chart and make an exception, or whatever, but I still -- I'm not going to take somebody's word for it.

COMMITTEE MEMBER DINIS: May I say something as well? May I say something as I'm the one who contacted Dr. Yvonne Lowe (phonetic)?

COMMITTEE MEMBER KURTURAL: Absolutely.

COMMITTEE MEMBER DINIS: All right. When I talked to Dr. Yvonne Lowe she did say anytime a researcher has private and identifiable information, meaning they have names, they have emails, they have ways to be able to identify persons, that becomes an activity, research involving human subjects. That's what she told me. That's what the email --

COMMITTEE MEMBER DICKEY: Can I raise my hand and say something? The operative words in this chart are "obtains or generates." It doesn't say releases, and, so if we -- if researchers in the agency obtain identifiable information from somebody else for research purposes, then we would have to be IRB for that and we would be the ones to have to review it as Common Rule.

There's very -- I can't really remember many instances where that's the case. But if our researchers were obtaining data, then we would have to deal with the Common Rule, and that's probably not captured on your chart.

CHIEF COUNSEL SCHWARTZ: Probably not. In addition, this chart intends to be a simple sort of at a glance, but it doesn't have definitions such as what does identifiable kind of information mean because it is small style identifiable.

So, is it just names and addresses, or is it such that if there's a, you know, it provides enough demographic information where you might be able to reidentify a person, that's also identifiable.

So, what Carrie is suggesting is that we go back to the law and take a look and see what the intent behind it was. This is really important that we do it right, so it's really important that we follow what the law says, and if the law indicates that we need to add more pieces to the flow chart, then we need to add more pieces to the flow chart. But I don't feel comfortable providing these bright line analyses today.

Again, I apologize. I wish I had seen this. I did not, so that's on me. But I think Carrie's suggestion of going back, taking a look, understanding the intent that is written in the Federal Rule Register about the folks who

wrote the regulations is critical to understanding what they intended around the regulations, themselves, and what's included and what's not included.

What I don't want to do is provide inaccurate advice to the Board because if the Board acts outside of its jurisdiction, its positions are void and we don't want that. So, what we want to do is we want to make sure that we provide accurate advice to the Board.

Carrie, I think your suggestion is totally on point and I agree completely with it, to go back and look and see.

And to what extent that we have received guidance verbally from an organization, I don't see that we can necessarily stand on that only because if it's not written guidance it's really hard for us to point to that as justifications for and why.

COMMITTEE MEMBER DICKEY: Jennifer, there is written guidance, they publish written guidance on their website.

CHIEF COUNSEL SCHWARTZ: Okay.

COMMITTEE MEMBER DICKEY: It's the same that I submitted.

CHIEF COUNSEL SCHWARTZ: I need the material.

CHAIR DELGADO: Actually, sorry, sorry. I'm going to pause us for a second just to update.

So, Dr. Dinis had previously talked about the Federal, the FWA. Let's put -- Sussan, if we could put that up on the screen, and then, Dr. Dinis, can we hand it over to you to talk about the FWDA (sic) and also any of the other documents you submitted. I think there was some written correspondence. Anything else that you want to -- luckily we have nothing else to do this morning except talk about this.

I don't -- while, yes, we won't be able to come to any ultimate decision making, I really want to hold space for all of the documents that were sent and space for everyone to convey their thoughts. So, go ahead, Dr. Dinis.

COMMITTEE MEMBER DINIS: Yeah, so let's -- okay. On the FWA do we see if we check the box?

MR. ZADROZNA: Where do you want me to scroll down to?

COMMITTEE MEMBER DINIS: I'm not. Why don't we check a box. There's a place at the bottom I think somewhere we say we'll check a box for (indiscernible) research.

COMMITTEE MEMBER DICKEY: I think it's under number four.

COMMITTEE MEMBER DINIS: Number four. No, I don't think so.

COMMITTEE MEMBER DICKEY: No, it says "option"

along the bottom.

COMMITTEE MEMBER DINIS: Somewhere there's a box.

COMMITTEE MEMBER DICKEY: It's not a box, but there's a statement.

COMMITTEE MEMBER DINIS: Okay. Well, we call it check the box.

COMMITTEE MEMBER DICKEY: Number four --

CHIEF COUNSEL SCHWARTZ: If you go to number 4B.

CHAIR DELGADO: There we go.

CHIEF COUNSEL SCHWARTZ: It says there the IRB essentially elects to apply the following to all of its human subjects research. So, we --

COMMITTEE MEMBER DICKEY: It says -- she's talking about under B, regardless of the source of support. So, basically we're saying we're electing to apply this as the Common Rule to human subject research benefits just funded by the State or a private entity as opposed to being funded by the Federal Government.

There used to be a box there where you actually checked, but now it's a statement.

COMMITTEE MEMBER DINIS: Okay. So, we have a statement, so we did elect to --

COMMITTEE MEMBER DICKEY: But that's regardless of the source of --

CHAIR DELGADO: I'm sorry. Can we let Dr. Dinis

kind of explain her thoughts on this?

COMMITTEE MEMBER DICKEY: Sure.

CHAIR DELGADO: Thank you.

COMMITTEE MEMBER DINIS: Well, not so much mine as it is all HRB. If we -- you know, there's ways of doing this, and some agencies, some state universities like ours, they didn't check the box, for lack of a better word. They do not have the optional part B. They only have part A. This FWA from the State, theirs include part B for whatever reason. My guess is to have to do something with IPA in order to cover themselves in other areas that it was not necessarily required maybe at the Federal level but at the State level. So, there like another reasoning at the time.

So, that's, I think, one thing that we need to be aware of is from the Fed's perspective we are essentially checking a box or having an optional statement that says that we are going to review regardless of source of support. So, that was the first (indiscernible) to make about them.

CHAIR DELGADO: Okay, awesome. So, before you move to the next part showing any of your other communications, Dr. Dickey, what are your thoughts about this optional part B box that we have checked?

COMMITTEE MEMBER DICKEY: Well, it was always to deal with the source of support issue because the Federal Common Rule -- the reason it's termed the Common Rule is

because it's a Common Rule between Federal departments, and the Federal departments have all agreed that for research to base on that they'll use this Common Rule. But they always left it as an option is that the IRB wants to elect to apply the Common Rule to research regardless of source of support. And this is standard language that's dictated. It's not -- I don't think -- it's always been in there even before the IPA. So --

COMMITTEE MEMBER DINIS: Yeah. I think it was every institution wished to do this and some opted out in recent years, but, you know, there's some -- you know, this one seemed to continue to elect to apply to human subjects research, you know, review without the source of support.

CHIEF COUNSEL SCHWARTZ: So, when the IRB is reviewing human subjects research under the Common Rule, then we are agreeing to use the Common Rule to do that review. That's what option B says.

COMMITTEE MEMBER DICKEY: Yes, but it's always been there. It was -- before the IPA we've always done that.

CHAIR DELGADO: It's super helpful to see all of the different puzzle pieces, so why don't we take down the FWDA (sic) -- why do I keep saying that -- FWA -- I have a bad feeling that that's like a rock group or something that I listened to. Let's take down that, and then, Maria, do

you want to walk us through any other documents that you provided for the group?

COMMITTEE MEMBER DINIS: Well, we can put up the documents that I sent before. Maybe that's helpful for people to see, the email exchange, I think that's helpful.

CHAIR DELGADO: Right. So, just give us 30 seconds. Let's give Sussan an internal round of applause for all of the document switching and screen sharing she's doing today. I feel like all of us will get like a junior badge law degree after this conversation. Carrie and Jennifer will be handing them out.

Okay, here we go, Dr. Dinis.

COMMITTEE MEMBER DICKEY: I have a question. Can we see your emails that you sent to them?

COMMITTEE MEMBER DINIS: This is right here. I'm showing it to you.

COMMITTEE MEMBER DICKEY: This is a reply to you.

COMMITTEE MEMBER DINIS: I think -- maybe let's go to the bottom I suppose. Oh, I see, I didn't have that. Yeah, okay.

COMMITTEE MEMBER DICKEY: It's kind of hard to interpret these without having the questions.

COMMITTEE MEMBER DINIS: All right, let me see what my email is. I don't have that ready to go here. Yeah, I can't. I can't give you the email. Sorry.

CHAIR DELGADO: Can you summarize for us what you asked in your original email?

COMMITTEE MEMBER DINIS: Yeah, I can do that, okay. So, here one of the questions I had that I thought, to me, was an issue was a conflict of interest in joining CDII and this Committee, meaning this, to me, CDII's main goal and objective was to get data out as soon as possible to anybody -- only not to anybody, but to the researchers requesting, and the support seems to be for the researchers and less so for this Committee.

I've been on this Committee for 20 years, never had so many difficulties since we've moved to CDII, and it's more like -- it seems to be more like a conflict of interest because we seem to be a board that stands in the way of them putting out data as fast as possible. So, that was my first question. What other questions I had was this conflict of interest and the FWA.

And Dr. Lowe said that CPHS was a committee. She was not aware of CDII, as you can see here. She did not know. She knew that we were under the California Health and Human Service Agency. She's the one who checks out the FWA, and she says, you know, they check the box and all that kind of language that we are familiar with, some of us.

Then she realized and saw that CDII is also technically under the California Health and Human Service

Agency, and, so -- so, that's what that first question is about, number three.

CHAIR DELGADO: Got it. Okay, can we scroll through the email, please.

COMMITTEE MEMBER DINIS: That's for number three, but she answered back with my questions one, two, three.

CHAIR DELGADO: Got it.

COMMITTEE MEMBER DINIS: Or maybe I should say I asked questions backwards.

CHAIR DELGADO: Just as an aside, as we move through to the second and third paragraph, just want to acknowledge the concern that you have about feeling as though CDII staff or the department have differing approaches or values when it comes to the data. Super happy for you and I to have an off-line conversation with some of the CDII staff and the director just to voice some of those concerns so that we can, one, hear them but also make changes if necessary.

COMMITTEE MEMBER DINIS: Well, I bring up this word "independence." This is what I have also thought about this Board, is that we were independent, but I think it hasn't felt that way since CDII took over, and that's another reason I think that document this morning did not go our way. It feels like we're being told what to do and how to make decisions on what to decide things.

CHIEF COUNSEL SCHWARTZ: Can I sort of address that a little bit because I can understand how frustrating it would be for things to see like they've changed.

What we've done for CDII is to sort of explain the legal authority that the CPHS has under the law. We haven't told you whether you should approve or deny research, whether you should modify consent forms. We haven't been involved in dictating or obstructing the actual decision the Board makes with respect to approvals. It makes more to how an approval happens in the sense of pieces of the approval, what your voting should be. What we're telling you is just what your lawful, legal jurisdiction is, what authority does the Board have.

That's -- you should know from the standpoint of that if the Board acts outside of your legal authority, your decisions are void, and it's possible that if you do that, the Board members may have personal liability for acting outside of your legal jurisdiction. That's important for you to know. That's not a threat, but it's simply a statement of what the law is. (Indiscernible-both parties speaking over each other)

COMMITTEE MEMBER DINIS: Jen, it actually feels like a threat and usually I'm familiar with the parent agency protecting its members, not threatening them. But it does feel like a threat I'm sorry to say, but it does. We

would not have liability --

CHIEF COUNSEL SCHWARTZ: You should know --

COMMITTEE MEMBER DINIS: I feel that it is though. Yeah, but we do not have liability to make decisions incorrectly, you know, if we -- if it's our opinion. But you just told us at one of our meetings that we did not -- when it was that other project back in May for the working people basically that -- I don't know exactly what you said, but it was basically that we could not make that decision, so you were telling us what to do.

CHIEF COUNSEL SCHWARTZ: So, what I am telling you is what your legal authority is. If you choose to make decisions, you can make those decisions. That doesn't mean, however, that a court would agree with you. My goal is to tell you what the law says, but I didn't tell you you're not allowed to do something. I told you this is your jurisdiction, and I told you that it's very possible that a court would not agree with it.

So, it's important for you to know that you are independents in the decisions you make. Your decision stood as a Board on that project. Nobody overturned it at CDII, nobody voided it. The decision is still standing.

And you should also be aware of the Board's legal authority, what your authority is to act, what your jurisdiction is, and what it means if you don't go -- or if

you don't stay within the jurisdiction. That's any -- any board, any State department, any committee, anything. That's the same rule for CDII, for CalHHS, for CAPH. We only have the authority that is granted to us by statute and law. And, so, it's my job to simply tell you what that is, and you make the decisions, but it's important for you to understand that there may be consequences. Your decision stood. No one overturned it.

COMMITTEE MEMBER DINIS: Well, there's been -- this is how I feel. This has been hell ever since with all these different things, and it's, you know, because I think that we have a matter of difference in terms of applying the ethics or how we interpret ethics here for this Committee. So, it's not been a pleasant year for sure, and a lot of work on our part, and, remember, we are volunteers, most of us here --

CHIEF COUNSEL SCHWARTZ: Yes.

CHAIR DELGADO: Yes.

COMMITTEE MEMBER DINIS: -- for our time, and so it's not fair and exactly the best experience I had working for the -- on this Committee for --

CHAIR DELGADO: Let me just -- I'm sorry, go ahead, finish, Maria, please.

COMMITTEE MEMBER DINIS: No, with that aside, the ethics to me was what was most important. That's what I was

working with. And I would love to see a lawyer try to throw out my ethics. I welcome the challenge from the State or anybody to take me up on that. I not give a shit about them. Go ahead, sue me if you want to.

CHAIR DELGADO: I am glad that I am not the only one who sometimes wants to use curse words during this meeting. I will acknowledge --

COMMITTEE MEMBER DINIS: It just really pisses me off.

CHAIR DELGADO: No, I completely understand, and also I want to go on record in saying that any transition, especially one from HCAI to agency, to CDII with changes an administrator, multiple changes in administrators, questions about who is the Chair, who is the Vice Chair is super frustrating, and that I feel like that has contributed to a lot of the -- kind of, Maria, what you were saying a lot of the extra work, a lot of the kind of head butting that has been happening.

I'll also acknowledge, I feel like I can say this with a hundred percent certainty, that every single person on this Board, as well as our CDII staff, feels very strongly and passionate about protecting human subjects, and Board members, especially those like Maria who have been on for decades, that that is a passion for them as well. So, I don't -- I would love to take some of these conversations

offline and more one-on-one discussions because I don't want any Board members to feel like the staff is blocking them from being an independent Board, and again, if there are changes that we need to -- that we need to implement to make sure folks feel comfortable that they can, one, take legal advice from CDII and also operate independently as a Board, like that's a super important dynamic and without that threatens the integrity of our Board and not something -- and that's not okay.

So, we'd love to have follow up conversations, Maria, with you and with others. Anybody, please reach out to me so we can -- but I'm really glad these are getting thrown out on the table because otherwise we will just continue to have these kind of conflicts. I know Laura wants to say something.

COMMITTEE MEMBER LUND: Yeah. Actually, I just wondered if we could put Maria's -- that email back up because she didn't get to question number one yet which was right on point with what we were talking about earlier in regard to the (indiscernible - coughing) data sources.

CHAIR DELGADO: Yes. So, let's get back to the issue at hand about the IPA Common Rule in all of these questions. But, Maria, definitely want to acknowledge your frustration and your passion about ensuring that the Board is independent while also recognizing Jen's amazing

expertise in her legal suggestions for our board, and we have to find a happy medium with that, and it's not going to happen today, but to do offline -- hopefully, Maria, you'll take me up on that.

COMMITTEE MEMBER LUND: And I have one more question.

COMMITTEE MEMBER DICKEY: Can I say one thing before we go on?

CHAIR DELGADO: Sure, go ahead and then Laura.

COMMITTEE MEMBER DICKEY: Yeah. There are policies and procedures that the Secretary has approved, and they address this issue of what are the limits for review. I believe that the Secretary has the ability to set our policies and procedures, and we have to operate within them, but I do not believe that the Secretary has the ability to influence any one decision. That's where the line is.

And the Federal regulations dictate that an IRB must have policies and procedures. So, we have some that were approved probably four or five months ago that basically you draw the line -- basically are in compliance with the decision chart that Jennifer showed.

CHAIR DELGADO: Yes. Understood completely, and while I think that that can -- is that what you just said, can exist alongside Maria's frustration that despite that she feels like her decision making has been thwarted and

something that we need to make sure we address.

COMMITTEE MEMBER DICKEY: I understand. I agree. That's why we're having this meeting.

CHAIR DELGADO: Awesome. Laura, can I just request you move forward a little so the mike picks you up. We're getting feedback.

COMMITTEE MEMBER LUND: Just one more comment, because it hasn't ever really been made clear when things that come from CDII are advisory and when they're proscriptive, and I think it would be very helpful for the Committee to know what things are imposed on us and what things we can choose to decide for ourselves based on the advice that we're given.

The policy and procedures, I understand they were signed by the Secretary, were imposed on us, and a review of those suggest that they might not be correct in some regard based on some -- what some of us believe are inaccuracies in the decision tree, and I think we feel like things are -- I won't speak for others. I sometimes feel like things are imposed on us without actually involving the Committee in the decision making process, so I would have to second a lot of Maria's expressed concerns about that. Thank you.

CHAIR DELGADO: Super helpful and I think will probably be a solution to help move us into a more positive trajectory is to be more explicit about what you just

articulated.

Okay. Any other thoughts before we move back to the documents? Thank you, Laura.

COMMITTEE MEMBER DINIS: No one has heard questions, so we went down too fast. There was three and then I think there's something with two. Can scroll back up a little bit? Okay, two.

CHAIR DELGADO: Okay. Can you walk us through what your number two question was, Maria?

COMMITTEE MEMBER DINIS: Yeah, sure. So that allows assuming that we have to follow 45 CFR 46 for review of the human subject research, which review, you know, for the Common Rule, and then that old guidance document of OHRP I think is the same that Dr. (indiscernible) has used.

I think one interesting difference here is what they call the data repository. Now, the State of California is not considered a data repository, and this is where CDII has, you know, I'll say extra powers or extra -- yeah, extra powers. They can do other things with their data. It does not necessarily mean that this Board is required to review and all that. I know it is because it's under the legislation, but they could, choose to remove it from the legislation because it is not a data repository. But instead, if it were a data repository and they had identifiable information, and the CPHS oversees and has

identifiable information, then the expectation that 45 CFR 46 is a CPHS IRB, would have reviewed and approved this under, you know, the secondary -- what they call downstream secondary research. And then if the downstream researchers are going to be receiving identifiable data for their secondary research, then the IRB for these researchers have to review the project as well.

So, I think that one of the conflicts I see right now is the fact that the CDII is not -- or the State is not a data repository, so technically they don't have to follow some of these rules, but they make it complicated because they require CPHS to approve. Technically, you guys can go back to the legislation and relook CPH (indiscernible) and then you approve all the State (indiscernible) and just send it out yourself as you like.

But I think that's one of the problems right now is, you know, which way is it going to be. If you send it to us then I think the conflict becomes if the members want to treat it as we do with any research under IRB rules, so that's a conflict right there, so I would prefer to go to question number one. I think we should talk about that or people may ask questions about that.

CHAIR DELGADO: Thank you.

COMMITTEE MEMBER DICKEY: I'd like to make a statement about that.

CHAIR DELGADO: Okay. Why don't you go ahead, Dr. Dickey, and then Carrie has thoughts, too.

COMMITTEE MEMBER DICKEY: You'll see in the materials I provided there is something in the Common Rule, and actually it was introduced in 2018, that IRBs can review data centers. What they do is they review the protocol and procedures of the data center, they don't review every release. So, it's -- we do that for like CHIS and a couple of other things where there is a data center, and we review their policies and procedures and approve that. We don't do that for any of the State data such as -- and one could make a point that HCAI has -- itself is a data center or a data repository for research. And should we be reviewing their procedures? I think there's a good question that we probably should.

COMMITTEE MEMBER KURTURAL: I was going to tag on on question two, and I don't know if the members are aware of this or not, but I can speak for my department, Department of Developmental Services. We have a specific agreement that this Board will serve as DDS's IRB.

So, for example, if a project comes through and, you know, it involves our data, and we have our internal processes, obviously our privacy and security processes on, you know, making sure every T is crossed and I is dotted, but at the end of the day we're a HIPAA covered entity and

we have to have an IRB, you know, approve the project that comes through my department as well as other departments in this agency. And, so, there's an agreement for this Board to approve -- basically approve that because it is State data, so I just didn't know if you guys were aware of that, but that's why, you know, I think even though we're not a data repository, as question two is mentioning, that overall, there is agreements in place with what do we have, ten departments and agencies with CPHS to kind of serve that role.

COMMITTEE MEMBER DICKEY: So, there may have been -- you know, that may have been inactive even before the Information Practices Act.

COMMITTEE MEMBER KURTURAL: It's recent. They are pending contracts.

COMMITTEE MEMBER DICKEY: Pardon me?

COMMITTEE MEMBER KURTURAL: There are pending contracts just recent. I mean my department probably pays CDII about 25,000. I don't know what the current contract is. It probably has something similar. So, each of --

COMMITTEE MEMBER DICKEY: I'm just saying that the language of it may have been inherited from before.

COMMITTEE MEMBER KURTURAL: Okay.

COMMITTEE MEMBER DICKEY: The question is does it say in there that we have to review it under the Common Rule

or do we have to review it under the IPA, and when the IPA was enacted in 2005, it became clear that we had to review it under the IPA. The history on this is in 2005 the IPA came in place, and in 2008 CMS issued guidance saying that releasing data is no longer considered to be engaged in research. So, there were some expectations from before that kind of went away in 2008 when CMS issued this guidance, OHRP.

COMMITTEE MEMBER DINIS: I think what Dr. Dickey was essentially saying is, yeah, it's not considered research but if you have identifiable data then it goes back to being research and (indiscernible). So, this is where I think our confusion is for a lot of us.

COMMITTEE MEMBER DICKEY: And CMS's and the OHRP is trying to -- and even in these (indiscernible) you can see that they're saying the same thing, is if you are releasing data, that institution's IRB does not have to review it under the Common Rule, but the receiving institution's IRB has to review it under the Common Rule. It is human research, it's just under whose purview is it.

COMMITTEE MEMBER DINIS: Right, then that may be -- question one kind of goes into that a little bit here where the oversight -- you know, who has oversight and Dr. Lowe is saying, you know, here -- again, it kind of depends I suppose, but if you have identifiable private information

and the 45 CPR applies to the research, then there will be an IRB designated to review it. On occasions it's been asked, it could be the researcher's IRB, and it goes on to talk about, obviously, if the researcher responded by a Common Rule agency and it's not and yet those researcher institutions also check the box, as you put it, when they file an FWA.

But then she says this important thing, you know, I want to draw your attention to the definition of identifiable in the Common Rule, and that's what I think is, you know --

COMMITTEE MEMBER KURTURAL: Yeah --

COMMITTEE MEMBER DICKEY: I've always thought to identify it as data unless it's identifiable is not to be considered to be human subjects research. When -- if it is identifiable, it is. But if you go up and read in the middle of the paragraph above it says for this the researcher's institution -- (indiscernible).

COMMITTEE MEMBER DINIS: Right, absolutely, and sometimes they do, but a lot of times they are not coming to us because, why, because the IPA they come to us, so it's back to us.

COMMITTEE MEMBER DICKEY: Well, they come to us because the (indiscernible) come to us because of the IPA, but do we have to review it now under the Common Rule, and

that's the box that Jennifer has at the bottom which says if they request to review it under the Common Rule, they really can, but --

COMMITTEE MEMBER DINIS: Yeah. Well, Lois was my mentor here. She's not here today, but, you know, she's been on this Committee 40 years so, something like that. When I got first got, you know, I would stand by her she would say that this IRB stood, you know, but what was significant or different was that the IPA was above and beyond the Feds. But it meant -- it didn't mean that she threw out the Feds and then review IPA separately. It wasn't above and beyond the requirements of the Feds. So, I don't know if that's the case and I don't know what was the intent of the law back when they wrote it, if it was to be above and beyond the Feds. What I find --

COMMITTEE MEMBER DICKEY: The language says at a minimum.

COMMITTEE MEMBER DINIS: At a minimum, well --

COMMITTEE MEMBER DICKEY: At a minimum.

COMMITTEE MEMBER DINIS: And the IRB and the Fed's IRB also has these minimum requirements, but they never said you cannot do more, it just cannot be less, and I think the same applies to the IPA this precise goals.

COMMITTEE MEMBER DICKEY: If you make the point that when the IPA is written the Committee could make the

choice to review under more than just saying so in the IPA. But who makes the decision?

COMMITTEE MEMBER DINIS: Or, or is there language before when this bill was written that we were to review the IPA on top of the Federal requirements, or like separate it out. I mean what I heard from Jen, CDII is roughly to separate it out. So, I want to see that written somewhere because, you know, that's not always (indiscernible) and for this Committee. So, I want to see if that says yes, when you're an IPA (indiscernible - several people talking at once). And that I have not seen in any document except Laura says, you know, it was supposed to be the Feds and IPA on top not in place of.

CHAIR DELGADO: Okay.

COMMITTEE MEMBER DICKEY: I can give you the history of the IPA. I was there, okay. I was the Chair when the IPA was enacted.

CHAIR DELGADO: Okay. Sorry. Carrie has had her hand raised for a second.

COMMITTEE MEMBER KURTURAL: I just wanted to say that I do think -- I want to thank, you know, the members for raising this as an issue because from a legal perspective I do take a step back on whether what we have and our materials is completely accurate or not. This is a complex legal analysis. It's a preemption analysis of the

IPA and the Federal regulations. It's going to take a deep dive where you need to go back and really look at Federal intent and what they meant in the comments when this was presented and came out in the definition. And I absolutely think there needs to be an in-depth legal memorandum on this, not as I'm telling the Board to do this, but as a suggestion on solutions on how to handle it, because after hearing everything just from a legal perspective it's not an easy like we can't provide advice in a vacuum, so to speak. It is a deep dive that will have to go beyond just even talking the work that, Maria, thank you for doing, but it is something that is going to cause pause and could require a few carve outs.

But also, I want to talk about there is -- we do protect human subjects on the board, but there's that balance on the other side, and the balance on the other side is what's the result if we interpret the common law applying to essentially anything involving PII, right.

What happens is, is the department gets a request for data and it could involve all of my consumers, 436,000 consumers. Is it practical to go out and get informed consent because of common laws applying? You know, not really, but, you know, that might be a different project than taking (indiscernible) data and merging it with biospecimen data, and do you see the distinction there.

And, so, I think not only do we need to do a deep dive and a preemption analysis, but we also need to have exemplars of like certain use cases that we've seen pop up because this stuff gets complicated. I mean my brain is on fire today with all of this.

CHAIR DELGADO: Okay, Laura.

COMMITTEE MEMBER LUND: Yeah. I'll get closer because you told me that I have to.

So, I think that this is an example, since we're talking about the IPA, to go back to the concern about things that are imposed on us as opposed to Committee members making decisions. And one of the things that we've been told is that we may only consider those factors that are listed in the IPA. But one of the reasons I provided the actual IPA language is it says "at a minimum." And that's permissive in law. That gives us as the Committee the opportunity to consider other factors. And I would strongly urge that we talk about, and I agree, I think it's not an instant click, we're going to get this done in two hours conversation, but what other factors of the Committee would we consider, and we can codify that. We can put that in the policies and procedures.

For example, one of the guiding documents that underlies this Committee and all other IRBs is the Belmont Report, and the Belmont Report allows us to consider ethics.

It allows us to consider fairness and justice and other kinds of criteria when we're reviewing studies. It says that we're supposed to do that. So, to what extent are we allowed to apply those kinds of criteria in an IPA situation? I know that we have had projects that are IPA only come up before this Committee because people had some concerns about the ethics of that research, and it would be really good if we decided what we as a Committee should consider.

COMMITTEE MEMBER KURTURAL: I think that is great, because I think there is a lot of gray area and that even when we get an in-depth preemption type of legal memorandum on this, which I'm sure Jennifer's group can do after they conduct a deep dive, then that's when -- that's perfect for the Board to step in, okay, what does that mean for us, you know, what type of commonalities are we seeing where we could put in some -- use cases and tweaks for the policies. I mean I think that's great. It's a good idea.

CHAIR DELGADO: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Can I talk about what I see is the elephant in the room that has not been discussed yet?

CHAIR DELGADO: I love talking about elephants in rooms. Yes, please do. Can all of you hear Dr. Schaeuble on Zoom?

COMMITTEE MEMBER SCHAEUBLE: Carrie very briefly mentioned it a moment ago, but the ultimate concern I see here is that the policy document that was given to us as already approved without any discussion by the Committee and what Jennifer is describing as guidance but seems more -- seems stronger than that certainly in some vast instances where the Committee has had particular protocols to review. Those are saying that we are limited in what an IPA review can consider, even though the language there says those criteria are a minimum.

And where this really comes into conflict for me is the very question of the consent for the data that the researchers want to use. We know that researchers asking for data don't have the original consent for the information on their radar. They pretty much assume if an agency is willing to release the data, it must be appropriate for them to use it.

Now, in theory we might hope that the researcher's institution if it has an IRB reviewing the study would take into account whether the original collection of the information provided consent for the kind of uses being requested, but, in fact, we know that is not happening. We've seen reviews that researchers institutions do. We can easily tell from what we see there that they are approaching this from the same angle as the researcher, assuming if an

agency is releasing data it must be appropriate for it to be used.

The agency, itself, that is releasing data really has no skin in the game on this either. They collected the information originally for some other purposes for the agency's use. At best, if there was some consent requested at the time it was with the goals of the agency in mind for how it would use the data. Any contemplation of other uses later on for other purposes by researches, or whomever, that's far down the list of any consideration for the agency.

And what happens here is that if we as a Committee assume that we are limited to only the criteria stated in the Information Practices Act and do not go beyond that to questions like what permission did the people give for the use of their information, then really that never gets considered at all by anybody.

And what's the quality of the consent we're talking about here? I have a good personal firsthand experience because, as some of you know, my wife had surgery recently, and I can describe to you exactly what the consent process was like. We get up in the middle of the night to arrive by 5:00 a.m. so that they can do whatever they need to do before the surgeon and anesthetist come in.

At the check-in desk there's a tiny screen, same size

as what you typically see in stores when you're asked to sign your name for a purchase that you're making using a card. The person at the desk swipes three or four times across the screen. You can see several pages of text fly by, and she says, so this is the agreement for you to have the surgery today, and you need to sign here to approve the agreement. Okay, that's step one.

Next she says if there were an emergency are you willing to have a blood transfusion. We have to ask that. If you are willing, you need to sign this. Okay, second signature.

And last, this is the privacy agreement saying that we won't share your information without your consent. Sign here. Okay. So, that's it. You're done. Now go wait to be called in for your procedure.

All of these signatures, of course, said you agree with everything in the document and you've been provided with a copy of the document, and interestingly enough, there were no copies of anything.

Not taking that kind of thing very well, after my wife go into the process of actually having the surgery I went back and asked for copies.

Well, the first time around I got the copy of the first thing she signed, the agreement with the hospital, which, of course, eight or nine pages basically all about if

your insurance doesn't pay we'll come after you. That's the essence of all it said.

Attached to the back of that was the signature page only with regard to blood transfusions and a signature page only with regard to the privacy document, not the documents, themselves, but just a signature page.

So, I had to go back a second time and ask, well, I'd like to see the privacy document, and they had to route around on their computer to even find it, but eventually she brought it out.

Buried within four or five pages of the privacy document was one, and only one, portion related to using information for research under a general heading "How else can we use or share your health information." One of the topics covered as a subheading "Do research," with a single sentence, we can use or share your health information for health research.

Now, that's totally nonspecific, says nothing about what kind of health information, says nothing about what kind of research might be contemplated. I'm sure the attorneys are thrilled with this because they can point to the document and say, well, you signed this. You agreed to it. It doesn't have any limits on what information or how that information might be used. The hospital is covered, physicians are covered. It doesn't do a thing for the

patients.

And do you think anything about the process I'm describing here qualifies as a voluntary informed consent obtained under stressful circumstances to begin with when one comes in early in the morning for surgery with no real information provided about any of these things before a signature is requested, and, if anything, misleading statements verbally that, of course won't count saying that we won't share information without your consent. And, yet, when we look at anything that agencies can point to about any consent they contain, have obtained in the past, this is pretty much the level of what we see. They either have no record of obtaining consent at all, or if they do, it really is not any better than what I've just described to you as our recent experience.

Now, I cannot justify in my head saying that Information Practices Act reviews should not be able to look at the totality of what are the variables being requested, how are they going to be used, how sensitive is the information, what is the -- what kind of consent was ever obtained in the first place for the information, would those individuals be likely to object if they had any knowledge of the research use that's being proposed here. I cannot justify doing that, and yet, we are being advised that we may not be supported, we may not be legally protected if we

do the very thing that seems like we are most obligated to be doing as a review board. That's my quandary in this and that's my elephant in the room on all of this.

COMMITTEE MEMBER DICKEY: John, can I respond to that?

COMMITTEE MEMBER SCHAEUBLE: Sure.

COMMITTEE MEMBER DICKEY: I think it's really -- what you are saying is really understandable. I really do, and I'm sure it was not a pleasant experience for you.

But in 2018, OHRP introduced something into the Common Rule that says that IRB as the releasing organization can do limited reviews of the (indiscernible). And those limited reviews basically have to do with reviewing their broad consent procedures, that is, is the consent that the individuals have provided for this data, is it adequate to enable them to release it. It doesn't go into -- it doesn't go into project by project, but it says are the procedures in the center of the page established and the broad consent that they have obtained is not adequate, and that's why I was bringing it up.

I think under the Common Rule we can review data centers for the adequacy of their consent, but we can't do that project by project. So, one thing, it would be extremely difficult to do it project by project, and they assume that the other -- the reviewing receiving

institution's IRB will be also looking at it. But, you know, if -- you know, I think that's a policy decision for the agency probably is, you know, can and should we be doing this limited review of data centers.

CHAIR DELGADO: Okay.

COMMITTEE MEMBER SCHAEUBLE: Can I respond?

CHAIR DELGADO: Yes, you should definitely respond. I'm just going to pause for 30 seconds on this discussion just to update folks.

Maria, what you said earlier about your feeling like this Board does not have independence really struck deep in me because of the recognition of how important that facet is. Our Board's decisions mean nothing if we are not an independent entity, so at 11:00 o'clock -- so, we're going to continue this discussion. At 11:00 o'clock we are going to be joined virtually by John Ohanian, the Director of CDII, as well as in person by Marko Mijic who is the Undersecretary. He's basically John's boss.

I would love if folks -- this is a conversation that needs to happen in public with full transparency, and so I would love for folks to kind of -- we'll take a five-minute pause before 11:00 to gather their thoughts, but would really love for people to feel like they can articulate those concerns, both to Director Ohanian as well as Undersecretary Mijic, because again, as I said, like it's

one thing for me to say we're independent, folks' voices need to be heard, but the big bosses need to hear that, too, and understand this dynamic in a fully transparent environment. So, just want to let folks know that that's our plan for 11:00 a.m. We will pause at 10:55, but don't want to thwart this discussion about the data repository. So, I think Dr. Schaeuble was about to respond to that.

COMMITTEE MEMBER PALACIO: Before he responds, are we scheduling to end at noon?

CHAIR DELGADO: We are scheduling to end at noon.

COMMITTEE MEMBER PALACIO: Good, because I need to leave.

CHAIR DELGADO: We won't handcuff to you the table.

COMMITTEE MEMBER PALACIO: Good.

CHAIR DELGADO: Okay. Sorry. Dr. Schaeuble, please proceed.

COMMITTEE MEMBER SCHAEUBLE: Well, I think my concerns goes certainly beyond what Dr. Dickey was talking about most recently here, because looking only at the circumstance where we are doing a review under the Information Practices Act, the language there specifies a minimum set of criteria that need to be reviewed, and what I'm saying is that if we truly treated that as a minimum instead of a maximum, I think we would be looking at the

question of consent as part of our thinking.

Let's face it here. Let's be honest about what we're doing. If we say we do not in any way consider the consent of individuals originally in providing their information, if we say we're not going to look at that at all, what we are, in fact, doing is saying that we are giving a blanket waiver of informed consent for any data only project being reviewed under the IPA only, and I don't think that's appropriate.

Now, there may be many instances, I think there are many instances in which the nature of the research study is such that if we were consciously thinking about it we would say the greater good here is to waive consent. The sensitivity of the information is not so extreme as to raise huge concerns about doing that.

But we've also seen, especially in the past year, that there are certain projects that are very concerning where clearly it's not appropriate to ignore the question of the consent for the information. And I'm not willing -- I'm not willing as a person to operate in a way that amounts to a blanket consent, a blanket waiver of informed consent for all data projects. That just isn't reasonable to me.

COMMITTEE MEMBER KURTURAL: I think I -- I mean I know being on the ground floor and seeing some of the concerning projects to me, the concern being mix matching of

data, connecting data sets, so they're usually the ones that have my ears up for the reviews.

And another middle ground option, you know, talking about this, that might be the extreme informed consent, another option is like some of the projects I feel basically full board review, right. Maybe you don't make them get consent for a half a million people, but it's an important enough issues that, you know, due diligence is just getting full board review instead of an expedited review, and, you know, I think you could do that under the IPA with that added minimums, but, go on.

COMMITTEE MEMBER LUND: No, I absolutely agree, and I think that one of the things that perhaps we don't use as a tool often enough is -- perhaps one of the things that we don't do often enough as a Committee is acknowledgments of the informed consent issues. I think, John, you're right on point with that. And one of the ways to handle that is not to say that the research can't be done because we can't obtain reasonably informed consent from 500,000 people, but to acknowledge that the research, if it is important enough, is important enough to give a waiver of informed consent. So that waiver means that the Committee has considered all of the aspects of the research and made a determination that it is important enough to go forward, even though the consent may not have been adequate, and to can consider only

the things Dr. Schaeuble just raised.

COMMITTEE MEMBER KURTURAL: Yeah. And I think that, you know, that the creative solution, you know, what you're describing and I think that in order to get there with that creative solution we just need to have Jennifer's group do a deeper dive to see the legislative intent of that one section and then we can start discussing, and that's the flexibility that we would have as an independent board. I absolutely think we can because IPA does use the "at a minimum" language, and, you know, maybe it's not like a HIPAA waiver informed consent situation, you know, but it's a full board review.

COMMITTEE MEMBER SCHAEUBLE: It seems to --

COMMITTEE MEMBER DICKEY: I think --

CHAIR DELGADO: Oh, sorry. Hold on. Dr. Schaeuble had just started, and then we'll go to you, Dr. Dickey.

COMMITTEE MEMBER SCHAEUBLE: It seems to me there are a whole range of possibilities here, and we really should not be ruling out any of them.

As I said earlier, there may be many projects for which the notion of waiving informed consent seems fairly reasonable at the offset. There may be others that definitely need to be discussed by the full Committee at a minimum.

And going beyond that, I would also say there's -- I think there should not be a presumption that, of course, because the researcher has requested data it will be approved. We may have an obligation to work with the researchers to change what's being done with the data so that it is less likely that if the people whose information is being used less likely that they would object if they knew what was going on. There may be changes maybe to be made. In rare instances, I think they would be rare, but again, we know from recent experience it's not impossible. In rare instances it may be that the researchers cannot come up with a satisfactory way to resolve conflict between what they want to do and the absence of consent, or incompleteness of consent, or whatever. And we should be prepared for the possibility that we might sometimes have to say no.

So, I mean, we should have the ability. We should not only be able, we should be encouraged to use our professional expertise to make the appropriate judgments about what the circumstances are, not to try to follow some cookie cutter list of topics and limit ourselves only to that. I'm done.

CHAIR DELGADO: Thank you. Dr. Dickey.

COMMITTEE MEMBER DICKEY: I was just going to say that I think the Common Rule is quite clear that we don't

have to review it, review data releases under the Common Rule, but we can review data centers, so, I think Legal really needs to look at that because it may be that by reviewing data centers we can accomplish just as much.

And also, Legal really needs to look at the information packets of that because there is that word "minimum," "at a minimum," and what did that mean. I think it meant that there were going to be some projects that we had to review under the Common Rule so they didn't want to restrict us, just to be like hundreds of them under the IPA. But, I mean, that's something that just as looking at the background on the Common Rule we need to look at the background on the IPA.

I know Jennifer has said in the past that if we want to review beyond the minimum, then we have to pass some sort of regulations. I don't know if she still feels that way or not, but, you know, the door is open I think.

CHAIR DELGADO: Thank you.

CHIEF COUNSEL SCHWARTZ: I'm going to jump in because I want to clarify something with respect to the advice I try to fix them. A lot of conversation around what the minimum of the IPA is, and during that conversation we had the document of the statute up and we were talking about the language, and the IPA language does say "at a minimum the following criteria need to be considered." My advice to

the Committee was actually a bit nuanced. It was that, yes, these are at minimum of what the Board should consider in terms of approving the State data research, but that the -- because of the way that this statute is written the Board should consider things that are similar to those criteria rather than bringing in an importing things that are outside of those criteria.

So, I'm happy to put the statute up. I'm happy to have folks discuss it. We certainly can take a legal look at it and provide -- I'll bring it right into the Board. That might be much appreciated so that the Board can see exactly what it says and then ask questions about that. We're happy to do that.

COMMITTEE MEMBER DICKEY: Do you mean to display it right now. Was that the question?

CHIEF COUNSEL SCHWARTZ: If the Board would like, I can display it right now. It will take me a moment to pull it up, but I'm not sure. I don't want to derail the conversation or interrupt the conversation.

CHAIR DELGADO: Sure, why don't you if you could, Jennifer, pull it up for now and then it can -- you know, I do think that we're going to leave today probably a bit unsatisfied in having decisions made, which let's all start to feel okay with that unsatisfied feeling. But also, you know, I do think -- I'm taking a list of all of the concrete

issues that we're talking about and adding this to it, but I think, Jennifer, what you are about to pull up on screen is part of what folks need to be considering, so I think that's super helpful.

CHIEF COUNSEL SCHWARTZ: Can folks see this?

CHAIR DELGADO: Yes, we can.

CHIEF COUNSEL SCHWARTZ: Okay. So, there's two sort of pieces to the criteria in the IPA. And the first piece is this portion here, which is inspection number one, and we're looking at 1798.24, subdivision (t), and now we're on (t1).

The first piece is this section right here, which is the approval of the CPHS of research in projects involving state data include a review in determining that all of these three criteria have been met. And, so, of course, a lot of the application that a researcher filled out contains all of this information.

So, that's sort of the first piece. I think where folks have been focusing their attention is this next bit, which is that right here that the CPHS shall at a minimum accomplish all of the following as part of this review and approval of research to determine whether personal information is needed for the access, to only if it's needed, to access only to a minimum necessary personal information that's needed require assignment of unique

subject codes. In other words, mask certain types of identifiers, and then, if feasible any kind of cost if the agency is needed to conduct a portion of the data processing to sort of -- in order to minimize the release.

So, for example CPHS could say to the State department we want you to address masking of certain portion of the data so that the least amount of data can be released. The Board has the authority to do that. So, that "at a minimum" language is in this portion here, right in here.

And one of my recommendations was is that, yes, it says "at a minimum," and that the Board consider that these are the pieces of criteria that the Board is required to consider and to minimize. So, clearly here this is intended to limit the amount of personal information that is released for research or mask the information that is being released for research.

So, that all goes to sort of what the CPHS can sort of do in terms of its review. So, my advice was that when you consider how to address this portion, consider that this portion, the essence of it is releasing the least amount of information to accomplish their research objective. Is there any masking or an itemization that needs to happen so that the research may not need to have that information, limit it to the minimum necessary, and

decide whether or not, in fact, personal information is needed in order to do the research at all.

So, I just want to be very clear about that because I'm a little concerned that because we had conversations, and the conversations have been, you know, robust conversations, I want to make sure that folks understand that my recommendation was that the Board consider the essence of this in terms of how to import additional criteria for your review. Does that make sense to folks I'm going to sort of ask folks to open it up, the question, but I can see your beautiful faces now. I put you back up.

CHAIR DELGADO: I see a hand from Dr. Schaeuble.

CHIEF COUNSEL SCHWARTZ: Yes.

COMMITTEE MEMBER SCHAEUBLE: So, we're looking at the document here, and the initial sentence says, "The Board shall at a minimum accomplish all the following for the purpose of protecting personal information." And what I'm hearing is what I would consider to be a very narrow interpretation of that phase for the purpose of protecting personal information as opposed to a broader interpretation that would recognize the autonomy of people is that they have the final say on how their personal information is used. They can share it with an agency with some initial understanding of the purposes for which that agency has

requested the information, but they don't lose their rights to protect that personal information from other uses that they might not want. And in that regard the question of consent that I was talking about at length earlier would be an important part of protecting personal information if that phrase is interpreted in a broader sense than what you were doing.

And I think my direct question to you, Jennifer, is it certainly sounds like you are saying if Committee members using their professional expertise consider things beyond the very narrow interpretation you're talking about, legal staff may not act to protect us if our actions are questioned, and we might be exposed to liability that presumably the only way we could cover would be to obtain additional professional liability insurance of some sort for our totally volunteer activities here on the Committee, which would be yet another unreimbursed cost for all of the work that we do, and I'm getting very unhappy following that train of thought.

CHAIR DELGADO: Understood.

CHIEF COUNSEL SCHWARTZ: So, I want to clarify that seems to be a misunderstanding that folks have. I never once said that the State wasn't going to defend your decisions. That never was what I said. What I said was that I'm informing you of what I believe the jurisdiction --

the legal jurisdiction, the legal authority of the CPHS is. Whether the State -- whether you will be sued is a question. Anybody can sue anybody. That I can't prevent. I can be sued tomorrow for something I may not have done, and I can't prevent that.

Whether the State will choose to represent is a totally different question. My advice to the Committee has been based on my understanding and interpretation of the legal authority of the CPHS.

What happens when a body acts in excess of their legal authority is that their decisions are often considered void as acting in excess of their authority, and then what would usually be something that under the jurisdiction is outside of the jurisdiction. That's what I've been saying this time. I want to be very clear about that.

CHAIR DELGADO: Understood. I'm going to pause us. I gave everybody we have five minutes. You have two minutes to just get up, get some coffee, stretch your legs. We in two minutes are going to be -- we're going to start right on the top of hour, going to be joined by Director Ohanian as well as Undersecretary Mijic. They have 30 minutes. I'm going to open with, you know, just my own personal reflections on some of the things that were said today and then open it up to the group for, hopefully, folks feel comfortable sharing in this space some of the things

that they shared earlier. And then probably right around 11:30 we're going to move to make some motions specific to what's written on the board, and so let's pause now for 60 seconds because I'm continuing to talk and cutting away your time. So, we'll come right back.

(Thereupon, meeting recessed.)

CHAIR DELGADO: I want to bring attention to Director John Ohanian who is on Zoom. He is on camera. He is waving. For those of you who are in the room, Undersecretary Marko Mijic.

Just so everyone understands kind of the chain of command, especially as we talk about concerns today, please know that Undersecretary Mijic is the Undersecretary of California Health and Human Services, so the agency as a whole. Underneath the agency there are 12 -- I should know this -- 12 departments, five offices, one of which is CDII, so CDII being one of the offices under Marko's purview is Director John Ohanian. So, we have representatives here. So, thank you John and Marko for literally coming on 30-minute notice.

One of the reasons why I personally asked you guys to join today is because we've had a great meeting with holding space for some concerns that have come up from CPH Board members -- CPHS Board members about the Board's autonomy. And I know personally as Chair and having been on

the Board for a very long time before this, that the autonomy of the Board is of the utmost importance. And if folks are feeling as though that is being challenged, then it's incredibly important for Director Ohanian to hear that as well as Undersecretary Mijic, so we can have a very open and transparent discussion about these concerns.

At first I had said, oh, we can meet afterwards behind closed door and then I thought you know what, that doesn't give the transparency that's necessary for this type of discussion.

So, I'll lead just by opening that there were a number of people who expressed concerns about this, and so I'd like to open the floor for, I don't know Dr. Dinis, don't want to put you on the spot, but if you wouldn't mind starting us off and then others kind of fill in behind her.

COMMITTEE MEMBER DINIS: Sure. I was muted.

So, before we became part of CDII, this question of the Board's independence was never an issue in all the 20 years I've been here, and when Lois was here the 40 years, that was always of utmost importance, the Board felt they were completely independent and we know that, you know, Nickily, whoever is the RO for this Committee, you know, they may approve a project on their own, I guess. I think that's how it goes. But if the Committee makes a decision, they cannot reverse that Committee's decision, and I'm not

implying that that was ever done. That's never been done to my knowledge.

So, I know that technically we have this independence, but the pressure I have felt from CDII in the instance they've become -- since we've gone under them -- it feels like we're under them -- is just not -- it's just really bad, you know. It seems like it's in conflict of interest. It seems like we're converted to what they -- their needs. Their needs is to really state as fast e possible the needs of researchers and the pressure is on for us to approve faster, faster, faster and faster. And, so, it's sort of contrary to what our rule is in IRB with this efficiency is at the moment we're under their motions, like we're under them, and so that's been the issue for me, feeling like we're not truly independent, and the guidance we get now and then, it seems -- the guidance we get it seems more like not necessarily legal guidance, but this is what you're going to have to do. And, so, I mean there's certain amount of intimidation to me and I feel about. I fear that, yeah, if you make a decision and it's going to be -- and which decisions, you know, you've got these protections legally because you've went outside of the means here of legal context you may be sued or something to that effect. I mean it bothers me because I know it's the ethics that we're talking about here. You know, it's not the law.

We've been arguing about ethics, whether this is ethically correct or not in my view. And, you know, how are you going to sue me on my ethics. I mean I'd like to know. So, I think that's my concern.

CHAIR DELGADO: Got it. Thank you, Maria.

UNDERSECRETARY MIJIC: Can I?

CHAIR DELGADO: Yeah, go ahead.

UNDERSECRETARY MIJIC: Thank you for sharing that, and just to make sure I understand, so it sounds like there are two pieces that I want to make sure I clearly understand the concerns you're raising.

One is the workload, and related to the workload, and obviously it sounds like there's a lot of things for folks to approve, and you want to take some time to do that, rightfully so.

The second, and I want to unpack that a little bit more, I'm hearing is issues related to legal opinions around what you as a Board are ultimately doing. And what I'm hearing you say is a feeling that the interpretation from the lawyers is such that you feel like your authority or your ability from an ethical side is being put into question because you're being told that you are doing something that might be illegal. Is that -- would that be accurate?

COMMITTEE MEMBER DINIS: Yes, and the late part, the workload, it's not necessarily more of a workload than

there's ever been before. The workload is what it is. It's more of a pressure. I think there's a certain amount of pressure because it's like these two agencies, the IRB and the CDII are opposite of each other. Their goal is to release data. Ours is to make sure that the data is released properly. So, we both have different aims, and, to me, this position that we've been housed under them is completely out of whatever. It's inappropriate to me, as far as I can see because it's like almost a conflict of interest. It doesn't work.

UNDERSECRETARY MIJIC: I don't know that -- I guess I struggle to understand how it is a conflict of interest because our role and responsibility as a steward of government information is to ensure that that data is released appropriately. So, your role and responsibility is no different than ours as a State entity who is responsible to make sure that this data is released in a way that meets all of the different standards that we have both with regard to State and Federal law, but also with the standards that we as an organization have put in place. So, I struggle to fully understand how there is a conflict of interest between our duty and obligation under the law as a State organization and your duty and obligation as a Board in this particular instance. Can you unpack that a little bit for me?

COMMITTEE MEMBER DINIS: Well, it has felt under this organization that the CDII is more protecting the researchers and looking after the researchers and their needs and interests and less so in the sense of not -- not protecting members to me, you know, like members are more like -- it's almost like intimidation, a soft intimidation I'll say, but a bit of that and so that the focus is -- is on the researchers, and we need to focus on the data, the human subjects, the vulnerable populations. It's not to focus on the IRB. It's not to focus on the researchers. The researchers are making a career. They're doing this for their own needs and purposes. I understand that. But the focus here should be on the vulnerable populations and I think some of them are exploited and that's what I object to, and that's what I mean both of our agencies or departments are in opposite direction.

COMMITTEE MEMBER DICKEY: Yeah, I think that --

UNDERSECRETARY MIJIC: Go ahead, Doctor.

CHAIR DELGADO: Dr. Dickey.

UNDERSECRETARY MIJIC: Go ahead.

COMMITTEE MEMBER DICKEY: Dickey.

UNDERSECRETARY MIJIC: Yeah, go ahead.

COMMITTEE MEMBER DICKEY: Just to make it a little more concrete for you, the Information Practices Act designates certain criteria at a minimum what it is to

review data releases, and those criteria are really restricted to minimum necessary data and is the date going to be adequately protected and secured. It doesn't address when is informed consent obtained properly originally from the people, is it ethical to conduct such research. So, the Information Practices Act is pretty narrow as currently being interpreted, and that's I think the crux of the issue.

CHAIR DELGADO: And that when Board members feel like per their ethics they need to put their foot down and say no, this is not appropriate. Maria, I'm speaking for you so correct me. But that you have felt pressure from CDII that you need to pivot on that opinion or you need to reverse your opinion because we need to be good stewards of State data and make sure researchers have access.

COMMITTEE MEMBER DINIS: Yes. Otherwise, I get in trouble, might get sued, and on and on. Yes.

UNDERSECRETARY MIJIC: I think I'm just trying to unpack -- I mean there's a lot here to unpack and I'm not going to be able to do that in 30 minutes, but I think this is, hopefully, one of many conversations to figure out a path forward here.

The issue around -- and maybe it would be helpful to understand what -- you know, it was my doing, directing the move of this body under CDII. And we did that for a few different reasons. One is we established the Center for

Data Insights in a way to create a locus of this work across our organization because no one entity in our organization is kind of the only place where people look to ultimately get information from.

And what I mean by that is as we continue to think about how people do research and how we engage in the conversation around our programs and services, the recognition that the people we serve and the people that are engaged with us are coming to us from various different parts of the organization. You may have somebody that is a Medicaid beneficiary who also is an individual who's getting CalFresh or CalWORKS, and so their recognition that these are all interconnected efforts.

The other idea here really was how do we beef up our own capacity internally to be able to create a space for us to engage with the research community so that we are not waiting until a paper is published in the "New England Journal of Medicine" or "JAMA" five years from now, but rather, engage with them proactively now to understand how they are looking at the data to perhaps use it in a way to inform our policy and programmatic work. And, so, one task really is to figure out how do we -- the customers that are coming to us to get data, and you may -- you know, you may think that people are exploiting individuals, and it's your responsibility to think that through and determine that, but

it is also responsibility to figure out how do we create an environment where people do come to us and have a good experience in getting access to data, but it's not bureaucratic. And it's not just data, also, when we think about somebody's research protocol, but that research protocol really is routed in kind of the standards of an IRB.

And, so, I think that we have a responsibility to build trust with the community who is coming to us and to not do something that is bureaucratic. But it also is our responsibility to ensure that the information we release meets all of the standards by State and Federal law, and, so, I think trying to unpack some of those pieces to make sure that we're thinking about it more holistically.

Maybe, I think -- Alicia, you have your hand raised. Would love to kind of get your feedback on this as well.

COMMITTEE MEMBER BAZZANO: Thank you. Just a couple of things to -- to paraphrase what I heard of your perspective, it has to do very, very meaningfully with wanting to utilize the data that we have to be able to do better, absolutely, to do better absolutely -- to do better for the -- for all people across California who use and utilize across services of (indiscernible), absolutely.

And at the same time what I heard was you defining that

the customer is the researcher and that there's an underlying assumption that the purpose of CDII is to get the data released. And I think fundamentally (indiscernible) and maybe this is my introspective on CPHS, but I'm pretty sure it's held across, our customer at CPHS is a research subject. That's who we're there to represent as to we are trying to make the best decisions on behalf of. And that's who -- honestly who we -- if there's any bureaucracy, it's to protect their subjects.

And, so, one, there's a difference between the customer, and, two, there's a difference between the assumption, because our assumption is that -- not that the data is going to be released. Our assumption is that sometimes the data is going to be released and sometimes it's not based on an ethical ramp. And, so, there are some fundamental assumptions and models that are different and that can definitely be in conflict, as you can imagine.

UNDERSECRETARY MIJIC: Yeah.

COMMITTEE MEMBER BAZZANO: I do think the problem is when you've got multiple principals in conflict, differences in ethics, is how do we prioritize those. And what is becoming apparent to us is that the priority is towards the researcher, and this is any regulatory body, right. If you're talking about the FDA, if -- everybody has to work with the -- just different constituents here, but in

our case our most sole purpose is to represent and to hold the research subject as our both beneficiary and, you know, in that sense the -- I think where we're coming in conflict is that our purview, like sometimes happens in different settings, is becoming very, very narrowed based on the interpretations that we've gotten from the legal counsel. So, that's concerning.

UNDERSECRETARY MIJIC: Yes. So, I mean, there's a lot to unpack here. I think that just to clarify, CDII's role is not to release data. CDII's role really is to harness the data internally to help us internally, figure out how do we actually use that information to inform the policy and programmatic development of our work across the organization. So, just to clarify.

And I think this isn't an or, it's not the researcher or the subject, I think this is an and. And I think it's really important to think about it in those two contexts, that those might be in conflict at some time, and you all have your responsibility to focus on the research subject, but I don't think that this an or. It's not the researcher or the subject. I think it is a both in the end.

And I think it would be -- you know, we need to probably do some digging into -- your last comment is particularly interesting to me about your authority being narrowed. I think I want to begin with the legal team to

understand what is changing in terms of legal opinion that narrows the scope. And I would love specific examples where you feel like your authority pursuant to the legal analysis has been narrowed. So, my ask to you is to really demonstrate to me in what particular instance was your authority narrowed by the legal team so that we can kind of figure that out in short order.

Is there anyone in person that wants to weigh in here, too?

COMMITTEE MEMBER KURTURAL: There is == there is a question that I have coming from a legal perspective on whether CDII's team did a deep enough dive into Title 45 of the California Code of Federal Regulations. And I would like to see some further research, like a preemption-type analysis, and particularly over section 46.102, subdivision e(1). It talks about personally identifiable information potentially being subject by the common law, and I think there's some confusion, you know, because right now it's more a (indiscernible) between what's a data-only project and what is a human subject project, whereas I think there needs to be -- for data only there could be some carve outs there where it actually does need to go through, full blown comment on that subject. So, I do think like a deeper dive. You can't provide advice in a vacuum, you know, but a deeper dive needs to be made on IPA data only versus Title 45,

Section 46.102, subdivision (e). My -- you know, it is confusing the way the Federal Reg. is specified because it talks about PII in there, but it also has for an identifiable biospecimen, so I don't know if that just means clinical research or if that means beyond, so I'd like to see what the Federal Register comment has to say about that.

CHAIR DELGADO: And, Carrie, if I could just interrupt. That's actually a perfect example of where, you know, in some instances when there are questions like that CDII is legal to no issue -- a briefing on that, and I think what the Board is asking is that they are allowed to make a decision with that legal interpretation in mind, but also, don't feel like that legal interpretation is exactly how they need to act moving forward.

UNDERSECRETARY MIJIC: Oh, that's absolutely -- but I should be (indiscernible) the process.

CHAIR DELGADO: Which one, the latter?

UNDERSECRETARY MIJIC: You can ask the legal counsel for interpretation, but you all have to make a decision weighing the interpretation of legal counsel, but that is not -- you should not, you know -- you have to make the decision on whether or not you need that legal counsel or not.

CHAIR DELGADO: Yes. And, Carrie, you say that out loud. Again, we only have Marko and John for seven more

minutes. I want to make sure, in addition to some of these examples that people feel space to express how they've been feeling out in the open.

COMMITTEE MEMBER LUND: Thank you. Thank you for being here and taking your time. I just wanted to say that I agree with everything that Dr. Bazzano said, and she was much more articulate than I would be so I'm not going to rehash that.

In your response you said both and, and I just wanted to point out that I think therein lies what I and perhaps some others on the Board experienced perhaps a conflict of interest, because sometimes it can't be both and.

For us as a Board the welfare of the research subjects has privacy, and sometimes it means it isn't both and. Sometimes it's a zero sum game and the research subjects win from this Board's perspective, and we may have to deny researchers, and there's not a way around that.

UNDERSECRETARY MIJIC: That's fine. That's your job, right.

COMMITTEE MEMBER LUND: Yeah.

UNDERSECRETARY MIJIC: But my comment about and and --

COMMITTEE MEMBER LUND: So, if I could just finish.

UNDERSECRETARY MIJIC: Yeah, go ahead.

COMMITTEE MEMBER LUND: So, I think what makes us feel perhaps that there's a conflict of interest and unsupported is that it seems that both and is the imperative instead of we'd like you to get to this if you can.

So, thank you. Go ahead.

UNDERSECRETARY MIJIC: Yeah. So, I think the and is when I look at the organization as a whole not your responsibility as a body, right. We have to -- I have to juggle multiple pieces, and each entity within our organization has their responsibility. But it isn't just -- I can't just say that our sole responsibility is one thing over another. Your responsibility as a Board is to solely focus on the subject, and that should be your responsibility. And, you know, whatever white noise is happening around you, you have the authority to make an independent decision.

Now, I think the question to Maria's point earlier, if you're being made to feel that if you make a decision, then you're doing something illegally, right. I think that is the question that we need to think through in terms of what counsel you get and how that counsel is presented to you. But your decision is the decision you need to make and your authority is focused on the subject. We as an organization more broadly outside of this body have

to think about the and, right. But just to be very clear, I am not asking you to do an and. I am asking you to focus on your statutory authority which is the human subject. And if you come forward and you say in this instance based off of our review we believe that we must deny that, that is your prerogative and we will stick with that. But if the question is around whether or not you're being -- you feel like the counsel that's being presented to you makes you feel as if you're doing something illegally, that is a whole different thing that we need to kind of think through and figure out how you do not feel that way. You are getting advice from counsel, but it's up to you all collectively to make a determination on whether or not you take the advice of counsel or not. In my day job on a daily basis, I get advice from counsel. There are instances and vast majority of instances where I take their advice and counsel. In some instances, I might not because I think that there are other factors that have to weigh in in terms of my decision making. And you all are grownups to make the decision in that way, too, right.

So, I just want be very clear. I am not saying you have to look at the researchers versus the subjects. You have one sole responsibility pursuant to the statute, and that is that the research subject, and you should make those decisions based on that. Nobody is filtering that,

nor should anybody be filtering that.

And, you know, I think it would be helpful for me to understand what a path forward here is because we do believe in a strong IRB, and as I said before, we do want a world class IRB within our institution, and we want people to come here to feel like they're getting world class service, not bickering between people or institutions, but they feel like they're actually coming to a place where something is being thoroughly vetted to understand whether or not a research project should be moving forward. And there's also a difference, and your role and responsibility over time has changed. You were solely focused for many, many years on real research where human subjects were actually involved. The whole addition of the release of data is a whole different element of your work, and I think that also needs to be looked at in terms of what is the role of this entity and should it be focused also on the release of data as well as the use of human subjects in a particular research protocol. Those, to me, are two very different things, but I think that also is something we need to think about, whether or not we need to delve into clarification within the statutory framework of this work.

CHAIR DELGADO: So, just to be mindful of time because I know you have to leave, Marko, but this is just a first discussion. I am so glad, Maria, that you brought it

up earlier so we could have this in a very open forum because otherwise threatening the independence and your voices, and so, just really appreciate you bringing this up. While we won't come to a resolution today on this, I think having John and Marko here to understand your concerns is the transparency that we need.

UNDERSECRETARY MIJIC: And I would just in closing I understand that there was a letter that was sent to the Federal Government, so I think it would be good to get a copy of that letter because I don't think I've seen a copy of the letter, so I would love to get a copy of the letter.

I would also urge you to kind of come together as a group to make a recommendation to me around how you want to proceed and what you want to do next. It is easy to point to the problem. It is harder to point to the solution. And I would just ask folks to just -- and no one's feelings are going to be hurt, but I would ask you to kind of outline what the pass forward really looks like based on what you think is going to ensure that you all have the right environment to do the work that you need to do pursuant to the statute.

COMMITTEE MEMBER KURTURAL: I don't think we can come up with a path forward or options without getting a legal opinion from CDII to do the deeper dive because then you don't know the boundaries we're working with.

CHAIR DELGADO: I think that would be part of it.

UNDERSECRETARY MIJIC: Well, then perhaps.

CHAIR DELGADO: That would be part of it.

UNDERSECRETARY MIJIC: Well, perhaps if it's not CDII giving you the legal opinion, maybe we need to look at outside counsel or others.

COMMITTEE MEMBER KURTURAL: Maybe, yeah. I think it --

CHAIR DELGADO: John, I know you have your hand raised. We're going to thank Marko for your time, and Marko also has an open door, so, you know, if you want to speak with him individually, please don't hesitate to reach out.

John, I know you've had your hand raised a couple of times. If you want to speak, and then, Dr. Dickey, I know you had your hand raised as well.

DIRECTOR OHANIAN: Just more echoing Marko, I just wanted this room to hear our goal at CDII, and my goal has always -- I've always tried to approach it from a point that CDII and our team are a supportive role to CPHS. I don't see CDII hampering CPHS. Never as in the days I've tried to work well with Dr. Dickey, Dr. Ruiz and others in terms of seeing how we can provide additional support to all of the things that you have maybe and where CPHS is -- maybe where you would like this organization continue to grow, and how we as a fiscal agent in a way is really just trying to

support your effort. So, if that's not been clear, if that's not always how it's been received, you know. I apologize for that, but our goal really has been to be a support to help you achieve your mission, so I just wanted to share that, so thank you.

CHAIR DELGADO: Dr. Dickey, do you want to go ahead.

COMMITTEE MEMBER DICKEY: Yeah. I just wanted -- you know, when we first go to the CDII, you know, Dr. Ruiz and I talked with Marko and John a lot about limits in terms of the agency, and those were regarding the perception that there was some interference with individual project decisions, and so I we got that very well cleared up.

But the question is now the responsible official for the Committee, which is the Secretary, has to approve our policies and procedures, and we have to have policy and procedure by Federal law. And, so, right now those policies and procedures define the purview of the Committee.

So, the (indiscernible) who makes recommendation for approval of what they want the purview to be, but it's the Secretary who is going to have to approve of that purview.

CHAIR DELGADO: I think that's a really good point. That's going to be the vehicle. That's going to be the vehicle for any change, right, is that if there is

something that needs to be reflected in the policies and procedures that is a group decision in a way that change can be brought about.

COMMITTEE MEMBER SCHAEUBLE: And I think following up on what Dr. Dickey was just saying, a significant part of the conflict we are feeling is that the policies and procedures have recently incorporated into them some limitations on our approach, in particular with regard to reviews under the Information Practices Act, limitations that were never brought to the Committee, never discussed by the Committee that the --

CHAIR DELGADO: That's the example.

UNDERSECRETARY MIJIC: And I think that is --

COMMITTEE MEMBER SCHAEUBLE: And the policies and procedures are simply presented to us as approved by the secretary --

UNDERSECRETARY MIJIC: Yes, so that's not fair to you all and that should not have happened. If that actually did happen, that is not fair and that shouldn't happen.

To be very clear, I see everything that's going before the secretary. That did not go before the secretary. I can tell you that for certain

And, so, I think what I would like to see what changes do you want to see made to this and what changes do you as a body not agree, and I think maybe that is the more

concrete way to ensure that we move forward, and I will commit to reviewing and approving what is within the scope, but I need to know that moving forward the standard -- that the policy on this is as staff we need to make recommendations to do all -- we need to vote on whether or not you approve the changes of that, and I assure you that the Secretary would not approve something if there was dissent from this body to be part of it.

So, I really appreciate you raising this because that is a concrete way for me to understand what the crux of the problem really is. And, so, I want you to know, and I want you to -- for me to be very clear, all of you, that if something is in here that you disagree with, then we need to know that, and we need to figure out how we proceed and figure out how we reconcile that before we move forward on the policy and procedures.

So, my ask to all of you is take a look at this and within the next 30 days I would love to have a copy of this edited about things that you as a body disagree with, as well as the things that you want changed in here so that we can look at that, present it to you as a board, you vote on what you want included or excluded and we can take that to the Secretary.

COMMITTEE MEMBER LUND: In order to do that we will need the deeper dive of which Carrie has spoken.

UNDERSECRETARY MIJIC: And we will -- yes, totally agree, and we are happy to follow up with our legal counsel, and if we need to pull in outside counsel, I'm happy to make that happen.

COMMITTEE MEMBER LUND: So, I'd really like to recommend, people think that have blown off OHRP. OHRP is our Federal guidance agency. They are the experts in Title 45 for all IRBs nationally, and I would strongly urge our legal folks to reach out there.

UNDERSECRETARY MIJIC: We're happy to reach out to them. We can reach out to them.

COMMITTEE MEMBER LUND: They're very approachable, and they will sit down and have a discussion about this.

UNDERSECRETARY MIJIC: Yeah, we'll reach out to them for sure.

COMMITTEE MEMBER LUND: Thank you.

UNDERSECRETARY MIJIC: Okay. Thank you all. Can I keep this? My weekend reading.

CHAIR DELGADO: Thank you all for your comments, and again, I think number one and most important goal is transparency, so that -- this discuss needed to happen and just really appreciate everyone feeling the willingness to share.

I know we are coming close to time. I wanted to let folks know, I was trying to track kind of the decision

making that still needs to happen related to what we've talked about today, and so, it's on the white board. Those of you who are online can't really see it, but one of the -- I just want to review it so maybe we can move towards a motion.

Let me go to number two first, which is a deep dive, taking Marko up on the deep dive with counsel on reviewing Title 45 and OHRP guidance to resolve the issue of reviewing data-only projects under the Common Rule when we are the IRB of record.

Yes, thank you for the reminder, Nicholas.

So, I'll review this and then we can have discussion. I have to open it up for public comments. I forgot that. Thank you. So, that's kind of the first deep dive, right, which will help us understand scope and lane.

Then moving to number one, are there other criteria that we as a board need to consider when we reviewing IPA projects? Once we have a deep dive in legal guidance on those issues, that legal guidance will be presented to the Board for a decision making session. It won't be today, will be probably in an upcoming meeting to be determined.

COMMITTEE MEMBER LUND: Darcy, can I just on number one?

CHAIR DELGADO: Yes.

COMMITTEE MEMBER LUND: Could we phrase this for legal as is there anything in the IPA that prevents us from considering other criteria, and then the Board can decide what criteria it wants.

CHAIR DELGADO: Anything in the IPA that prevents us?

COMMITTEE MEMBER LUND: Yes, from considering other criteria.

COMMITTEE MEMBER KURTURAL: Okay. Tagging on to number one, can we get review by outside legal counsel, not in-house but outside?

CHAIR DELGADO: Okay. And then once we have that deep dive, it comes back to the Board at which point there is decision making. So, again, that's what the Undersecretary said, recommendations can be made by legal which then we as a board have a decision making authority on whether or not there needs to be a change in the decision tree imposing the procedures and/or -- oh, wait. Let me put this aside. I'm going to reach back for a second. If we need to have any changes in the decision tree and our policy group procedures.

That is a wrap up of what we kind of talked about today and what the next steps are. And then I think there's a whole other issue of data repository which we will note for a future discussion.

So, I'm using this to just kind of sum this up, keeping an eye on the clock, to sum up what we talked about today, what the next steps are going to be. Thoughts before we open it up for public comment.

COMMITTEE MEMBER PALACIO: Perhaps a subcommittee needs to look at the policy and procedures, a subcommittee of -- and I wouldn't be on that, but --

CHAIR DELGADO: I feel everybody needs to do a deep dive on the policies and procedures.

COMMITTEE MEMBER PALACIO: You think? Okay.

COMMITTEE MEMBER LUND: And the problem is that a subcommittee of two people isn't enough and a subcommittee of three or more requires a public meeting.

COMMITTEE MEMBER PALACIO: Oh, okay, okay.

COMMITTEE MEMBER LUND: We might as well do it at the Board.

COMMITTEE MEMBER PALACIO: Okay.

CHAIR DELGADO: And, so, that will be another thing --

COMMITTEE MEMBER PALACIO: Good point.

CHAIR DELGADO: -- another action item is that all will review the policies and procedures over the next few weeks, and maybe the admin. team can compile feedback on areas where you're like, oh, didn't realize this was in here, I disagree with it, or here's where I need more

clarity.

COMMITTEE MEMBER LUND: And in some ways we can't really complete that until we have one and two, because the policies and procedures really have to do with one and two.

CHAIR DELGADO: Okay. So, start looking at it now, just familiarize yourself, but this might be like a step three after --

COMMITTEE MEMBER LUND: Yeah. You said like the next few weeks and I'm like only if we get one and two.

CHAIR DELGADO: Yes, good point. Good point.

I think Dr. Bazzano was trying to talk earlier, and then I see Dr. Dickey's hand is raised.

COMMITTEE MEMBER BAZZANO: Hi. Real quick. Can you hear me?

CHAIR DELGADO: Yeah.

COMMITTEE MEMBER BAZZANO: Okay, great . So, Dr. Schaeuble and I have been on a work project with the group at RMS redoing the common app, and I think one of the actions that appear ultimately leave your number, a lot of pressure to get that completed, and that whole project is going to need to take at least another month for us to be able to do this work before we can roll out a new system for the researchers to use and a new application online.

So, I support the things that it really needs to go back to the Undersecretary because can't wait for the

Undersecretaries who have been pushing for this timeline for this common app to be responsive to researchers because the whole purpose -- the goal of this common app revamp is to make the process better for researchers and confirm that, you know, we've had a very short timeline for that to get in our comments, and if it doesn't get back to him that we need the extra time, I just don't want the comments to go forward and then either need to be revised or not be able to be revised. In other words, can we change the timeline on that?

CHAIR DELGADO: Yes. You probably don't see our admin. staff Agnieszka nodding her head yes, so let's put on record that needs to -- we need to back burner the common app for now because it is not as strong a priority as what's up on the white board. Thank you for bringing that up.

COMMITTEE MEMBER RYKACZEWSKA: And I will note that I think there's dependencies to. We would want the common app to reflect the decision from the updated policy and procedures, so completely agree.

COMMITTEE MEMBER BAZZANO: Exactly the problem, yeah. Thank you.

CHAIR DELGADO: Okay, Dr. Dickey.

COMMITTEE MEMBER DICKEY: On the issue of data repositories or data centers, I would like that incorporated into number one, asking Legal to look at that also, because

the thing is all tied up. It's all part of the Common Rule.

CHAIR DELGADO: Okay.

COMMITTEE MEMBER DICKEY: You know, if it can be done, but I do think it's a place that we have actually been dropping the ball.

CHAIR DELGADO: Okay. You didn't see me, but I just wrote it up on the board with it, too, which means it's super official because it's on the white board.

Okay. Any other comments before we go to public comments? Okay, see none. Let's open it up for public comments. Is there anyone, you can either raise your virtual hand or if you are in the room raise your actual hand if you would like to make public comment at this time? Seeing none. Okay, public comment is closed.

So, wondering if anybody might be willing to make a motion -- make a motion.

COMMITTEE MEMBER LUND: Can we do separate motions?

CHAIR DELGADO: Let's make multiple motions.

COMMITTEE MEMBER LUND: I will move.

CHAIR DELGADO: Laura is making a motion.

COMMITTEE MEMBER LUND: Carrie will need to help me with this. I'm going to address number one. I move that the Committee take up the issue of considering what other criteria we wish to consider when reviewing IPA projects.

In particular, the Committee moves that we will seek outside legal counsel to provide advice on whether anything in the IPA prevents us from considering other criteria. And subsequent to that review by outside legal counsel, the Committee will consider as a Board what other criteria should be considered to include in the policies and procedures.

CHAIR DELGADO: Okay. We have a motion. Do we have a second?

COMMITTEE MEMBER SCHAEUBLE: I will second.

CHAIR DELGADO: Dr. Schaeuble seconds.

Sussan, could we do roll call, please.

MS. ATIFEH: Dr. Ruiz.

CHAIR DELGADO: Dr. Ruiz, are you there? We can come back to Dr. Ruiz.

MS. ATIFEH: Dr. Dickey.

COMMITTEE MEMBER DICKEY: Approve.

MS. ATIFEH: Dr. Dinis.

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural.

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Mr. Palacio.

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura.

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson.

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Bazzano.

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Ruiz.

(No audible reply.)

MS. ATIFEH: The motion has passed.

CHAIR DELGADO: Okay. So, that motion passes. Will somebody like to make a second motion?

COMMITTEE MEMBER LUND: All right. I move that -- do we want to do outside legal counsel on this one, too, or do we want to have -- yes?

CHAIR DELGADO: Yeah.

COMMITTEE MEMBER LUND: I move that the Committee seek outside legal counsel to review Title 45 and the Office of Human Research Protection's guidance to resolve the issue of when data-only projects shall be reviewed under the Common Rule by this Committee when we are the IRB of record and when this Committee has the responsibility to review data repositories under Title 45.

CHAIR DELGADO: Okay, that is our motion.

COMMITTEE MEMBER PALACIO: Second.

CHAIR DELGADO: Dr. Palacio seconds it. Can we

get a roll call please, Sussan. Thank you.

MS. ATIFEH: Dr. Ruiz.

(No audible reply.)

MS. ATIFEH: Dr. Dickey. Dr. Dickey.

COMMITTEE MEMBER DICKEY: I'm sorry. I approve. I just -- well, anyway, I approve that, but I would also add seek advice from inside legal counsel, too. Would that be okay if --

CHAIR DELGADO: Sure, I'll add that, to seek outside and inside legal counsel. Okay. To be clear, Dr. Palacio, do you second that motion?

COMMITTEE MEMBER PALACIO: I still second that motion.

CHAIR DELGADO: Okay. The motion is to seek outside and inside legal counsel to review Title 45 and OHRP as one project regarding human subjects and data repository.

COMMITTEE MEMBER LUND: We should say OHRP guidance.

CHAIR DELGADO: Guidance, thank you.

MS. ATIFEH: Dr. Dinis.

COMMITTEE MEMBER DINIS: Approve.

CHIEF COUNSEL SCHWARTZ: So, may I interject real quick? I just want to advise the Committee that, of course, different lawyers can interpret things a different way. If you seek inside and outside counsel for this you may not get

sort of an ultimate opinion. My recommendation would be to be consistent, we have no -- CDII Legal has no objection about external counsel, so my suggestion would be to consider having the same, consistent opinion for all of this from the same person because they're so intertwined. But it's, of course, up to the Board however you decide.

COMMITTEE MEMBER KURTURAL: I'm sorry that it -- let's just have outside counsel. Can we do that?

COMMITTEE MEMBER LUND: Dr. Dickey, would you still be okay if we went back to the original wording of the motion and said seek outside legal counsel based on --

COMMITTEE MEMBER DICKEY: Yes, sure, certainly, having heard from Jennifer.

CHAIR DELGADO: Okay, thank you. So, we're back to the original --

COMMITTEE MEMBER BAZZANO: Can I (indiscernible) that change? Sorry, if I -- I value diverse opinion, but I just want to understand what the implications are here. If we just have outside counsel, does there -- does internal counsel then make another opinion later, divest completely, or what are the implications of only having outside counsel versus having both opinions. To me, I think -- personally, I think a diversity opinion would be very helpful to understand different people's perspectives, and then we could weigh it and take that into consideration. So, can

you guys explain that a little bit before we decide on only speaking with outside counsel?

CHIEF COUNSEL SCHWARTZ: I think that's a fair question. I think that there's a little concern in my mind certainly about what was waived by the Board members. You know what, I'm sorry, I can't do this right now.

CHAIR DELGADO: No problem. Why don't you go ahead, Carrie.

COMMITTEE MEMBER KURTURAL: Yeah. So, you know, in matters like this the thing is we had a number of Board members kind of mention some biases with CDII, and I think it would be a little bit more, you know, for situations like this in my opinion to get outside counsel opinion. I think if we look at that, I think there is an implication, just to talk about here's what the law means, right, and here's what it says, and here's what the Federal intent says about the law.

Now, if we have questions about that, again, it's going to be recommendation. It's not going to be a mandate that we have to follow this opinion, and at that time we're looking at this we're like I don't know if this is accurate, sure, we can go back to in-house counsel. So, I don't think we're prohibited at all. I just think that at this time, because, you know, it would be most appropriate for outside counsel to look at it. That's just my opinion. And if we

feel as a board we need to have inside counsel look at that opinion, I don't think anything prevents us from doing that, but there's no point in having the two indices, you know, doing work in parallel, right. And plus, they can hire the expertise in the area, there are specific firms that work in this area that have relationships like with the Federal agency we're talking about that can easily reach out. You know, I say it's appropriate so --

CHAIR DELGADO: Will that help? Alicia, are you okay with that?

COMMITTEE MEMBER BAZZANO: I just wanted to understand that (indiscernible) okay if we need to rely on outside legal counsel are there any implications to that and not relying on internal.

COMMITTEE MEMBER DICKEY: Can I ask, when you say outside, how outside?

COMMITTEE MEMBER BAZZANO: How is that obtained?

COMMITTEE MEMBER DICKEY: Outside, if it's outside the Government --

CHAIR DELGADO: Yeah, I think -- I can speak for --

COMMITTEE MEMBER DICKEY: It's going to be a (indiscernible) issue.

CHAIR DELGADO: Yeah, I --

COMMITTEE MEMBER DICKEY: You know what I'm

saying, it just might.

CHAIR DELGADO: To --

COMMITTEE MEMBER DINIS: Well, Marko was suggesting outside counsel of some sort, he must -- maybe we can (indiscernible) .

CHAIR DELGADO: Yeah.

COMMITTEE MEMBER DINIS: (Indiscernible)

COMMITTEE MEMBER KURTURAL: Yeah, there is a number of firms out there that if it's on policy matters that only do this, right. And there is exception where it doesn't have to go through an RFP process under the Public Contracts Code where it's like a specialized legal expertise kind of area. It happens a lot, you know, and I think that it's just a deeper dive needs to be done and with someone that has like very distinct experience in this area.

CHAIR DELGADO: Okay, and then just to go on record, Jennifer put in the chat I agree with Carrie and John said he also agrees.

So, I'd like to move forward with the vote on -- Laura, if you wouldn't mind repeating the motion.

COMMITTEE MEMBER LUND: So, we're back to the original wording. The Committee will seek out, find legal counsel to review Title 45 and OHRP guidance for when projects regarding -- this should not read human subjects here. It should read data-only projects -- regarding when

data-only projects should be reviewed under the Common Rule and when the Committee should review data repositories under the Common Rule.

COMMITTEE MEMBER PALACIO: Second.

COMMITTEE MEMBER SCHAEUBLE: Couple of words that don't belong in there in the first line, after the word "guidance" take "when projects" because the next line is the continuation.

(inaudible)

COMMITTEE MEMBER DR. DINIS: Approve.

CHAIR DELGADO: Sorry. She said Dr. Ruiz.

COMMITTEE MEMBER DINIS: Similar names.

CHAIR DELGADO: Yes.

MS. ATIFEH: Dr. Dickey.

COMMITTEE MEMBER DICKEY: I approve this and any other future variations.

(Laughter)

MS. ATIFEH: Dr. Dinis.

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural.

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Are you ready for an (indiscernible). The word "when" is missing.

CHAIR DELGADO: After --

COMMITTEE MEMBER SCHAEUBLE: And the word --

COMMITTEE MEMBER DICKEY: I'm not voting.

COMMITTEE MEMBER SCHAEUBLE: Regarding when (indiscernible - several people talking over each other.)

CHAIR DELGADO: When?

COMMITTEE MEMBER LUND: When?

CHAIR DELGADO: Yes.

COMMITTEE MEMBER LUND: Data only, okay.

CHAIR DELGADO: Now do you approve?

COMMITTEE MEMBER SCHAEUBLE: Now I approve.

CHAIR DELGADO: Now he approves. Thank you.

MS. ATIFEH: Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura.

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson.

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Bazzano.

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Thank you. The motion passed.

COMMITTEE MEMBER LUND: Okay. We have a third motion and if we lose a number we can't make it.

CHAIR DELGADO: Third motion. Well, I don't know that that's a motion. I think it's going to be our -- I think it's our next step in our vehicle.

COMMITTEE MEMBER LUND: Okay, then we don't

CHAIR DELGADO: But I don't think we need a motion today. Okay. I'm going to adjourn the meeting. I'm going to again express my --

MS. ATIFEH: Public comment, final.

CHAIR DELGADO: Final public comment? Anyone?

MR. KUMAR: (indiscernible)

CHAIR DELGADO: Thank you so much. Thank you for being here.

COMMITTEE MEMBER DINIS: What was said? I couldn't hear.

CHAIR DELGADO: Appreciation for the Board and the work that you're doing, especially a shout out for Dr. Bazzano.

Okay, with that I'm going to close public comment and move to adjourn the meeting. Do I have to do roll call or do we just adjourn?

MS. ATIFEH: (indiscernible)

CHAIR DELGADO: Okay, we just adjourn. Thank you all.

(Thereupon, the meeting was adjourned at 11:58 a.m.)

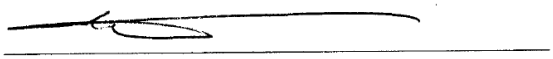
--oOo--

REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 25th day of March, 2024.



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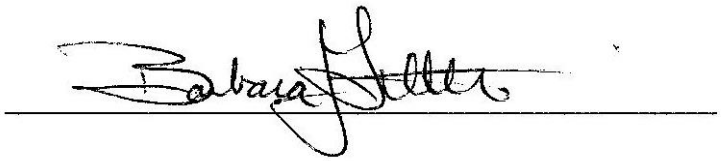

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