MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

REGULATIONS SUBCOMMITTEE MEETING

FRIDAY, NOVEMBER 8, 2024

8:31 A.M.

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ALLENBY BUILDING

MEETING ROOM 1181

SACRAMENTO, CALIFORNIA 95814

AND

ZOOM ONLINE MEETING PLATFORM

Reported by:
Peter Petty

APPEARANCES

COMMITTEE MEMBERS

Laura Lund, MA, Chair

Maria Dinis, PhD, MSW

Carrie Kurtural, JD

John Schaeuble, PhD, MS

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna

ALSO PRESENT

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Jared Goldman, General Counsel

PUBLIC

Evan White, JD/MPP, California Policy Lab

Agnes Balla, University of California Office of the President

I n d e x

P R O C E E D I N G S

SUBCOMMITTEE CHAIR LUND: Okay, good morning everybody. This is the Committee for the Protection of Human Subjects Subcommittee for Development of Regulations to Support IPA Reviews. And calling the meeting to order, it's 8:31.

Would Dr. Dinis please turn on her camera, if she's able to? Thank you.

And Sussan, would you please do a roll call?

MS. ATIFEH: Sure. Okay, Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Ms. Kurtural?

SUBCOMMITTEE MEMBER KURTURAL: Yes.

MS. ATIFEH: Ms. Lund?

CHAIR LUND: Here.

MS. ATIFEH: Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Okay, a quorum is established.

SUBCOMMITTEE CHAIR LUND: Great. Thank you.

And do we have any members of the public on the call, who would like to introduce themselves or put their names in the chat? That's optional. You don't have to put your name in the chat. I'm not hearing anything.

DR. RYKACZEWSKA: Nick, any members of the public in person?

MR. ZADROZNA: No one in person.

SUBCOMMITTEE CHAIR LUND: Okay, great. Thank you, everybody.

Okay, so the next item is Agenda Item B. And I will now introduce Agenda Item B, which is to review the revised materials and drafts that have been submitted.

And before we actually start, I would like to put it out there to the other Committee members. We've had a lot of public comments on our process here, and I think -- I've read through all of them and I think that there's some misunderstanding about some of our documents and some of what we're trying to do with the documents that we're developing.

And I'd like to suggest, if other Committee members are okay with it, that we slow down just a little bit and when we go through these documents today that we actually describe the document itself, and its purpose, and what we're hoping to achieve with it, so that all of that information -- because we understand that. But members of the public who are tuning into us, just for this brief time, might not understand these things completely, that we understand implicitly. And that might help with some of the understanding of this information in the general public.

So, if that's okay with the other members of the Committee, I think that would be helpful if we could proceed

that way today.

So, having said that, there have been two documents that were submitted in preparation for today's meeting. The document that was initially prepared by Dr. Schaeuble at our last meeting. The Subcommittee requested and motioned a couple of changes to that document and I believe Dr. Schaeuble has been working with Jared Goldman, our attorney, to revise that draft.

And we have a copy of the revision and I'm wondering, Dr. Schaeuble, would you go over that for us, your changes and your thoughts on that.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay.

SUBCOMMITTEE CHAIR LUND: So, just before, I'm sorry to interrupt you after I just handed it over to you, in the spirit of slowing down a little that I just talked about, I would like to say for the public that this document does not in itself represent any regulations language. This document is intended to be supporting documentation that contains the Committee's beliefs about potential risk in IPA projects, and the Committee's concerns about those projects, and how the Committee might like to move forward in reviewing those projects.

So, this document is not in and of itself a regulations document. So, maybe I'm just going to refer to this document as the supporting document so that that

becomes very clear when we have our discussion.

So, thank you, Dr. Schaeuble, if you would go over this supporting document and discuss your changes.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, if you compare the newest draft that we were looking at to the version that the Committee discussed at its last meeting, which is labeled a fifth draft in our earlier discussions, there are no changes on the first page.

On the second page, as the Committee requested at the last meeting, the final item in the middle section of this document was removed.

And then, the third section is completely revised, both the initial statement at the beginning of the third section and the items listed underneath it.

And this reflects conversations that I had primarily with Jared, although Maggie also made suggestions in the conversations back and forth.

And I think it's fair to say that the intent of the final section here is to more clearly say what we are hoping to expect from researchers and that that zeros in on two particular things.

To the extent that researchers can get a meaningful response when they apply for data, if they also ask the question what were individuals told when the data were originally collected.

We are wanting to understand what language was used and the kind of context or situation in which that language was provided to those individuals.

And at least from my vantage point, I think it's fair to say that we understand that in many, perhaps a great many instances researchers may not get a meaningful answer to that question even if they ask the entity or agency that is going to provide the data. But if it is available, that's something we would want to know.

Other than that, the final item here is saying that the risks that have been identified in the middle portion of this document as potential risks for a data project, that might be particularly troublesome, are risks that the researchers should describe which of those might apply in their research, to what degree in what they are doing to try to minimize the impact of those risks.

So, that would be my description. And particularly, since most of what I did was to reword in a little bit ideas that mostly came from Jared and some of them from Maggie, I think Jared should probably chime in with any additional comments about his thoughts here, if he has any to add.

MR. GOLDMAN: Well, in the spirit of backing up a little bit, I'll just say that overall our aim is to ensure the sufficiency of the privacy plan that's being submitted,

the plans that protect personal information from improper use and disclosure, and to ensure there's a sufficient plan to destroy information when the project's over, and to ensure we have sufficient written assurances that personal information won't be reused, or disclosed in a manner that is improper.

And so, in order to to understand the sufficiency of those plans and assurances, the Subcommittee had identified all of these risks that are worth considering in determining the sufficiency of those plans and assurances.

And the things we primarily modified since the last draft, in the last section of the document, I think the aim of the changes were really to make the language more efficient.

And really, what we're trying to do is elicit information from researchers which would allow us to identify and assess the risks that are described in the second section. That is the last sentence in the document, sort of the catchall request for information about the risks.

And the one request above it, the other action item, I think is the one item that isn't -- that is connected to all these other risks, or at least a few of them, which isn't naturally captured by the last sentence. So, we're asking for folks to provide information about the

risks that are identified and then we're also asking people to provide information about the disclosure or consent process that they engaged with, if there was one, so that we can assess what subjects understood before they became subjects.

SUBCOMMITTEE CHAIR LUND: Thank you. Also, in the interest of backing up, I just would like to make clear that these -- when we're talking about these risks, they are things that the Committee is reasonably concerned with because it's our role to assess the risk of people whose data are being used in the study.

These risks are not intended to convey that if this risk -- the risks that we've enumerated here, are not intended to convey to researchers that if these risks are present in your study it means that we will not approve your study. They're risks that we need to take into consideration and assure are mitigated prior to approving the study.

So, that's -- when we're talking about these risks, because in reading some of the comments from the public, I believe the concern is that they will be denied access to the data if their study contains one or more of these risks.

And I just, and maybe I'm wrong and other Subcommittee members should chime in, but my understanding

is that that is not the intent of enumerating these risks. It's merely so that we can look at them clearly and talk about mitigation.

MR. GOLDMAN: I think that's well said.

SUBCOMMITTEE CHAIR LUND: Okay.

SUBCOMMITTEE MEMBER SCHAEUBLE: That is an important thing to say because it has been very prevalent in the communications we've received. And it's really important for the public to understand that, at least as I see it and I think other members also, CPHS is not in the business of disapproving research. Our ordinary circumstances are that we work extremely hard with researchers for any concerns that might arise in the review process to see that research can be approved.

And as a personal thing, I would note that in my years of experience on this Committee I think I can probably count on one hand the number of times that research has actually been disapproved by the Committee.

And I could add to that, that I have more than four decades of experience with IRB committees. And probably on one hand, certainly on two hands, I could count the number of instances in which research has been disapproved during all of those years of experience.

Personally, I don't anticipate that there would be a radical change in that kind of situation from what we are

proposing to ask researchers to do.

SUBCOMMITTEE CHAIR LUND: Great. Thank you.

So, I think, I'm very glad that we were able to have that discussion and make it explicit for ourselves and for the public that that's the intention of enumerating these risks.

I just have one more comment. I really -- actually, probably two comments. Thank you for the work. I think that the third section of this much clearer and I believe it conveys the intent of what we hope to accomplish.

I do have one concern about the language and I'm just wondering if the language can be tweaked.

And here's the background on that. So, it says, "If the individuals whose information will be used were told when the data were originally collected that their information might be used for research," et cetera.

So, in these very large administrative datasets that the state collects and, you know, I'm thinking of the CCR, and the various CDPH datasets, and the Medi-Cal data, and so forth, I think it's an unrealistic -- the way that this is worded, it sounds like we're asking for people to know for certain that individuals were provided with their privacy notice. And I think we can't know that and that's an undue burden.

My suggestion would be that we have language that

refers to whether or not the agency obtaining the data has a process in place for ensuring that the individuals receive the information. Because it isn't the agency's fault and it shouldn't be a burden on the researcher if somebody dropped the ball in giving a privacy notice. And I think that it's just too high a bar for us to require that they ensure that everybody actually got their privacy notice.

So, that would be only request in regard to the language and I don't know how others feel about that.

SUBCOMMITTEE MEMBER SCHAEUBLE: I don't think I read the language in quite the way that you seem to be suggesting. Because I would assume that if agencies don't know whether people were informed in some way that they would simply say so or not respond to a question about what individuals were told.

SUBCOMMITTEE CHAIR LUND: So, they can't know in many cases. So, I'll just give you one example. So --

SUBCOMMITTEE MEMBER SCHAEUBLE: And that's a perfectly legitimate response.

SUBCOMMITTEE CHAIR LUND: Well, they do know, but they don't know -- so, the answer would be, in the example that you gave, that all agencies would come back and say I don't know.

Because let me just give you the example from the birth data. So, in California, the way that the birth data

work under the law is that the administrator of the hospital where the birth occurred is actually the one on the hook for filling out the birth certificate, and submitting that to the county, and for providing all of the information to the parent giving birth, including the privacy notice that goes along with I'm collecting your data, and here's that.

Okay, so the parent giving birth gets a packet, that's about this thick, of all of the information that they're supposed to know about, you know, their birth certificate.

And that information is given to them by employees who are called birth clerks at the hospital. And the hospitals are all supposed to have this process in place where they get all the information. And then, the administrator submits the information to the county, and then the county submits it to the state, and the state turns it into the birth data that everybody's always requesting.

The state, releasing the birth data, has no way of knowing that in each and every case a birth clerk at the hospital gave that privacy notice to the parent giving birth. Even though that process is in place and they're required to by law, there's no way, there's no quality control check on that.

So, if you were to put them on the spot and say do you know for sure that the individuals whose information

were collected got this information about how their data would be used, they would have to, in all honesty, say, well, no, here's what we -- here's what's supposed to happen, but we don't know in each and every case.

So, and I would bet that the same is true for all state data that are collected locally first, and then given to the state.

SUBCOMMITTEE MEMBER KURTURAL: Well, you know, that's what it is. It's you have your contractors, whether it's 58 counties or the 21 regional centers, and you have these requirements and the various healthcare services, you know, contracts with the counties versus our contracts with the regional centers, with a business associate agreement that says you have to have an NPP. And, you know, the NPP has to have a minimum criteria, just as our NPP has at the state. And it's a contract requirement. And then, there are contractors and we expect them to follow what our contract says.

So, do we -- you know, at a high level, I can speak for my department, will monitor, you know, on a high level about, all right, we have, say, some amendments to our notice of privacy practices and then each, you know, regional center will have their own privacy officer that can go ahead and implement it.

But whether it's actually implemented in every

case is very difficult to tell.

And it looks like we're offline. Are we on Zoom?

DR. RYKACZEWSKA: We are experiencing some technical difficulties. We're going to pull the Zoom back up.

SUBCOMMITTEE CHAIR LUND: So, we should probably halt the conversation until that happens.

DR. RYKACZEWSKA: Yes.

SUBCOMMITTEE CHAIR LUND: Okay.

(Off the record at 8:52 a.m.)

(On the record at 8:53 a.m.)

DR. RYKACZEWSKA: Should we -- oh, I'm curious where the Zoom cut off, where you couldn't hear us anymore. Just in case we --

SUBCOMMITTEE CHAIR LUND: Ms. Kurtural was speaking. Were you able to hear everything she said?

SUBCOMMITTEE MEMBER DINIS: Yes. Yes, I was able to hear that.

DR. RYKACZEWSKA: Okay.

SUBCOMMITTEE CHAIR LUND: Okay. So, Dr. Dinis, you have a question?

SUBCOMMITTEE MEMBER DINIS: Yeah, so, I guess I think we've had situations where it seems from the other side, even that basically -- well, at least one case I'm thinking about. Where they agency is saying, basically,

that there will -- their data is not going to be used for research purposes, but yet it's still being given to other researchers for a research purpose.

So, I don't know in those circumstances what do we do?

SUBCOMMITTEE CHAIR LUND: So, I would think that the purpose of the regulations here is to provide a basis for us to evaluate that. And if the agency originally collecting the data told the individuals at the time the data were collected that it would not be used for research, I think that represents a burden on the agency and the researcher before we could approve that. Right.

So, most agencies do have a privacy notice or multiple ones, depending on how many databases they're releasing and what statutes they're covering. I'm not aware that any actually tell people their data won't be used for research. They may be silent about it.

What agency, in particular, are you thinking of, Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Well, in the -- for example in the Student Aid Commission, on their website it says that their information is not going to be used for research purposes so --

SUBCOMMITTEE CHAIR LUND: Ah, okay. Yeah, that's --

SUBCOMMITTEE MEMBER DINIS: So, that's a problem, you know, when you might have some of these entities that do that, that they want to collect very private data and they're assuring the respondent that it's not going to be outside, you know, in any way. So, then that's when it becomes a conflict, I think.

SUBCOMMITTEE CHAIR LUND: Okay. So, I was just going to say in regard to the wording of this, I guess my suggestion or request would be we just modify the wording slightly to say something like if the state agency releasing the data has a process in place to ensure that individuals whose information will be used, blah, blah, blah.

And they can describe that process to us, even though they can't ensure that in every case the individual was in fact informed.

SUBCOMMITTEE MEMBER KURTURAL: So, what about this idea. So, we should know as representative of the department kind of what their process is, what, you know, the notice of privacy practice.

But where the rubber kind of meets the road with me, and what Dr. Dinis is talking about, is when they connect our data with another entity's data and that other entity has a rule set they can't use the research -- you know, the data for research purposes. Like, we don't necessarily know that.

And so, would it be more fitting to put this application requirement, if they know any information about the outside agency.

SUBCOMMITTEE CHAIR LUND: See, I don't think we have purview over the outside agency.

SUBCOMMITTEE MEMBER KURTURAL: Okay.

SUBCOMMITTEE CHAIR LUND: I think, in my opinion --

SUBCOMMITTEE MEMBER KURTURAL: Okay.

SUBCOMMITTEE CHAIR LUND: -- our purview is over the state data and ensuring that the people whose state data was collected were told how it was going to be used, and if it's going to be used for research.

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: And if they gave their information to another entity that's outside our purview we can't, I don't think, control or oversee.

SUBCOMMITTEE MEMBER KURTURAL: And I'm trying to think how it would be a regulatory application requirement. I'm just trying to think in my mind how that would be laid out.

SUBCOMMITTEE MEMBER SCHAEUBLE: Can we backtrack here just a little bit on this?

SUBCOMMITTEE CHAIR LUND: Uh-hum.

SUBCOMMITTEE MEMBER SCHAEUBLE: Because I'm seeing

two very different situations and you're talking, I think, about only one of them. There certainly are instances in which an agency receives data from a number of different sources and compiles it together into an information system that they can offer to researchers. I understand that is one option.

There certainly are also other instances in which an agency is directly collecting information from individuals and that's a different situation than compiling it from other entities.

Now, with regard to the things that you've been talking about, I think it's a perfectly appropriate response for an agency to say here's the -- what we understand other people are telling individuals when data are collected, but we don't know anything more than that.

In which case I think we, as reviewers, have an obligation to understand whatever individuals were told is really rather murky. We don't know, for the most part, the total extent to which information was or was not conveyed or the context in which it was conveyed.

And that should be the perspective that we are taking when we look to assess the kinds of risks that are listed in the middle part of the document. That's very different from knowing that people were clearly told your information might be used for research, here some examples

of kinds of research it might be used. Here is some information about the kinds of protections that would be in place for that.

Because I'm suggesting that all of those statements are probably missing in the situations that you're describing, where agencies have collected information from a variety of sources and they really don't know what was said, and perhaps very little was actually said to those individuals.

SUBCOMMITTEE CHAIR LUND: Actually, they do know because the privacy notice is standard because the data are collected on behalf of the state.

So, this process I described where a hospital collects the data, sends it to the county, sends it to the state, the state is actually on the hook for the data collection. So, the privacy notice, the state is actually responsible for that privacy notice, but the hospital is responsible for making sure it's administered. I know that's clear as mud.

But and the CCR operates the same way. So, because the privacy notice is about the state requirements and they're state data. But the state doesn't directly interact with the person whose data is being collected. Someone interacts on behalf of the state. So, it's not --

SUBCOMMITTEE MEMBER SCHAEUBLE: So, do we know

what the content of that privacy notice looks like?

SUBCOMMITTEE CHAIR LUND: Sure, we can find out. We can find out for all of the CDPH databases. The immunization branch, CCR, birth data, yeah.

DR. RYKACZEWSKA: Yeah.

SUBCOMMITTEE MEMBER KURTURAL: That's what I was thinking is -- maybe it's how you word it. Because my main concern as a reviewer of a project is when you're mixing with another outside entity's data, and we don't know what they're doing.

We can find out internally, you know, what each of the departments are doing and make suggestions or recommendations. But it would be helpful to know, like on the community college front, you know, if you know, not make it necessarily a requirement, but it's helpful for the application and the review process, if you know that, you know, you're going to take our data and mix it with other financial data, that on the financial side, or the FAFSA side, you've been forewarned about how your -- this data could be used for research, let us know in the application. Because we're going to just consider that.

So, we're not -- it's still you're reviewing for minimal risk because they're connecting our data with that outside data.

SUBCOMMITTEE CHAIR LUND: Uh-hum.

SUBCOMMITTEE MEMBER KURTURAL: I'm probably not explaining this very well but what I'm -- not making it a requirement but a, if you can help your case on this project to tell us if there was any sort of notice provided on the student side of things, let us know in your application, essentially.

SUBCOMMITTEE CHAIR LUND: Uh-hum.

SUBCOMMITTEE MEMBER KURTURAL: And then, because I think on the state side that, you know, like I already provided, like Department of Development Services Notice of Privacy Practices. And, you know, happy to provide the contract that says, yes, you know, regional centers, you have to have the same thing.

And, you know, if we find, we take a look at those and we find, you know, the research allowance there needs to be modified a little bit, you know, we can make a recommendation and think about that, and see what the departments say.

But we have a lot more control over our data. It's just when our data gets mixed with outside data and we do have review for minimal risk.

And so, maybe we keep this first part, that Dr. Schaeuble and Jared wrote, and we pigeonhole that to if you know for outside agencies. I don't know. Go ahead.

DR. RYKACZEWSKA: I think a --

SUBCOMMITTEE MEMBER SCHAEUBLE: Is the language -- are you telling me that the language would be uniform in privacy notices that any agency would use?

SUBCOMMITTEE CHAIR LUND: No. And in fact, it's not even uniform within the agency. It is specific to the statutes that govern the data being collected.

So, the privacy notice for CCR is different than the privacy notice for the birth data, is different than the privacy notice for the immunization branch. Because the collection of data for those purposes falls under all different statutes.

So, the statutes have to be referenced in the privacy notice and what can be done with the data may be different across the statutes. So, that's -- at least in the case of CDPH, they're all different.

SUBCOMMITTEE MEMBER KURTURAL: Yeah. But typically -- and that might be true, but typically, you know, it's common, just like in any other confidentiality statute, to have a research function and to notify of that.

SUBCOMMITTEE MEMBER SCHAEUBLE: And how prominently would this be featured within the document?

SUBCOMMITTEE CHAIR LUND: Well, so the privacy notice, at least -- once again, I'm just going to use birth data as an example, because it's different for all of the different databases.

Well, so, the privacy notice for birth data used to be at the bottom of the birth certificate that the parent giving birth had to sign. But it got too big and didn't fit on the page. So, about five years ago they went to a standalone privacy notice, so that the parent giving birth signs the birth certificate and also gets handed that standalone privacy notice in the stack of documents containing other information about the birth, like when to get your kid immunized and that kind of thing.

So, not that it was any better when it was part of the birth certificate, because I'm sure that at that point in time the parent giving birth is not really excited about reading through all that language.

So, for immunization the privacy notice is given at the time that the information is collected, when the immunization occurs and goes into the database by the county. So, it varies considerably about how prominent it is.

And, usually, the privacy notices for the CDPH databases are the minimum required by law. They don't go into a lot of detail and explanation because that's not required by law and because it just takes up way to much space for them in terms of administration. So, it's not going to say example, example.

Agnieszka, I'm sorry.

DR. RYKACZEWSKA: No, no, no, no. I just -- I did want to ask a couple clarifying questions, if that's okay. One of them is when you said it's the researcher making the case, right. And I just wanted to make sure that I understood, they're making the case that their privacy and security plans are sufficient --

SUBCOMMITTEE MEMBER KURTURAL: Correct.

DR. RYKACZEWSKA: -- given what information was shared. We're recognizing that the sufficiency of the plan is kind of dependent on what data is being collected. And should there be an adverse event, these types of data that we've enumerated here could have much more harm than maybe other types of data. And so, the sufficiency of the plan has to be stronger --

SUBCOMMITTEE MEMBER KURTURAL: That's right.

DR. RYKACZEWSKA: -- and they need to make the case for that. Is that --

SUBCOMMITTEE MEMBER KURTURAL: That's absolutely right.

DR. RYKACZEWSKA: Okay.

SUBCOMMITTEE MEMBER KURTURAL: And so, it wouldn't necessarily be a mandate because not necessarily every research is going to -- researcher is going to know, you know, the answers, but they might. They might have looked into it. And if they could provide that, rather than when

we, as a reviewer are getting this, and going down rabbit holes to try to say, well, what is our data going to be connected with. You know, what are these requirements over here with another entity.

Because at the end of the day we're just trying to protect our data, our individuals we serve.

DR. RYKACZEWSKA: Yeah, that's very helpful.

And then, the second piece that I wanted to follow up on was the mention of amendments. Because that's the part where -- of the privacy statements.

SUBCOMMITTEE MEMBER KURTURAL: Oh.

DR. RYKACZEWSKA: That's the part where I'm getting a little caught up of if they're asking for, I don't know, a hundred thousand people's data, we would have to track back to when did those individuals enroll. Because they might be asking about their services two, three years later after enrollment, and track back to what was the privacy statement for each individual that enrolled. And that's the piece I don't --

SUBCOMMITTEE MEMBER KURTURAL: Something we probably don't collect. We don't collect that, yeah, it's too granular.

DR. RYKACZEWSKA: Right. And so that's, I think that's where the piece around overall process resonates with me. Because I think the process can be described. I think

they can give examples of what are the privacy statements maybe now or the last couple --

SUBCOMMITTEE MEMBER KURTURAL: Yeah. So, not specific to if individuals whose information will be used were told specifically. Because 9 times out of 10 nobody's collecting that data point. But just say, just point to the process. That's a good point. So, maybe we should revise it a bit, you know, to have it as an application requirement that, if known, please describe the process of individual -- you know, if know, please describe the process or any processes of individuals being told, you know, or forewarned about --

COMMITTEE MEMBER LUND: Yeah, I think the language --

SUBCOMMITTEE MEMBER SCHAEUBLE: What I'm concerned about in the language I'm hearing is that this doesn't seem to keep in mind the agency of the individuals whose information is being used in the sense that if you only say what is the process, in other words were people given a document that says something or other about potential use of research information, that really doesn't tell us anything about whether that was an effective communication or not.

And for me, at least, that's the fly in the ointment here. And particularly so because I've had two recent experiences, now, with my wife signing documents on

entering a hospital. And what happens in those situations is that somewhere, two-thirds of the way through an 8-, or 10-, or 12-page document there is one sentence like your medical information may be used for research period, nothing more, effectively buried in a long document, signed under stressful circumstances.

That doesn't allow us to say that -- you know, you can say, okay, there was a process there, she signed the document. But that does not constitute anything that we would normally think of as informing people that their information might be used in ways that they're not anticipating.

So, if we don't ask what are the -- what's the context, what's the situation in which a communication's taking place, I don't think we can say that we know anything about what people have really been told. And, certainly, not about what they might have understood.

COMMITTEE MEMBER JOHNSON: So, I think that might be too high a bar for this Committee, in all honesty. And your use of the word "agency" was an excellent choice. Because state law actually takes away the agency of many of the people whose information is collected, when it's collected for these large databases.

Once again, I'm just going to use the birth data as an example, you cannot refuse to provide the data. You

can't. So, effectively, agency has been removed from the process.

And while one hopes that people are told, through this process that's supposed to be established that, you know, they get their privacy notice and they're told how their data will be used, they can't do anything about it. Right.

And I think that's true for a lot of the databases that are collected by state agencies. I think a healthcare environment is different. I'm less familiar with those data, so I'm not going to speak to that.

But I think trying to go back, with some of these large administrative databases that, you know, is kind of our stock and trade in terms of what we review and what researchers use, I think it's too high a bar to ask researchers to ensure that people were informed in a way that they truly understood. Informed consent is not possible in these situations.

And even asking state agencies to change their process is way outside of -- in my opinion, way outside of our scope.

I truly think the best that we can do is knowing that a process was in place -- what it helps for me, as a reviewer, knowing that a process was in place and that there was at least an opportunity for people to be informed about

the fact that their data would be used for research, because for me that's a, were they informed about the research or not.

As opposed to finding out, yeah, these data were collected and people were never told that they were going to be used or never had the opportunity to be told that they were never going to be used for research. Or, in fact, they were told they wouldn't be used for research.

So that, for me, is the dividing line as a reviewer.

And I understand your point, yes, having been through the hospital process several times myself this year, I agree that these things are buried and people are not in a frame of mind to sit down and go, oh, let me review these documents, you know.

But I really think it's too high a barrier for us, as a Committee, to try and take on.

SUBCOMMITTEE MEMBER KURTURAL: I also think that we have to work within the structure of the laws that we already have. Right. And the process that we have in place. I mean, we can't change everything in regards to privacy on this board. We can't change HIPAA. We can't change, you know, the requirements on whether someone -- you know, like right now I think a -- I don't even remember the rule, but I think a signature is required, you know, on a

notice of privacy of practices now. But, you know, who knows, two years down the line it might -- a signature might not be required, but just notice to be provided.

So, we don't have control over a lot of the privacy concerns. And we also, it's kind of when you look at the data-only projects, they're getting individuals like 400,000 like individuals' information. They're not going to sit and go through -- even if we collected the data point, let's say wishful seeking state agencies, which I know are not, but are collecting that type of granular data, if they got a notice of privacy practices or not, and that was somehow collected. To actually go through, the database to see that, whether they got that and understood, I just don't think it's going to be possible.

But what I would like to know, as a reviewer, is the opportunity that they did have outside of the agency and for, you know, that to be added on, to be considered in our minimal risk analysis. I agree with that.

But the devil's kind of in the details in how it's worded in the regulation. And so, we can always come back and hear from the public on that point, too. But I have a funny feeling they're -- you know, that's going to be too high of a bar.

SUBCOMMITTEE CHAIR LUND: Dr. Dinis, any comments from you on this item?

SUBCOMMITTEE MEMBER DINIS: Well, I think I agree with what you're all saying, it's probably too high of a bar to require that. So. But I am concerned, you know, what is unclear in these privacy notices is it says information can be shared with researchers. It doesn't say that they're going to -- that it's okay for them to then merge with this dataset and that dataset. And I think, for me, that's what the problem is here.

It's one thing to analyze the data that's there. It's another when they share. Because, and even in the privacy notice it is conflicting because sometimes they say, you know, that these identifiers will not be shared with them and then in another situation it says it will be shared. So, it's confusing even to the person reading the information.

SUBCOMMITTEE MEMBER KURTURAL: Yeah. Well, you know, usually the privacy practices are posted on an entity's website so, you know, like to the extent they -- you know, if someone has it, an outside agency's privacy practices, and they can attach it to an application because they have it, you know, we can look at that, instead of us trying to hunt that down. We can look at what's -- and then, take that into consideration in the analysis.

SUBCOMMITTEE CHAIR LUND: So, what I'm hearing, I'm generally hearing that it sounds like as an additional

piece of information in the application to provide reviewers with assurance about mitigation of risks, it would be good, if available, for the research to provide the privacy notices that were provided to the people from whom data were collected, for all of the databases being considered in the application.

I'm seeing Ms. Kurtural nodding. Did I -- did I capture that, do you think? So, that's one thing.

Was there anything else that we might want to add, or change about this section? I mean, my objection is it's strong. If no one else wants to change the wording of this first sentence, because I really do think that this working of the first sentence puts the burden on making sure that individuals were provided with the information, rather than on state agencies providing information about the process to ensure individuals were provided with the information.

So, I would still request that that change be made. But if no one else thinks that's necessary, I would back off from that.

And I would ask Jared to weigh in on any of this, if he has thoughts or suggestions.

MR. GOLDMAN: I don't have any strong view. I mean, I'm okay with what Dr. Schaeuble had initially proposed. I'm also okay with striking that and replacing it with a requirement that the researcher provide, to the

extent known, a copy of the notice of privacy practices that would ordinarily be provided to the subjects.

SUBCOMMITTEE CHAIR LUND: And the description of the process for providing it.

So, what's everybody's thoughts on how you'd like to go with this?

SUBCOMMITTEE MEMBER KURTURAL: I liked what -- that option that Jared just mentioned about, if available provide copies of any notice, notices of practices originally provided to the individuals that would be subject to the data.

SUBCOMMITTEE CHAIR LUND: And a description of the process?

SUBCOMMITTEE MEMBER KURTURAL: And a description of the process and/or, you know, really any information. But, yeah.

SUBCOMMITTEE CHAIR LUND: Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: Would you include in your language anything about what Maria was just talking about a moment ago?

SUBCOMMITTEE CHAIR LUND: And what would you add? Dr. Dinis or Dr. Schaeuble, what would you add to that?

SUBCOMMITTEE MEMBER DINIS: Well, yeah, that's the hard one here. I mean, I'm concerned that the -- some language about, you know, whether these datasets can be --

and I think this is -- I guess for these entities to answer the question, actually. You know, it's for them. You know, is there events that they could merge the data with anything they want? You know, because that's what I don't know.

SUBCOMMITTEE CHAIR LUND: So, in all honesty, there's not going to be a single privacy notice from the state that tells people --

SUBCOMMITTEE MEMBER DINIS: Yes, that's what --

SUBCOMMITTEE CHAIR LUND: -- that their data will be merged with other datasets. That's just -- that's just not -- that's not realistic to expect and they're not going to change it.

So, that being the case, how -- what kinds of things could we say in regulation -- because, really, what we're trying to do, we are going to get requests for data linkages. And we've identified in Section 2 of this document what the risks are that we're concerned about. And, you know, I think these are all legitimate risks and they will -- some of them will definitely come up when these large linkages are requests.

But given that people will not have been told specifically that they're data will be linked, what can we put in to ensure that we are mitigating these risks to the extent possible?

SUBCOMMITTEE MEMBER SCHAEUBLE: Well, so far the

language you've proposed only asks about process with regard to the state agencies releasing data. And if those data are to be linked with data from other sources, then unless we say something we don't know anything about what kind of process was, or was not in place for those additional sources of data.

SUBCOMMITTEE CHAIR LUND: So, I think we--

SUBCOMMITTEE MEMBER SCHAEUBLE: And that's a stumbling block for me.

SUBCOMMITTEE CHAIR LUND: No, I think we solved it. I think Ms. Kurtural's point was that very thing, that she was also concerned with outside databases and wanted the language to reflect that, if available, the privacy notices and processes for all of the data that are being considered in the application would be provided, not just the state agency data. Am I correct about that?

SUBCOMMITTEE MEMBER KURTURAL: Yes.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay, so if you're saying all of the data, then yes, I agree, as long as we're covering everything that might be included within the research project.

SUBCOMMITTEE MEMBER KURTURAL: Yes.

SUBCOMMITTEE CHAIR LUND: If available is a way to show reviewers that risks are being mitigated to the extent possible. Because sometimes it may not be available, and

then reviewers will have to look at other things to make a decision. Yes?

SUBCOMMITTEE MEMBER KURTURAL: Correct. Yeah, I think it will be more amenable with other researchers, too.

DR. RYKACZEWSKA: And --

SUBCOMMITTEE MEMBER KURTURAL: I was going to say do you -- do we want to make a motion on a revision to the --

SUBCOMMITTEE CHAIR LUND: So, I think I want to make sure that everybody has had the opportunity on the Committee, and then I think Agnieszka wanted to add something. And then, before we make a motion, I think we have to open it up for public comment.

SUBCOMMITTEE MEMBER KURTURAL: Okay. Okay, thanks.

DR. RYKACZEWSKA: Okay. Committee first, then?

SUBCOMMITTEE CHAIR LUND: Yes, anyone else on the Committee. I think what I'm hearing is that instead of -- for this first bullet item, instead of this language, that we will have language that says something to the effect that if available, researchers will provide the privacy notices and the process for providing people with those notices associated with all databases that they're including in their application, or words to that effect. Don't quote me, just words to that effect.

And I think that's the only change that we're actually suggesting to the document that we have here. I think that I didn't hear anything else.

So, anyone else on the Committee? Going once, going twice.

Okay, Agnieszka.

DR. RYKACZEWSKA: Thank you. So, this is again me trying to marinate and really make sure I'm following.

So, what I'm understanding in terms of this is that in order for us to determine that the plan to protect personal information and the written assurances that the information will not be reused are sufficient, one of the things that we need to consider is to what extent did individuals know that their information would be used this way. Because should there be an adverse event the extent of potential harm that could be caused is greater when individuals didn't know.

So, that's kind of the -- we're trying to determine, at the end of the day, the sufficiency. And so, that's why this information, if available, would be provided to help understand, essentially, the sensitivity of the data that's being protected. Is that right?

SUBCOMMITTEE CHAIR LUND: Yes, I think that's a good summary.

DR. RYKACZEWSKA: Okay.

SUBCOMMITTEE MEMBER KURTURAL: I just -- again, this is more clarifying the IPA and what does the minimal risk mean. And it's just going to be an application and criteria point.

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: Yeah.

DR. RYKACZEWSKA: And so, and this is me just trying to be explicit, it's also not saying that it won't be -- it's not an automatic no if there's no privacy statement available or provided, even.

SUBCOMMITTEE MEMBER KURTURAL: That's right, yeah.

DR. RYKACZEWSKA: But that, rather, the bar for the sufficiency of the plan would be higher if they're not there.

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: Possibly higher, possibly higher. I would say possibly higher.

DR. RYKACZEWSKA: Yes. That's a variation.

SUBCOMMITTEE CHAIR LUND: Yeah.

DR. RYKACZEWSKA: Less black and white statement.

SUBCOMMITTEE CHAIR LUND: And I think having language to the effect that says "if available", you know, as Ms. Kurtural said, makes that clear that, you know, if it's not available, it's not available. But it is a thing that we would like to see and consider if it is available.

DR. RYKACZEWSKA: Yes.

SUBCOMMITTEE CHAIR LUND: I would point out, "if available" is already in the stem sentence before the two items that are listed here. So, that part of it --

SUBCOMMITTEE CHAIR LUND: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: -- that has already been emphasized.

SUBCOMMITTEE CHAIR LUND: Good point, thank you.

Okay, I think we may be ready to open up for comments, if there any, from members of the public.

DR. RYKACZEWSKA: There is a comment in the chat from earlier, and we do have a hand as well.

I think we're reading the chat.

SUBCOMMITTEE CHAIR LUND: So, there's a comment in the chat. Do we need to put that in the record?

DR. RYKACZEWSKA: That's a great question.

DR. WHITE: I put the comment in the chat. It was just I thought that the Committee might want the correct information about the information on the Student Aid Commission's website.

DR. RYKACZEWSKA: Oh, okay.

SUBCOMMITTEE CHAIR LUND: Great, thank you.

DR. RYKACZEWSKA: I see a hand. Should we --

SUBCOMMITTEE CHAIR LUND: Yeah, could you just --

DR. RYKACZEWSKA: Please, opening it up for your

present comment. Dr. White?

DR. WHITE: Oh, okay. Great. Let me change the -- there we go.

So, I want to start by applauding this Subcommittee on what is clearly and thoughtful consideration of these issues. It's very clear to me that your heart is in the right place and you want to get this right. And I understand that this Committee is made up of volunteers, and I thank you for serving and for trying to carefully get to the right outcome.

However, on the substance I continue to strenuously disagree with this effort. I think that the draft regulations are both legally flawed and are misguided from a policy perspective.

I want to start out by acknowledging Dr. Lund's distinction between the eventual regs which will come in the supporting material. I used to be a regulatory attorney, so I know that distinction. But this is the document that we have in front of us, so that's what I'm reacting to.

Legally, I believe that these fall outside the scope of the IPA, which pretty clearly, to me, limits the CPHS review to data security matters.

I understand that agency counsel believes that the IPA preamble, which discusses data privacy, gives you license to expand the criteria in the fashion you're

proposing to do.

But the majority of the IPA does not relate to CPHS, only subsection T does. And subsection T limits that down to a narrower scope.

The other legal caution I would make is that the CPHS doesn't have the expertise or, in most cases the training, although I understand that some of you are lawyers. And more importantly, it doesn't have the legal authority to perform a legal review of whether the data being released complies with existing privacy policies, or other laws and regulations.

That's the responsibility of the agency who's releasing the data. They have the expertise, they have the training, they have the legal authority to make those determinations.

So, I worry that all this inquiry into what happened when the data was originally collected is going to lead to sometimes erroneous, or just outside-the-law determinations of what is legal and permissible.

But putting the sort of legal concerns that I have to the side, I'm far more worried about the policy implications here. It seems to me that this entire effort arose out of a desire to claw back authority that this Committee was exercising unlawfully in applying IRB authority to IPA-only projects.

And when you were informed that you were doing so, you then wanted to write these regulations as a way of clawing back that authority.

The aims, as laid out in the supporting materials, as you're calling them, reflect a desire to second guess considered judgments by federal and state legislatures, and by the agency releasing the data. And that's not this body's role.

Whatever your personal views are about individual privacy regs, and I assure you that I respect those opinions. I've written data privacy regulations at the Consumer Financial Protection Bureau. I also drafted some that were proposed to the California Public Utilities Commission and then adopted.

So, whatever your person views are they cannot and should not be relevant to your review under the IPA. Which say that you should check that there's a plan to protect personal information, a plan to destroy it or return it, and written assurances against further disclosure.

It really is not about all of the stuff that you've loaded into this set of supporting materials. You keep using IRB language, minimal risk, consent, vulnerable groups. Those terms are nowhere found in the IPA and they're not part of this limited review that the state has assigned to this Committee.

Lastly, I just want to address something that you -- that was mentioned at the top. I heard it suggested that these new criteria would not be automatic disqualifiers. And I agree with that. It's not automatic. But they are new criteria for disqualification.

And the IPA is currently about routine data security matters and you're transforming it into something that's much more complex, that approximates an IRB review, and in some cases exceeds the Common Rule.

And you may choose to call it mitigation, risk mitigation, but when you ask a researcher to go back and get consent for previous administrative data, or go back and find all the different things that were said to people when data was collected, even when legally they've been assured by the people who are responsible that this is permissible, that is implicitly grounds for disapproving the research.

So, I don't think it's accurate to sugarcoat this effort as merely risk mitigation. It can and it will prevent valuable research, which has to date been routine across the social sciences.

Thank you.

DR. RYKACZEWSKA: Thank you, Dr. White.

We do have a second public comment from Agnes Balla. You have the floor.

MS. BALLA: Yes. Thank you very much, thank you

for having me. I'm Agnes Balla. I am the Director of Researcher Policy and Analysis in coordination within the UC Office of the President.

I work on a range of topics, including working with our IRB directors, with whom we've been discussing these efforts.

And I provided public comments in preparation for this meeting. And in listening to today's discussion, the comments that I provided are even more true that I'm very concerned that there's muddling of the role of CPHS.

You know, as I understand it, CPHS has the role of being the IRB for CalHHS, for whatever studies that are supported by CalHHS. And then, separately, has the role of conducting reviews laid out under the Information Practices Act.

But a lot of the discussion today seems to fall more into the role of an IRB, as opposed to that, the technical and security review laid out by the IPA.

And that is troubling for many reasons. But not only does it complicate an already complicated pictures for our researchers, but it also, I don't think, really gets us anywhere.

You know, I think I fully support and echo the comments that Evan White made that, you know, when using terms like "minimal risk" that are defined under the Common

Rule for something that is unrelated to conducting reviews under a Common Rule really, really, really complicates the picture. And that's not the direction that I think we should be going in.

The other -- the other points that I want to make real quick, just in terms of the discussion today, it seems like there is a legitimate concern around privacy protections, but mainly around how state agencies are collecting state information.

There was the, you know, case talked about in terms of birth certificates. That was the concern that was brought up was how do we guarantee that the state's contractors are actually providing notice of privacy practices.

I am very concerned that we're now, all of the sudden, penalizing the researchers because of what state agencies are doing. If that is a concern, that is a concern that should be legislated, but not by this Committee.

And so, I strongly, strongly suggest that this effort be revisited and, quite frankly, not carried forward.

Thank you.

DR. RYKACZEWSKA: Thank you for your public comment.

Are there any further public comments? I am not seeing hands on the Zoom.

Nick, is there any -- is there any public comments in person.

MR. ZADROZNA: None in person, but we just received one more in the chat from Evan White.

DR. RYKACZEWSKA: "I did have one question which (indiscernible) -- what is the status of the proposal to impose fees that was mentioned at the August meeting?"

There will be an update on the fees, conversation at the December meeting, I believe. The agenda has not been finalized for December, so I don't want to over commit. But they are being revised based off of the feedback that we received at the August meeting.

So, that's where we are in the process is in the revisions process and we've received feedback.

Any other public comment? Going once, going twice. Back to you.

SUBCOMMITTEE CHAIR LUND: Thank you. Thank you all for the public comments. I think we need a motion.

SUBCOMMITTEE MEMBER KURTURAL: I would actually have a suggestion with what's written up here on this Word document, and wanted to get everyone's -- my idea with the NPPs is that it's not only if it's available, but it's -- and if data is to be linked with other sources.

Because I really feel that as, you know, we're the contract for the -- we contract with all of the departments

within agency. So, we should not put that burden on the researchers, but it's only my concern was in reviewing. Because I don't necessarily know.

We heard from Dr. White on a requirement with the Student Aid Commission. I didn't know that information. You know, and so if that's include, you know, you have a project with that agency and it's available, and that type of information is available, please provide it in an application. It's helpful to us to review for the data-only projects.

So, I don't necessarily agree to opening it up, the NPP saying, you know, tell me what healthcare services NPP says that. I mean, we should have that as a privacy board.

SUBCOMMITTEE MEMBER SCHAEUBLE: How would we have it?

SUBCOMMITTEE MEMBER KURTURAL: Well, we contract with them and we can ask for it, and it's also on their website. So.

SUBCOMMITTEE MEMBER SCHAEUBLE: But as reviewers how -- how would we have that information?

SUBCOMMITTEE MEMBER KURTURAL: We could ask the departments that we contract with for the information.

SUBCOMMITTEE CHAIR LUND: I think it would be very hard for some departments because they have so many

datasets. There's not a central, you know, based centrally.

Yeah, I do think that the burden needs to go with the dataset, itself.

But I agree with your suggestion because this is where the level of risk goes up. Right.

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: So, that's -- and that's our concern is with the level of risk.

SUBCOMMITTEE MEMBER KURTURAL: And, you know, if -- it really --

SUBCOMMITTEE MEMBER SCHAEUBLE: So, we will not know, then, if there's no proposal to link data, we will not otherwise know what privacy information was provided to individuals?

SUBCOMMITTEE CHAIR LUND: And do you -- are you concerned that we need to know that when we have -- we have lots and lots of routine requests for single databases. Are you concerned with those kinds of requests that we need to know the privacy notice in those situations?

SUBCOMMITTEE MEMBER SCHAEUBLE: I think it would depend on the situation. For some of them, I think the answer would be yes, for some of them probably not. It would -- for me it would depend largely on the particularly sensitivity of the information and the way it's being used which, in some instances, I would want to know.

SUBCOMMITTEE CHAIR LUND: So, let me ask you, Ms. Kurtural, thinking back to the risks that are specified, because what I'm hearing you say is that even with proposals that don't propose to link data, but are proposing a use of the data that may fit into some of these other risk categories that we've enumerated, that it would be helpful to have the privacy notice in those -- to know what the privacy notice said and what the process was in those situations.

SUBCOMMITTEE MEMBER SCHAEUBLE: Yes.

SUBCOMMITTEE CHAIR LUND: So --

SUBCOMMITTEE MEMBER SCHAEUBLE: Because, I mean, you can pick any one of the examples here, but many of them point to a category of information where many such pieces of information may be relatively unconcerning as far as our reviews would be concerned. But in some instances, the particular variables being requested would lead us to have greater concerns. And if that's the case, then I would think reviewers need to know the extent to which, or the way in which, the process in which people were ever advised about the potential for research.

SUBCOMMITTEE CHAIR LUND: So, having heard that, would you be okay with going back to the original wording, or do you still think that this should be a linkage-only proposal?

SUBCOMMITTEE MEMBER KURTURAL: I feel like at the high bar that, I mean, I think -- I would make the motion if it's in the case of to being linked with other sources, personally. But -- or, we can make a motion to take this back to the next meeting and to get proposals on this particular topic.

SUBCOMMITTEE CHAIR LUND: Do you mean asking the full Committee for their thoughts on this before we make a --

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE CHAIR LUND: -- final decision about the wording?

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

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

SUBCOMMITTEE MEMBER KURTURAL: And seek comments on the wording for this one.

SUBCOMMITTEE MEMBER SCHAEUBLE: Well, that's up to the Committee, of course. I would point out one other thing here, because the text that we're now looking at begins with the words "if available" and that's repetitive of what's in the stem sentence above, and I'm seeing -- I think I'm seeing a conflict in that stem sentence which would also apply to the second item on this list, but I don't think it should.

I think the information about which of the risks are enumerative of or application in the research and steps taken to minimize those risks, I don't think that should have the preamble "if available from the researcher".

So, I think we'd have to modify the additional sentence, in addition to your proposal to modify the first item below it.

SUBCOMMITTEE CHAIR LUND: Well, this is supporting documents. I mean, it's not regulatory text, yet. It's just an idea. So.

So, I agree that -- because I think that and I think this is a really important point that before we finalize -- because this is going to be an important distinction regarding whether or not we ask for this only for projects that are linkage projects or projects that meet any of the potential risk criteria.

So, I would support the suggestion to take this back to the full Committee for a discussion and decision. So, it is important.

Are you okay with that, Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: Well, can we try to wordsmith a bit so that maybe we have two alternatives that we can ask the full Committee to discuss, rather than just sort of vaguely bring this back to the full Committee?

SUBCOMMITTEE CHAIR LUND: So, I think what I heard

--

SUBCOMMITTEE MEMBER SCHAEUBLE: Can --

SUBCOMMITTEE CHAIR LUND: I'm not sure we need wordsmithing. I think what I heard, if I'm correct, is that the only difference in the two options is this italicized phrased, "and if data is to be linked with other sources". That's really -- the two distinctions are do we ask everybody who submits an application under the IPA for the NPP, or do we only ask it in situations where data are to be linked with other sources.

Did you have a different distinction?

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay, let's go back to that first sentence. And what I was saying a moment ago is to the extent it is available to the researcher doesn't seem to belong if we are saying that the first item is going to begin with the words "if available".

And the second item, I think, is not if available, the researchers should be able to discuss the risk that we have enumerated in the middle part, and how those risks are being minimized.

So, I would say with the changes we're talking about we should remove "to the extent it is available to the researcher" in that first sentence.

SUBCOMMITTEE MEMBER KURTURAL: Okay.

SUBCOMMITTEE CHAIR LUND: Okay, I'm agreeable to

that.

Dr. Dinis, is that okay with you?

SUBCOMMITTEE MEMBER DINIS: Yes.

SUBCOMMITTEE CHAIR LUND: Great.

SUBCOMMITTEE MEMBER SCHAEUBLE: And then, let me look here at -- I'm going to ask you to consider one other change in the first item and see whether it makes sense to you or not.

So, I understand we're talking about asking the full Committee to consider whether the italicized words in red should be included or should not be included.

The additional part that I'm wanting you to think about is on the third line, it says, "description of a process of providing this statement". I'm wondering -- personally, I would prefer saying something like a description of the context or situation in providing this statement, rather than process.

SUBCOMMITTEE CHAIR LUND: So, I think that -- I don't think that that covers most of the databases that I'm personally familiar with. I really think they have written procedures for how it's done. And it may vary, the context may vary depending on specific situations.

In the healthcare setting it's different, but for some of these other items I think that that doesn't capture it as clearly, for me, as knowing what the documented

procedures are.

So, they're going to be in the contracts for you, with your local folks, they're going to be in the requirements of the State Registrar for birth and death data. They're going to be in the contracts the state has with ICB clinics for, you know, ICB data.

So, I think saying, oh, they fill it out in the waiting room, okay, but that's not true for everybody. But the procedures for somebody is going to hand this document to this person at some point in the process so that they'll be informed is what matters to me.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, what all is included in your understanding of process, then, for providing a statement? Does it -- does it cover the context in the situation in which people are receiving the information?

SUBCOMMITTEE CHAIR LUND: There's, I don't -- and again, I think the bar is too high. I don't think it's possible for the agencies releasing the data to provide the scenario or the context for how that information -- for the point of receipt of the information.

You know, in the healthcare setting it might be, you know, they're standing there, checking in, and they have to do a little digital signature.

It's different for births, and for immunization

clinics, and for the Cancer Registry data. And so, I think describing the context is too high a bar.

I think the best, in my opinion, the best we can ask for is what are the documentation and the procedures that are used, and that's what I mean by process.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, when you say birth certificate data as an example, what does the situation look like when that information is acquired?

SUBCOMMITTEE CHAIR LUND: So, how big is your hospital and what kind of birthing experience are you having, right. So, really it varies, literally, from hospital to hospital. This may be a packet of information that, you know, the mom gets at the very moment where she's signing the certificate. This may be part of the folder of information that's handed to her as part of her hospital stay.

This could be done in the patient room if she's got -- you know, if she's in a birthing room, it happens in the birthing room. If she's not in the birthing room, it could happen in the hallway. It could happen when she's coming out of anesthesia.

So, it's -- it is -- there is no standardized environment for when the person giving birth receives this information. It is done as part of the process of obtaining the information for the birth certificate. And that

information can be obtained at different points in the process.

When you check in, the birth clerk is there, okay, name, father's name, information. And then, there's other information that is acquired as part of the birth outcome. What kind of birth was it, were there complications, so on and so forth.

And so, this is all variable. So, there is no single way for anyone to tell you what the context is for acquiring the information. They can tell you the procedures. They can tell you that the parent giving birth gets this privacy document as part of the hospital's process of acquiring information for the certificate and giving the parent's signature on the certificate. The parent's signature isn't even required on the certificate.

So, that's why I'm saying we can know the procedures, we can't know the context in which they're implemented.

SUBCOMMITTEE MEMBER KURTURAL: I second that.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, a process statement is basically only going to say at some point parents -- well, you're saying they may or may not even have signed a document.

So, what exactly is it going to say? How would an agency describe process in those circumstances?

SUBCOMMITTEE CHAIR LUND: So, the agency would be able to provide the privacy notice that they are required, by law, to give to the person whose data is being obtained. And they can state the procedures for doing that. That is in the course of implementing their legal requirement for filling out and submitting the birth certificate the hospital shall provide, to the parent giving birth, the privacy notice associated with the birth certificate.

Right. So, that's it. That's all you're going to get. That's all that's required.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay. Well, to me that's not a process. That doesn't really go beyond saying that the privacy -- the notice of privacy was provided. I don't see that you're adding anything on top of that.

SUBCOMMITTEE MEMBER KURTURAL: You could get a privacy -- ask, you know, and for a privacy statement. There's always going to be, you know, typically, some kind of privacy statement, if you want to take a look at that. I don't think it's going to say much.

You know, how high do you want it to go? Because, I mean, agencies, even outside agencies are going to have privacy policies and how they execute the actual procedural part, and what they do with these notices of privacy practices.

So, we could put an and/or, you know, after and

put "if available", and if the data's to be linked with other sources, the researcher will provide a copy of the NPP that would ordinarily be provided to individuals whose data is being collected, and/or a description of the procedures for -- a description of the procedure, instead of process, for notifying the individuals that will be subject to the data.

SUBCOMMITTEE CHAIR LUND: I would say for providing the individuals with the NPP.

SUBCOMMITTEE MEMBER KURTURAL: Yeah, okay. So, just be more specific. Description of the procedure for providing the individual with the NPP. Yeah, and just cut off the rest of that, delete the rest.

DR. RYKACZEWSKA: Including the (indiscernible) --

SUBCOMMITTEE MEMBER KURTURAL: Uh-hum. Oh, you're confusing, we can't provide the -- I mean, we're kind of going in circles here.

SUBCOMMITTEE CHAIR LUND: Yeah, I think at some point -- I think, you know, in the interest of time, I think at some point what we need to get to is not the perfect text, but the essential information that we want to capture.

And I think we've agreed that we're going to take that essential information back to the full Committee and ask for a final decision about the wording, about what they're comfortable with.

And to go back, Dr. Schaeuble, to your initial question, I think what we want to take back to the Committee, the full Committee, is the choice between whether or not we want to restrict this request to protocols that are only talking about linking data or whether we want to make this more widely applicable to all research studies we review under the IPA which, you know, is -- and I don't know if we want to distinguish between, well, if they meet the risk criteria that we've laid out.

Because we review a lot of studies under the IPA that don't -- don't have any of these risks. And I think, personally, since we're talking about this, it's a burden for the researchers to have to provide this information if we, as reviewers, don't really need it.

So, those might be the things that we want to have the Committee -- those three things, have the Committee weigh in on those and come up with some final language.

Would that be okay with the group?

SUBCOMMITTEE MEMBER KURTURAL: I think that's great because, you know, these questions are going to pop up as we work through these regulations. And these higher level sort of issues, I would feel more comfortable with full board input.

SUBCOMMITTEE CHAIR LUND: Right. Because I mean the thing is the full board will have input. We can take

our recommendations to the full board and they can accept or not.

SUBCOMMITTEE MEMBER KURTURAL: Right.

SUBCOMMITTEE CHAIR LUND: But if we tell the full board we think it's important enough that they really -- we, as the Subcommittee, don't want to make the recommendation, we want the full board to weigh and discuss. I think that that's a reasonable thing.

SUBCOMMITTEE MEMBER KURTURAL: Okay.

SUBCOMMITTEE CHAIR LUND: Are you okay with that?

SUBCOMMITTEE MEMBER SCHAEUBLE: I think -- my concern here -- I'm fine with, of course, going to the full board to weigh in and make the decision on this.

My concern is that I think we should have, as clear cut as possible, what the alternatives are that we are asking the full board to look at. Not just some kind of generalized should we do this or that, but what are the alternatives that we have pondered and we think the full board should be trying to make a decision about.

And I'm not entirely comfortable that we're there at this particular moment.

SUBCOMMITTEE CHAIR LUND: What else would you add because I think we have really captured the -- you know, the kind of the crux of the points.

SUBCOMMITTEE MEMBER SCHAEUBLE: Well. Well, a

couple things here, now. A few moments ago the entire end of a sentence was deleted, but the last words had said for -- something to the effect about for all of the data being used in the study. And that seems like an important phrase that suddenly got lost in one of the last deletions.

And then, you've raised another.

SUBCOMMITTEE CHAIR LUND: So, I do feel that we may be, at this point, going in circles just a little bit. I certainly don't want to put a damper on the discussion because I think all of this is really important. But I don't think that we can wordsmith to perfect the language at this point.

I think, and I -- I do think it's okay to take the general concerns to the Committee, have the Committee make a decision about the general concerns, and then come back to the Subcommittee for the very final, perfected language that we would really like to see captured. Because they may weigh in on that as well, and I really don't want to see us spend a lot of time perfecting language that may get changed.

So, perhaps, it sounds to me like what we want to ask for input from the full Committee, from the full board, is do we want to restrict this request for NPP documents and process, and we can discuss the specific language around process and procedures in context, either with the Committee

or at a later time. Do we want to restrict those requests to only studies where the data will be linked, multiple data sources will be linked.

Or, a second option is do we want to have an NPP and description of procedures provided with every study that's submitted for IPA review.

And the third is do we want to have the NPP and a description of the procedures provided only for studies meeting one of the risk criteria in our supporting document.

I think that that captures the three things that I've heard.

And then, we can provide them with this as draft language that we've come up with. And we can tell them about our struggle. You know, some of this is very important and we want to make sure we capture it correctly. And that the Subcommittee had a really hard time finalizing wording, so that they'll understand. And have the discussion with them.

How would that be?

SUBCOMMITTEE MEMBER SCHAEUBLE: Laura?

SUBCOMMITTEE CHAIR LUND: Uh-hum.

SUBCOMMITTEE MEMBER SCHAEUBLE: I know you're trying to move things along here and I'm sorry for pushing back a little bit. But can you scroll up on the screen just a bit.

SUBCOMMITTEE MEMBER KURTURAL: I think we need to give Agnieszka a chance.

DR. RYKACZEWSKA: Sorry, I'm typing as fast as I can.

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay. So, can we say to the Committee that we are recommending the deletion as marked in the first sentence, that we're asking the Committee to consider whether or not to include the phrase in red, on the first line of the next part.

I don't think the last part of that item needs to be in red or italics. Isn't that language that we've said we are satisfied with recommending to the Committee.

SUBCOMMITTEE CHAIR LUND: Yeah, so I really -- I strongly would like to not wordsmith to this level of detail at this point because we have, you know, other things that we have to consider on the agenda today. And I think those are, you know, wordsmithing questions.

I think the questions for the full board have captured our concerns.

If you have objections to the language that's written, that would be good for us to capture in our questions for the full board. But at this point, if it's italics, and just the addition, or deletion of a few words, I really, really --

SUBCOMMITTEE MEMBER SCHAEUBLE: I'm not trying to change it. I'm trying to confirm that the only alternative we're talking about on that first item is the phrase in the first line, and that the -- what's in red or italics at the end should just be in black text like the rest of it.

SUBCOMMITTEE CHAIR LUND: I -- we can put it in whatever color, I'm fine.

SUBCOMMITTEE MEMBER SCHAEUBLE: Because I don't think it represents any disagreement.

SUBCOMMITTEE MEMBER KURTURAL: No objection.

SUBCOMMITTEE CHAIR LUND: No, let's -- whatever color you would like to put in that's fine.

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE MEMBER SCHAEUBLE: And the only other thing I'll say is, for the record, my thinking all along has been that these concerns would only apply in situations where the risks identified in the middle section of the document are applicable to the research study.

So, I would never have requested us to be asking for privacy information for all studies. That was not -- not part of my thinking, personally.

And one of the items in the middle section specifically talks about linkage. So, if you say we will only ask for studies that involve data linkage, then you're picking out one of those risks, and only one, as a situation

in which we would do a more exhaustive kind of review process, which would tend to negate the other risks that we have enumerated in the middle section.

SUBCOMMITTEE CHAIR LUND: So, I think this is -- this is an excellent point to make to the full board. So, I think at this point it definitely falls inside of the discussion that we have for questions for the full board.

I think, because we've had further discussion of this item and we have not yet had a motion, I think we need to open it back up for public comment before we have a motion on this.

So, let's go ahead and do that now. Do we have any?

DR. RYKACZEWSKA: Any further public comments? I'm looking for hands in the Zoom. Or, Nick, is there any public comment in the room?

MR. ZADROZNA: None in person.

DR. RYKACZEWSKA: No public comments in the room. And I am not seeing any hands on the Zoom. Going once, going twice. I don't believe we have any public comment.

SUBCOMMITTEE CHAIR LUND: Okay. Great. So, I do think we need a motion to take these -- this text, the draft text and the questions back to the full board for consideration and decision.

Do you want to make that?

SUBCOMMITTEE MEMBER KURTURAL: Sure. Okay, so I would like to make a motion that we take this text above, and I'm happy to read it, if we need to.

SUBCOMMITTEE CHAIR LUND: I don't think we need to read it.

SUBCOMMITTEE MEMBER KURTURAL: Back to the full board for review and questions. Do you think I need to review the questions?

SUBCOMMITTEE CHAIR LUND: Probably read the questions.

SUBCOMMITTEE MEMBER KURTURAL: Okay.

SUBCOMMITTEE MEMBER DINIS: And the amendments with your recommendations, maybe.

SUBCOMMITTEE MEMBER KURTURAL: Yes. Okay, the motion is that the Subcommittee will take the text above back to the full board for review and recommendations. And then, further, that the Committee will take the following questions to the full board.

SUBCOMMITTEE CHAIR LUND: Just copy them.

SUBCOMMITTEE MEMBER KURTURAL: You can copy them and I can say it.

One, do we want to restrict/request for notice of privacy practice documents and procedure to only studies that propose to link data from multiple data sources?

Or, two, do we want to include requests for a

notice of privacy practice documents and procedure to all studies reviewed under the IPA?

Three, do we want to have notice of privacy practices and description of procedures only for studies meeting one of the risk criteria enumerated in the document?

SUBCOMMITTEE MEMBER SCHAEUBLE: We really should say "or" after number two as well, because these are three alternatives.

SUBCOMMITTEE CHAIR LUND: Yes.

MS. SCHWARTZ: Yeah.

SUBCOMMITTEE CHAIR LUND: Okay, I second.

SUBCOMMITTEE MEMBER SCHAEUBLE: And is it -- is it understood in or does it need to be stated in this kind of motion that the -- well, what are we asking the full Committee to do? Is the full Committee potentially going to decide and make whatever language changes they want, and potentially approve this statement as an indication of the purpose and goals we're trying to accomplish?

Or, are you asking the full Committee to discuss and refer back to the Subcommittee?

SUBCOMMITTEE CHAIR LUND: I think that will be up to the full Committee, right. I think that -- because we serve at the pleasure of the full Committee, so whatever the full Committee wants to do, having presented with this, in regard to approving at the meeting or referring back to the

Subcommittee for more work, I think that's the -- I think that that's up to the Committee, the full Committee.

SUBCOMMITTEE MEMBER SCHAEUBLE: So, my question was when it says review and recommendations does that prevent the full Committee from acting, if it chooses to act?

SUBCOMMITTEE CHAIR LUND: No, action can be one of its recommendations.

SUBCOMMITTEE MEMBER KURTURAL: I agree.

SUBCOMMITTEE MEMBER SCHAEUBLE: Okay.

SUBCOMMITTEE MEMBER KURTURAL: I mean, they could make a vote on the language.

SUBCOMMITTEE CHAIR LUND: Yeah,

SUBCOMMITTEE MEMBER KURTURAL: Who knows.

SUBCOMMITTEE CHAIR LUND: Yeah. Okay, I second.

MS. ATIFEH: Okay. Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Okay, the motion passed.

SUBCOMMITTEE CHAIR LUND: Okay. So, the next item is to review the proposed draft framework for potential regulations that was prepared by Ms. Kurtural.

Ms. Kurtural, would you like to go over that for us, please.

SUBCOMMITTEE MEMBER KURTURAL: Yes, so this is -- can we get the proposed regulatory -- we're going to pop it up here. This is -- we're going to step back because we got pretty in the weeds there with the criteria for IPA-only reviews.

And so, now, I'd like to kind of step back a little bit and talk about and get back to talking about just in general the regulations. And this is an outline I prepared.

So, first, I want to let everyone know the process that I utilized. Obviously, we need to clarify the IPA-only review process in these regulations.

But what I also did is I went back to look at the Committee's procedures. And I also went back to look at the Health and Safety Code which outlines the board's authority, statutory authority.

And because we have not developed any sort of regs in the past for the Committee, what I did was a comprehensive outline of just what I think needs to be basically in the regulations. Anything from definitions to looking back what is the purpose of our Committee, how is our Committee set up. I know it's in contract, but to put that in regulation.

And also, what are the application requirements. What type of projects are defined as an IPA-only project.

What could be potentially a hybrid between an IPA and a Common Rule project. And when are we serving just as an IRB, you know, for state-funded projects.

And so, none of that is defined yet in the Health and Safety Code. And so, the purpose of regulations to make the law specific and to clarify it. And I think, really, we need to clarify much more than just the criteria. We need to have definitions.

And I think it's going to be helpful to the public so they have clarity on what is our process as a Committee in general.

And I didn't get very far with this, yet and, you know, we have to talk. But I think we can start with the definitions. And one of kind of the basic things that I need the most feedback on initially is talking about stepping back and defining what is an IPA-only project, what is a hybrid project, and what is a Common Rule-only project.

And, you know, I have a start here on the definitions, but I think we need to clearly defined the use cases and what this means.

So, I would propose starting there and then moving on. The regulatory process is a long process. This isn't going to get done immediately. But you'll see that even in the criteria we just went through, Dr. Schaeuble's criteria that he drafted, we can still see that, hey, maybe some of

that information could be plugged in under criteria, you know, for IPA-only project, the minimal risk criteria section, and the application requirements, maybe, you know, if we decide to include having some new requests for researchers in the application process, you know, for that to be outlined there.

So, it's a lot to take in and to think about. But, you know, this is part of the regulatory process and that step one is sort of get your draft together of what we're going to do. So.

SUBCOMMITTEE CHAIR LUND: I agree completely on the definition. And, actually, what you presented at the board last week in regard to Common Rule versus IPA was just so valuable. And, actually --

SUBCOMMITTEE MEMBER KURTURAL: Like people to plug in.

SUBCOMMITTEE CHAIR LUND: Yeah, you can plug it in.

SUBCOMMITTEE MEMBER KURTURAL: Yeah.

SUBCOMMITTEE CHAIR LUND: Because it was very clear. It was what we have been looking for, for years, in terms of which projects fit under the Common Rule.

The, I think, only discussion we had we don't want to have -- it's beyond the Subcommittee. But was the discussion around what does it mean to engage in research

for a state agency, and I'm looking at Jared, because the board wanted answers to that question. And that is, you know, that may not be something that you can clarify. But certainly the structure of how do we determine an IRB using the Common Rule only, an IRB using the Common Rule plus the IPA, and an IRB -- not an IRB, but some sort of other kind of privacy board, if you want to call it that, looking at IPA-only. Because I think we're not acting as an IRB when we're looking at IPA-only projects.

And maybe, just thinking out loud, months ago we had this discussion around use being a privacy board for the purposes of approving HIPAA waivers, when we were not reviewing under the Common Rule. And that might be something that we want to establish in the regulation.

SUBCOMMITTEE MEMBER KURTURAL: And that would be something to clarify under application requirements --

SUBCOMMITTEE CHAIR LUND: Yes.

SUBCOMMITTEE MEMBER KURTURAL: -- for each of those different sorts of projects.

But I think where we have to start, and we're not going to have definitions, right, during this meeting. We're not going to create them right here.

SUBCOMMITTEE CHAIR LUND: Yes.

SUBCOMMITTEE MEMBER KURTURAL: This is something that takes much thought process is -- you know, I would like

to actually start with, I would suggest collecting suggestions from not only us at the Subcommittee, but with the public, as well, to start, you know, how -- what would be defined as an IPA-only project, a Common Rule-only project, and a hybrid project. That's where I would start and then we could branch out from there on criteria and requirements. But that's just my recommendation.

SUBCOMMITTEE CHAIR LUND: So, I think that those things are already defined, we just need to put them into text, right.

SUBCOMMITTEE MEMBER KURTURAL: Uh-hum.

SUBCOMMITTEE CHAIR LUND: Because I think the discussion at the last board meeting really clarified how those are defined because the Common Rule ones are actually defined in our FWA, and the language around FWA. And Jared could weigh in because we did have this extensive discussion last week.

So, I'm not sure that -- I don't think those are things that are changeable except for some places where the language is ambiguous. For example, what does it mean to engage in research. This is for a state agency to engage in research, so we had that discussion at the last board meeting.

But other than that, the definitions of what constitute those three categories are pretty set already.

Jared?

MR. GOLDMAN: My only observation would be that we don't need to repeat the requirements that are in the FWA or in the Common Rule in our own regulations.

So, what I would limit the regulations to are those things in addition to what's in the Common Rule or clarifications that are needed for the IPA, as far as how this board operates.

The only other observation I'd make is this is -- the scope of what Carrie has shared here is big. And if we want to promulgate regulations any time soon, I think we would really want to narrow the scope of what we actually want to tackle.

SUBCOMMITTEE CHAIR LUND: Okay.

MR. GOLDMAN: This is quite ambitious. And we might want to approach our regulatory process in bite sized chunks, rather than try to put a complete regulatory package together all at once, that covers every issue we might conceivably want to regulate on.

SUBCOMMITTEE MEMBER SCHAEUBLE: Well, can I ask a global kind of question here then, because I'm really unfamiliar with this whole regulatory process, so trying to start out on it is just new stuff for me all the way around.

And, you know, I can see a lot of work that you put in to just trying to come up with something initially

here. And I don't know how that interfaces with the kind of work that Jared and Maggie would have to do as our legal counsel. I don't know what the process really has to look like when you begin drafting this regulatory kind of approach, and who does what, and how it all works. I need some clarity there that I don't have.

SUBCOMMITTEE MEMBER KURTURAL: That's why I think we need to break it up. And, you know, we can absolutely narrow it. I just took a comprehensive approach and review like, you know.

But I do think we need to define an IPA-only project. I think it's been a question with the public and we need to review, you know, the requirements regarding that. And if we think there's going to be a hybrid, we need to review that, you know, and we need to define these things.

SUBCOMMITTEE CHAIR LUND: Do you have the document that was circulated last week to the Committee, because that was --

SUBCOMMITTEE MEMBER KURTURAL: I was not at the meeting at the last Committee.

SUBCOMMITTEE CHAIR LUND: Oh. Can you make sure that Ms. Kurtural has that? Because we think that clarifies a lot of things.

SUBCOMMITTEE MEMBER KURTURAL: Okay.

DR. RYKACZEWSKA: Happy to resend it. For members of the public, it is posted on last week's meeting, on the website. This is the flow chart. So, happy to resend that.

SUBCOMMITTEE CHAIR LUND: Any other comments or discussion about this item, next steps?

I do have a question.

SUBCOMMITTEE MEMBER SCHAEUBLE: I'd like to hear from Jared, too, because I think I still don't understand how does what you and Maggie would be involved in relate to what Carrie has just been working on here?

Because I think I don't know.

MR. GOLDMAN: Ordinarily, what we would do is receive general policy direction from our clients, in this case you, and we would have staff, including the lawyers, take a stab at draft regulatory text. We would do the drafting for you and then get feedback from you on what we propose. That is just one piece of it.

There are a number of other documents that go with a regulatory package. And once we land the policy and the reg text, then we proceed with the documents that explain to the public what the regulations do, what they say. We draft economic impact statements and we draft notices to the public. And those are all things that we would handle for the Committee. The Committee wouldn't have to prepare any of that.

SUBCOMMITTEE CHAIR LUND: So, if this -- if the full board approved language, for example what we're taking them to take a look at, at the next board meeting, approve language that generally, generally captures what the board would like to move forward with in regard to the regulations, because I think we're -- we're almost there with this final round. We could turn that over to you and your team, and you guys would then take that and craft sort of the boilerplate regulation stuff?

MR. GOLDMAN: Yes, that would be my suggestion.

SUBCOMMITTEE CHAIR LUND: Okay.

MR. GOLDMAN: Is that you allow us to propose to you draft reg text, rather than having the Committee try to draft it themselves.

SUBCOMMITTEE MEMBER KURTURAL: Okay.

SUBCOMMITTEE CHAIR LUND: Okay. Would that be okay?

SUBCOMMITTEE MEMBER KURTURAL: Yes.

SUBCOMMITTEE CHAIR LUND: You put a lot of work into what we have so far.

SUBCOMMITTEE MEMBER KURTURAL: Honestly, I only put like two hours into this. I have to be honest with you. But it's -- I think that makes sense to kind of turn it like here's a comprehensive and then, you know, think about what should be narrowed and, you know, what you're ready for and

what you're not.

SUBCOMMITTEE CHAIR LUND: And, of course, this would be an iterative process of you coming back to us with additional questions if it's not clear, and that kind of thing. So, we're not just lobbing it over the fence and getting back a final product, okay.

Is that okay with you, Dr. Schaeuble?

SUBCOMMITTEE MEMBER SCHAEUBLE: Uh-hum.

SUBCOMMITTEE CHAIR LUND: And Dr. Dinis, does that sound like an okay approach to you?

SUBCOMMITTEE MEMBER DINIS: Yes, it does because we're not really lawyers, so I'm happy to have them draft it.

SUBCOMMITTEE CHAIR LUND: Do we need a motion on this one? If we need a motion -- well, I'll wait until public comment for a motion, but I'm not sure we need a motion.

SUBCOMMITTEE MEMBER DINIS: I don't think we do.

SUBCOMMITTEE CHAIR LUND: Okay. All right.

Is there any public comment on this item?

DR. RYKACZEWSKA: Looking for virtual hands from the public. And Nick, any public comment in the room?

MR. ZADROZNA: No public comment in the room.

DR. RYKACZEWSKA: No comments. And I am not seeing any virtual hands. Just giving one more, two more

seconds. I do not see any public comments.

SUBCOMMITTEE CHAIR LUND: Okay, so just for the record, I believe my understanding of this item is that we will not, at the Subcommittee, draft the regulations ourselves. That we will turn over policy statements to the legal team and allow them to do the drafting, to come back to the full Committee for approval. Okay.

Next item. Now, we can move to Item C. And I think that we've incorporated Item C in our discussion of Item B, so I don't think there's anything additional on that.

Members of the Committee, is there anything additionally on Item C that we should address?

And hearing none, members of the public is there any comment on Item C, additionally?

DR. RYKACZEWSKA: Giving time for virtual hands. And Nick, any public comment?

MR. ZADROZNA: No comments in the room.

DR. RYKACZEWSKA: No comments in the room and I am not seeing any virtual hands.

SUBCOMMITTEE CHAIR LUND: Okay, great.

So, Agenda Item D on the agenda, next meeting. Do we believe that the Subcommittee should meet again and, if so, when?

SUBCOMMITTEE MEMBER SCHAEUBLE: I suppose we need

to set a possible date simply because we can't know what the full Committee may decide at its next meeting, whether it's going to be referring something back to us or not, or taking action on its own.

And also, if the full Committee were to approve the document we've been working on as a statement of purpose and goals for this process, then maybe the pending meeting date would be to have whatever initial discussion might be necessary with Maggie and Jared about things that they're going to be working on.

Those are the two possibilities that I can see coming up for a future meeting.

SUBCOMMITTEE CHAIR LUND: I think it's a good idea to plan for another meeting. We can always cancel it if we decide that the Subcommittee doesn't need to meet again.

Would that be okay with Ms. Kurtural and Dr. Dinis?

SUBCOMMITTEE MEMBER DINIS: Yeah, like December 13th?

DR. RYKACZEWSKA: That would be the --

SUBCOMMITTEE CHAIR LUND: It's going to be hard for me to do December. So, I'm thinking possibly after the first of the year.

SUBCOMMITTEE MEMBER DINIS: Okay.

SUBCOMMITTEE CHAIR LUND: Although, if I can't be

here will we have a quorum?

DR. RYKACZEWSKA: It depends. So, we need three in person.

SUBCOMMITTEE CHAIR LUND: Okay, so we won't. Yeah.

DR. RYKACZEWSKA: So, might I suggest the 10th of January, kind of recognizing that first week of the year is a little tough a lot of the times, but the 10th of January?

SUBCOMMITTEE CHAIR LUND: That would work for me.

SUBCOMMITTEE MEMBER DINIS: Okay.

DR. RYKACZEWSKA: I can't see what I'm writing. So, I'm just writing potential language here. January 10th.

SUBCOMMITTEE CHAIR LUND: And I don't think we need a motion on that, do we? It says here we need a motion, but I don't think we need to make a motion to set the date. You can if you want, go motion crazy.

DR. RYKACZEWSKA: I don't know. Jared, is this the type of thing that would need a motion?

MR. GOLDMAN: We don't need a motion to calendar this.

SUBCOMMITTEE CHAIR LUND: Okay, thank you.

DR. RYKACZEWSKA: Okay, then it is not a motion.

SUBCOMMITTEE CHAIR LUND: Do we need public comment?

DR. RYKACZEWSKA: I think to close out the item.

SUBCOMMITTEE CHAIR LUND: Okay, any public comment?

MR. ZADROZNA: No public comments in person.

DR. RYKACZEWSKA: Thank you, Nick.

I am not seeing any virtual hands. So, if you do have a public comment, please raise your virtual hand. I am not seeing any virtual hands. No public hands.

SUBCOMMITTEE CHAIR LUND: Okay, great. So, Item E, adjournment. Thank you, all for your contributions and participation today.

With no further items on the agenda, I adjourn the meeting at 10:36.

(Thereupon, the meeting was adjourned at 10:36 a.m.)

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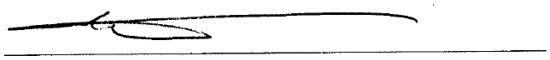
REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 18th day of November, 2024.



PETER PETTY, CER**D-493

TRANSCRIBER'S CERTIFICATE

I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber. And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.
IN WITNESS WHEREOF, I have hereunto set my hand this 18th day of November, 2024.

Barbara Little, AAERT No. CET**D-520