MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, JULY 12, 2024

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APPEARANCES

COMMITTEE MEMBERS

Darci Delgado, PsyD, Interim Chair (via Zoom)

Larry L. Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD (via Zoom)

Alicia Bazzano, MD, PhD (via Zoom)

Maria Dinis, PhD, MSW (via Zoom)

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund

Philip Palacio, EdD, MS (via Zoom)

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

John Schaeuble, PhD, MS

Maria Ventura

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator, CDII Deputy Director

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna (via Zoom)

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Jennifer Schwartz, Chief Counsel

APPEARANCES (CONT.)

PUBLIC

James Yi

I n d e x

P R O C E E D I N G S

VICE CHAIR DICKEY: Okay, so this is the July 19, 2024 meeting of the Committee for the Protection of Human Subjects. I'm Larry Dickey, Vice Chair, and I'll turn it over to Darci right now, who is the Chair.

CHAIR DELGADO: Hi, good to see everyone. Apologies, I am not able to be in person today for this important meeting. Really appreciative of all the Board members who have agreed to move to a monthly cadence so that we could check lots of things off of our to-do list in terms of all of the administrative items that have been pending for the last six to nine months. So excited to be able to get through some of those items today and just so much appreciation for Board members to be willing to meet with an increased frequency.

I am remote today, so I've asked Dr. Dickey -- it's kind of hard to manage the room in person when I'm not physically there, so I asked Dr. Dickey if he could lead today's meeting, and he agreed.

So thank you so much, Dr. Dickey. I'll hand it back to you.

VICE CHAIR DICKEY: Sure, thank you. You're actually very imposing there on the screen. You're about five feet high.

CHAIR DELGADO: Sorry.

VICE CHAIR DICKEY: So, yes, could we have everybody make -- does everybody have their cameras on who is remote? Okay.

And actually now I'm just going to turn it over to Nieszka to explain how we are having this meeting.

DR. RYKACZEWSKA: Yes. So as we all know, the Bagley-Keene Open Meeting Act requires that a majority of members attend in person in in order to have quorum. That said, the Act also includes a few criteria where if a member is not able to attend in person for reasons that meet those criteria, and they inform the administrator of this prior to the meeting, they can actually attend remotely while being counted towards the quorum.

And so ahead of today's meeting, two of our members, Dr. Rubis and Ms. Lund, have shared with me reasons for participating in a remote location that we have checked to satisfy those requirements. And as so, they are going to be attending remotely, but being counted towards our quorum.

So if there's ever any reasons that are coming up where you want to attend in person, but there's something preventing you, please feel free to reach out to me and we can see if that would meet those criteria.

So I think Dr. Dickey, with that, we can hand it off to Suzanne for roll call, yes?

MS. ATIFEH: Sure. Okay, good morning everyone.

Actually, the Chair has already announced their presence, so I'm going to start with Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Here.

MS. ATIFEH: Okay. Thank you.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

COMMITTEE MEMBER PALACIO: Dr. Palacio?

DR. RYKACZEWSKA: I see a thumbs up from Dr. Palacio on the screen.

MS. ATIFEH: Yeah, okay, good.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Azizian? Oh, you are muted, Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: My apologies. Here.

MS. ATIFEH: No problem. Okay. Thank you.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Thank you. Okay, the quorum is established.

VICE CHAIR DICKEY: Okay. I guess the first issue here is we have -- is to approve some meeting minutes.

DR. RYKACZEWSKA: Yes. So if you remember, due to an error, the March meeting minutes were not included in the June packets when we sent it out to Committee members. So we did send it out this time around, correcting that error. and we're returning to this item today.

I do want to note that Dr. Schaeuble did identify some needed revisions, and so we made those updates and sent out the meeting minutes with tracked changes, so that has been shared.

And I wanted to check if there's any additional changes that any of the members saw that would need to be incorporated?

VICE CHAIR DICKEY: If no changes, could somebody make a motion to adopt the minutes?

COMMITTEE MEMBER KURTURAL: I'll make a motion to approve the minutes for the March 2024.

VICE CHAIR DICKEY: Okay. Second it?

COMMITTEE MEMBER JOHNSON: I'll second.

(Colloquy between Committee members)

VICE CHAIR DICKEY: Thank you.

MS. ATIFEH: Okay, we need to do a roll call.

VICE CHAIR DICKEY: Okay. Can you call the roll?

MS. ATIFEH: Yes, sure.

Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz? Oh, you are muted, doctor.

COMMITTEE MEMBER RUIZ: Approve. Sorry.

MS. ATIFEH: No problem.

Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Dinis?

Approved.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion is passed.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: One check.

VICE CHAIR DICKEY: All right, the first item on our agenda is to talk about the UCPs. Well, Jennifer Schwartz is going to actually talk to us about what these are and a question has come up as to whether they can serve as letters of support from departments, as opposed to having our usual standard letter of support.

So I think without saying anything more about that, Jennifer, do you want to take it away?

MS. SCHWARTZ: Sure. Thank you Dr. Dickey. Good morning everyone. Happy Friday. I hope you're all doing well. I know it's very hot. Certainly, it's hot for me here.

So I'm going to sort of give you an overview, and feel free to ask questions, or if I'm not sort of clarifying things well enough, to just sort of let me know.

So the interagency data exchange agreements and the business use case proposal is sort of a universal data sharing agreement between state departments. What happened was that the interagency agreements used to share data between departments were taking years to complete, and they were very inflexible and difficult, and departments often need to share data in order to do service provision and quality improvement and various operational tasks.

So the idea streamlines the process between data sharing for departments, state departments, in that it sort

of created the idea, which is a high-level terms and conditions where all the departments signed onto it, and a separate business use case proposal, or BUCP, which details the project or the programmatic work that requires the data. Those two things together sort of encompass the entire agreement between a department and another department to share and exchange data between each other.

The BUCPs contain sort of all the details. What is the project? What is the use of the data? What are the data elements? How is the data going to be formatted and presented? What is the cadence of sharing? What is the term of sharing? How will it be destroyed? And are there any special sort of, you know, privacy or security requirements for that data? Because some data has specific requirements involved, such as social security data.

So the way that those are approved in almost every department I've seen so far is through a process where the programs come together and discuss the project and the need for the data, and then they fill out the BUCP together and detail sort of all those things I described in the BUCP.

Then that BUCP is sent to the legal departments of both departments, the privacy and security folks in both departments, and is approved by manager-level folks, often a chief data officer or chief deputy, it just depends on the size of the department and who has the authority to sign on

behalf of the department. Usually it's a program manager that is providing the data and, you know, a program manager that is accepting the data to use that data.

The process is really about looking at that BUCP to ensure that there are sort of legal justifications, it's lawful to share that data, and that the data will be protected. Those are the focuses of the BUCP review over that process.

So as we sort of take a look, and I'm sure you're very familiar with the process when it comes to research review proposals, so there often is a Committee when somebody is requesting data for research at a department, and the Committee is comprised of, you know, a lot of the same folks, right, legal, the information security officer, a privacy officer.

But in addition to those folks and managers, there's also usually experts who are familiar with research principles and practices who, when they're looking through a research application proposal, will look at the research application to ensure that the question, you know, is clear and makes sense and is relevant to what is being requested, that the research is valuable and ethical, whether there is a cost to the department or any impacts on the department or any impacts on the individuals whose information or whose sort of activity is going to be the basis of their research.

So the focus of that Research Review Committee is more than just, is this lawful to share and are you going to protect it, but also the research itself, is it valuable, is it ethical, et cetera. So you can use the idea in a BUCP for research. And as you may have seen, if you're familiar with the template, it does talk about there's a space there for that.

But the process of approving a BUCP by a department does not generally go through that research review process. It goes through a separate data release process, where, again, it's program to program, and legal and privacy are looking at it from the perspective of, is it lawful, and is the data going to be protected, not from the perspective of, is this research project actually ethical, valuable, you know, maintaining the principles of, you know, standards that are expected in the research community, and et cetera.

Could it, you know, also sort of simultaneously go through that process? Yes. I have not seen a department do that with a business use case proposal. Usually they have two separate processes. So I understand that there's a question around whether a BUCP, you know, could be used to show that the department supports a research project.

My suggestion would be that it primarily says that the department supports the data release and use, but that

doesn't necessarily mean that the department actually knows, you know, what the research sort of report is going to be, whether the department has weighed in on being able to have a say over the way that its data is presented in a public, you know, report or a public journal, whether a department has determined that the research is, you know, sort of under those principles of and standards of research as opposed to peer data release and whether it's lawful and the data will be protected.

So my suggestion would be that you consider getting a letter of support from a department so that you know for sure that the department has taken a look at the research itself, has weighed in on whether, again, it's ethical, valuable, impacting the department, has an opportunity to weigh in with the, you know, researcher, in this case, another department, on how the data will be presented, on knowing about the results of the research, and just have a voice in the process in general from the perspective of research as opposed to sharing for operational needs.

I'm wondering if you have questions? That was a lot of information.

Yes, Laura.

COMMITTEE MEMBER LUND: Hang on. Hi. Thank you. That was a great summary. Thank you very much. I'm a

little familiar with the BUCP process from my days back at CPH, so thank you, that was really helpful.

I've got a question. So the two things that, as a reviewer, I look for in the letter of support that for me are critical are that the department that owns the data is willing to release the data for the project that we're reviewing as reviewers, and the second item is the statement that whoever is releasing the data, generally when we get a letter of support it's the actual department that owns the data that's releasing the data, but they are going to release the data in compliance with all laws.

And that's the piece that I think is missing from the BUCP. I mean I could stretch it to BUCP satisfies my first concern, but not my second. So what are your thoughts on that?

MS. SCHWARTZ: So what you're missing when you just look at the BUCP is that idea universal terms and conditions piece. So you're just looking at half the agreement, essentially, when you look at a BUCP. You're not looking at all of the restrictions, terms, and conditions around the use of the data. All that is located within the interagency data exchange agreement portion that the departments have all signed on to. And all you're seeing is the individual project level sort of programmatic information.

So the idea does say that a department will comply with all the laws, as well as state policies. It does not reiterate that in the BUCP because it's already in the idea. And those two are -- together make the complete agreement. Does that make sense?

COMMITTEE MEMBER LUND: Thank you.

MS. SCHWARTZ: You're welcome.

VICE CHAIR DICKEY: I just like to --

CHAIR DELGADO: Just, if I could?

VICE CHAIR DICKEY: Go ahead, Darci.

CHAIR DELGADO: Sorry, Jen, if I could just repeat back? I need more coffee, but just want to make sure that I'm fully tracking.

So what I hear you saying is it's really helpful for us to know what a BUCP is in the event it pops up in one of our protocols, but your recommendation is that it should not take the place of a letter of support because it may or may not include all of the details that we need for those letters of support; is that correct?

MS. SCHWARTZ: So, yes, and in large part it's because of the two different ways that departments generally process data release. One is sort of for operational needs going to other departments. They're not looking at it from the lens of ensuring all of those research standards. They're just looking at it from the lens of is this lawful

and do you need it and does it comply with, usually, the Information Practices Act in an exception?

The other way is definitely looking at the research in a Committee, you know, with folks who are used to research, have experience in research and in analyzing, you know, research itself and are familiar with the standards that apply, such as the Common Rule, and determining whether that research is appropriate and valuable and etc.

And so those two different processes generally do not meet. And so that's why I'm suggesting a letter of support is a formalization that the department's actually looked at it from a research review lens as opposed to just a data release lens. And that's why I'm suggesting it might be helpful to you to have greater formality around a letter of support.

CHAIR DELGADO: Thank you.

VICE CHAIR DICKEY: I just wanted to set the context in which we receive these. Departments can exchange information between themselves, not through Section T of the Information Practices Act, which is relevant to us. They can do it through other sections, particularly Section E, I think it is, that says in order to conduct their business they need this.

So there are going to be a lot of these exchanges

where they never come to us. And they really don't need to come to us unless it's actually going to be researched and they feel a need to get something for a publication. And so most of these, we're going to -- there are going to be a lot of these projects that go through BUCPs we never see.

So I think that we maybe, if this is a policy we want to adopt, we need to put it in our policies and procedures as that letters of support need to be provided for all projects, even if BUCPs are provided, so they can build this process of getting the letters into their whole review process as of when they're doing the BUCPs and not after the fact.

Anybody else have comments or --

COMMITTEE MEMBER KURTURAL: I'll just comment that in practice we've always seen it as two parallel processes that, you know, one is an operational-type sharing purposes whether it's an exception under the IPA or HIPAA if you're HIPAA covered, and then the other one being the research process.

It's interesting that you raise it because I have never myself seen any department go the research route through the BUCP process. We certainly have never done that. I always thought it was memorialized in a policy that we do a letter of support and go through our research processes.

VICE CHAIR DICKEY: Well I don't think -- I think there was some time, vaguely, in the past where we kind of discussed this, I think, I don't know, and may have thought, well, informally, BUCPs would be okay, but we never put anything in writing.

MS. SCHWARTZ: Right. Right.

COMMITTEE MEMBER LUND: Oh --

VICE CHAIR DICKEY: Yes, go ahead.

COMMITTEE MEMBER LUND: -- Chair and Laura, I just wanted to let you know that I am the troublemaker here because CDPH uses this BUCP. And I did a lot of CDPH projects and I have had several recently in the past six months that have wanted to -- (audio feedback) -- (indiscernible). So I think that's primarily because CDPH has statutory authority to do research for surveillance purposes and to sort of understand public health risks and to look at sort of solutions for impacts to health and solutions to those impacts.

So CDPH is one of those rare birds where they have sort of a lot of authority to be able to do that as part of their operations. And so I'm not surprised that they're the main focus of the research BCPs that you're seeing because they're doing that for operations, but it's also research so, you know, to a certain extent. I'm not I'm not suggesting that all of them meet the definition of research

under the Common Rule, I'm just suggesting that they're doing a study and they're using the results of that study to inform decisions.

COMMITTEE MEMBER KURTURAL: But in those projects, don't they attach some sort of exemption from the CPHS Board with CDPH? So maybe, Laura, you would know better than I because I'm not at CDPH.

COMMITTEE MEMBER LUND: So what's happening with the BUCP, I think the reason that we're having this discussion about whether or not we actually need a letter of support, and I appreciate, Jennifer, your input on this, because I think we were all a little puzzled when these things started to pop up, is that CDPH, through the BUCP, is releasing data that they receive from other agencies.

So typically, what's happened, is that they will -- CDPH receives HCAI data, they merge that data and create a linked data file, and then they want to release that linked data file for research. So now they're releasing HCHI data with PII that are linked with CDPH data, and they want to sub in a BUCP instead of what we would have had in the past, is a letter of support from HCAI saying, yes, we've reviewed this research study, it's fine with us, we agree to the release of the data, and we promise that the data will be released in compliance with state laws.

And now that CDPH wants to release HCAI- and CDPH-

linked data, we were told, or CDPH was hoping that we would accept the BUCP in lieu of getting a letter of support from HCAI in addition to the letter of support from CDPH because they're the actual releasers of the data.

So that's where the complexity of this has come in.

COMMITTEE MEMBER KURTURAL: Thank you for that background.

VICE CHAIR DICKEY: And it's not -- getting a letter from HCAI is not something HCHI wants to do.

COMMITTEE MEMBER LUND: Right. Yeah, they punted to the BUCP. They were like, there's a BUCP, it's all good.

So I personally, as the reviewer who has had to come across this, was uncomfortable with accepting the BUCP and I would support the Committee adopting Jennifer's suggestion that we continue to ask for letters of support from the agencies that own the data so that we know that they've looked at the research and that they're ensuring and promising us that the release of those data does comply with all the laws.

CHAIR DELGADO: Is that a motion? I would second that motion.

COMMITTEE MEMBER AZIZIAN: Ask a question, please?

COMMITTEE MEMBER LUND: Oh, sorry. I'll go ahead.

COMMITTEE MEMBER AZIZIAN: I'm sorry about that.

So I'm involved, and Dr. Ventura as well, at the Department of State Hospitals at the level in which we review applications and we make a recommendation for the director to give a letter of approval. We run into this issue that there are forensic evaluations that are conducted in the DSH that includes like various variables, but the forensic evaluators also obtain information from DOJ on recidivism, and they include that as part of their forensic evaluations.

So if a researcher applies to us, and they want to have access to those evaluations, that evaluation includes information that was gathered within DSH, but also includes information that DOJ had released to the evaluator for purpose of conducting the evaluation. Now, is that data, the DOJ data that's in the DSH evaluation, owned by DSH? Or would the researchers have to go and obtain a separate approval from DOJ? Because DOJ had released that data to DSH in the spirit of conducting a forensic evaluation, not necessarily release that for research purposes.

And we run into similar types of things frequently, so kind of what is the guide, if there are any suggestions in there?

MS. SCHWARTZ: I'm happy to jump in. I'm certain that DOJ would consider that they own that data and that they are sharing with DSH, and there's probably an agreement

of some kind that details how DSH can use that data and or release it.

So the question really is: What's in that agreement and is DSH allowed to do the things that it's doing to the extent it's doing, in the sense of releasing that data for research? And if somebody has looked at that and determined that the agreement does allow that, then you should be fine.

I hope that sort of answers the question.

COMMITTEE MEMBER AZIZIAN: That's helpful. So it may be different. I mean, the agreement doesn't say anything in terms of that this can be released for research purposes. And we've been recommending people to have to go and obtain a separate release from DOJ.

So thanks for sharing that.

VICE CHAIR DICKEY: All right, so in this case, I believe there's, in the BUCP and in the document that supports it, that there is an agreement that, for example, CDPH can release this data for research, because there is a research portion in that. So what we're saying is even though that might be in the BUCP, and they have an agreement already with HCAI that they can release this for research, that we have to go back to HCI to get them to agree again?

DR. RYKACZEWSKA: Yes.

VICE CHAIR DICKEY: I'm just, I'm asking,

actually, Jennifer.

DR. RYKACZEWSKA: Sorry, Jen. I don't want to talk for you.

MS. CHANGUS: So you raise an excellent point, because, really, the BUCP is mutual conversations between programs. It's not written by lawyers generally, it's written by the program folks, and then it's reviewed by an internal process. So depending on everyone's understanding when they filled out the BUCP, that question of further release, right, because what we're talking about is HCAI release data to CDPH. (Indiscernible.) CDPH is releasing as a linked data set, that's a further release. And so the question that becomes, is HCAI aware of that? And are they in agreement with that? And sometimes -- and the BUCP should talk about that. If it doesn't, then we, I mean, it would be useful for HCIA to sort of look at that and then approve it.

There's a, of course, sophistication element to filling out the BUCPs. Some BUCPs are detailed and very, very thorough, and some are very, very, very lacking in detail and very quick, very quickly filled out. And so to a certain extent, the ones that are not filled out very thoroughly, it would certainly be helpful to have the department take eyes on a research perspective.

And also, again, the BUCP process, that process is

generally a separate and distinct process from a lens of legal and privacy as opposed to research lens. And so I'm suggesting that even though the department has approved the BUCP, it's still helpful for you to understand that from a research review perspective, they have also taken a look at it from that lens and approved it from that lens.

That's your decision.

VICE CHAIR DICKEY: I would suspect there are going to be more of these, probably, as more linked data sets are created. And the problem is us trying to read these BUCPs, it's really a legal thing. And do we have the bandwidth to do that?

Jared?

MR. GOLDMAN: Well, the question of whether you have the bandwidth to do it is a question for you. I'm very supportive of -- you know, I don't think, you know, I shouldn't speak for the departments, but I'm certainly willing personally to put the burden on them of drafting a letter of support. I mean, I think that is -- it's clear, it's fair, it's good for us, I think it's good for them. You know, it might take them a few extra hours, but that doesn't concern me too much.

VICE CHAIR DICKEY: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I guess I'd add to that the question of whether we have the bandwidth, which,

frankly, I doubt that we do? It seems sort of irrelevant to me. I don't think we should be trying to make a judgment about what's in the BUCP documents when really it seems like it's the responsibility of the departments to let us know what's going on.

VICE CHAIR DICKEY: But what if a department says, like HCAI, all of our BUCPs have basically satisfied the requirement and we -- you know, as part of our process of review and so don't --

CHAIR DELGADO: Then we'll go to their assistant secretary and tell them. Their assistant secretary can inform the department that that's not how we're going to operate.

VICE CHAIR DICKEY: As spoken by an assistant secretary.

CHAIR DELGADO: Yeah.

COMMITTEE MEMBER LUND: I mean, it does seem to me that the decision is ours about what we need as reviewers in order to approve a project. And I think it's a burden on reviewers and not really -- it shouldn't be our burden to have to wade through the BUCPs. Some of these things are 30 pages long, some are 2 pages long, but we're not legal experts.

From a reviewer perspective, I believe it's the responsibility of the person who's applying for us to

approve their project and the department releasing the data to provide us with the information we need to make that happen.

COMMITTEE MEMBER KURTURAL: I see it's like, we start reviewing BUCPs, it's like akin to us reviewing the data use agreements for every single research project we approve statewide, and we don't do that now. We just look at the applications. And so I really feel like, you know, in a day-to-day practice of what's in a BUCP, it's no different than what's in a data use agreement, once research, you know, goes through the normal process.

So I, I don't know if we're ready to vote yet.

VICE CHAIR DICKEY: Any more comments?

CHAIR DELGADO: I have one more comment.

Jen, thank you so much for giving us clarity on this. Super helpful for us to have the background so that we can make that informed decision, so thank you.

VICE CHAIR DICKEY: Would anybody like to make a motion?

COMMITTEE MEMBER KURTURAL: What would it be? So I'd like to make a motion that all state departments for state sponsored research be required to issue letters of support and that the Board not be responsible for reviewing the BUCPs attached to that report.

VICE CHAIR DICKEY: Or that --

COMMITTEE MEMBER LUND: Can I ask, are you willing to leave out the state-sponsored portion of the research? Because the research might not be state-sponsored, but we would still want a letter of support.

COMMITTEE MEMBER KURTURAL: For all research projects?

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER KURTURAL: Okay.

VICE CHAIR DICKEY: Currently, that is our policy, that we need it for all research projects. I would say, but that BUCPs do not satisfy this requirement.

COMMITTEE MEMBER KURTURAL: Okay. So, the motion is for all research projects to require letters of support and that the BUCP not be a part of that process.

VICE CHAIR DICKEY: Could we say letters of support from all departments whose data are involved?

COMMITTEE MEMBER KURTURAL: Support from all departments whose data are involved.

VICE CHAIR DICKEY: Well, because they could say, in this case, CDPH could say, here's a letter of support, that should satisfy you.

COMMITTEE MEMBER KURTURAL: Right.

VICE CHAIR DICKEY: But the problem is we also want one from HCAI. So for all departments whose data is involved, that there be a letter of support, and BUCP is not

supposed to do that. I can't make a motion, but --

COMMITTEE MEMBER KURTURAL: Okay, so it would only be in the process of departments exchanging?

VICE CHAIR DICKEY: No, it would be any research project where a department's data is involved, and it could be a combined data set and then you're going to be getting them from both departments.

COMMITTEE MEMBER KURTURAL: Okay, so requiring from all -- for all projects, that they require letters of support where department data is involved whether it's, you know, combined data of departments or singular data within a department, and that the BUCP not be included in the process.

VICE CHAIR DICKEY: Is that clear enough to you to write a motion?

MS. ATIFEH: Yes. Thank you.

COMMITTEE MEMBER LUND: Can I just, for clarity, ask a question, maybe to simplify that just a little bit? Because the issue is, which department is the original owner of the data? So could we just say that we need letters of support for data release for research projects from all departments that are original owners of the data involved in the research, or words to that effect? Or not, if that doesn't help.

VICE CHAIR DICKEY: I think in this case we would

want it both from CDPH and from HCAI, and CDPH is not going to say they're not the original owners necessarily.

COMMITTEE MEMBER LUND: No, in this case, in all the examples I gave, CDPH is an original owner and HCAI is an original owner --

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER LUND: -- so we would need two letters of support for that project from both departments that were original owners of the data.

VICE CHAIR DICKEY: That's fine.

COMMITTEE MEMBER LUND: I think that's really data that does not also include their data.

COMMITTEE MEMBER KURTURAL: Oh, I see what you mean. So you would need letters of support from HPI as well as CDPH. I'm not opposed to that.

Laura, why don't you make your motion?

COMMITTEE MEMBER LUND: Oh, you were doing good. I'm sorry. I didn't mean to interfere. I just wanted to make sure that we got this concept of the department that originally owned the data across. Because once they give it to CDPH, they've thrown it over the fence and don't consider it theirs. And I just wanted to make sure we captured that.

COMMITTEE MEMBER KURTURAL: So let's add to that motion that all letters of support shall come from all departments involved --

VICE CHAIR DICKEY: Whose data it is.

COMMITTEE MEMBER KURTURAL: -- whose data is owned by that department.

MS. ATIFEH: Okay. Clear. And I think that's it.

VICE CHAIR DICKEY: Any other questions, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Have you got the motion the way you want it now?

VICE CHAIR DICKEY: Well, let's see.

COMMITTEE MEMBER SCHAEUBLE: Because I was going to try to -- I was going to try to say it if it needed any more clarity.

VICE CHAIR DICKEY: Can we have it read back by whoever's recording it?

MS. ATIFEH: Oh, Nicholas is sharing it.

DR. RYKACZEWSKA: Can we zoom in a little bit, Nick?

Okay, all research projects require letters of supports. Okay. So the all-research project requires take out all letters of supports from each department.

COMMITTEE MEMBER KURTURAL: Take out all?

VICE CHAIR DICKEY: Take out all before letter and make letter plural. No, not possibly, just plural.

VICE CHAIR DICKEY: I think that looks like what you were saying.

COMMITTEE MEMBER LUND: Instead of who is involved, say who are the original owners of the data being requested.

MR. GOLDMAN: Or maybe instead of saying original owners, say the source --

VICE CHAIR DICKEY: Yeah.

MR. GOLDMAN: -- the source of the data involved?

COMMITTEE MEMBER LUND: Well, CDPH and HCAI are both going to claim that CDPH is now the source of the data since HCAI gave it to them and gave them authorization to release it. That's what they'll say.

VICE CHAIR DICKEY: And I would say, rather than the BUCP project, and a BUCP does not satisfy the requirement.

Is that okay, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: That’s good.

COMMITTEE MEMBER KURTURAL: Yeah, that's fair.

VICE CHAIR DICKEY: Do I have a second?

COMMITTEE MEMBER SCHAEUBLE: I'll second.

VICE CHAIR DICKEY: Okay.

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

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

Dr. Bazzano?

Dr. Dinis?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

DR. RYKACZEWSKA: Dr. Palacio? I wonder if we're having audio issues.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Ruiz? Oh, Dr. Ruiz, you are muted.

VICE CHAIR DICKEY: Can you see him?

COMMITTEE MEMBER RUIZ: I voted with the approve.

MS. ATIFEH: Thank you.

COMMITTEE MEMBER RUIZ: Is that --

DR. RYKACZEWSKA: We couldn't hear you.

VICE CHAIR DICKEY: We didn't hear you.

MS. ATIFEH: Dr. Bazzano?

And I'm going to ask one more time, Dr. Palacio?

COMMITTEE MEMBER RUIZ: There's a message from Dr. Palacio that he's having issues with his mic.

DR. RYKACZEWSKA: But I'm seeing a thumbs up on

the screen. Is that sufficient?

VICE CHAIR DICKEY: I would think that would be.

CHAIR DELGADO: A thumbs up would.

MS. ATIFEH: For Dr. Palacios?

DR. RYKACZEWSKA: Yes, we have a thumbs up for Dr. Palacios.

VICE CHAIR DICKEY: Is it actually his thumb or somebody else?

DR. RYKACZEWSKA: It is physically his thumb.

MS. ATIFEH: Okay, so good, the motion passed.

MS. MUHAMMAD: Can you hear us, Dr. Palacios? Oh, you know, I have to say, each of these things, we should open them up for public comment before we do them. I don't see any members of the public on this conference, on this call. Is there?

CHAIR DELGADO: There might be, so maybe we should open it up --

VICE CHAIR DICKEY: Yeah.

CHAIR DELGADO: -- for public comment and then do the vote again.

VICE CHAIR DICKEY: Yeah. Are there any members of the public that would like to comment?

MR. ZADROZNA: I do want to note there's no public physically present downstairs.

VICE CHAIR DICKEY: All right, so I'd say if there

are.

DR. RYKACZEWSKA: There is.

CHAIR DELGADO: Yes, we can hear. Whoever is J., we can hear you trying to talk, if you're trying to talk for public comment.

(Colloquy between Committee members)

MR. YI: Oh, you got me?

CHAIR DELGADO: Yes.

MR. YI: Okay, my name is James. I'm a attorney for the Department of Health Care Access and Information, and so I was a little surprised that my department had come up. I'm not involved in that issue that I think the Committee was talking about, but I just wanted to note that we have some statutes that require us to make our data available to the public health. And the statute doesn't really let us kind of control that or alter how Public Health uses that data.

And the statute also says -- it seems to indicate that Public Health has all the responsibility to comply with the requirements for CPHS. And so I was just trying to note that there might be some statutes that kind of prevent or kind of prevent the department from possibly doing the letter of support. I don't know any of the details, but I just wanted to note that.

VICE CHAIR DICKEY: Can Mr. James spell his name

by chance?

MR. YI: The last name is spelled Y-I.

VICE CHAIR DICKEY: Oh, the first name is James? Got it.

MR. YI: Yes.

VICE CHAIR DICKEY: Thank you.

Okay, well based on that, do you want to change your motion?

COMMITTEE MEMBER KURTURAL: I actually don't want to change the motion because what you're discussing, James, is you're trying to get it out of the research group possibly completely and the type of projects that CDPH is doing is human subject; right? These are human subject research projects they're doing?

VICE CHAIR DICKEY: Usually they're data. And we don't consider them human subjects unless there's actual contact with individuals.

COMMITTEE MEMBER LUND: Except that they fall under the Common Rule is research as secondary data with PII. So they aren’t --

VICE CHAIR DICKEY: But they don’t --

COMMITTEE MEMBER LUND: -- considered to be human subjects under federal law. That's the second part of the Common Rule.

VICE CHAIR DICKEY: Wait, hold on.

(Indiscernible.) We've talked about this extensively. They don't fall under our purview for the Common Rule because we only review them under the IPA. If, you know, --

COMMITTEE MEMBER LUND: The agency --

VICE CHAIR DICKEY: Do you agree with that?

MR. GOLDMAN: No, I would say we don't have all the information now.

VICE CHAIR DICKEY: Right.

MR. GOLDMAN: So I would suggest we let the motion stand. Let me connect with James and we'll take a look at this --

COMMITTEE MEMBER LUND: Yeah.

MR. GOLDMAN: -- and if there's any clarification that's needed, we can make that at our next meeting.

VICE CHAIR DICKEY: Yeah, I think so.

COMMITTEE MEMBER KURTURAL: Yeah, that sounds good.

VICE CHAIR DICKEY: I agree.

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: Do we need to re-vote? I think maybe we should.

CHAIR DELGADO: I think we should adjust to.

VICE CHAIR DICKEY: Yeah.

CHAIR DELGADO: I mean, we've got Attorney Goldman here, so we want to make sure we're following all of our

Bagley-Keene --

MS. ATIFEH: Sure.

CHAIR DELGADO: -- rules.

VICE CHAIR DICKEY: Yeah. So can you remake the motion with sort of incorporating what Jared just said?

COMMITTEE MEMBER KURTURAL: Yeah. So we would add all research projects require letters of support from all departments who are the original owners of the data being requested if BUCP does not satisfy that requirement. Should the require modification --

VICE CHAIR DICKEY: Well, part of the motion would be that that Jared speak with --

COMMITTEE MEMBER KURTURAL: Okay.

COMMITTEE MEMBER SCHAEUBLE: Is that necessary to be in the motion? Can it not happen regardless?

VICE CHAIR DICKEY: I don't know. What do you think, Jared?

MR. GOLDMAN: Yeah, I think you don't need to move me to connect with James to --

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: Well, I just think -- do we need to note that this is contingent upon approval by our legal?

CHAIR DELGADO: No, because we can always just come back to you --

MR. GOLDMAN: I'll be back. I'll just say (indiscernible).

VICE CHAIR DICKEY: All right.

CHAIR DELGADO: -- as we get new information. But at least we have a decision that stands. That's my opinion.

COMMITTEE MEMBER KURTURAL: I was just going to add, you know, if it requires a modification, we'll come back for a vote. But if we don't think that it needs it, don't worry about it.

VICE CHAIR DICKEY: Okay. And second again?

COMMITTEE MEMBER SCHAEUBLE: I'll second.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve. Can you hear me this time?

MS. ATIFEH: Yes. Yes.

COMMITTEE MEMBER BAZZANO: Okay, great.

MS. ATIFEH: Dr. Dinis?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio? Thumbs up?

DR. RYKACZEWSKA: He gave the thumbs up.

MS. ATIFEH: Again?

DR. RYKACZEWSKA: Yes.

MS. ATIFEH: Okay. Good.

Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay. Next, we're moving on to the issue of HIPAA waivers.

I noted in reviewing a project that the HIPAA approval letters that we issue don't meet the federal requirements for what needs to be in a HIPAA approval letter. Basically, what we've been doing is just putting in our approval letter that says -- and we also approve a HIPAA waiver. The federal law requires us to specify all the data exactly that's being waived, and a number of other things that need to be in an official letter.

So I think, Suzanne, you worked on a revision --

MS. ATIFEH: Yeah.

VICE CHAIR DICKEY: -- of a draft of a letter.

MS. ATIFEH: Yes.

VICE CHAIR DICKEY: Do you want to display that? Do we have that today?

MS. ATIFEH: Yes, it's ready and Nicholas is displaying.

VICE CHAIR DICKEY: And then there's also an issue of our authority under the HIPAA rule.

So this is what the draft HIPAA approval letter would state. And this is straight out of what the federal law requires.

COMMITTEE MEMBER KURTURAL: And did legal look at this?

VICE CHAIR DICKEY: Yes, I believe we sent it to Jared.

MR. GOLDMAN: I haven't looked at this, but if I find any issues with it, I can change it.

COMMITTEE MEMBER KURTURAL: I say that because there are specific requirements.

VICE CHAIR DICKEY: Yeah. Can you go down further? Is there more on this, Suzanne?

MS. ATIFEH: Yes.

VICE CHAIR DICKEY: So, you know, we can check this against the federal law. We also have the federal law to display; right?

MS. ATIFEH: You know, when you spoke about it with me, you sent the requirement.

VICE CHAIR DICKEY: I know.

MS. ATIFEH: Yeah.

VICE CHAIR DICKEY: Do we have it to show? There we go, right now.

So this is the part of the HIPAA law. No, this is the wrong page, I think.

DR. RYKACZEWSKA: It's a little bit further, yeah. It's on the second page. That has to be --

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: -- included.

COMMITTEE MEMBER LUND: So could I ask for a clarification? I have a question. I have been asked to provide -- to approve HIPAA waivers.

VICE CHAIR DICKEY: Yeah, we'll get there.

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: Laura --

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: -- we'll get there. Right now we're just talking about if we approve it, what needs to be in the letter. And right here in there, too, it says documentation of waiver, and it says what needs to be in the documentation. But this, I'm surprised that we haven't gotten more pushback from researchers because our approval

letters have just said you got to HIPAA waiver.

So I guess if the Committee is in agreement -- and I don't know that this actually requires a motion because this is basically just following the federal law.

MR. GOLDMAN: Yeah, I was just saying that I'll work with staff to make sure that the letter is updated to comply with the law.

VICE CHAIR DICKEY: Yeah. Is that okay with everybody?

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm curious, by the way, looking at the federal law which talks about HIPAA waiver in the context of death data, does anybody know why that's the way in which it comes up? That seemed curious to me.

VICE CHAIR DICKEY: That HIPAA applies to death data?

COMMITTEE MEMBER SCHAEUBLE: The beginning of the section that talks about HIPAA waivers seems to refer to death data as opposed to other situations, and I just was surprised when I saw that.

VICE CHAIR DICKEY: Yeah. When you actually read the details of these laws sometimes it's like, oh, I didn't know that. I think that's, I can't answer that question.

COMMITTEE MEMBER SCHAEUBLE: Okay.

VICE CHAIR DICKEY: I think it's kind of aside from what we're talking about now.

COMMITTEE MEMBER SCHAEUBLE: Yeah, I was just curious.

VICE CHAIR DICKEY: Yeah.

Hearing no objection, we'll move on to the next issue, which is, if you keep that up, keep up the law for us, can you go back to where the law is? It says review and approval procedures. It says that HIPAA waivers can be granted by an IRB operating under the Common Rule, or it can be granted by a Privacy Board. And the Privacy Board is not bound to all of the components of the Common Rule.

The question comes up, now that we're trying to be clear that there's Common Rule reviews and there's IPA reviews, most of these HIPAA waivers we're granting for reviews that were done under the IPA because they're data only. And so then, in that context, we're not operating under the Common Rule. So how can we approve these if we are not operating under the Common Rule?

I looked into this. And Jared and we've had discussions about this, a number of IRBs state, you know, they are operating an IRB, but they're also operating as a Privacy Board. And discussions with Jared, et cetera, it seems that the requirements for a primary privacy, any IRB would satisfy the requirements for a Privacy Board, because

the requirements for a Privacy Board are much less stringent than they are for an IRB.

But, Jared, I'll turn it over to you to discuss that.

MR. GOLDMAN: Yeah, I'd agree. There's a pretty low bar for what's a Privacy Board.

And if you scroll up a little bit, let's see if we can find the requirements for a Privacy Board. No, scroll up a bit more. Keep going.

So B, on the right-hand side of the screen, those are Privacy Board data, and there's those three paragraphs,

> "As members with varying backgrounds and appropriate professional competency is necessary to review the effect of a research protocol, includes at least one member who's not affiliated with the covered entity."

And you can read it. I don't need to read it all out loud for you. But these are criteria that CPHS clearly meets. And so at least under the HIPAA privacy rule, there's no -- I have no concerns with this body acting as a Privacy Board for the purpose of granting a HIPAA waiver of authorization.

COMMITTEE MEMBER KURTURAL: This is an interesting thing because it is something that has been on my radar for a while, being on the department side, but I'm wondering. I agree with the Privacy Board group. And for certain

departments that this applies to like DHCS and us at DDS, some parts of CDPH that the contract reflect that the Board is acting as a Privacy Board when HIPAA waivers are needed. So they those contracts might have to have like a -- well, or when they're up for renewal, have a blurb about that or something.

But would we need to come back like to have us operate as a Privacy Board in lieu of an IRB? Do we need to vote on that?

MR. GOLDMAN: I don't think so. I mean, I think we -- the privacy rule doesn't require that you do some magic procedure --

COMMITTEE MEMBER KURTURAL: Okay.

MR. GOLDMAN: -- to be a Privacy Board. I think you inherently are one by virtue of how you're constituted. So I wouldn't worry about --

COMMITTEE MEMBER KURTURAL: Okay.

MR. GOLDMAN: -- deeming yourself as a Privacy Board in addition to an IRB.

VICE CHAIR DICKEY: So my question is, should we put something on our website that says that we serve as the Institutional Review Board for the Health and Human Services Agency and the Privacy Board for state government?

COMMITTEE MEMBER KURTURAL: I mean, probably. I think it would look good from a regulatory standpoint. I'm

thinking more so for OCR than the researchers, but the researchers' compliance divisions or whatever, when they're looking at us, can see that on our website and see our logic there when granting HIPAA waivers. I think it's a good idea.

VICE CHAIR DICKEY: Maybe we should vote on this, you know, just to say that we will not consider ourselves to be a Privacy Board for state government, and that we'll post that on our website.

Do you think it's necessary to vote?

MR. GOLDMAN: That you consider yourselves Privacy Boards for the purpose of issuing HIPAA waivers?

VICE CHAIR DICKEY: Yes.

MR. GOLDMAN: And that you'll publicize that?

VICE CHAIR DICKEY: Right.

MR. GOLDMAN: And make it --

VICE CHAIR DICKEY: Right. Any opposition? So I'll open this up.

COMMITTEE MEMBER DINIS: Well, really a question.

At that moment, don't you become an IRB, though, under the IRB Common Rule?

COMMITTEE MEMBER KURTURAL: Not if it's on a (indiscernible).

VICE CHAIR DICKEY: Not if we're not enforcing all of the Common Rule requirements.

COMMITTEE MEMBER KURTURAL: You're on mute.

COMMITTEE MEMBER DINIS: Sorry, I got on mute. It seems like it's picking and choosing.

So, you know, if we had to do a HIPAA waiver, wouldn't it be an IRB at that moment?

MR. GOLDMAN: That doesn't follow. So IRBs -- or Privacy Boards are often used for waivers of authorization where the Common Rule does not apply. So the classic example would be research that is exempt from the Common Rule might need a Privacy Board to approve the waiver of authorization.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER KURTURAL: Yeah, it's an entirely separate law from Common Rule too. You know, it's under HIPAA. So it actually really applies, the HIPAA waiver authorization, just to HIPAA-covered department data.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER KURTURAL: So you --

COMMITTEE MEMBER BAZZANO: Hey, can you explain this one more time? I'm sorry, I need a recap, and if you can give me examples of when this would apply and not apply, I'm getting a little lost.

MR. GOLDMAN: So the easy example would be instances where there is a request for the disclosure of PII for the purpose of research and there is an express

exemption to the Common Rule where IRB review isn't required. So that's sort of like the simple case.

I think the case that you probably see more often than that is where there is an IRB that has worked with the researcher to approve the disclosure, but maybe the department isn't super familiar with the IRB or may not have all the confidence in the world in the IRB that issued the waiver of authorization and would prefer a belt-and-suspenders approach of having the state's own body take a look at it as well.

You know, for example, I know that DHCS, when they disclose data, they want a HIPAA waiver of authorization.

VICE CHAIR DICKEY: From us?

MR. GOLDMAN: From us. It's not required that we do it, but I think this body has had a practice of doing that as a courtesy for the Department of Health Care Services, and so I think that's the more typical example.

COMMITTEE MEMBER BAZZANO: Okay, going back to your first example, to me that's -- I mean, when would you get an exemption that would be research that would involve PII that you wouldn't need a waiver for? I can't understand what that would look like.

VICE CHAIR DICKEY: The perfect example is all these projects that we approve under the IPA where it's a department that's releasing data and it has no human subject

to contact in terms of being used to contact people, we approve those under the IPA, and that's what we've been talking about for the last few meetings. And if we're approving them under the IPA, then we have to have the liability as a -- to grant a HIPAA waiver under -- as a Privacy Board.

COMMITTEE MEMBER KURTURAL: Yeah. It's like it pops up in the context of say like someone wants Medi-Cal information. And what is it now, 40, 50 percent of folks in California are on Medi-Cal, and they need to do a research project, you know, looking at demographic information, they're going to need information that involving millions of people. And that is the minimal amount of data that they could get. And they're looking at that.

If they go through IRB, like they normally do, they're not going to get consent for 20 million people or whatever data set that they're getting from Medi-Cal, because they're just looking -- you know, it's for those projects. But the other projects that are more human subject, where they're going out to interview one-on-one folks and they're not looking at a subset of hundreds of thousands of people and it goes through IRB review, you wouldn't get a HIPAA authorization then. So --

COMMITTEE MEMBER BAZZANO: No, I understand all of that.

COMMITTEE MEMBER KURTURAL: -- you know what I mean?

COMMITTEE MEMBER BAZZANO: My question is how does this, how does Dr. Dickey's motion, change what we've been doing in the past? I'm not understanding how -- what I understood at first, when you were flashing up the law around HIPAA, was that we had to strengthen our requirements for HIPAA waivers. And now the second thing I heard in the motion was that we would maybe not require HIPAA waivers.

So I think I went from understanding that this was a strengthening motion or something that needed more assurance, and then I understood it now to be something that we're having less authority or purview over, and that's where I'm getting confused.

It also feels like maybe we still have -- not just maybe, I'm aware that we still have a lot of discussion around the IPA to come. And I don't know if this question should be happening now or perhaps when we are able to further discuss our varied viewpoints on the IPA, especially with regard to the information that we got from the legal opinion.

So just those two things, I don't quite understand, is this strengthening or weakening what we're planning on taking responsibility for? And then secondly, you know, does it belong now or does it belong later?

VICE CHAIR DICKEY: I think that it certainly doesn't weaken it. It just, it specifies that we have the authority to act either as an IRB or a Privacy Board. We're not changing the requirements for what it takes to get a waiver.

In fact, partly, I think this came up because the Department of Health Care Services was saying we wanted approval just from you guys for the HIPAA waiver, not from their own IRB of the receiving entity. And we couldn't do that because we're not reviewing those projects under the Common Rule but we can if we're a Privacy Board. We can review the HIPAA waivers as a Privacy Board.

COMMITTEE MEMBER KURTURAL: It's clarifying what we've been doing already in practice, so it does strengthen. And it also complies with all the legal requirements because we've been granting HIPAA authorizations for a long while, but we need to have specific language in our granting of those authorizations, so I believe that the updated letter does that.

So does that clarify, Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Yes, that helps. Okay.

COMMITTEE MEMBER KURTURAL: Okay.

COMMITTEE MEMBER LUND: So I have a question to pose, just for consideration, if we're thinking about, you know, sometimes we're an IRB and sometimes we're a Privacy

Board. If these are research projects and we're only reviewing them as IPA, can we not say that the HIPAA waiver should be issued by whatever IRB is reviewing the project? If we're not reviewing as an IRB? And then we wouldn't need to have this, you know, two hats.

I guess I'm uncomfortable granting a HIPAA waiver if I haven't reviewed a project for all of the research considerations that need to go into a HIPAA waiver. And I've been told that when we review as IPA only, we don't review for those considerations. So I am uncomfortable with the suggestion that we should issue the HIPAA waiver rather than the IRB responsible for the research aspects of the project.

COMMITTEE MEMBER KURTURAL: Well, I think that many departments -- and I'm sorry for chiming in --

VICE CHAIR DICKEY: That's okay.

COMMITTEE MEMBER KURTURAL: -- many departments in the state, like that portion of CDPH, Health Care Services, my department, DDS, they are HIPAA covered; right? And so they are required by law, if they don't get out the individual consents for these large data-only research projects, to actually get a HIPAA authorization. And the criteria for HIPAA waiver authorization actually is quite similar --

VICE CHAIR DICKEY: To the IPA.

COMMITTEE MEMBER KURTURAL: -- to the IPA. It pretty much mirrors it. And we can always, you know, come back and get clarification, just if you want to see a crosswalk or something like that, just to ensure. But my recollection is they're pretty minimal risk, you know, and that it's minimum necessary to accomplish the research purposes.

So, and then in addition, you know, this is why the departments contract with us, because we are looking at that anyways, the same criteria when we look at a research project. And that's why they, you know, the department's contract with us because we are their pseudo IRB Privacy Board. It just hasn't ever been clarified, and I think it's a good idea, myself, that it be clarified that we're acting in that capacity.

VICE CHAIR DICKEY: But we have to do the IPA reviews anyway.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER DINIS: For me, though, I think the crucial point to be made is that PII under the federal regulations is considered -- it puts it back to a human subject, it's a human subject. And so to me, you know, it doesn't make any sense that we say, no, it's not human subject's data, it's secondary data. Yes, but secondary data, once you have identifiable information, becomes a

human subject. So it puts us back to the scope we're on.

MR. GOLDMAN: Can I?

VICE CHAIR DICKEY: Jared?

MR. GOLDMAN: Yeah, I would say that what the departments are asking us to do is a belt-and-suspenders approach. I completely agree with you that most of these cases are going to be, if not all, human subjects research and that there should be an IRB that's associated with the researcher that's approving this.

I think, even though the researchers are getting IRB review, and they may even be getting a HIPAA waiver of authorization from their own institution, I think what we're seeing in this Committee is that our own departments are imposing conditions on the researchers to obtain a waiver of authorization from this body. And so when the researchers are coming to us, they're checking the box requesting the HIPAA waiver of authorization.

COMMITTEE MEMBER DINIS: I don't disagree with you.

What I think is more important is to have a Common Rule plus the IPA on top. I don't see them as separate, like we can just do -- we can only do -- yeah, we can do IPA when there is no PII, but when there is, I don't think we can. And that's where the disagreement is in this Committee.

VICE CHAIR DICKEY: Would we have --

COMMITTEE MEMBER BAZZANO: Right, because I was thinking that we needed to have this discussion after our IPA discussion.

COMMITTEE MEMBER DINIS: I agree with you, Alicia.

VICE CHAIR DICKEY: It seems that there's a number of us who still don't believe that the separation of the Common Rule from the IPA and still believe that every project that comes to us should be reviewed under the Common Rule.

COMMITTEE MEMBER DINIS: Only if there's PII, Dr. Dickey.

VICE CHAIR DICKEY: Well, I understand.

COMMITTEE MEMBER DINIS: If there's PII. That's where the disagreement is.

VICE CHAIR DICKEY: Yeah, I understand that. But the federal law says that we are not the IRB to review those projects. It's the receiving institution's IRB that reviews those projects under the COPA law.

COMMITTEE MEMBER KURTURAL: And can I just add something? Even if what we say, your interpretation is correct, right, which I disagree, but let's say it is correct, that HIPAA does allow a waiver of consent authorization, so I think the question is, what should be -- because this is following the federal law. This has nothing

to do -- I mean, we're giving you examples of when it's going to pop up as an issue, and we're saying that the data-only projects, that's when it's going to pop up, but this actually has nothing -- this has to do 100% with just following the requirements of the federal law, and just having the authorization have the requisite language in there once we authorize.

VICE CHAIR DICKEY: I think you're concerned that if we --

COMMITTEE MEMBER BAZZANO: May I ask one more question?

VICE CHAIR DICKEY: Go ahead.

COMMITTEE MEMBER BAZZANO: I have a different question, if you don't mind. And if this is too much of an aside, please just let me know, because I'm happy to take it. But I was curious to try to understand a little bit about how our HIPAA waiver interacts or doesn't with the right to be forgotten. Can you explain that to me just for a moment? Or maybe it's not relevant, in which case, please forgive me, lack of legal knowledge.

VICE CHAIR DICKEY: Can I just ask you to explain the right to be forgotten?

COMMITTEE MEMBER BAZZANO: I can't, because I understand it's a legal concept that's in California law, privacy law, that my understanding is that there has to be

some ability for people to not have their data be shared, and there are certain -- and this is a legal question. You know, I punt that to everybody at the table who might be able to give me more information.

MR. GOLDMAN: I'm aware of no such requirement under California law.

COMMITTEE MEMBER BAZZANO: Can you say that again?

MR. GOLDMAN: I'm aware of no such right under California law. I've never seen a right to be forgotten. I don't believe there is one.

COMMITTEE MEMBER KURTURAL: Yeah, I second that.

COMMITTEE MEMBER JOHNSON: It looks like there's a California Consumer Privacy Act.

COMMITTEE MEMBER KURTURAL: Yeah, the California Consumer Privacy Act does not apply to the State of California government and it doesn't apply to non-profits either, to the extent, you know, states contract with non-profit contractors like regional centers.

COMMITTEE MEMBER BAZZANO: Okay. Will it apply to --

MR. GOLDMAN: It applies to --

COMMITTEE MEMBER BAZZANO: -- data that was released to commercial interests or for profit?

MR. GOLDMAN: No, it applies to businesses, which isn't us.

COMMITTEE MEMBER BAZZANO: Okay. Thank you.

MR. GOLDMAN: Hmm-hmm.

COMMITTEE MEMBER KURTURAL: You're welcome.

VICE CHAIR DICKEY: I'm not quite sure where to go with this now. Somebody else? Do you want to make a motion?

COMMITTEE MEMBER KURTURAL: Well, I mean, if we feel we need to make a motion, we can make a motion that, you know, that we clarify, perhaps, that we are operating as a Privacy Board when we're reviewing labor authorization requests coming in from researchers, and that we clarify this, as well, on our CPHS website. I don't have anything else.

Does anyone else have anything to add to that?

VICE CHAIR DICKEY: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I guess I was going to maybe try to rephrase that just a little bit and say that in stating the responsibilities of CPHS, we include that CPHS may act as a Privacy Board when the context requires. So moving forward.

COMMITTEE MEMBER KURTURAL: Okay, so moving forward --

VICE CHAIR DICKEY: Okay, before we go any further, any comments from the public?

DR. RYKACZEWSKA: And Nick, can you put up the

motion on the screen, please?

"In stating the responsibilities of the CPHS, we include that CPHS may act as a Privacy Board when the context requires, and to clarify this on the CPHS website."

COMMITTEE MEMBER SCHAEUBLE: Perhaps I should add to that, when the context requires for HIPAA approval, since that's what we're talking about.

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: Yeah, say act as a Privacy Board for HIPAA --

COMMITTEE MEMBER KURTURAL: For the approval.

VICE CHAIR DICKEY: -- HIPAA waivers.

DR. RYKACZEWSKA: For the approval, yeah, of HIPAA waiver authorizations, so approval of HIPAA, two ways, waiver authorizations after that.

VICE CHAIR DICKEY: No S on waivers.

COMMITTEE MEMBER KURTURAL: Can I add to this that -- never mind. I don't think this needs to be added on potential addition to the department amendments.

COMMITTEE MEMBER SCHAEUBLE: Authorization should be plural and take out the word form.

COMMITTEE MEMBER KURTURAL: Do we think we need to add that -- anything about the actual approval form itself to this?

VICE CHAIR DICKEY: I don't think so. We're just complying with the federal law.

COMMITTEE MEMBER KURTURAL: Yeah, yeah, yeah, yeah. Okay, that's the motion. In stating the responsibilities of CPHS, we include that CPHS may act as a Privacy Board when the context requires for the approval of HIPAA waiver authorization, and clarify this on the CPHS website.

VICE CHAIR DICKEY: Yeah, why don't we just say and state this, really, for this? Change clarify to state. Yeah. Okay, there have -- can we change clarify to state? Okay.

So no public comment?

Do we have a second?

COMMITTEE MEMBER VENTURA: Second.

VICE CHAIR DICKEY: Okay. Can you call the roll?

MS. ATIFEH: Sure.

Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

Dr. Dinis?

COMMITTEE MEMBER BAZZANO: Approve. Can you hear me?

MS. ATIFEH: Oh, yes. Yes. Thank you. Thank you.

COMMITTEE MEMBER BAZZANO: Okay.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Abstain.

MS. ATIFEH: Okay. Ms. Lund?

COMMITTEE MEMBER LUND: Abstain.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Aye.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: And Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay, we're moving on to the issue of regulations and how regulations are passed. And this is in the context of any regulations that the Committee might want to propose for changing the IPA.

And so I'll turn this over to Jared to give us an overview of the regulation process.

MR. GOLDMAN: Sure.

CHAIR DELGADO: Jared, can I, sorry, can I interject before you get started?

MR. GOLDMAN: Sure.

CHAIR DELGADO: Thank you, Dr. Dickey. I think there is actually two contexts that we want to make sure the Board is fully knowledgeable on the regulation process.

We're going to be talking about the IPA Common Rule where there is a potential that the regulation's process could be necessary, but depending on how that conversation goes, we'll see if that is necessary.

But also, we've talked for years about the Board charging fees for users to be -- for research teams or for entities outside of CalHHS. CalHHS departments pay for our services, but other entities don't. And so we, for years, have talked about a process by which other entities would have to pay the Board. If that is the direction we're proceeding, we also need regulations to have that happen.

So Jared's going to give a little background on the regulations process, where the Board members would be involved, where they wouldn't be involved. But just want to make sure for context there are multiple scenarios in which this issue of regulations might pop up.

Sorry, Jared, go ahead.

MR. GOLDMAN: Would it be helpful for me to do a recap of the last memo we presented on the Common Rule IPA issue or should we just move right into (indiscernible)?

VICE CHAIR DICKEY: We'll get to that later.

MR. GOLDMAN: Okay.

VICE CHAIR DICKEY: I think the first has to do what the process is.

MR. GOLDMAN: Okay. So you want to go ahead and put those slides up? You can go to the next slide. Next one. Great.

So a regulation is a standard of general application, and by general application we mean that it applies to an open class of people, not to, you know, a named party in a lawsuit or in a contract or something like that. It's a standard of procedure that open -- that applies to a group of people, and it's a procedure that implements, interprets, or makes specific the law. So in this case it would be making specific the law that authorizes this body to approve IPA releases or the IPA itself.

So the very beginning of the rulemaking process is having an idea. And so this is a very -- this sort of conceptual part of the process is a very informal piece and this is where you all discuss and collaborate and collect information on what exactly you might want to accomplish. And as part of this process, you can include the public, you can not include the public. Generally, as applied to this body, it would be inclusive of the public since because you inherently include the public in your process and your

meetings.

You can go to the next slide.

And I would add, if anyone wants to stop me at any point, please don't wait to the end of the presentation, just raise your hand. I can't see if you're raising your hand, but maybe Darci, if you see anyone, you can holler and I'll stop and I can address any questions.

So the beginning of formal rulemaking is posting a notice in the state register that we are planning on issuing the notice -- or that we're planning on issuing regulations. And then once we post that notice, then we have a year to complete the rulemaking process, to get all our ducks in a row, and to present our rulemaking package to the Office of Administrative Law. And the Office of Administrative Law is the body in state government that reviews regulatory packages and makes sure all the boxes are checked and all the rules have been followed. And then once they approve a reg package then it becomes a regulation and a regulation, of course, has the force of law.

You can go to the next slide.

So the documents needed for a rulemaking package are the text of the regulation. So that's, I think, pretty self-apparent, so the regulation itself. You need a Notice of Proposed Action. So this is the notice that we would put in the state register. This is also a notice that we would

place on our website. And this basically explains the procedure for how the review of the regulation will happen. It basically invites the public to comment on our proposed regulation and it gives folks the timeframes and the manner in which folks can comment on our regulations.

In addition, we have to include what's called an Initial Statement of Reasons, and this is a document which is the why document. It explains why we are promulgating regulations and why the text that we're putting forward accomplishes the purpose that we believe it is.

And last but not least, there's a document which puts forward the economic and fiscal impact of the regulation. So we have to identify the cost of the regulation, both on state government and also on the business or healthcare community or the subjects of the regulation.

CHAIR DELGADO: Jared, can I ask a question real quick, just for clarification?

MR. GOLDMAN: Sure.

CHAIR DELGADO: What's the line, like as to when we need to do regulations and when we don't? Like, so for example, we made, you know, a decision earlier about the Privacy Board issue. We could make that decision ourselves, we passed, you know, we voted, we made a motion and moved a bit forward. Why, for example, the charging people fees or

a potential on like IPA Common Rule decision, like why does that bump into the regulations process where other decisions that we make don't?

MR. GOLDMAN: So when regulations apply mostly when you are dealing with a granting or a deprivation of a right or a privilege. So, you know, a great example is charging fees. When you are imposing a fee on folks, that's the kind of thing, if you're authorized to do that, that's the kind of thing that would require a regulation.

If you are interpreting a statute which either, you know, grants or denies approval of something, and in our case that would be the right to do research, it would be best to do that in rulemaking. If you don't do it through rulemaking, you run the risk of your principle, of your policy being challenged as an underground regulation.

So typically, the way I think of it is policies and procedures govern internal processes. We don't need to do regulations for that. Sort of keeping our own business in order generally can be done through less formal policies and procedures. And when we're doing things that really have a significant impact on our on our community or on the public, then we would engage in rulemaking. That's typically how it works.

CHAIR DELGADO: Got it. Thanks.

MR. GOLDMAN: Yep.

COMMITTEE MEMBER BAZZANO: Can I just also ask this kind of the same question? I'm not entirely understanding policies and procedures and how significant an impact is significant.

For example, we've been using the same interpretation for, you know, 15 years. So, you know, to mean that this is a change would mean going back 15 years. I understand the question of, you know, imposing a fee. But what I don't understand is the other question around the IPA, you know, how much of a significance are we talking about to be significant?

And you mentioned this concern about underground regulations. Who raises that concern and how does that play out in a lawsuit or how does that work?

MR. GOLDMAN: Yeah, so to ground it in exactly what we're probably going to be talking about, think about the list of criteria under the IPA that we use to review a release of information. There's, you know, some enumerated set of criteria. And our interpretation of the IPA is that the list of criteria is non-exclusive, and so theoretically additional criteria could be added by this body. And it's our view that that's the kind of thing that we would need to do through a regulation.

So something as significant as, you know, making the determination about whether or not we approve a research

group's ability to receive information for research, if we are adding a whole new criteria outside of what's expressly stated in the IPA, that kind of implementation or extension of the law or implementation of the statute would require the adoption of a regulation, at least --

COMMITTEE MEMBER BAZZANO: Okay, forgive me. Maybe I'm not understanding because I thought that you said that, you know, the determination of a research group, a research group is not an open class of people; right? It's --

MR. GOLDMAN: Sure.

COMMITTEE MEMBER BAZZANO: -- (indiscernible).

MR. GOLDMAN: It is. It is. It's --

COMMITTEE MEMBER BAZZANO: -- so then it wouldn’t --

MR. GOLDMAN: It is an open class.

COMMITTEE MEMBER BAZZANO: -- (indiscernible) --

MR. GOLDMAN: Sorry.

COMMITTEE MEMBER BAZZANO: -- right?

MR. GOLDMAN: Sorry to interrupt you, but that is an open class. It doesn't have to be wide open, it doesn't have to be the whole universe, it just -- an open class wouldn't be if we were singling out a requirement that applied only to Alicia Bazzano. That would be a closed class. Or if this applied only to, you know, the Department

of Anthropology at UC Berkeley, that would be more like a closed class. But an open class would be one that applies to all researchers --

VICE CHAIR DICKEY: (Indiscernible).)

MR. GOLDMAN: -- all universities.

COMMITTEE MEMBER BAZZANO: Oh, sorry.

MR. GOLDMAN: Does that make sense? An open class is one where --

COMMITTEE MEMBER BAZZANO: I couldn't hear the end of what you said.

MR. GOLDMAN: Oh. An open class is one where you can fill in the blanks. It doesn't have to be the whole universe, but it could be researchers in general.

COMMITTEE MEMBER BAZZANO: Okay, but researcher-specific is not an open class; is that correct?

MR. GOLDMAN: If we were taking a state action that applied only to you, that would not be an open class.

You know, for example, benefit to --

COMMITTEE MEMBER BAZZANO: Right.

MR. GOLDMAN: -- benefit -- here's the classic example of something that's not an open class. A department's benefit determination as applied to one specific person, that would not be a regulation.

COMMITTEE MEMBER BAZZANO: Okay. Can you just define the limits? Because there's such a big range between

all researchers and just one single researcher. Where does the line go? Is it --

MR. GOLDMAN: I would say a named individual or a named business would not be an open class, whereas if it was a group of businesses or a group of universities that there was an open possibility of who it might apply to, that would be an open class. Basically, closed classes is when we're talking about government decisions that apply only to a specific individual or entity.

COMMITTEE MEMBER DINIS: And is one university an open class?

MR. GOLDMAN: It could be, but maybe we're getting too far in the weeds here.

VICE CHAIR DICKEY: Yeah, I think so.

COMMITTEE MEMBER BAZZANO: No, sorry, I'm just trying to if we individually look at each case, at each proposal, as we do, at each protocol and make a determination for each protocol, to me that seems like, in my understanding of it, is that that's not an open class, that's an individual-specific protocol --

MR. GOLDMAN: Yeah.

COMMITTEE MEMBER BAZZANO: -- for a specific situation, for a specific, you know, university or whoever's bringing, for a specific group who's bringing the particular protocol.

MR. GOLDMAN: That's correct. So if you were to issue a policy that all projects that came in front of the body, came in front of CPHS, were going to be subject to some additional criteria, that would probably require a regulation. But if you were to decide to extend new criteria under the IPA on an ad hoc basis, on a project-by-project basis, then that potentially could avoid the definition of a regulation.

But that kind of approach poses other risks. And those are risks we discussed in our memo, which were that you could get a challenge that you were applying additional criteria either on an arbitrary basis or on a discriminatory basis. And I'm not saying those challenges would necessarily win, but you expose yourself to those kinds of challenges.

COMMITTEE MEMBER BAZZANO: Okay. Thank you.

MR. GOLDMAN: Hmm-hmm.

VICE CHAIR DICKEY: Do you want to go on, Jared?

MR. GOLDMAN: Sure.

So once you get all your documents out and once you post your notice of the regulation, then the public has at least, you decide how long, but it needs to be at least 45 days for comment.

And then in addition to providing the opportunity for written comment on your regulation, you have the option

of holding a public hearing on the rulemaking action. If you decide not to hold a hearing, the public can still request a hearing, and if a hearing is requested, then you have to hold one. If you hold a hearing, comment can be provided at the hearing, both verbally and in writing. So someone could show up with a letter at the hearing and hand it to you and you would accept that.

So once you receive all of the public comments, there are a couple things you do with those comments. One either is that you make a change to your regulation based on a comment, and then so you would issue a further document explaining what changes you had made based on the comment, or if you receive comments that you disagree with, you would note the comment and you would explain why you're not changing the regulation for whatever reason.

You don't necessarily -- like, you know, some of the reg packages we see in state government receive thousands of comments, and you don't necessarily have to respond to each one individually. If some of them are repetitive or say the exact same thing, you can respond to a group of comments that have the same thrust and say, you know, we received a hundred comments that said you should do this, and we are going to do -- we are not going to do that for this reason or we are going to do it and here's how we did it in the regulation.

And then you provide that summary of what you're doing with the comments in your final reg package which is submitted to the Office of Administrative Law.

If you make changes, if after receiving comment you make changes to the right text, if they are substantial changes, so if they really change the policy, you know, if they're not just typo fixes or, you know, messing around the margins with the language, if they're really meaningful changes then you would go back out for an additional comment period so folks could comment on the changes that you issued.

You can go to the next slide.

And then the last step after you've gone through the whole process is to submit your final rulemaking package to the Office of Administrative Law. The Office of Administrative Law reviews the package to make sure that you've complied with all of the appropriate procedures and to make sure that the regulations substantively comply with the law. And then assuming it does, then they send a notice to the Secretary of State, and the regulation becomes final. And that's the end of the process.

VICE CHAIR DICKEY: Can I ask a question?

MR. GOLDMAN: Sure.

VICE CHAIR DICKEY: So the Supreme Court's Chevron decision, is it going to get rid of this entirely?

MR. GOLDMAN: No.

COMMITTEE MEMBER LUND: So I have a question, just a point of clarification. You've been using the pronouns you and we. It's actually CDII --

MR. GOLDMAN: That's correct.

COMMITTEE MEMBER LUND: -- that is responsible for the regulations; is that correct? It's not this Committee who would have interest, but CDII is responsible for the process?

MR. GOLDMAN: These regulations would be issued in partnership with CDII. So the place that the statute that creates this body exists is within the division of law relating to CDII. And so this is, while you are afforded independent decision-making authority, this body is housed within CDII. It's CDII that has the authority to issue regulations and you would be working in partnership with CDII and their staff to promulgate these regulations.

COMMITTEE MEMBER LUND: Great. Thank you.

MR. GOLDMAN: Hmm-hmm.

COMMITTEE MEMBER LUND: Just a follow-up question. Since we never done this before, I just wanted a little clarification around is it possible for CDII to move regulations forward without the approval of this Board or is approval of this Board required for any regulations package that moves forward?

MR. GOLDMAN: I would say that CDII probably would not move any regulations relating to this body without this body's approval. I mean, I don't think that's something that would happen. Whether they could legally or not, I'm just not sure that's an important issue because it just wouldn't happen.

COMMITTEE MEMBER LUND: Okay. Thank you.

VICE CHAIR DICKEY: Can I ask the opposite question?

MR. GOLDMAN: Yeah.

VICE CHAIR DICKEY: Is it possible that CDII would not move forward if regulations that are recommended by this body?

MR. GOLDMAN: I think that it's possible, depending on what the policy is. For example, if the policy was clearly illegal, I don't think CDII would promulgate it. But I think as a practical matter, and knowing the staff at CDII and knowing this body, I am anticipating a partnership where a policy decision is reached and where we work in partnership with CDII to promulgate a reg package if that's the path that this body decides to go down.

CHAIR DELGADO: I would just echo as Chair, I see this as an incredibly collaborative process that neither side would be moving forward without the consent and approval of the others, and that that collaboration is

something that's been a top priority for me over the last six months as Chair. Six months? I'm not sure how long I've been doing this. But that this is why we are not -- we're taking the slope.

We asked Jared to put together a beautiful slide deck to talk about this process because we want to make sure that absolutely everyone is fully cognizant and aware, understands this process when we are making decisions that could result in regulations.

MR. GOLDMAN: And maybe I could add, just for your awareness, that developing a regulation package like this is extremely labor intensive. These are complicated documents to pull together. It requires professional staff who are really familiar with the regulation process. And often, getting a regulation from an idea across the finish line can take a year or more. Sometimes they can move faster, but typically I see these things, the development of a regulation, taking about a year or so.

COMMITTEE MEMBER KURTURAL: And that's after you have --

MR. GOLDMAN: That’s developing --

COMMITTEE MEMBER KURTURAL: -- a good working draft --

MR. GOLDMAN: -- that's developing --

COMMITTEE MEMBER KURTURAL: -- of the regulation

package.

MR. GOLDMAN: -- the regulation package, not including the public process, yeah.

DR. RYKACZEWSKA: I'll just jump in, as well, briefly, removing my CDHS administrator hat and putting on my CDII deputy director of Insights Lab hat, just want to also echo the words that have been already shared around this is something we would want to do with partnership, in partnership with the Board, where we're both moving together and approving what would be put forth.

So briefly switching hats here, but really, I think for me this is a really critical piece to be in concert together. And I would certainly put forth the efforts to make sure that whatever is put forth is put forth together.

VICE CHAIR DICKEY: Okay. If there's no more -- actually, I guess I'll ask, is there any public comment on what Jared Goldman has said? I know we're not making a motion, but still.

Being none, Jared, do you want to go ahead? And it looks like our next agenda item is talking about the Common Rule on the IPA issue. And do you want to -- I think you wanted to review your opinion letter?

MR. GOLDMAN: Sure. So a super quick recap of what we shared at the last meeting was that this body acts

under the Common Rule when it relates to research that the state is engaging in. So Common Rule review is for research engaged in by CalHHS.

IPA review is engaged in for disclosures to entities outside of the state where we are not necessarily engaged in the research ourselves, and by we, I mean CalHHS. The IPA has a list of criteria for disclosure information. It's our opinion that that is a non-exclusive list of criteria, and that this body could, if it chose to, use additional criteria as part of its decision-making for the disclosure of PII.

That decision would be constrained by the purpose of the IPA, so you could not impose criteria outside of the general purpose of the IPA, which has a thrust of protecting individuals' privacy and security. So additional criteria would have to be to that end. It could not be based, we do not believe, on issues related to broader considerations, like the general well-being of the individuals who are the subject of the information being disclosed.

There are a couple ways that you could approach applying additional criteria. One would be to apply additional criteria on an ad hoc basis. So this would be without regulations. This would be without establishing any policy about when or how you establish additional criteria. This would avoid the problem, the underground regulation

problem, where you're looking at each case on a case-by-case basis and adding additional criteria based on the facts in front of you.

This approach, however, comes with the risks of inconsistent application of additional criteria. And you would run the risk of researchers claiming, you know, if you denied the disclosure of information, you would run the risk of researchers claiming that you had applied additional criteria either arbitrarily or on a discriminatory basis.

The other approach would be to create standards of general application for when and how you apply additional criteria, and this would be the regulation route that we just discussed.

And so the next step for that, if you chose to take that route, would be to come up with a basic policy framework for how you would envision doing that. It wouldn't have to be super precise or exact at this point, but I think you just want to come up with a set of principles or ideas that we could then start workshopping and turning into language for the Committee to consider.

VICE CHAIR DICKEY: I guess I'd ask or open it up to other questions from the Committee regarding --

COMMITTEE MEMBER LUND: I have just a couple of questions and clarifications.

So I understand the point that if the criteria we

use are not clearly stated in law that someone could object to how we decide on any particular protocol if we use criteria other than the ones that are stated in law. And IPA lays out like three criteria. But the language of the IPA also seems to leave it open to applying the other criteria.

So the purpose of the regulation that we're talking about would be to operationalize those additional criteria that we as a Committee would like to be able to apply to IPA projects; is that correct? Have I understood that?

MR. GOLDMAN: Yeah, I agree with that.

COMMITTEE MEMBER LUND: Okay. And I'm wondering if you have thoughts on what the scope of those criteria might look like? Because I know we've had a lot of discussions over the past few months about concerns about this and concerns about that. And the criteria that are currently actually explicitly in the statute are all related to essentially data security issues.

And there's been much concern by Committee members about not being able to apply other perhaps very important criteria that are associated with research projects, like the ethics of the research and concerns about other aspects of the research that we would be considering if we were reviewing the project under Common Rule as opposed to IPA.

So would the scope of the regulations be broad enough to be able to capture some of those non-data security related criteria, or are you saying that we can enhance a little bit beyond what's actually made explicit in the law, that we can't go very far?

MR. GOLDMAN: I do not believe that -- the purpose of the regulation is to implement the IPA, to implement or interpret it. I don't think we could go beyond the purpose of the IPA. So I do not believe you could create criteria that strayed beyond the goal of protecting individuals' privacy and security.

COMMITTEE MEMBER LUND: Great. Thank you.

VICE CHAIR DICKEY: Do we have any other questions? I don’t see any hands raised.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: To what extent could the Committee try to come up with statements in its policies and procedures that would describe additional aspects related to privacy, for example, that might be considered on an individual project basis? And if the Committee could do such a thing, where does that fit in between the two basic alternatives that you were outlining for us?

MR. GOLDMAN: So just to repeat what you're saying, you're describing adding sort of a menu of possibilities to within our policies and procedures that

could be applied by a reviewer on an ad hoc basis; is that what you're suggesting?

COMMITTEE MEMBER SCHAEUBLE: Or at least examples of additional criteria that could be applied in an individual situation if the reviewer thinks the project would require it.

MR. GOLDMAN: I'll have to think about that one. I think there's a there's sort of a spectrum, of course, of -- there's a line of risk and this one might not be perfectly clear. I think I'd have to see it to think about it. If it was completely open list of examples and there was no requirement to consider any of those examples, if it was merely sort of a food for thought for reviewers, I think it's a possibility. But I think we'd have to take a close look at exactly what would be proposed to be added into the policies and procedures.

But I'm not -- I'm saying that's an interesting idea and one that I think could be worth exploring. But you would still run into the same problems, of course, if you were to do any ad hoc application of any of those criteria with running into the problem of, you know, the claims of those criteria being applied on an arbitrary or discriminatory basis. So the same risks would apply even if you created this menu of possibilities in the policies and procedures for ad hoc addition of additional criteria.

VICE CHAIR DICKEY: And the secretary has to sign off on our policies and procedures. That's definitely putting the secretary's office at risk.

MR. GOLDMAN: We would have to look at what's proposed to be included in.

VICE CHAIR DICKEY: Right.

MR. GOLDMAN: I would say that any ad hoc application of additional criteria creates risk for the Committee and the agency.

COMMITTEE MEMBER SCHAEUBLE: Well, of course, what I'm trying to determine is what options we really have here. And you're certainly leaning in the direction of any consideration of any additional criteria should be a regulation process.

MR. GOLDMAN: That’s my bias.

COMMITTEE MEMBER SCHAEUBLE: At least that's what I think I'm hearing from you.

MR. GOLDMAN: That's my bias.

COMMITTEE MEMBER SCHAEUBLE: And, of course, what you've outlined is unfortunately a very cumbersome process. And if that's the way that we have to consider going, then, I mean, we have to deal with that. But we obviously should know if there are workable alternatives that would not be so cumbersome.

And of course, you know, this all gets back to

what's the essence of what we've been talking about in all these discussions. And a lot of it really is that for some individual projects the nature of the situation is such that privacy does not seem to be adequately protected by a few things that are listed in the IPA and therefore reviewers, if they behave in the way that they think they should behave, feel a need to consider additional criteria. That, to my mind, that's the essence of what we're dealing with.

MR. GOLDMAN: I can appreciate that.

VICE CHAIR DICKEY: Dr. Ventura?

COMMITTEE MEMBER VENTURA: If I can build a little bit on what Dr. Schaeuble is talking about? Like it feels like we -- there is the regulation route, which is where we have we have to go if we're going to apply additional criteria.

But in like our current practice, if we get an IPA data-only review and there's PII and we feel like, for those who believe it goes into the Common Rule realm, if we don't review that for the CalHHS agency requesting us to review it, we are their IRB, so if we don't go the regulation route and allow ourselves that ability to review it under Common Rule, then I'm just kind of wondering, like is that even an option for us? Like what happens to that project? Do we just not operate as the IRB then and, you know --

MR. GOLDMAN: If it's research that's being

engaged in by CalHHS, then you would do a Common Rule review. So if it's the state's own research, then you would act as the IRB and you would do a full Common Rule review.

The circumstances where you would not do Common Rule review is where the state is not engaged in the research itself, where it's merely being asked to disclose information to outside researchers.

VICE CHAIR DICKEY: So it just comes down to this thing, we can't change the federal law and the way that OHRP is interpreting, which is that we have to be engaged to review it as under the Common Rule. And just releasing data is not considered to be engagement.

COMMITTEE MEMBER VENTURA: So they have an IRB -- their IRB --

VICE CHAIR DICKEY: Their IRB has to review it.

COMMITTEE MEMBER VENTURA: And then that will be there?

So in the instances, though, that have come to us as IPA review and some Committee members believe additional criteria should be considered, we kick that back to their IRB? Like why does it -- I'm not quite understanding our decision-making at that point. I don't know, maybe I'm just confused on the issue.

COMMITTEE MEMBER KURTURAL: It's a question of whether, you know, we want to add additional criteria into

the IPA analysis at the data center, not in an IRB.

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER KURTURAL: And, you know, it's a lot to think about because there's different cases we've had where there's been mixture of data, financial information and whatnot. And so I get it that there are some higher risk, let's put it that way, data-only projects that might need to have the additional criteria as we supply information of the data center to them.

VICE CHAIR DICKEY: I'll just say something. You bring up data centers, and Jared's not going to like me for saying this, but there is something in the federal Common Rule, or at least the guidance on the OHRP website that says that the institution that's releasing or is formulating a research data center should review the policies and procedures of the data center, and that includes informed consent, et cetera. It just says should. It doesn't say must.

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: And that's where we're -- we've never done that but the question is should we be doing that?

So who -- Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Well, I was going to say a moment ago, going back to some of the questions being

asked here, again, the crux of the dilemma as I'm seeing it is, on the one hand, Common Rule defines the situation in which it applies, although OHRP has been very clear that even in situations where the Common Rule is not being applied, reviewers may want or need to apply criteria that come from some or all of the Common Rule in other situations. So we have that as one angle on things.

We have the distinction between who was engaged in the research and who was distributing the data with the researcher's institution presumably being responsible for the main IRB review, and yet, we as a Committee find that what they -- what those researchers' institutions are, apparently, are looking at, particularly with regard to privacy, sometimes seems less complete than we would like when we are reviewing the projects here. And we have the limited list under the IPA and the question of what, if anything, can be added to the specific criteria listed there.

So these are all, you know, creating various levels of tension among the different thrusts there.

VICE CHAIR DICKEY: Who else is -- I'm sorry.

COMMITTEE MEMBER DINIS: Please.

VICE CHAIR DICKEY: Dr. Dinis.

COMMITTEE MEMBER DINIS: Yes, thanks.

So what I see is a situation, or the perfect

storm, if you will, for things to fall through the cracks for the human subjects. Because when this goes to universities, they just put this as exempt. They don't consider secondary data often even as human subjects, so those are put as exempt. When it comes to us, we have this other level with the IPA, but we can't apply the Common Rule, et cetera.

So it becomes a strange situation for the person whose data is being used, to me. And if I was one of them, you know, in that data set, I might be upset that that would have no control over my information, unless you ahead of time, you know, know all about it and you specify you don't want your date used, et cetera, et cetera.

And hen the IPA is old, so then we have this problem of, back in the day, they weren't merging data sets with other data sets and being able to come up with 10,000 different ways you can identify the human subject and all the problems involved. And so to me the IPA needs to be, you know, amended.

My question to you as the lawyer, who is the first person to contact to amend the IPA? Because that's what I feel that needs to happen is amend the IPA.

VICE CHAIR DICKEY: That would be the legislature.

COMMITTEE MEMBER KURTURAL: Yeah.

MR. GOLDMAN: Yeah, the legislature is who amends

it. You know, you can always work with your representative and, I mean, there's no one stopping anyone on this body from sending a letter in their individual capacity to their own members to make suggestions. Yeah.

COMMITTEE MEMBER DINIS: I mean, that seems to be what leads to, you know, that the IPA needs to be updated from the 1970s, you know, almost 50 years ago, whatever, to something that's more current and, too, with the web, the online, the whole the whole thing, artificial intelligence, et cetera, et cetera. It seems to be a disaster in the making if it's not updated.

COMMITTEE MEMBER KURTURAL: Yeah, it might be. You're more than welcome to do that.

But another option, just an alternative, would be to go the regulation route because the IPA is kind of broad on what it means by determining whether a certain project has -- well, like what does minimal risk mean, right, it just says that, and then we'd be able to clarify and kind of get. You'd have more -- you have more control over the regulatory process versus going straight to the legislature and, you know, if you go straight to --

COMMITTEE MEMBER DINIS: Do we? Do we really? I mean, you know, in the 1970s from people who were there, and like Laura, she would say that the IPA came on top of the Common Rule and not in place of, but this body now decides

it's in place of. So do we really have more control? I mean, you can't use ethics supposedly, you can't use this, you can't use that, so I don't know that we do.

COMMITTEE MEMBER KURTURAL: As far as describing what is minimal risk and the IPA and what type additional criteria, you know, this Board wants it to be, you could do that through regulations. But to actually change completely the IPA what I'm saying is that it's a policy thing where the legislature would have to decide it. So it's more it's out of our hands, so to speak. Like you could write a letter, like Jared's saying. But, you know, it's out of our hands to actually bring the bill, so to speak.

But the very least you could do is you could do regulations; right? And at least I think it's pretty broad. What does minimal risk mean? And you can describe it.

VICE CHAIR DICKEY: Well, I think you mean minimum necessary.

COMMITTEE MEMBER KURTURAL: Minimum necessary.

VICE CHAIR DICKEY: Minimum necessary.

COMMITTEE MEMBER KURTURAL: Yeah. And what, you know, you could get into, like in regulations, for example, you're talking about the merging of different data, and we can even create a two-tier, right, like this is a criteria used if you're going to you're going to mix with certain data. Because, you know, alarming to us has been the

financial stuff; right? We can we can get into those kinds of descriptions and the regulations where I think we'd have real flexibility, versus talking an assemblymember into bringing a bill.

VICE CHAIR DICKEY: Any other comments, questions?

CHAIR DELGADO: I would just, just from the experience of working on statutory language with the legislature, I would vote -- in my own experience, my experience is that regulations are -- we would have much more control and it would be a much easier process than the legislature, for what it's worth.

VICE CHAIR DICKEY: I'm sorry, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: I guess I'm going to suggest that, if we put our minds to it, I think we could come up with at least a partial list of what kinds of situations and what kinds of criteria we might think needs to be applied in at least some IPA reviews.

I mean, we've talked about this, Jared, with you in the past, about how it's likely to be incomplete and likely not to cover everything, but I think the starter, at least, is a possibility. And I guess from what I'm hearing, it seems to me that we should be pursuing both the direction of how that might be implemented in regulations and whether there is a workable alternative that would not involve excessive risk to try to incorporate that into the policies

and procedures as an alternative to the regulatory process, because if we have to think about what it is we think should be done, we'd have to decide that for either of those directions anyway.

So I'll ask if that makes sense to you, Jared, since you're the expert here on what we're trying to presumably accomplish.

MR. GOLDMAN: I guess I would say that you have nothing to lose in not making the decision today and instead putting together a list of the additional criteria that you'd like to be able to consider. And so you could say, you know, let's take a look at those criteria first. You know, maybe we don't even know what we want yet. Maybe after we put the list together, we'll realize that, oh, clearly we need regulations, or maybe the additional criteria we have in our mind aren't so different from what's already in the IPA that it doesn't, you know, why bother?

But you're not there yet because you don't have the -- you don't know what the policy is yet. And so, you know, it might be worth some time to explore that. I'm not disagreeing with you at all.

VICE CHAIR DICKEY: So asking the Committee members to submit ideas, any Committee member to submit ideas as to what might be changes?

COMMITTEE MEMBER SCHAEUBLE: I think we need some

more definitive group of people to work on it, rather than just leaving it open, will Committee members send in comments? That's likely to lead to not much of anything happening, unfortunately.

COMMITTEE MEMBER KURTURAL: Like a brainstorming-type of question?

COMMITTEE MEMBER SCHAEUBLE: Could be. I don't know what the best way is of doing this. I'm open to ideas.

COMMITTEE MEMBER KURTURAL: Well, I mean, from hearing from this Board, it might be good to start off with some like you cases, you know, of like, oh, these were sticking points, like what were the ones that we've dealt with in the past that rubbed us the wrong way, the data-only projects? And then we'll take a look at that and then we'll start brainstorming solutions from there on how to handle. Because, I mean, I think I need a clear -- I mean, I'm guessing, I could think of a few of them where it's been real concerning with financial data.

COMMITTEE MEMBER SCHAEUBLE: Well, I think several of us could easily --

COMMITTEE MEMBER KURTURAL: Come up with --

COMMITTEE MEMBER SCHAEUBLE: -- even right now at this moment, describe some of those situations that have occurred.

COMMITTEE MEMBER KURTURAL: You know, we almost

need to write it out, though.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER KURTURAL: Memorialize it.

VICE CHAIR DICKEY: It's a procedural issue. If we get into a smaller group, we have to have, you know, permission. We have to have this Bagley-Keene in effect. Whereas if we, everybody, just sort of submits their ideas, maybe to the administrator, that we can get around the Bagley team thing; right?

COMMITTEE MEMBER SCHAEUBLE: Well, can we set aside time at one of these meetings --

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: -- to specifically do the discussion of this?

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Because just submitting things again doesn't get us very far.

VICE CHAIR DICKEY: I know, it's just a problem when you get a group together and they're collaborating, that it needs to be an Open Meeting Act, sir.

DR. RYKACZEWSKA: I think a potential pathway is to do it both hand, to have Committee members submit something ahead of the meeting but still have --

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: -- a time set aside --

VICE CHAIR DICKEY: Exactly.

DR. RYKACZEWSKA: -- for a meeting to discuss.

VICE CHAIR DICKEY: Like one of these administrative meetings that's going to --

COMMITTEE MEMBER DINIS: What, we can't have a subcommittee of two people that that still invokes Bagley-Keene or whatever?

VICE CHAIR DICKEY: I don't know about two people, but --

COMMITTEE MEMBER DINIS: Three does; right?

MR. GOLDMAN: Three creates a Bagley-Keene obligation. Two people can talk, but I'm not sure how effective a group of -- I mean, that would be up to you --

COMMITTEE MEMBER DINIS: Right.

MR. GOLDMAN: -- how effective you think two people would be.

COMMITTEE MEMBER DINIS: Right.

VICE CHAIR DICKEY: Okay.

CHAIR DELGADO: Well, that's part of the reason why we're pivoting to monthly for six months, is to be able to have more frequent cadence to talk about these types of administrative issues. So I really like, Nieszka, your idea of, you know, folks sending things in and then setting aside 30 to 45 minutes at the August meeting -- sorry, I'm not oriented to date -- at the August meeting to follow up on

this.

VICE CHAIR DICKEY: Well, the August meeting is mainly devoted to projects; right? I mean, if we have time, but it would even seem cleaner to keep it to the next administrative meeting, which would be --

COMMITTEE MEMBER KURTURAL: That would be September.

VICE CHAIR DICKEY: -- September, but --

CHAIR DELGADO: I hear you completely. I would also suggest that maybe if we look to see how many projects we have --

VICE CHAIR DICKEY: Yeah.

CHAIR DELGADO: -- there may be a potential to squeeze it in.

VICE CHAIR DICKEY: Sure.

CHAIR DELGADO: But, yes, thanks. Thanks for reminding me that we're pivoting between projects and administrative stuff.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER DINIS: And who do we send it to?

DR. RYKACZEWSKA: To me?

VICE CHAIR DICKEY: Yeah, to Nieszka.

DR. RYKACZEWSKA: To Nieszka.

COMMITTEE MEMBER DINIS: To who?

DR. RYKACZEWSKA: To Nieszka.

COMMITTEE MEMBER DINIS: Well, I have a list, so, okay.

VICE CHAIR DICKEY: It's going to appear on your computer.

COMMITTEE MEMBER SCHAEUBLE: Can I ask you a question then? Doing this sort of implies something, but I'm not sure whether the Committee is saying it or not, and maybe we should be making it explicit.

Does this represent a consensus that there are indeed situations where the limited criteria in IPA are insufficient in our view to be doing the review process and therefore we are going into a path of trying to determine what additional factors might need to be considered, including the possibility that that may be a regulatory process? Because there's very little point of trying to say what the problems are that need to be addressed if we haven't decided there are indeed problems that need to be addressed.

VICE CHAIR DICKEY: I think we're saying that we're acknowledging that there may be and we need to investigate it and we need to know what those things are.

COMMITTEE MEMBER SCHAEUBLE: Well, again, I'm thinking we've talked about this quite a lot over several meetings now. Personally, I would hope that we're at a place where we can say, yes, there are issues here that need

to be addressed in some form and we're going to try to see how best to do that rather than just saying maybe. Maybe is not very convincing somehow.

VICE CHAIR DICKEY: It's kind of --

COMMITTEE MEMBER SCHAEUBLE: And I'll ask other people to weigh in. I mean, maybe I'm talking out of turn but --

VICE CHAIR DICKEY: I think the fact that Committee members are not happy about -- a number of Committee members are not happy about it because there's evidence that there's some issue that needs to be addressed. The question is how to address it.

COMMITTEE MEMBER KURTURAL: I'd love to see if we can somehow compartmentalize it. I know it's like a ton of work, but if you looked at, say, the past two, three years, let's look at like the adverse incidents we got and like maybe the data-only projects, and if there's a way we can categorize the problem, you know? Because some of them might be very easy. They're just asking for data. They have a HIPAA waiver authorization. There's no merging of data sets. There's that category. And then there's other categories where it's not like that and they're merging data, and we need to look at those specific use cases to figure out the problems.

And then as far as the adverse incidents, I can't

recall, unless if you guys can, any issues popping up regarding data sharing.

VICE CHAIR DICKEY: I don't think there's been any public complaints.

COMMITTEE MEMBER KURTURAL: Okay. Well, then maybe we don't look at that, we just look at the what's gone through the past couple years for data-only projects and try to loop them in different categories and then we can objectively, all right, this is what's before us, this is what's happening kind of like now, right, the past 24 months, this is we've had to deal with. And then once we kind of see those two, we can start brainstorming from their solutions. I don't know.

COMMITTEE MEMBER SCHAEUBLE: Well, certainly several of us have had some very troublesome projects that the Committee has discussed at considerable length, so we have some information from those situations about --

COMMITTEE MEMBER KURTURAL: Sure.

COMMITTEE MEMBER SCHAEUBLE: -- why they have been problematic for us.

VICE CHAIR DICKEY: Dr. Bazzano, did you want to say something?

COMMITTEE MEMBER BAZZANO: Yeah. I appreciate the efforts to try to categorize the data and get some information from them. I don't know if the past 24 months

or whether we should, you know, kind of do a couple little time lapses to kind of take a decent -- a bit longer of a look back because there has been so much discussion in the past 24 months. I think before that kind of as a before and during time series might be a little bit better to give a little bit more information.

and I completely agree with Dr. Schaeuble that I think I think we have specific cases that we can -- that I think we can all come up with that are -- that we've all had just challenges with. That may not be -- it may not be so clear from the outcomes as from the processes.

COMMITTEE MEMBER LUND: And a lot of these go through expedited review and have not been seen by the full Committee unless a reviewer wanted to bring it to the full Committee. The reviewers may have struggled with this decision-making process on their own or with their secondary reviewer without bringing it to the Committee. So there may be issues that the rest of the Committee is not aware about that some reviewers may have experienced with many of these projects.

And I'm wondering, just as a -- this is something I would like to ask Jared to weigh in on. So I think we are falsely dichotomizing data-only projects versus human subjects projects when it seems to me that the real issue is IPA projects versus Common Rule projects, because there can

be data-only Common Rule projects.

For example, I think Jared spoke earlier that we are the IRB if any of the agency departments are doing research, and that would be whether or not, and correct me if I'm wrong, Jared, they're doing -- they're personally doing the research in house, whether they're funding the research, paying a contractor to do the research, or paying a university to do the research, or whether they are providing staff support in collaboration with another researcher, like a university researcher, to do the project research. And under the Common Rule, secondary data, PII, would require a Common Rule review under an IRB, that would be us, even if there are no human subjects contact.

So dichotomizing this into data-only is very confusing because some of the things we've been talking about do apply to IPA data-only projects, but if it's Common Rule, then we don't need to worry because we can absolutely apply the Common Rule.

So I'm wondering if we could find a different way to refer to these projects rather than data only because I personally find that to be very confusing and not helpful in moving this forward.

MR. GOLDMAN: Yeah, I completely agree with you. I think that's a great distinction and thumbs up to everything you just said.

VICE CHAIR DICKEY: So I'm going to try to summarize this. It seems like we're in agreement of Committee members submitting issues or examples of cases of where there has been problems in the passed which to Nieszka so that they can be compiled and discussed in a subsequent meeting. I don't mean to just be, you know, to curt in summarizing that but it seems, is that true? Anybody object to that?

COMMITTEE MEMBER SCHAEUBLE: No.

CHAIR DELGADO: I don't object to it, I would just -- oh, sorry, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: I would just add to it suggestions for particular situations that are likely to need additional scrutiny beyond the minimum IPA requirements and what additional criteria --

VICE CHAIR DICKEY: Sure.

COMMITTEE MEMBER SCHAEUBLE: -- might be considered in those situations, trying to be a little more specific.

VICE CHAIR DICKEY: I'm not putting this as a motion, I just want to make sure we all understand --

COMMITTEE MEMBER SCHAEUBLE: Right.

VICE CHAIR DICKEY: -- we're in agreement of what we're expecting.

Darci?

CHAIR DELGADO: The only thing I was going to add, just to build off of Dr. Schaeuble comments, is that, and again, speaking just as a member, not trying to make a motion, but I do think that the length of this conversation, the number of meetings that we're having about it, and the level of concern, as well as the level of engagement that we've had with both Maggie and Jared, to me, feels like I personally, as a Committee member, really question how satisfactory some of these IPA requirements are.

And really appreciate everyone kind bringing this knowledge together to get to a common -- I shouldn't use the word common, not to confuse with Common Rule -- to get to a joint place where we all feel comfortable with the protection of the data, the protection of the human subjects, and that we have collectively come to a group decision that all the Committee members feel good about, or at least, you know, feel better about than we started this process six to eight months ago.

COMMITTEE MEMBER SCHAEUBLE: Would it be helpful, I don't -- maybe you won't like the idea, I don't know. Would it be helpful to have a specific motion that the Committee acknowledges that the criteria stated in the IPA may not provide sufficient protection for data privacy and security in all instances and is investigating situations where other criteria should be considered? Would it be

helpful to state in some form that we are that far along in our process of thinking or is that not helpful? I'm just asking.

VICE CHAIR DICKEY: I don't have a problem with that. Does anybody else? I think you summarized, basically, what we've been saying.

CHAIR DELGADO: I think that's a great suggestion to also just document where we are in the process, and also to help, you know, if we do, in future meetings, end up in a decision where we're moving towards regulations or we end up in a decision where we are only using the IPA and not adding any additional components through any other process. It does at least document kind of point in time where we are at.

VICE CHAIR DICKEY: Do I have a second?

COMMITTEE MEMBER KURTURAL: I'll second.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: I think there might be a couple words missing.

COMMITTEE MEMBER SCHAEUBLE: Yeah.

DR. RYKACZEWSKA: And please correct me, Dr. Schaeuble. I think after --

COMMITTEE MEMBER SCHAEUBLE: Data.

DR. RYKACZEWSKA: -- "data privacy and security," in front of "instances," I think we're missing, "in all

instances."

VICE CHAIR DICKEY: "In some."

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. RYKACZEWSKA: "In some instances?"

COMMITTEE MEMBER SCHAEUBLE: Yeah --

VICE CHAIR DICKEY: "In some instances."

COMMITTEE MEMBER SCHAEUBLE: -- "in all instances."

VICE CHAIR DICKEY: that would be "in some instances."

DR. RYKACZEWSKA: I just want to make sure we captured it correctly.

VICE CHAIR DICKEY: You still seconded it, though.

COMMITTEE MEMBER KURTURAL: I still second it.

MS. ATIFEH: So I will start with Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Sorry. Approve.

MS. ATIFEH: Good. Thank you.

Dr. Dinis?

VICE CHAIR DICKEY: Approve.

Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approved.

MS. ATIFEH: Dr. Palacio?

MS. MUHAMMAD: There's a thumbs up.

MS. ATIFEH: Is there?

MS. MUHAMMAD: I gave the thumbs up.

MS. ATIFEH: Again?

MS. MUHAMMAD: Yes.

MS. ATIFEH: Okay, good.

Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Yes. Approve.

MS. ATIFEH: Thank you.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay, great.

Moving on to the next item, this has to do with clarification and reasons for abstentions and objections.

CHAIR DELGADO: Dr. Dickey, can we just say thank you again to Jared and Maggie? Sorry to interrupt. I know we're moving on to the next item, but your guys' expertise and guidance in this space to help us get to an alternate conclusion, so just very appreciative of you all, so thank you so much.

VICE CHAIR DICKEY: I thought they were going to

stay around.

CHAIR DELGADO: I mean, they could become Committee members if they want.

Thank you guys.

DR. RYKACZEWSKA: We will send it out after, yes. The presentation that you were provided, we will be sending out after the meeting, and we will post to the website, as well, after the meeting.

MR. GOLDMAN: And I'll give credit where credit's due. My presentation is based largely on the information that's presented on the website of the Office of Administrative Law. So if you want even greater detail about the regulation process, you can go to their website and see what I stole from them.

DR. RYKACZEWSKA: Thank you.

MR. GOLDMAN: Uh-huh.

VICE CHAIR DICKEY: Okay. And, actually, I have to acknowledge, we didn't have -- I didn't ask for public comment before we made that last motion, but I will ask now, would there -- is there any public comment? Okay. I don't think we need to revote then.

VICE CHAIR DICKEY: So this next one has to do with -- maybe, could we display what it says in the policies and procedures right now --

MS. ATIFEH: Yes.

VICE CHAIR DICKEY: -- on this issue? Sorry to surprise you on that.

How about we take like a five-minute break right now?

(Off the record at 11:02 a.m.)

(On the record at 11:10 a.m.)

VICE CHAIR DICKEY: Okay, we're reconvening. Is everybody back? Can you tell if everybody's back?

DR. RYKACZEWSKA: If you're back, if you could either turn on your camera or raise your virtual hand if you don't have your camera on? I am seeing Dr. Delgado. I am seeing Ms. Lund. I am seeing Dr. Dinis, Dr. Azizian, Dr. Palacio. I think we might just be waiting on Dr. Ruiz.

Dr. Ruiz, are you back? Dr. Ruiz, I think he might be waiting on us.

VICE CHAIR DICKEY: Oh, okay. Well, he's one of our quorum.

DR. RYKACZEWSKA: That's true.

VICE CHAIR DICKEY: For those of you out there, we're waiting on Dr. Ruiz since he's part of our quorum.

COMMITTEE MEMBER RUIZ: I'm back.

DR. RYKACZEWSKA: Welcome back, Dr. Ruiz.

VICE CHAIR DICKEY: Okay, great. All right, well, we're right on time.

So Dr. Schaeuble would like to talk about, I

think, the language that we have in the policies and procedures now, particularly that middle bullet there, basically stating a motion, "Members voting no are required to express reasons for opposition. And then I think there's section that says. "A member having made a motion cannot vote against their own motion."

The policies and procedures previously said, and I think you'll get into this, Dr. Schaeuble, said that the reason for minority votes must be specified . And I think when the policies procedures got revised, I don't think legal did this, they put in there that minority division votes would always basically be no, so express your opposition.

And then I think the thing about can't vote against their own motion is just a procedural thing because typically we don't ask those who make the motion whether they support their own motion or not and we don't record that, we assume that.

MS. ATIFEH: Yes, exactly.

VICE CHAIR DICKEY: So anyway, take it away, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: So can you put on the screen --

MS. ATIFEH: Yes, let me just put it up.

COMMITTEE MEMBER SCHAEUBLE: -- the document that

I sent in?

MS. ATIFEH: Yes, this is the one.

COMMITTEE MEMBER SCHAEUBLE: So you can see here in the first paragraph language that had been in an earlier policy manual, and in the second paragraph language in the manual that was most recently sent to us, and in the third paragraph what I'm proposing as a revision.

This comes about, you'll remember, well, several meetings ago there was a question about asking people to state why they had voted as they did. And at that particular meeting I talked a bit at the end of the meeting about how requiring people to justify the way they have voted does not seem consistent, to me, with any other situation in which people cast their votes, one way or another, and that did not seem fair to me. So I rephrased this to say that such members are encouraged to express the reasons but not using the word required.

And also because the most recent language, as Dr. Dickey said, assumed that the decision of the Committee would always be to approve, I tried to make the language neutral by, again, saying that those whose votes that are in a minority are encouraged to express their opinions.

And going down to the next three paragraphs, we have the other place where language about this occurs, first paragraph, what had existed at an earlier time, second

paragraph in the most recent policy manual, third paragraph, what I'm proposing, which says, again, that the minutes should include reasons for minority votes as they have been if they have been stated.

Now, normally I don't think this is likely to be a big issue because in most circumstances the minutes are already going to reflect what was discussed during the meeting and likely the reasons for people voting in the minority would already be apparent from what was discussed during the meeting. And certainly, if people are willing to, as most likely are, to comment on why they are opposed to a motion that the majority of the Committee has passed, that's fine too. It's just that I don't think that should be a requirement that is placed on people to force them to say something if for some reason they choose not to.

So that's the reason for the proposed changes here that I've asked the Committee to consider.

VICE CHAIR DICKEY: Open it up for a comment.

CHAIR DELGADO: I appreciate Dr. Schaeuble diving into this, proposing new language. Thank you so much. I'm in support.

VICE CHAIR DICKEY: I think that we owe it to researchers to let them know why we are turning down their projects, because then they can't really revise their projects so that to accommodate what the Committee's

concerns are, and I think it's only fair to them to give them the reasons. This is not a -- it's not like a voting. You know one of the responsibilities of being on this Committee is expressing your opinion.

And I'm just concerned. It's always been in there that minority opinions need to be justified. And now in the context of all this disagreement of what our standards are, unless we, members, tell us exactly why they are voting the way they are, it leaves it open leaves ourselves open to a lot of misinterpretation from researchers.

COMMITTEE MEMBER LUND: But, Dr. Dickey, this is Laura, by definition, if there are minority members then the project received a majority vote and it was either approved or not approved. And so the reasons for the minority votes are not really feedback for the researcher. I mean, it seems to me if that is --

VICE CHAIR DICKEY: Researchers are always allowed to resubmit their projects and make changes. Just because we turn a project down once doesn't mean they can't reapply.

COMMITTEE MEMBER LUND: No, I'm not saying that at all. I'm saying that this refers to the minority votes, which did not influence whether or not the project, right, the project is either approved or not approved based on the majority votes. By your logic, we should be asking the people who voted in the majority to provide their reasons,

not the minority.

VICE CHAIR DICKEY: But given the fact that most all of our decisions that are, whether it's an issue, a controversy, have to do with the ones that we've turned down, and those are the ones where it's useful for the researchers to know what the reasons are.

CHAIR DELGADO: Yeah, but if we turned it down, then all the no votes would be majority, in which case this doesn't apply.

COMMITTEE MEMBER LUND: Correct.

COMMITTEE MEMBER RUIZ: Agreed.

VICE CHAIR DICKEY: Well, wait. No, I think what we're talking about is, let's see, well, the way it's phrased in the current policies and procedures is it says no votes.

CHAIR DELGADO: Okay.

VICE CHAIR DICKEY: And, you know, I think that's probably why legal changed it to no as opposed to keeping it at minority.

CHAIR DELGADO: Yeah, I think that the scenario that you're -- and if we need to adjust the verbiage as such, I think that we're happy to do so, but I don't think the scenario in which you just described is the reason for this topic to come up for our Board and to make these revisions. The reason is because there may be personal

reasons why people want to abstain or vote in the minority, in which case I don't think that they need to be providing justification in the event that they are the minority vote. And so --

VICE CHAIR DICKEY: Well, if there's some different inconsistency in the language, because higher up it says, "justify no votes," and then further down it says, "reasons for abstaining and opposing," I don't think anybody who abstains should have to say why they're abstaining, but I do believe somebody who's opposing a project should justify why they're opposing it.

COMMITTEE MEMBER SCHAEUBLE: I don't see the conflict you're talking about, Dr. Dickey. I really don't.

VICE CHAIR DICKEY: Do you not believe that we should give justification to researchers when we turn down the project?

COMMITTEE MEMBER SCHAEUBLE: That will all automatically have already happened because the majority of the Committee will have voted, they will have stated their reasons during the discussion for why they are --

VICE CHAIR DICKEY: Some may not have.

COMMITTEE MEMBER SCHAEUBLE: Well, how would the Committee arrive at a not to approve a project without having brought up reasons for that to happen? I can't imagine how.

VICE CHAIR DICKEY: I just think that there are some people who may have different reasons, that's all.

COMMITTEE MEMBER RUIZ: (Indiscernible.) Right.

COMMITTEE MEMBER SCHAEUBLE: And in any case the --

VICE CHAIR DICKEY: I just think in the context of the disagreements we've had as to which standards we're using, that what is the harm of being explicit about it?

CHAIR DELGADO: Because some people don't want like --

COMMITTEE MEMBER SCHAEUBLE: Look, read what's there.

VICE CHAIR DICKEY: I see what you're trying to say.

COMMITTEE MEMBER SCHAEUBLE: In the current paragraph, in the current policy manual, it says "report the votes in favor, opposed abstentions in absent, as well as reasons for abstaining and opposing." Now if a majority of the people have voted not to approve a project --

VICE CHAIR DICKEY: Those are nos.

COMMITTEE MEMBER SCHAEUBLE: -- then reasons for abstaining and opposing are those people who voted for the project or didn't vote.

VICE CHAIR DICKEY: The abstaining is the ones who didn't vote.

COMMITTEE MEMBER SCHAEUBLE: The abstaining is the ones who didn't vote. The opposing would be the ones who voted --

VICE CHAIR DICKEY: Who said no.

COMMITTEE MEMBER SCHAEUBLE: -- no, who voted for the project, because if the vote is against the project overall, then the minority is those who voted for.

VICE CHAIR DICKEY: Well, forget the minority language here. The current policy procedures don't use the word minority. That was from a previous version. The current ones, which is why I had them shown earlier, says "no votes."

COMMITTEE MEMBER SCHAEUBLE: The reasons for opposing a motion to disapprove would say that the people are voting in favor of the motion.

VICE CHAIR DICKEY: Well, that's if the motion was to disapprove. Virtually, all of our projects, all of the motions are to approve.

COMMITTEE MEMBER SCHAEUBLE: Okay. And if the motion is to approve, then the opinions of people who are disapproving really don't matter because the project's been approved.

VICE CHAIR DICKEY: No.

Is there a comment from somebody else?

DR. RYKACZEWSKA: Dr. Ruiz, did you have a

comment? I see you're unmuted.

COMMITTEE MEMBER RUIZ: Yes. I just don't see the need to really state the reasons for abstaining or opposing. I feel that if someone wants to oppose or abstain, that's their right. I don't think it makes a different to on it for the investigator to know.

VICE CHAIR DICKEY: I agree with you on the abstain. I don't necessarily agree with you on the oppose because there are circumstances where researchers need to know, what is the problem with the project? We could have a close vote and they say, well, okay, people could be opposing for different reasons, and the researcher could say, well, if I change my project this way, maybe I could pass. It's really just a matter of informing researchers. But, you know --

CHAIR DELGADO: Well, we don't need to change anything, because we approved it.

VICE CHAIR DICKEY: Hmm-hmm.

DR. RYKACZEWSKA: Isn't that in the -- sorry.

COMMITTEE MEMBER LUND: In the context where the majority voted against to oppose, that it wouldn't be clearer from the context of the discussion that a researcher could be provided with the minutes of all of the issues that were raised, since it's a pretty rare event? It's a pretty major thing and there's lots of discussion. I'm sorry, I've

been on the Committee almost ten years. If we all opposed a project, there is lots of discussion and it would be very clear to anyone reading the minutes what the issues were. If they want to resubmit, they can work with their reviewer on specific issues and any questions or problems to resolve those before it comes back to Committee.

So I don't think it's fair to reviewers to put them on the spot and make them, force them, compel them to give a reason if they choose not to.

VICE CHAIR DICKEY: So do you --

COMMITTEE MEMBER SCHAEUBLE: And I would add to that, if there is a situation where a project is not being approved by the Committee, it seems to me that the motion to not approve the project would itself be saying what the Committee found not approvable, else why would there be a motion not to approve? So that's already in the motion. Asking in that instance for some other justification from people when they vote, it doesn't make sense to me. I'm sorry, it just doesn't.

VICE CHAIR DICKEY: I think the instance that Laura referred to is where things are tabled and they go back and they have a chance to talk to their reviewers and to work it out. I'm talking about cases where something is opposed and they're not going to be necessarily coming back to the same reviewers, they're going to be resubmitting.

And the more information they have as to why we're opposing it, the better.

But, you know, I agree with you, I don't think this is a big issue on one way or another because, in most cases, our reasons are justified. But, you know, I wasn't the source of this language, and there has been language in there for a long time but it's been confusing because it used the word minority and it was changed to "no.," yeah.

COMMITTEE MEMBER VENTURA: I have a question on a specific example from maybe our last or meeting or two where if you oppose or abstain for a personal reason, would that be sufficient?

VICE CHAIR DICKEY: I would think abstaining for personal reason would be fine. I don't know about voting no for personal reason. We're not supposed to introduce our personal reasons into our decisions.

COMMITTEE MEMBER SCHAEUBLE: And in any case that's rather asking people to do something that they might not feel comfortable with anyway. I mean, why should a person have to say I'm voting in this particular way for personal reasons. Why should the person have to be saying anything?

VICE CHAIR DICKEY: I don't think they should have to say anything if they're abstaining. But the question is, if they're opposing something as an official function, you

know, that it's not unreasonable to ask people to express the reasons why they're opposing something.

But it's not a huge issue one way another, but I just think it protects us more in terms of documentation, you know, for future issues.

COMMITTEE MEMBER DINIS: Or not. It could open us up to liability. Somebody could be, you know, questioning a particular regulation or something and something else for the lawyers to pick up, so it's -- I don't know.

I mean, usually in voting, I don't know, the bodies that they do that, at least in the IRBs I've sat on, we have never asked for a reason, so I'm not sure what -- why this -- what regulation or rule or law we would have here that would mandate us to do that.

VICE CHAIR DICKEY: I don't think it's -- Robert's Rules of Order or whatever doesn't say you have to do that. It's just been in our policies and procedures for 20 years or 30 years or whatever.

COMMITTEE MEMBER RUIZ: Well, maybe this is the right time to change it.

VICE CHAIR DICKEY: Okay. Do you want to make a motion?

COMMITTEE MEMBER SCHAEUBLE: I would move that the Committee approves the two proposed revisions that are before you.

VICE CHAIR DICKEY: Can you be more specific which one of these you're using?

COMMITTEE MEMBER SCHAEUBLE: Okay, scroll up, scroll up on the screen, please. Okay.

I will move that the Committee approves the proposed revision under proceedings on page, well, it's on -- excuse me, approval of the proposed revision for the text under Proceedings on page 19 to say what the third paragraph there says,

> "Approval of a motion requires votes in favor by a majority of CPH members present in person or remotely, excluding the Chair. The Chair may only cast a vote to break a tie or if needed to establish a quorum for the meeting. Motions receiving a tie vote do not pass. Members whose votes are in a minority are encouraged to express their reasons."

And I will also move, if you scroll down, that the text under Meeting Minutes on page 21 be changed as shown in the third paragraph here,

> "Motions and the decisions of the CPHS, including votes in favor, votes opposed, abstentions, and members absent at the time of the vote, for example, total equals 13, in favor equals 12, opposed 1, abstains 0, as well as the reasons for minority votes if they have been stated."

So those are the two paragraphs that would be substituted for text that's currently in the policy and procedures.

VICE CHAIR DICKEY: Do I have a second?

COMMITTEE MEMBER DINIS: Second.

MS. ATIFEH: Dr. Dinis, second. Okay.

VICE CHAIR DICKEY: You may call the vote.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Oppose, for the reasons that I've stated.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve (phonetic).

MS. ATIFEH: Dr. Bazzano? Dr. Bazzano?

DR. RYKACZEWSKA: I think we may have lost Dr. Bazzano.

COMMITTEE MEMBER SCHAEUBLE: Oh, okay.

Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

DR. RYKACZEWSKA: Dr. Palacio? Dr. Palacio shows a thumbs up.

MS. ATIFEH: Oh, okay. Good.

Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Okay, the motion passes.

VICE CHAIR DICKEY: So the next issue is -- oh, go ahead.

COMMITTEE MEMBER LUND: Oh, so sorry.

VICE CHAIR DICKEY: Any public comment? Okay.

All right, the section is it just a small issue. Some of you may not or may know or may not know that in 2018 OHRP changed the Common Rule to state that projects that are public health surveillance, could be considered public health surveillance, and gave it certain criteria, would be exempt from the Common Rule. And in that case they would not be under review currently or in the future by IRB. And this took effect in 2018.

We have a lot of projects or some projects from before 2018 that could be recategorized as public health surveillance. And the Common Rule states there are certain criteria you have to meet to do that, but it does not state that you have to recategorize projects from before 2018 as public health surveillance.

So this has come up at least once. And the

process that internally we decided on was that if you want to reclassify a project as public health surveillance, it needs to be done in conjunction with the Chair or the Vice Chair to do that. This is a pretty rare occurrence, but just to notify the Committee about that that's the procedure that we'd like to follow.

Any questions about that rather --

COMMITTEE MEMBER LUND: Why was that decision made and what's the reasoning behind that?

VICE CHAIR DICKEY: Well, it seemed rather than having -- well, it has implications for -- I mean, we could bring it back to the full Committee, but it just seemed better to -- rather than having individual members trying to make that decision, that it would be best the Chair and the Vice Chair be involved in it.

Any other questions or comments?

COMMITTEE MEMBER SCHAEUBLE: Did you have some thoughts on that, Laura? You were asking the question.

COMMITTEE MEMBER LUND: Yeah, I just, because this affects a project that I had that my finding was ruled by the Chairs, and I'm just wondering kind of, it seems arbitrary.

I have concerns about some of the projects that Dr. Dickey mentioned. They're very, very long-term projects. Some of them were approved back in the 90s and

the early 2000s, and they come back. All of the state agencies do this work, particularly CDPH. They come back all the time with amendments and changes and the project is really no longer research.

And it seems to me that some of what's happening is that the agencies are using CPHS as a workaround because there are some things that they can't do as an agency with routine work and surveillance that they can do if they get exemptions. But I object to providing research exemptions to allow government agencies to get around the rules, in essence.

So I think that when projects come up that have these long-standing review processes that if they're, in fact, public health surveillance under the new rules, that we should be categorizing them as public health surveillance. So those are my thoughts.

Thank you, Dr. Schaeuble.

VICE CHAIR DICKEY: Any other questions or concerns about that? All right.

CHAIR DELGADO: Well, a question.

Laura, is this something that you'd like to have the Board consider to adjust the policy, or like we put it on the agenda because we want to get people's feedback?

So if folks are not happy with that decision that I was a part of and that Dr. Dickey was a part of, please

let us know and we can readjust or open it up for more conversation and discussion.

COMMITTEE MEMBER LUND: Oh, thank you, Dr. Delgado. I guess my response to that would be it might be better if these projects, they don't come up all the time, but there are several longstanding ones that I've reviewed in the past year, it would be, in my opinion, best if those came before the Board for review and consideration and a Board decision as opposed to an executive decision on the part of the Chair.

So that would be my counter recommendation to the policy that's been presented to us, that in those cases, if a reviewer believes that these projects should be recategorized, then it should come to the full Board for review.

CHAIR DELGADO: Thank you.

Other people's thoughts, feedback?

COMMITTEE MEMBER DINIS: Well, it's odd that the Chairs would be making decisions like that without the full Board input because we don't do that in other things. When we have an issue, we bring it to the full Committee and other kinds of studies. So what's different about this one?

VICE CHAIR DICKEY: Well, this one was an interpretation of the law, I think, which was that projects are not required to be reclassified according to the Common

Rule. And actually, departments, you know, may not actually want to be. And in this particular circumstance, they were still doing interviews and had human subjects contact and they were asking for our review of their surveys, et cetera. And if we reclassified it as public health surveillance then they wouldn't have our review of their surveys, et cetera, in the future.

But I agree with the principle that if a reviewer does not agree with something that the Chair and the Vice Chair are doing, they should have the right to bring it to the full Committee. So maybe if we just say any of those decisions should be made in consultation of the Chair and Vice Chair but and then brought to the full Committee if there's agreement?

CHAIR DELGADO: I agree.

And, Maria, just to give a little bit more specificity, I think, at least in my mind following, like there's a lot of questions that Dr. Dickey and I feel in terms of like purview, exempt or not exempt, like I was kind of bucketing this and that at first. But this discussion is super helpful to understand the bigger context and understand larger implications in a way that makes me think that I'm glad that we put it on the agenda.

COMMITTEE MEMBER DINIS: Thank you.

VICE CHAIR DICKEY: And is there a basic agreement

about just at least they need to consult with the Chair and Vice Chair and if there's a disagreement then these things will all brought to the full Committee? Any disagreement with that?

CHAIR DELGADO: None from me.

VICE CHAIR DICKEY: All right. I mean, I think the principle in all these expedited reviews should be that any disagreement or whatever that can't be resolved needs to come to the full Committee. I don't think we need a motion on that. I think it's --

DR. RYKACZEWSKA: Yeah.

VICE CHAIR DICKEY: Does zoom I think we need a motion? Okay.

So any public comment on that?

Oh, I can't hear you Darci.

CHAIR DELGADO: Oh, I was just going to say, I'd love to find out, I don't know if it's through a motion, I don't know if it's through adding it to our policies and procedures, but I would love a way to memorialize this, only because, you know, one of the things that Nieszka and I have talked a lot about is this kind of institutional knowledge that we have across members that oftentimes we don't memorialize and then in two years things pop up again and we're kind of trying to play this memory game.

So I don't know if it's a motion, I don't know

what the vehicle is, but some way to memorialize this process, I am curious if anybody has any thoughts about that.

VICE CHAIR DICKEY: Well, I think it may be related to the issue of how do we deal with expedited reviews and disagreements on them. Nieszka and I have been talking about some sort of changes to the policy procedures that would specify that expedited reviews where there's a disagreement, either with the researcher or with and among the reviewers, here would be with the Chairs, I suppose, needs to be brought to the full Committee. Maybe that would memorialize it.

What do you think, Nieszka?

DR. RYKACZEWSKA: I'm seeing additional comments, so I'm going to create opportunity for them.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: But --

COMMITTEE MEMBER KURTURAL: I see it as, everyone's going to probably hate me for saying this, but I see that as being included in our reg package because for -- I mean, I think that that's where some of the reg comes from is disagreements and the type of requests and whether something goes expedited or not. But, you know, I understand others might see it differently.

VICE CHAIR DICKEY: Well, I mean the federal rule

is clear that only a full Committee can turn down a project. And you can't turn a project down by expedited review.

COMMITTEE MEMBER KURTURAL: Oh, okay. I didn't know that.

VICE CHAIR DICKEY: So anything that is going to result in a --

COMMITTEE MEMBER KURTURAL: (Indiscernible.)

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER KURTURAL: Yeah. Okay.

DR. RYKACZEWSKA: Asking for my opinion, that this is just a recommendation --

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: -- I would recommend a motion and maybe incorporate it into the policies and procedures just so that it's --

VICE CHAIR DICKEY: So are we talking about the motion on this issue of public health surveillance --

DR. RYKACZEWSKA: Yes.

VICE CHAIR DICKEY: -- or the wider issue of disagreement and expedited reviews?

DR. RYKACZEWSKA: I was just speaking to the piece around the reclassification.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER SCHAEUBLE: Because that was the agenda item today anyway.

VICE CHAIR DICKEY: Okay. Can we redisplay what we had up on the screen on this?

DR. RYKACZEWSKA: Nick, can you re-share the draft motion?

VICE CHAIR DICKEY: Well, that's the wider issue.

DR. RYKACZEWSKA: Yeah, that's the wider issue. Well, I'm not going to make the motion. I definitely can't make the motion.

VICE CHAIR DICKEY: Well, then let's just -- I would propose --

CHAIR DELGADO: So we can find no purview on expedited review, which would be what a public health surveillance project would be. So I think that this motion needs to be specific to what you want to do about handling these public health surveillance projects, because I don't think it falls into the larger class of denying on expedited review.

VICE CHAIR DICKEY: Okay. So where this came from, actually now that I think back on it, is currently the procedure is that the Chair or Vice Chair makes determinations about no purview and exempt before the projects ever get to the Committee. So and I think Dr. Ruiz is heavily involved in doing that now.

So it seemed to me most, since that the Chair and the Vice Chair are making the decisions about no purview,

that seemed most -- you know, have it back -- go back to them when you want to reclassify something. So maybe -- but maybe we just make this such that for public health surveillance projects that need to be reclassified as public health surveillance, the researchers need to -- the reviewer needs consult with the Chair or Vice Chair, and if there's disagreement it will come to the full Committee.

DR. ZARAGOZA-WATKINS: All right, you're going to have to talk a little bit slower.

VICE CHAIR DICKEY: Okay. For public health -- for projects that need to be reclassified as public health surveillance the reviewers should consult with the Chair or Vice Chair or/and Vice Chair -- well, the Chair or Vice Chair -- should consult with the Chair or Vice Chair, and a period, and if there is disagreement the determination should be brought to the full Committee. Yeah, that's okay.

I mean, does somebody want to say that they're making that as a primary motion since I can't, technically, I can't, I don't think? I mean, can I, since Darci's here and she's --

COMMITTEE MEMBER SCHAEUBLE: First line, probably project should be plural.

VICE CHAIR DICKEY: Yeah.

Any public comment? I guess since I'm not actually formally Chair, I could make that motion, I guess.

All right, is anybody willing to second it?

COMMITTEE MEMBER JOHNSON: I'll second.

VICE CHAIR DICKEY: All right.

MS. ATIFEH: Dr. Johnson, did you second?

COMMITTEE MEMBER JOHNSON: Yeah, I seconded.

MS. ATIFEH: Okay.

Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Mr. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio.

DR. RYKACZEWSKA: Has had to leave. Dr. Palacio has had to leave.

MS. ATIFEH: Oh, okay.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, thank you. The motion passed.

VICE CHAIR DICKEY: All right.

I have down here, we have one last time for the public to comment.

Not hearing any, we will adjourn the meeting and reconvene on August 2nd.

(The meeting adjourned at 11:53 a.m.)

--oOo--