MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

SUBCOMMITTEE ON DRAFTING RECOMMENDATIONS FOR REGULATIONS

FRIDAY, JANUARY 10, 2025

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Laura Lund, MA, Chair

Maria Dinis, PhD, MSW

Carrie Kurtural, JD

John Schaeuble, PhD, MS

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

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Evan White, JD/MPP, California Policy Lab

I n d e x

SUBCOMMITTEE CHAIR LUND: All right, good morning everyone, and I'm calling the meeting to order. We have three members in the room and one member participating remotely.

Dr. Dinis, would you please turn on your camera, if you can? Thank you. Good morning.

Sussan, would you please do a roll call?

MS. ATIFEH: Sure.

Okay, I start with Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Ms. Kurtural?

SUBCOMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

SUBCOMMITTEE CHAIR LUND: Here.

MS. ATIFEH: Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Okay, the quorum is established.

SUBCOMMITTEE CHAIR LUND: Great, thank you.

MS. ATIFEH: Sure.

SUBCOMMITTEE CHAIR LUND: And I have a note here. If members of the public would like to share their names, would you please put those in the chat, if you can. It's easier for your note keeping if we have the correct spelling and that's sometimes hard to capture on the fly.

If you don't want to put your name in the chat and you would rather introduce yourself live, we can do that now. I'm not hearing anyone. All right, great. Thank you.

So, the next item is Agenda Item B, which is a discussion of the revisions to the latest draft of the framework.

And Dr. Schaeuble, thank you so much for all of the work that you've done on this revision, and also for the supporting materials you provided. And I'm wondering if I could turn it over to you, so you can explain to the group what you've shared and what's in the framework.

SUBCOMMITTEE MEMBER SCHAEUBLE: Sure. So, as far as the latest draft of the suggested framework, there are changes in just three places. And I think we could discuss those individually, one at a time.

SUBCOMMITTEE CHAIR LUND: Could we share that on the screen, please? Thank you. Awesome.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, there are no changes on the first page.

On the second page, in response to what was discussed at the last full Committee meeting, there is an additional item in the middle section of the document. And as you're looking at it here, it would be the second full item on the second page, which says, "The researchers plan to use technology, such as artificial intelligence and

machine learning that may increase the risk of individuals being re-identified."

I can comment a bit on the particular words that I chose to put in there. I realized that much of the discussion at the last meeting specifically mentioned generative AI. And as I looked at the research literature and also at some recent protocols that have come through for review, my thought was that generative AI was a bit too specific. And especially in an area where technology keeps changing so rapidly, that the more general phrase "artificial intelligence" would have better lasting power as far as being relevant.

I added the words "machine learning." Machine learning turned out to be one of the more common phrases in the research literature dealing with this topic, and also has appeared in several protocols where researchers have said specifically that they were using machine learning techniques as a way of approaching the analysis of their data.

So, I thought "artificial intelligence" and "machine learning" was a good coupling of words to use there.

And I guess it's appropriate for me to ask at this point for Committee members, any particular comments or concern about the phrasing of this particular item? Jared

was satisfied with it, the way it was, so he did not make any suggested changes there. And would other Committee members like to comment in any way?

SUBCOMMITTEE MEMBER KURTURAL: I want to thank you for adding this point. I think it's really important and I think it makes sense the way that it was phrased.

When we get to the more granular detail of actually writing the regulations and defining what that means, I just wanted to point out that -- when I say "that", I mean artificial intelligence and machine learning. Swing back with Jared because the State of California might already have a definition in play for that, and that's something that you want to look at next when we get more into those details. Because, you know, I've always said the devil's in the details, you know, on how things are defined.

SUBCOMMITTEE MEMBER SCHAEUBLE: Uh-hum.

SUBCOMMITTEE MEMBER KURTURAL: But, I mean, from a practical stand point how I see this working, you know, if you're doing research and you have someone that's 7 foot tall, that is receiving, you know, specific services in the State of California and you type all that description information in ChatGPT, or something, and you're able to pop up who that individual is, I imagine that's kind of the intent here of what you're aiming at. That if you had typed descriptors into artificial intelligence that it would be

able to pop up other public information that could expose the identity.

So, I just want to make sure that's kind of what you were aiming at and it looks like it is, and I think it was -- it's pertinent to add it and protect human subjects. So.

SUBCOMMITTEE MEMBER SCHAEUBLE: I think so. And, of course, especially with artificial intelligence techniques more generally, it's difficult to know what the next technology will be making possible for people to do .

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, certainly it includes very much what you're describing right now. And I don't know how tomorrow's going to change.

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE CHAIR LUND: So, I think that this looks great. And I thank you because I believe that you captured the -- there was a lot of discussion about this at the larger meeting, at the last meeting, and I believe that you captured here what people were concerned about in a way that's broad enough. And I agree with your decision not to use gen AI because that's kind of a jargony, current buzzword thing, but it might be a passing phase and there might be a new thing. And if we're too specific, we lose the ability to kind of capture what we want to capture. So,

I think you've done a great job here.

I also just wanted to respond to Carrie, as a reminder about process. Once we're finished with this, we turn it over to Jared and his team and they'll be writing the regulation. So, he will be doing all of that checking for definitions and ensuring that what we write in the regulations is consistent with what the state already has in place in a number of areas. So, just to reassure you that that is going to happen.

SUBCOMMITTEE MEMBER KURTURAL: Thank you.

SUBCOMMITTEE MEMBER DINIS: Yeah, I also think this is great. Because in this day and age, you know, the possibilities of people being able to identify through artificial intelligence and machine learning is quite high. So, I think that this is a good thing to do and I'm glad it's in there.

DR. RYKACZEWSKA: Can I ask some clarification?

SUBCOMMITTEE MEMBER SCHAEUBLE: Sure.

DR. RYKACZEWSKA: So, just to make sure I'm understanding, this isn't saying that we can use artificial intelligence or machine learning but, rather, if you're going to use it you need to explain the risks associated with that for re-identification and what you're doing to mitigate those risks. Right?

SUBCOMMITTEE MEMBER SCHAEUBLE: Yes. To assess

the extent to which the possibility of re-identification is increased as a risk and how that risk is being handled.

DR. RYKACZEWSKA: Okay. Thank you.

SUBCOMMITTEE CHAIR LUND: Thank you for the clarification.

Since we're looking at page 2 and not page 1, just as a reminder for folks who may be here from the public, the second part to which this particular bullet point has been added describes the risks that the Committee is concerned about that should be paid specific attention to in IPA reviews. So, this is a risk, but this is not something that would disallow the protocol from being approved.

SUBCOMMITTEE MEMBER SCHAEUBLE: Which is true of all of the items in that middle section as well.

SUBCOMMITTEE CHAIR LUND: Correct. Correct.

Okay, thank you, Dr. Schaeuble. Next.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, the second change is the initial sentence at the beginning of the third part of the document that here says, "Applications to CPHS for an IPA review shall include the following information when any of the risks enumerative above are applicable in the research."

And that is simply a clarification to follow up on the full Committee's decision at the last meeting that we do want to have additional information when any of the risks in

the middle section are something that applies in the research.

And again, I'm hoping that's straight forward without any concern, but I'll ask just to be sure.

SUBCOMMITTEE CHAIR LUND: No. No concerns here.

SUBCOMMITTEE MEMBER KURTURAL: I do not have any concerns.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay. So, the third place where there's a change, then, is the first item directly below that where I began the item with the phrase, "To the extent it is available for the data sources to be used in the study," to make it clear that we are asking for information knowing that it might or might not always be available. But to the extent that it is, we would like to see what this item asks for.

To the extent it is available for the data sources to be used in the study, what information was given to individuals when their data was collected about the possible use of that data in research.

Then, there is a phrase which I put in bracket and flagged as optional. The phrase saying, "From a Notice of Privacy Practices or other communication about privacy."

Jared suggested, and I am inclined to agree, that that phrase may not really be necessary. That the first part of the sentence, asking what information was given to

individuals is likely enough.

And I debated whether to simply remove the phrase and not even show it to you here, but I was concerned because I know so much of the discussion at the last several meetings had particularly revolved around the words, naming of Notice of Privacy Practices.

So, I'm simply going to ask are you inclined to leave that phrase out or is it something that you would rather have in there?

SUBCOMMITTEE MEMBER KURTURAL: So, I kind of see it twofold. I think it's always helpful to be as direct as possible with the applicants, you know, in what we're asking for. And so, what we're basically looking at is any sorts of information about privacy rights or a Notice of Privacy Practices.

And I think that that doesn't necessarily have to be in the regulation, as Jared said, but on the -- perhaps the application form, itself, when we go to revise it, you know, you could have the question, right, as an additional portion of the app with like some italicized, for example, you know, these things. Like fact sheet on privacy rights, Notice of Privacy Rights, or the like, or something like that.

I just don't think that needs to be in regulation.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay.

SUBCOMMITTEE MEMBER KURTURAL: I think it's pretty clear as it stands. But I like the idea of providing examples in the application, itself.

SUBCOMMITTEE MEMBER DINIS: Yeah, I agree, too. I mean, it may not be needed in the regulation, but it's always good to provide examples. Because sometimes people ask, you know, what is an example of what you're asking, you know. So, that will give them an idea of where they could get that information.

SUBCOMMITTEE CHAIR LUND: And I agree with both of your comments. I don't think it's necessary. I don't think it adds any clarity or additional information to this first phrase. And I think providing people, which we do, when they fill out protocols we provide examples, such as, blah, blah, blah, would be the appropriate place. Because there may be other things that we would want to call out for them as examples, and not just an NPP. So, and I think that's work we could do without having to put it in the regulations. So, strike that.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay, so the conclusion here is that we will not include that in what goes to the full Committee for their consideration.

So, continuing, the rest of this item has two alternatives which I would like to say a little bit about as far as options for finishing the sentence.

One alternative is, "And the context or situation in which that information was provided." And another alternative is to say, "And how that information was provided."

In thinking about this, my personal belief is that the first alternative is closer to what we would ideally like to see, even if it may be difficult to achieve in practice. When I think about what I would really like to know with regard to information about use of data being provided to people, I would like to have some sense of what is the likelihood that they actually saw the information in the first place. If they did have a chance to see it, how much other information were they being burdened with at the same time. Were they in a situation where they likely could think about and understand the information that was being given to them or were they in very stressful circumstances where they likely would not.

And if researchers could obtain from agencies providing data just a couple of sentences saying, typically the data were obtained under the following circumstances that would go a long way towards giving me some understanding of what we're really talking about as the way the information was provided to people.

I don't know how willing or able agencies are going to be to do that, but that certainly is what I would

hope we would try to work towards.

The second alternative is certainly a, I guess, a shorter or more direct way of saying something. It does focus on simply how the information was provided. And I guess my concern in phrasing it that way is to me that question leads to typically responses probably being something like there was a web link that people could go to for privacy information, or privacy information was among various documents that were provided to people, with maybe not much clarity as to how many other documents and how much other information was there.

I just fear that phrasing the question in that way is going to lead us to rather unsatisfying kinds of responses from agencies about how the data was originally collected.

So, that's -- that's my (indiscernible) on this. And as you can tell, my preference was for the first alternative. Jared liked the simplification of the second alternative and that's why it's here for the rest of you to talk about and weigh in.

SUBCOMMITTEE CHAIR LUND: So, here are my thoughts. I hear what you want to know and I understand why you want to know it as a reviewer. But, and my first thought is that I think that when we're talking about the regulations we should be very specific in regard to what we

ask for to burden researchers and state agencies that the information we're asking for is actually something that we would use in making a decision about the protocol.

And as I read the IPA and what we, as a Committee, because this is IPA, this isn't Common Rule, and what we as a Committee can consider and make decisions about in an IPA, I don't think that the context -- I think that information about whether there was a privacy notice, or some such thing, and what it says and whether people receive it, whether the agency that collects the data has a mechanism for making sure people receive it, that satisfies their entire obligation under the law.

These are data that are collected for non-research purposes. Every single one of the databases we're talking about is collected for non-research purposes. It's collected for state agencies to perform some state agency function. And then, it is later used incidentally for research purposes because it's been captured.

So, when they are talking to people about their data, research is the last thing on everybody's mind. The state agency, the people who are getting the services and giving their information, and all of that.

So, I think when we are considering IPA projects we can't really consider whether they were informed. That's outside the scope of what we can consider in the IPA.

I also think it's a little burdensome. Because I don't know about every database in the state, but I know about a lot of them, and I know how they're captured, and I know that it's not going to be possible for you to get satisfactory answers to all of the questions that you enumerated that you would like to have information about.

I understand from a research perspective why you would want to know whether people, you know, had the opportunity to see the information and to make sure that they saw the information and to digest it. I know for a fact that they wouldn't have have had an opportunity to ask questions about, wait, they're going to use my information for research. And the birth worker or the mortuary attendant, whoever it is like, yeah, I can't help you with that, you'll have to call the state.

So, I just think from it's, from a regulations perspective, a burdensome thing to ask of researchers and of state agencies because people will spend time on something that we can't even take into consideration. I mean we would not be able to decline a protocol under the IPA if you were unsatisfied with how people got information about how their data would be used.

So, I don't think that there's a point in asking for it if we can't use it. So, those are my thoughts. I would leave both of these out, frankly, and stick with the,

to the extent it is available for the data sources to be used in the study, what information was given to individuals when their data was collected about the possible use of that data in research. I think that's the best we can do, in my opinion.

SUBCOMMITTEE MEMBER KURTURAL: I wanted to add to that thought. But and I don't know if it will alleviate some of the worry. So, there already is legal requirements, if you're a HIPAA covered entity and, you know, there's a good portion that are part of the CDPH, Health Care Services, us at DDS, state hospitals, and a few others that have to follow the federal law with respect to how they deliver that notice of somebody's privacy rights and practices which mentions, typically mentions research.

There -- the last time I checked, you had to have a signed acknowledgement when you receive services and how you get it.

Now, another thing is, you know, you have other documents, like Notice of Privacy Rights, notice of your rights which might contain similar information to the practices that any department can use, and even the Attorney Generals has their own privacy rights fact sheet. That might only be available on the website.

But what I'm trying to say is I think we do have to give deference to the departments and what they have

control over. When they submit a research project, they're attaching a letter of support that specifically says that the state department is going to comply with any state or federal privacy rules and laws.

And we have trust in them that they follow the current law and that they're not doing something that they shouldn't be doing.

So, I think we have to move forward that they're operating within the confines of all the privacy laws in providing this information to the end consumer. And I think that's in addition to support that we shouldn't be asking to get to -- not only burdensome on the researcher, but also it gets a little bit interfering with are the departments complying with their own privacy requirements. And I feel that that gets -- that's outside of our jurisdiction.

And I think we should -- we can put trust in the departments that they're delivering this information because they're required to do so by law, and there is a signed acknowledgement that's required by law.

SUBCOMMITTEE CHAIR LUND: For HIPAA.

SUBCOMMITTEE MEMBER KURTURAL: For HIPAA.

SUBCOMMITTEE CHAIR LUND: I'll just say that for the other, for the non-HIPAA databases there's not a signed acknowledgement.

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: But to your point, yes.

SUBCOMMITTEE MEMBER KURTURAL: For other departments, such as Social Services, for other areas of CDPH that might not be true. But you're going to know that you have input trust in the departments that they are, you know, doing what they need to do under the law. Because they're all subject to privacy laws and confidentiality laws.

I think that when you couple all that information in an application, so say you have an application and you know in the beginning, usually, if they're HIPAA covered or not, because it asks that question on the application, so you know that. And then, you're going to have the project in front of you and you're going to know what are the -- any sort of privacy rights or notice of practices that were delivered. And then, they're specifying the risks they're taking to minimize and then you have that support letter.

I don't think there's much else we can do. I mean, I think, you know, we have to assume in reviewing that the departments did what they had to do, you know, to get the word out about how someone's information and data is being utilized. That's just my two cents but --

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay.

SUBCOMMITTEE MEMBER KURTURAL: Yeah. So, I like the option of just keeping the first part there.

SUBCOMMITTEE MEMBER SCHAEUBLE: You -- you would -

SUBCOMMITTEE MEMBER DINIS: I like -- just the way the context or situation, one of those, and how the information -- or how the information was provided, so give the people options to describe it. So, they may just say how the information was provided or they may provide a context, if they have it.

Can we sort of go in the middle somewhere?

SUBCOMMITTEE CHAIR LUND: So, what I'm saying, Maria, this is Laura --

SUBCOMMITTEE MEMBER DINIS: So, like I was thinking in the context or how the information was provided.

SUBCOMMITTEE CHAIR LUND: Yeah, and I think what I'm saying, Maria, is that I think that that's really burdensome for the departments because they will --

SUBCOMMITTEE MEMBER DINIS: Yeah. No, I hear you saying that, yeah.

SUBCOMMITTEE CHAIR LUND: Yeah. You know, especially because it may be different. You know, I'm thinking of a lot of the CDPH databases are done at, you know, different clinics or at different hospitals, and they can have different procedures. As long as what they're doing complies with state law, they can do it different ways. There's no uniform way.

So, I understand why we would want to capture this

information. I think it's burdensome because I don't think it's possible to capture it in a way that we would want to. And we can't use it. If you -- if you got this information and you didn't like what they said, you couldn't use that information to decline to approve the IPA study because it's not within the purview of what we're allowed to do under the IPA.

SUBCOMMITTEE MEMBER DINIS: Okay. Well, then --

SUBCOMMITTEE CHAIR LUND: You know, so I guess my question -- no, I'm asking, my question is why would we ask it if we can't use it?

SUBCOMMITTEE MEMBER DINIS: So, that's a good point.

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE MEMBER DINIS: So, then I agree, then, let's just say how that information was provided and just leave it at that. That's okay because -- to us, right.

SUBCOMMITTEE CHAIR LUND: Actually, no. I was thinking that we would not do either two or three.

SUBCOMMITTEE MEMBER DINIS: Oh, I see. No, no, no, okay.

SUBCOMMITTEE CHAIR LUND: You know, yeah, but that's certainly up for group discussion. That's just my opinion. Because they won't be able to answer it. They won't be able to answer how.

SUBCOMMITTEE MEMBER SCHAEUBLE: Even to the extent of saying there was a web like, or it was in documents given to people, they would not even be able to provide that much information?

SUBCOMMITTEE CHAIR LUND: Yeah, probably not, truthfully, right. Because in some cases there are hundreds of different entities that might be --

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: -- you know, providing the information in all different ways. So, yeah, they could be different. And the agency won't know. So, I don't believe in asking questions where the majority answer is going to be I don't know.

SUBCOMMITTEE MEMBER KURTURAL: Yeah. I mean, the folks that -- for the departments, you know, you're talking 58 counties who do 58 different things, as I like to say, and 21 regionals and they do 21 different things. And it is different, I mean because we're providing services and support to these clients. And the local governments are executing that and signing folks up for eligibility.

And they go -- you know, like for example if you want Medi-Cal, you go to CalBenefits. You're filling out all kinds of information to get Medi-Cal benefits, SNAP benefits through a portal, an online portal.

And, you know, yeah Notice of Privacy Practices

might -- it's likely in there, right, and it might -- it's just a part of, you know, the way that this operates.

So, the only context I can think of where the Notice of Privacy Practices really wouldn't be buried is if you go into a medical facility for a specific procedure or something, and you haven't seen that doctor before and then they give you a Notice of Privacy Practices, you know.

And, but like if you're at Kaiser or something, I signed up for benefits five years ago and that's --

SUBCOMMITTEE CHAIR LUND: Well, and for other kinds of administrative data that are collected, so some of it is hospital based, right.

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE CHAIR LUND: But not HIPAA. So, it's an entirely different thing, right.

SUBCOMMITTEE MEMBER KURTURAL: Yeah. Yes.

SUBCOMMITTEE CHAIR LUND: So, and every hospital can have a different way of delivering the information.

SUBCOMMITTEE MEMBER KURTURAL: Correct.

SUBCOMMITTEE CHAIR LUND: Some might deliver it in person, some might choose to do it electronically. For death data, it's mortuary based and some mortuaries are corporate, and some are small, and you can have different procedures in place for how they deliver the privacy notice depending on the mortuary.

So, I just -- anyway, back to mine, I just don't think it's a practical thing to add.

SUBCOMMITTEE MEMBER KURTURAL: Yeah, I don't think we can do two and three.

SUBCOMMITTEE CHAIR LUND: Yeah, and my other point is that we can't use it, even if we ask it.

SUBCOMMITTEE MEMBER KURTURAL: Yeah, and that's the --

SUBCOMMITTEE CHAIR LUND: You know, so we could get it and we could go, oh, man, the people really didn't know that the IPA doesn't allow us, right.

SUBCOMMITTEE MEMBER KURTURAL: You can't hang your hat on it.

SUBCOMMITTEE CHAIR LUND: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: Well, I have to tell you, judging by my recent hospital experiences with my wife is that at check in the admissions clerk clicks off that privacy information was provided and the person signs without ever getting it.

SUBCOMMITTEE CHAIR LUND: Well, and that's HIPAA, right. So, that's the highest level that you're ever going to get, above and beyond the privacy notices for the other kinds of state databases. And with HIPAA, you've got extra protection because if they're going to go in and use those medical records for research they either have to have a

HIPAA authorization from you, or they have to get a HIPAA waiver from whatever IRB is overseeing the study. So, there's at least a level of protection there.

That's not true for the non-HIPAA data that is collected by the state, right.

So, and we're not going to change that. We, as a Committee, are not going to change that and we can't impose anything on state agencies. We can't -- they're regulated by state law. As long as they are complying in their practices with what the law requires of them, we can't do anything. So, even if we think that they're not doing what they're supposed to do, we don't have the authority, it's not in our purview to go to them and say you have to do it differently or people can't use your data for research. That's just -- that's out of our scope.

SUBCOMMITTEE MEMBER KURTURAL: You also don't want to risk having a regulation that says that and then to be challenged by it later on, you know, in litigation or something like that for accidentally stepping -- you know, just thinking a few years from now, if we're not on the board, and other people picked up these regulations and they did some -- they were hanging their hat on it and, you know, that was challenged legally.

And so, I don't want to like lead other board members awry kind of with that.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, if this item is ended right before the first set of brackets, are we satisfied with it otherwise?

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: Do we have agreement on that?

SUBCOMMITTEE CHAIR LUND: Yeah, I am. I think the wording's good.

SUBCOMMITTEE MEMBER DINIS: Yes.

SUBCOMMITTEE CHAIR LUND: Or if we're done with our discussion, then I'll ask. Are we done with our discussion or, Dr. Schaeuble is there more that you would like to talk about in this document?

SUBCOMMITTEE MEMBER SCHAEUBLE: These are the only places where the document is changed from everything that both we, as a Subcommittee, and also the full Committee have reviewed and discussed before. So, I don't have anything else to add on this document.

I did provide you with two of the research articles when I was looking for information, before working again on this document I tried to see what I could find in the research literature about artificial intelligence. And you have both of those articles that I hope you've been able to look at it. And I don't know whether there's anything you want to talk about in connection with those or not.

That was the only other information that I had sent to the Committee for this meeting.

SUBCOMMITTEE CHAIR LUND: So, let me hold that thought for just one minute, because I want for the minutes to summarize what I think I've heard from the Committee about this document. And then, ask for public comment about the document. And then, because I do have a couple things to say about the articles.

So, my understanding from our discussion is that the Subcommittee is satisfied with the language for the additional risk regarding artificial intelligence and machine learning, and doesn't have any suggestions for changes or revisions to that, that that looks good.

The introduction to the Part 3 looks good and nobody had any suggestions for changes to that.

And then, for the first item, and I want to make sure because I know we had a lot of discussion about this, and I wanted to make sure that there are no Committee members who feel like we're moving forward and they really didn't get heard, or they object. I really do want us to have consensus.

What I'm hearing is that the first phrase, prior to the first bracket, is what everybody agrees on and that based on the discussion we will not include the language from any of the three additional brackets.

And I just want to confirm that the Subcommittee as a whole is okay with that as a decision.

SUBCOMMITTEE MEMBER KURTURAL: Yes.

SUBCOMMITTEE MEMBER DINIS: Yes.

SUBCOMMITTEE CHAIR LUND: Are you okay with that, Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: Yes.

SUBCOMMITTEE CHAIR LUND: Because you were the one who had the strongest opinion, so I want to make sure that we respect that.

SUBCOMMITTEE MEMBER SCHAEUBLE: Well, yes, I agree with the conclusion of the Committee. I may be dissatisfied with the information that we have to work with, but that's a different matter.

SUBCOMMITTEE CHAIR LUND: Okay. Okay, all right, thank you.

Okay, so --

DR. RYKACZEWSKA: Just double-checking that we have -- the first section, just again I want to make sure I'm capturing correctly. The first section is the addition of the new risk leading to artificial intelligence and machine learning, and we're not changing the language of that.

The second one is the revision at the beginning of that last section, just to capture the decision of the full

board meeting of last meeting, and we're not making any revisions to that.

We are striking the language on Notice of Privacy Practices, and we're not moving forward with either alternative two or three that followed that. So that the final language to that section will just end at "research."

SUBCOMMITTEE CHAIR LUND: That looks good to me.

SUBCOMMITTEE MEMBER KURTURAL: Looks good.

SUBCOMMITTEE CHAIR LUND: Thank you, Agnieszka.

Okay, before we move on could we get -- if there's any public comment on that.

DR. RYKACZEWSKA: We do not have any members of the public in the room. If there's any members of the public online --

MR. WHITE: I'd like to give comment.

DR. RYKACZEWSKA: All right, Evan, please.

MR. WHITE: Hello and good morning. My name's Evan White. I'm the Executive Director of the California Policy Lab. Nice to see you all again.

As a reminder, I used to be a regulatory attorney for the federal government, working at the Consumer Financial Protection Bureau, specifically working on consumer privacy regulations.

The first thing, I'll just reiterate my objection again to these IPA regulations in their entirety. I'll get

more specific later, but I do think these fall outside of the authority under the IPA. And also, as I've mentioned before, I think they -- I think they wrong-headedly assume that you should substitute your own personal opinions for the considered judgments of the legislature and of the IRBs that are already reviewing these projects. So, just reiterating that.

And in regards to today's meeting, I guess I'll start with the artificial intelligence addition that you made. The first thing I'll say is it's, you know, with respect to the Committee members it's not clear to me that this Committee has sufficient expertise on artificial intelligence or machine learning to know exactly what you're adding when you add this language.

Just as an example, all regressions are machine learning and I would venture to say that most research projects that you guys review involve some sort of regressions in them. And it's not clear to me that you want all that information in these applications.

The terminology used here is so broad that it would include lots of things that are done sort of naturally in research projects as part of any sort of programming algorithm. And it's just not, it's not at all clear that -- it's not at all clear that this Committee has the expertise to find the right language here.

I also think it's a little startling, I don't know, the understanding of re-identification that the Committee has exhibited seems startling to me. Artificial intelligence isn't really the -- isn't really the threat to re-identification. And if you read the research beyond the two articles circulated by one of the Committee members, you know, the baseline risks for re-identification are already very high for any data that's person level, even if it's been quote/unquote de-identified.

The reason that the overall risk is low is because of the context in which this data is being given out, which is to a trusted researcher, who has demonstrated that they have the requisite data security requirements in place.

So, it's not that the data, themselves, couldn't be re-identified. I would venture to say that most of the datasets that are given out by the -- you know, at the person level, are re-identifiable. And really, that has again not to do with artificial intelligence, but it has to do with the amount of person level information that already exists on the internet. Right, it's not actually about artificial intelligence at all.

You know, there's been lots of demonstrations of re-identification being possible without any sort of machine learning algorithms.

So, you know, I guess I share your concerns about

re-identification and definitely think you're going about this the wrong way. I also think you should pause and considered why you're focused on re-identification when the IPA is only talking about identified data. Right, so the IPA is about personal information, which means information that can already be linked back to an individual.

So, why the focus on re-identified when these data are already identified. Again, it feels to me that you're importing your framework from the IRB that really just doesn't apply here in the context of the IPA.

So, that's about the artificial intelligence provision.

On the Notice of Privacy Practices provisions, I wholeheartedly agree with Laura, you know, why ask for it when you can't legally use it.

I do think that maybe the Committee has thrown on the brakes a little too late, though. I'm not sure you can use any of this legally under the IPA. And not just because, you know, I don't think the IPA allows for any of these regulations, but because on this specifically, you know, departments are the experts in their own laws and whether the data can be released. So, how does the Notice of Privacy Practices, like really in what context could you use that.

Essentially, what you'd be saying is you get the

Notice of Privacy Practices and then you're saying that in fact these data can't legally be released because of what's in the notice. But in fact that's the agency who owns that data who makes that determination.

So, it's just not clear to me that that entire subsection is you're able to use the information in it legally.

So, yeah, that concludes my comments. Thank you all for your careful consideration. Again, just because I disagree with you does not mean that I don't respect that you're trying to do the right thing here. And I hope that you take into account the things that I've said here.

SUBCOMMITTEE CHAIR LUND: Great, thank you.

Anyone else?

DR. RYKACZEWSKA: If you could raise your virtual hand if you would like to speak. Going once.

SUBCOMMITTEE CHAIR LUND: Is that a hand? It looks like a hand. It's David Ligh.

MS. ATIFEH: No, that was my last --

SUBCOMMITTEE CHAIR LUND: Oh, sorry.

DR. RYKACZEWSKA: I am not seeing any virtual hands. If you would like to raise your hand, please hit the react button at the bottom and then the raised hand button just making sure. Going once, going twice. I believe that concludes the public comment.

SUBCOMMITTEE CHAIR LUND: All right, great.

So, Dr. Schaeuble, thank you so much for sending these articles. I personally found the both interesting and eye opening. This isn't a literature that I'm overly familiar with, so I really appreciated the additional information. And I think it reinforced for me the work that we're doing here around the language of the IPA and determining that there are sufficient protections. I mean, that's our -- I think that's our operative word when we're considering the IPA reviews. And I just really appreciated having this information. So, thank you.

And I'm wondering if there's anything else you wanted to say about the articles or other Committee members wanted to weigh in on in regard to that information.

SUBCOMMITTEE MEMBER SCHAEUBLE: I think it's disturbing to see how easily re-identification can be possible. And it seems to me we see this concern in really two kinds of situations. One is where researchers obtain personally identifiable data and tell us they are removing identifiers, and then proceeding to analyze the dataset that has identifiers removed.

And another situation where researchers receive data where the identifiers have been removed before they actually receive the data.

The disturbing thing for me is that I have to

conclude, from what I'm reading, that the concept of de-identified data in either of those instances really doesn't exist in this world anymore. That we can properly talk about data in which common identifiers have been removed, which thankfully they have and thankfully that does make it more difficult to identify individuals, but the assertions that we've often heard in the past from researchers that the identifiers are gone and, therefore, people cannot possibly be identified just isn't anymore an accurate statement about the situation.

And that has to shape, from my view, the way in which we look at these situations of releasing data to really be cognizant that, yes, we can have data where people have a need to keep some identifiers for some purpose, while they're analyzing the data. Yes, we could have situations where they can remove identifiers before the analysis proceeds. Yes, we can have situations where they receive data that common identifiers have already been taking out.

But in any case, the possibility of re-identification is still there at some level, on some level that is not necessarily a near zero probability.

SUBCOMMITTEE CHAIR LUND: And --

SUBCOMMITTEE MEMBER SCHAEUBLE: Because the one article quoted how easily with just a modest number of pieces of demographic information individuals across the

whole country could be identified. I mean that was staggering to me.

SUBCOMMITTEE CHAIR LUND: Yeah. Yeah. And I just wanted to point out, following up on Dr. White's comment, the IPA applies when state agencies are releasing personally identifiable information. And one of the reasons, I believe, that our -- the Committee as a whole, and our Subcommittee, is focused on this notion of re-identification is that the number one risk mitigation strategy that people submit when they submit protocols for IPA review is this idea that they're going to de-identify the data. So, that's how they are mitigating the risk of having this personally identifiable information.

And so, I think that what we are trying to address is just how strong a mitigation that strategy is across various types of datasets, especially merged datasets and especially datasets that may have other kinds of variables in them that could be used in conjunction to re-identifying individuals.

So, I think I just wanted to make clear that that's why we're focused on re-identification. It's not that the data are coming from state agencies already de-identified, it's that that is being proposed to us as a risk mitigation strategy.

SUBCOMMITTEE MEMBER KURTURAL: That's true, yeah.

And I'm also concerned about re-identification on anything that gets published that might be at the individual record level. Where they say, you know, names or other things of the 18 identifiers are redacted, but then there's always going to be that potential for -- that has a higher propensity of a re-identification. That actually, you know, potentially wouldn't be properly de-identified.

So, it depends on the project. And I think we have a good set of core factors to really help us, you know, make that determination on the level of the risk, you know, upon reviewing. So, you know, I share that.

SUBCOMMITTEE CHAIR LUND: Dr. Dinis, did you have anything else?

SUBCOMMITTEE MEMBER DINIS: No, I agree with you all. I mean, that's our concern is that the people can be re-identified. And the law was written at a time when maybe they couldn't, but now they can. And I think that's the crux here.

SUBCOMMITTEE CHAIR LUND: So, I think what I'd like to suggest and I'm going to ask, since we had discussion since our last public comment, I'm going to ask one more time for public comment.

But I think after that we probably should have a motion to adopt the changes to the framework that we discussed today, to take that back to the larger Committee

for their review and approval.

So, before we have a motion, let me just open it up one more time for public comment about the documents that were submitted by Dr. Schaeuble and the subsequent Committee discussion -- Subcommittee discussion about those documents. Is there anything else?

DR. RYKACZEWSKA: If you'd like to speak, please raise your virtual hand. I am not seeing any virtual hands raised.

SUBCOMMITTEE CHAIR LUND: Okay, thank you.

DR. RYKACZEWSKA: And no one in the room.

SUBCOMMITTEE CHAIR LUND: So, does someone want to make a motion?

SUBCOMMITTEE MEMBER SCHAEUBLE: I suppose I can, if that's appropriate. I will move that the Subcommittee send the draft we've reviewed today to the full Committee for their review and approval, with the -- do I need to specifically say the changes that we've made or --

SUBCOMMITTEE CHAIR LUND: I think we accepted the document with the exclusion of the language in brackets.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay.

DR. RYKACZEWSKA: Do we want to just list the four things that I had captured before.

SUBCOMMITTEE CHAIR LUND: That's good, too, yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: Do we want to send

this as still the eighth draft or is now going to be a ninth draft?

DR. RYKACZEWSKA: I think that would be the ninth draft, yeah.

SUBCOMMITTEE CHAIR LUND: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay. So, let me phrase the motion this way, then.

The Subcommittee is forwarding to the full Committee a ninth draft of the suggested framework in which the bracketed phrases from the eight draft have been removed.

SUBCOMMITTEE CHAIR LUND: I think that covers it. I second that.

MS. ATIFEH: Okay. Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

SUBCOMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Okay, the motion passed.

SUBCOMMITTEE CHAIR LUND: Great. Thank you, everybody.

So, in terms of process, do we think we need another meeting? I think, because if the Committee agrees with the revision, the revised framework that we take forward, that then goes to Jared and legal counsel to begin drafting the regulations based on that document. So, we

don't really have any other work.

Do we want to schedule a next meeting in case the Committee sends us back to do more work, or do we want to wait to see what they say?

SUBCOMMITTEE MEMBER KURTURAL: I would suggest waiting. I don't -- I think that we might be here again, meeting, once we have some draft regulations. And then, we can see what happens next month.

SUBCOMMITTEE CHAIR LUND: Okay.

SUBCOMMITTEE MEMBER KURTURAL: If the full Committee agrees or not. If they agree, then we will wait on legal counsel and reconvene when they're ready.

SUBCOMMITTEE CHAIR LUND: Okay. That makes sense to me. Dr. Schaeuble, Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Yeah, I think that's a good idea.

SUBCOMMITTEE CHAIR LUND: Okay. All right.

DR. RYKACZEWSKA: Perfect.

SUBCOMMITTEE CHAIR LUND: So, we're done. Adjourned.

Unless there's something else?

DR. RYKACZEWSKA: No.

SUBCOMMITTEE CHAIR LUND: Okay. Yay, good work everybody, thank you.

DR. RYKACZEWSKA: Meeting adjourned at 9:30 a.m.

(Thereupon, the meeting was adjourned at 9:30 a.m.)

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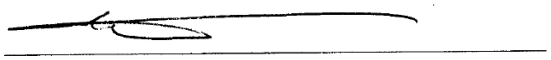

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