MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, APRIL 25, 2025

8:29 A.M.

1215 0 STREET, 11TH FLOOR

CLIFFORD B. ALLENBY BUILDING

MEETING ROOM 1181

SACRAMENTO, CALIFORNIA 95814

AND

ZOOM ONLINE MEETING PLATFORM

Reported by:
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APPEARANCES

COMMITTEE MEMBERS

Catherine Hess, PhD Dr., Chair

Larry Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD

Maria Dinis, PhD, MSW (Remotely attending)

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS (Remotely attending)

Juan Ruiz, MD, Dr.PH, MPH (Remotely attending)

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna

ALSO PRESENT

CalHHS

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Jared Goldman, General Counsel

Maggie Schuster, Attorney

Francis Brown

APPEARANCES (CONT.)

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

HCAI

Michael Valle, Chief Information Officer

Dionne Evans-Dean, Chief Data Programs Officer

Chris Craig, Chief Risk Management Officer

James Yi, Attorney

Wade Iuele, HPD Consultant

PUBLIC

None Present

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Dr. Linda Remy, Formerly affiliated with UCSF

Dr. Megan Mahoney, UCSF

Ms. Denise Modjeski, University of Southern California (USC)

Dr. Lauren Wellner, University of Michigan

Dr. Kimberly Miller, University of Southern California

Mr. Matthew La Rocque, Social Finance, Inc.

Ms. Alina Xu, Social Finance, Inc.

Dr. Lisa Shugarman, NORC at the University of Chicago

Ms. LeeAnn McCabe, NORC at the University of Chicago

Ms. Xueyin Yang, NORC at the University of Chicago

I n d e x

I n d e x (Cont.)

Page

J. New Projects - Expedited Review Requested

K. Projects Requiring Continuing Review
No Projects for Review

L. Amendments - Projects with Revisions Approved Through Expedited Review

M. Projects with Request for CPHS to Rely on Another IRB
No Projects for Review

N. Exemption/Not Research Approvals
No Projects for Review

O. Final Reports - Catherine Hess, Chair

Projects listed are submitted for closure and are recommended for approval by expedited review.
See attachment for list of projects - Action

P. Public Comments
None

Q. Next Meeting

The next CPHS meeting is Scheduled for Friday, June 6, 2025

P R O C E E D I N G S

CHAIR HESS: Let's get the meeting started. So, I'd like to call to order the April 25, 2025 meeting of CPHS.

Can participants and board members who are remote please turn their cameras on.

CHAIR HESS: Can you hear us remote board members? Can somebody give a thumbs up or --

COMMITTEE MEMBER LUND: It looks like you're muted. There's a mute thing where it says CPHS --

VICE CHAIR DICKEY: It looks it, yeah.

DR. RYKACZEWSKA: Can folks online hear us?

COMMITTEE MEMBER DINIS: Yes.

CHAIR HESS: Okay. Thank you, remote staff for turning -- or, remote board members for turning on your cameras.

Could we do the roll call, Sussan, whenever you're ready.

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

CHAIR HESS: Present.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Here.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: And Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Here.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Here.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Here.

MS. ATIFEH: Okay, quorum is established.

CHAIR HESS: Great, thank you.

I don't have any other opening remarks except to let everyone know that the item relating to our new IP, or considerations for our IPA review remarks is going to be continued and tabled. The Governor's Office has requested additional time to review. So, that is my only update.

I'll turn it over to you.

DR. RYKACZEWSKA: Okay, thank you, Dr. Hess.

So, for the administrator update we would like --

we are very happy to announce that we -- sorry, let me get my thoughts in order. With the departure of Dr. Delgado and Dr. Bazzano from the board recently, we are now recruiting new members for CPHS. And as noted in our policies and procedures, nominations can be made by members of the public, they can be made by CalHHS staff.

Department has -- so, if there are folks who are interested in making nominations for the board including, of course, our board members themselves, if you know of anybody who would be interested we ask that a cover letter, CV, and list of references be submitted to me, as the Administrator. You can also submit them to our inbox, the cphs@chhs.ca.gov.

But I thought I'd give a little bit of information in terms of what members must be knowledgeable of, and kind of what we're looking for in terms of members.

So, again, this is all noted in our policies and procedures. But members must be knowledgeable in the areas of research that CPHS reviews. Which is, of course, a very varied topic there, so you do not have to be knowledgeable in all of them, but at least in some of them.

And while knowledge of general principles of scientific research is important and considered, members' primary area of expertise can be nonscientific. In fact, we are required to have at least one member whose primary area of expertise is nonscientific.

So, areas such as data privacy laws, data security, experience working with vulnerable populations are also -- would be sought after.

In terms of what is it that members do, it is a lot. Members review about 15 to 25 projects every two months, as well as attend these full board meetings here in Sacramento. So, some of those projects are full board projects, a little bit more of an intensive full review. Others are expedited reviews. And so, board members do review both.

More information on the criteria that is used to prioritize candidates, as well as what the members' duties are can be found in our policies and procedures, on pages 9 and 10, which can be found on our website.

Additionally, on our website we do have a link with more information. And so, if you go to the main page of our website, there is a CPHS is recruiting new members. Select the join button for more information. And there is more details about recruitment there.

But I did also want to speak a little bit about what the process is. So, as the administrator I pre-review the applications and compile them together for the chair and the vice-chair's review.

The chair then uses the criteria that are specified in the policies and procedures to prioritize a

list of candidates, and submits these for the Cal-HHS secretary's consideration. And ultimately, the Cal-HHS secretary appoints the members and they are sworn into the Committee. So, members are appointed by the Cal-HHS secretary.

All that to say, if you have any questions or are interested and would like to speak more with us about it, just let us know by emailing us at CPHS, at chhs.ca.gov. And I will just note that while we do take nominations on an ongoing, rolling basis, we are hoping to start compiling documents to begin our review on May 5th. So, if folks would like to submit those documents, that's CV, cover letter and a list of references ahead of that, that would be helpful. Not to say that we won't consider you if it comes after that.

And I think that's it for my item.

VICE CHAIR DICKEY: Do we currently have any?

DR. RYKACZEWSKA: We have currently one candidate that has submitted materials and a couple others that have expressed interest, and have been asking questions, but not yet submitted anything. So.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: We are looking for more folks.

CHAIR HESS: Fingers crossed.

DR. RYKACZEWSKA: Uh-hum.

CHAIR HESS: Okay. Are we ready to move on to the next item? If that's it for --

DR. RYKACZEWSKA: That is it for me.

CHAIR HESS: Okay. So, our next item involves a discussion of updated data sharing guidance. And this is -- pertains to some issues that Ms. Lund raised at the previous meeting. We'd like to have Ms. Schuster give us a bit of a presentation or just information about some data sharing and the role of the board.

MS. SCHUSTER: Okay, yeah. Hi everyone, good morning. So, I've missed the last two meetings, but I've been filled in on a couple of questions that have come up that we will be discussing.

The first one relates to certificates of confidentiality. And so, I have been told that there is a question about whether the Committee could require researchers to submit certificates of confidentiality as part of their application for Committee approval.

A certificate -- I'm going to call them COCs, so I don't have to keep saying certificates of confidentiality. But, so COCs, these are certificates that been issued by the National Institute of Health, NIH. And the purpose of the certificate is to protect the privacy of research participants. They prohibit the disclosure of personally identifiable information, or PII, to those who are not

connected to the research. So, as you are very aware, CPHS reviews the PII under the IPA.

So, looking at the question of if we can require COCs to be a part of the application, we look to the IPA, the requirements that are in the IPA. One of the parts of your review under the IPA is a determination that researchers have provided a sufficient plan to protect PII from disclosure, improper disclosure.

But there is no requirement in the statute that researchers submit a COC as part of their review. And so, if the Committee were to begin requiring COCs to be submitted as part of your review, there would be a risk that you'd be creating an underground regulation, which would open the Committee up to legal risk.

So, just talked about while underground regulations are rules of general application that are not in statute and they're not in a properly, you know, past regulation to the IPA. So, if it was a new requirement that was added, essentially, to what researchers need to do to fulfill the IPA requirements that would be where it could be likely would be an underground regulation.

So, like I just mentioned, the Committee, you do have authority to look to see if a researcher has a sufficient plan to protect PII. Conceivably, you could look to see if a researcher has submitted a COC as part of their

kind of overall plan, as with one factor.

However, we would encourage that not to be a part of the analysis. And that's really just because -- so that these certificates are coming from the National Institute of Health, NIH. And NIH issues certificates for research that is funded by the NIH automatically. But if research is not funded by the NIH, the researcher has to apply to the NIH for a certificate. It's discretionary, so the NIH can choose whether or not to grant the certificate. It could take a few months. It seems like kind of a lengthy process.

And so, if the Committee was taking the existence or the nonexistence of COC into consideration, researchers that are funded by the NIH would have, you know, kind of a leg up in a way. And it might not be the best way of getting those privacy assurances that you're looking for.

So, we recommend that if you are looking for specific assurances that are part of these certifications, a better way to get those assurances would be through the privacy assurances that researchers are already required to submit to the Committee, rather than get a certificate.

So, if there's any like specific piece that you're looking for that is included in the certificate, we think a better vehicle for that would be part of your privacy assurances that you are already receiving.

Jared, did I miss anything? You have anything to

add?

MR. GOLDMAN: No, I think that's right on. And I think you could, without adopting a policy, you know, imposing a general -- a rule of general applicability, you look at each project that's presented to you on a case-by-case basis and request modifications to the assurances that are submitted to you to match the risks that are a part of the research project that's presented.

MS. SCHUSTER: Is there any questions about that?

COMMITTEE MEMBER AZIZIAN: Ask a clarification. I've been partially involved in the conversation about underground regulations. Would you mind defining that again, in a sense like how does -- like the basis of it?

MR. GOLDMAN: So, any rule of general application that is not just as your internal policy and procedure but is, you know, is going to impact the researchers who are applying for approval, if you've got a general rule of application for them, it has to be promulgated as a regulation.

This body has the authority to promulgate regulations.

COMMITTEE MEMBER AZIZIAN: Okay.

MR. GOLDMAN: It's a long and complex process and possibly a costly one, but it can be done. But usually what I would recommend, you know, for something like this where

you simply need to implement a particular assurance, you want something to be a part of someone's privacy plan it's better, I think, on a case-by-case basis without adopting a rule of general applicability, to just request what you need on a case-by-case basis.

An example of an underground regulation would be this body adopting a policy and procedure requiring a specific assurance across the board for -- for all projects. Something like that would need to promulgated in a regulation.

COMMITTEE MEMBER AZIZIAN: I'm sorry. If then something is considered to be an underground regulation, what are the consequences?

MR. GOLDMAN: Then it's unenforceable and someone could challenge it in the Office of Administrative Law.

COMMITTEE MEMBER LUND: So, for example, we might have, as reviewers, an application that we have concerns about because of the nature of the data being reviewed, and housed at a university that may be subject to pressure from the federal government to release those data, can we request as part of the application that the university assure that those data will not be released under any circumstances?

MR. GOLDMAN: I think you can include a condition that the information disclosed to the researcher won't be further disclosed except as required by law.

COMMITTEE MEMBER LUND: That required by law thing --

MR. GOLDMAN: I mean, you could -- yeah, you couldn't compel someone to refuse a lawful order to disclose information.

COMMITTEE MEMBER LUND: Yeah, this is what I'm concerned about. Because that's what the COC does, right, the COC prevents a subpoena, for example, from making the information available.

Okay, well, I think you've -- thank you for your review and I think you've answered the question. I just want to be on the record as having grave concerns about releasing data with personally identifiable information that also includes information about place of birth, if that is outside of this country, about women's reproductive health, which we have in a number of databases, and some other things that I believe are being targeted right now.

So, I think this is a conundrum for the Committee as to how to move forward without interfering with research, but with all due caution to protect that information of the people whose, you know, information we oversee.

MR. GOLDMAN: And I would encourage you to review projects on a case-by-case basis. And I'll give you just, you know, an extreme example of where I think it would be appropriate for you to step in.

Let's say, for example, you were reviewing a project that involved -- and I'm not saying this information exists or that even any department is hosting this information, or it could be disclosed. But let's say we had information about individuals who were coming to California from out of state and seeking abortions, and obtaining abortions in California, and then returning to their states of residence where abortions were illegal.

I think this body could decide in reviewing a project that they could limit the disclosure of the data or the use by researchers of that data. You could prohibit it from being taken and further developed or worked in the state where the abortion was illegal.

VICE CHAIR DICKEY: As I understand, there is no state law that specifies that IRBs need -- for issues of abortion data need to consider that. So, we're empowered by that state law.

But what about in the case where there's not a state law that empowers IRBs to do that?

MR. GOLDMAN: I think you could still consider the research project on a case-by-case basis. And I'll point out that the law that requires IRB review for the disclosure of abortion-related data is in the Confidentiality of Medical Information Act. And that act applies to providers, health plans, contractors, employers. So, there may be

individuals who are seeking disclosure information before this body that don't fit into t hose definitions.

VICE CHAIR DICKEY: Of research, yeah.

MR. GOLDMAN: Right.

VICE CHAIR DICKEY: Yeah, correct. But at least we have that state law. But are there any other state laws that might, or anything in the pipeline that might --

MR. GOLDMAN: Not that I'm aware of.

CHAIR HESS: Might --

COMMITTEE MEMBER LUND: My --

CHAIR HESS: Oh, go ahead. Go ahead.

COMMITTEE MEMBER LUND: I just have one more question.

CHAIR HESS: Uh-hum.

COMMITTEE MEMBER LUND: Might it be an option that we could request -- in the exact example that you gave, say it's a person from Georgia who's doing the research, might we request that they partner with someone at an institution in California so that the data could be used and accessed in California, and not sent out of state?

MR. GOLDMAN: I think there's really no limit on what you could -- I mean, I'm sure there are limits. But I think, you know, you have license to be creative in finding ways to protect individuals' information and to impose reasonable conditions on a research project which would

prevent, you know, what I would consider totally unacceptable outcomes. You know, for example, the release of information related to the abortion for the residents of a state where an abortion is illegal and where they are returning to that state. You wouldn't want that information following them back to that state.

COMMITTEE MEMBER LUND: All right, okay. Okay, it's good to know that we have some latitude here and that we can think outside the box a little bit in terms of solutions.

MR. GOLDMAN: And on really sensitive projects like that, I would really encourage you to -- individually, you should feel free to reach out to Maggie and I, and we can help you work through those really touchy ones.

COMMITTEE MEMBER LUND: Okay.

MR. GOLDMAN: And it's probably best that you do.

COMMITTEE MEMBER LUND: Sounds great, thank you.

VICE CHAIR DICKEY: And you'll defend us in court?

(Laughter)

MR. GOLDMAN: So long as you follow my advice.

(Laughter)

CHAIR HESS: I think another concern that came up, and I think we had discussed this before, is the release of datasets that contain that information, but may not be the subject of the researchers, like their focus.

So, I'm thinking, you know, medical records data, HCAI data that goes out, where abortion data is in the dataset, so is, you know, to some extent immigration-related data, but that's not the focus of the researcher. And we don't currently ask that HCAI, say, scrub the dataset to go out of any ICD-10 codes, or anything like that, that are related to reproductive care. Is that something that we could require, the limited datasets? It would be a big burden, I think, on the data owners but --

MR. GOLDMAN: Don't you already impose requirements for limited datasets?

COMMITTEE MEMBER LUND: It's in the IPA.

CHAIR HESS: It is, we can, but I don't think that -- it would be a matter of, say, with like emergency department data, HCAI basically doing a search of the appropriate ICD-10 codes and then removing records from the dataset with those associated codes.

VICE CHAIR DICKEY: But it's really an issue where it's there's identifiable data.

CHAIR HESS: Yeah.

VICE CHAIR DICKEY: So, HCAI has a lot of datasets that are not identifiable. But you're talking about when --

CHAIR HESS: I'm talking about when we're -- yeah, when it's identifiable data.

COMMITTEE MEMBER LUND: Like the Medi-Cal data

would have very specific codes related to reproductive health and PII.

CHAIR HESS: Yeah.

MR. GOLDMAN: And I think it's totally fair game for you to have a discussion or a negotiation with the researcher and to reach -- you know, they only need what they need, right. And they probably shouldn't be accessing information they don't need for the purpose of their research. So, I think it would be reasonable to limit the disclosure to the information which they actually need.

And I'd be surprised if you weren't already doing that in many cases. So.

VICE CHAIR DICKEY: We do that now, we're supposed to.

COMMITTEE MEMBER LUND: Yeah, we're supposed to.

CHAIR HESS: It's just harder, I think, with some datasets because it requires more data cleaning and data prep on behalf of the data owner.

DR. RYKACZEWSKA: Well, and I think the researcher provides the justification usually at the variable level, but not necessarily of the value of the variable.

CHAIR HESS: Yeah, exactly.

DR. RYKACZEWSKA: So, if they're requesting codes because they do have a reason to need some of the codes, but not necessarily all of the codes, is where I think they've

made the justification for the variable, but not necessarily for the -- like they really need only certain codes within that variable.

CHAIR HESS: Yes. Yeah.

DR. RYKACZEWSKA: And I think that's where it might be taking it a step further than our current practices.

CHAIR HESS: Yes. Which honestly, I mean state data Rs (phonetic) could push back on that and say they don't have the manpower to clean those -- to do that.

VICE CHAIR DICKEY: I think that state -- doesn't that state law say that the departments have a responsibility, also, it's not just us?

MR. GOLDMAN: Yeah. And we can have a conversation with the departments, too. So, it's --

CHAIR HESS: Okay.

MR. GOLDMAN: I don't think that's off the table.

COMMITTEE MEMBER LUND: I would think that they would be motivated to want to avoid disclosure because it's a liability for them as well.

CHAIR HESS: Yeah.

MR. GOLDMAN: The departments are feeling very sensitive right now about the disclosure of highly confidential information, so I think they'd be open to a conversation if you flag something.

CHAIR HESS: Okay. It's good to know, then, that we have -- we have some leeway, outside of a confidentiality certificate.

Does anyone on the board have additional comments or questions?

VICE CHAIR DICKEY: I just want to say on the confidentiality certificate, I looked into it regarding the project we're going to be discussing later with the HPD database. And NIH specifically states on the website that they will not give a certificate for databases. So.

And we have required, I think, at least we've said required when it's under the Common Rule where we've told people, well, you need to get a certificate of confidentiality. I don't know whether we can do that under the Common Rule. You're saying we can't do it under the IPA, but we've done it under the Common Rule.

MR. GOLDMAN: Yeah, I haven't explore whether -- sort of the boundaries of us doing that in your capacity as an IRB.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: So, from what you're saying, since it cannot apply at the level of the database, it would really only come up later on --

VICE CHAIR DICKEY: For individual projects.

COMMITTEE MEMBER SCHAEUBLE: -- for individual

projects.

VICE CHAIR DICKEY: Right.

CHAIR HESS: Any additional comments from remote board members?

DR. RYKACZEWSKA: I am not seeing anybody raise their hand or unmute.

CHAIR HESS: Any comment from members of the public on this matter?

DR. RYKACZEWSKA: If you have -- if you're participating remotely and have a comment, if you could just raise your hand, your virtual hand.

And Nick, do we have any comments in the room?

MR. BROWN: This is Francis, and I'm sitting here with Nick, who's stepped out for a second, there's no comments in the room.

DR. RYKACZEWSKA: Thank you, Francis.

CHAIR HESS: Thank you.

DR. RYKACZEWSKA: And I am not seeing any virtual hands.

CHAIR HESS: Okay. Are we ready to move on to projects?

COMMITTEE MEMBER LUND: And thank you very much for doing that for us, it's really appreciated.

CHAIR HESS: I didn't have my glasses on. First, we need to review and approve the meeting minutes. So, do I

have to ask for public comment first?

DR. RYKACZEWSKA: Uh-hum.

CHAIR HESS: Are any members of the public present with comments about the November 8, 2024 meeting minutes?

DR. RYKACZEWSKA: If you have any comments, please raise your virtual hand. And Francis, any public comments in the room?

MR. BROWN: No, ma'am.

DR. RYKACZEWSKA: Thank you. And I am not seeing any virtual hands.

CHAIR HESS: Okay, can I have a motion to approve the meeting minutes from November 8th, unless there's discussion?

VICE CHAIR DICKEY: So moved.

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: I'll second.

CHAIR HESS: Second. Okay.

MS. ATIFEH: Laura, you seconded?

COMMITTEE MEMBER LUND: Yes.

MS. ATIFEH: Okay. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Yes.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio? Dr. Palacio?

DR. RYKACZEWSKA: Dr. Palacio, if you said anything, we cannot hear you.

MS. ATIFEH: Okay. Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Okay, thank you.

So, I think we can move on to our first project, which is an adverse event, unanticipated problem. I believe we have the --

VICE CHAIR DICKEY: And I may be leaving --

CHAIR HESS: Okay. Do we need to state for the record that --

VICE CHAIR DICKEY: Yeah, we do.

DR. RYKACZEWSKA: Thank you.

CHAIR HESS: So, to state for the record, Dr. Dickey --

VICE CHAIR DICKEY: Conflict of interest.

CHAIR HESS: -- has a conflict of interest and

will be stepping out while we discuss this.

DR. RYKACZEWSKA: All right. And we do have Dr. Mahoney, Dr. Remy, and Dr. Okumura on the line.

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: Yeah, great. Thank you. Good morning, Drs. Mahoney, Okumura and Dr. Remy. I'm going to present the adverse event for the Committee and then I have some questions and would like you to address the adverse event. And then, we will open up to the Committee for discussion.

So, all of you have probably seen the adverse event report. It's very brief and somewhat incomplete. So, I'd like to fill everyone in more fully on the adverse event.

So, this is a long-standing research project. It was originally approved back in the '90s. So, it's been ongoing for many, many, many years. And it has birth data, with PII. So, one of the most sensitive and confidential datasets that's protected in statute. And those birth data are linked to other data as part of the work that the researchers have done on this project.

So, this project allowed their continuing review to expire. And, in fact, we reached out multiple times and got no response from the research team on the continuing review and the status of this project. And it wasn't until

the Committee admin, at my request and the chair's request, actually made a phone call to one of the research team that we were able to find out what was going on.

And what we found out is that the PIs had left the institution at which they were approved to have these data, and they did not report that to us or ask for an amendment. And the PIs had retained the data associated with this project, even though they had an expired project.

So, as a result of the fact-finding, and thank you, Agnieszka who did all of the leg work on making contact and so forth, we agreed -- because these data are actually very valuable data, this has been, as I said, a long-standing research project. So, the data were being stored on a standalone computer in the co-PI's home, which was not accessible to the internet and not accessible to anyone else, and it was actually my understanding it's shut down while it was in storage, so she was not accessing the data.

Those data were, by agreement with CDPH, moved from that PC to a secure network environment at UCSF which was the approved institution, so that we were very sure that those data were protected. We have worked -- yes?

DR. RYKACZEWSKA: Sorry, just a clarification. I believe my understanding is that the actual computer was physically moved to a secure UCSF storage facility.

COMMITTEE MEMBER LUND: Oh, okay.

DR. RYKACZEWSKA: Not put on the network.

COMMITTEE MEMBER LUND: Okay, thank you for that clarification. I trust Agnieszka on this.

So, anyway, I think that we were satisfied. And CDPH, again these are their data, were satisfied with the storage of the data until the remaining issues could be resolved.

We have told the Committee, with CDPH's agreement, told the investigators that they have to shut down this project and we'll need a closure report, and we're pending the closure report. We wanted to present all of this to the board to see if there was anything that the board wanted to be included in that closure report.

The institution, UCSF, does want to use these data and continue a project similar to the project that was being done by the original investigating team. So, they have identified someone who's willing to be a new principal investigator. And we have said that they can submit a new project application and go through the process of having that approved by CDPH and by this Committee in order to be able to reuse those data. And those stipulations will be in that new project's application.

But this project, for which we're reviewing an adverse event, will be closed.

So, I think that's the entirety. Agnieszka?

DR. RYKACZEWSKA: The only other thing that I would add was that in the meantime UCSF has submitted an updated continuing review application.

COMMITTEE MEMBER LUND: Oh, thank you.

DR. RYKACZEWSKA: Purely for the storage of the data in the meantime, while we resolve and transition to a new project, a new PI. So, they do have approval currently to store the data.

COMMITTEE MEMBER LUND: Thank you for that. So, just to make sure, the continuing review is time limiting. This project, regardless of anything else, will no longer exist after June 1st. That's the limit that we put on them to allow them time to resolve all of the standing issues. And at that time the data will either need to be transferred to the new project or destroyed per CDPH's requirements.

So, this has been a very concerning adverse event to me. I just want to say the -- the principal investigators have been out of compliance with their data use agreement with CDPH. They have not had an approved CPHS protocol and they've retained the data even though their project lapsed. And I believe they're out of compliance with state law, which does not allow unauthorized people to have access to the secure birth data. Which is actually, just to let you know the level of seriousness here, a potential misdemeanor under state law.

So, I'm really concerned. We, as a Committee, rely on researchers to follow the rules, to ensure that the data are safe. These data belong to the people from whom they were collected. State agencies are only allowed to release these data under very strict requirements in the law and we rely on researchers to follow that.

So, having said that, I would like to turn to the research team. Dr. Remy, I believe, asked for the protocol to be distributed so that you would see that the data, when this protocol was approved the data were being stored in a way that was approved under the protocol. So they were, "really safe." And I think that's great, thank goodness they were really safe.

My concern is that they shouldn't have been stored at all. So, I'll just put that out there.

So, I'm wondering if the research team could talk a little bit about how this happened and why it happened, and any information that the Committee should know about this adverse event.

DR. REMY: Hello. This is Dr. Remy speaking.

DR. RYKACZEWSKA: Hi, Dr. Remy.

DR. REMY: Can you hear me?

DR. RYKACZEWSKA: Yes, we can hear you.

DR. REMY: Hi. It's important for you to know that the reason that we had to move, that we had to put the

data on my -- on the computer that I used, which was encrypted, and everything, as it said in the documents that I sent you, is that the contract with the State of California had ended and we had to download the data from the server at the University of California in order to protect it.

And so, it has been on my computer until we hired a number of programmers, and then when the programmers were gone we had no money to keep it back on the server. So, I moved it back down to my very, very highly protected computer. And then, I closed up the computer and stopped.

And so, I stay -- I had to buy a new computer because we were no longer on the server. So, I have now a different computer. I had to buy a different computer. I had to stop using the one that had the confidential data on it. But it was important to protect it. The computer was never used after the data was downloaded from the UCSF server to -- back to this computer where it had always been before we had so many programmers working with us.

So, it was always approved to be on my computer. And then, for a few years it was also on the server at UCSF and I moved it back. And if I did anything that was wrong, it was really not my intention. And I certainly did not mean to put this data in any risk because I think it's a national treasure and needs to be protected and used.

And so, I'm sorry if I did anything wrong. It was certainly not my intention.

COMMITTEE MEMBER KURTURAL: One thing that I'm confused about is how long was this downloaded on -- did she have this on her laptop?

DR. RYKACZEWSKA: It was a standalone computer, not a laptop.

DR. REMY: It was never -- it was never on a laptop.

COMMITTEE MEMBER KURTURAL: All right, okay, a standalone computer.

How long was it on your -- how long did you have the data on your standalone desktop?

DR. REMY: For about -- it took me about a week and a half to download all the data from the server, and then I closed it up and that was it.

DR. RYKACZEWSKA: But how long was it on -- on the computer after you downloaded it, I think is the question.

COMMITTEE MEMBER KURTURAL: Yes.

DR. REMY: Well, it's from -- from, say, I downloaded it in -- at the end of August. So, from let's say the end of August forward.

COMMITTEE MEMBER KURTURAL: 2024.

DR. REMY: But it was not here at my office, it was at UC.

COMMITTEE MEMBER KURTURAL: What year was that? Last August?

DR. REMY: 2024, yeah.

COMMITTEE MEMBER KURTURAL: Okay. Thank you.

COMMITTEE MEMBER VENTURA: And Dr. Remy, can you please clarify, so programmers, you mentioned programmers accessing the data.

DR. REMY: When it was on the server, yes.

COMMITTEE MEMBER VENTURA: And were they approved on your protocol?

DR. REMY: Yes. Yes, they were approved.

COMMITTEE MEMBER VENTURA: Those individuals, each one was on the protocol?

DR. RYKACZEWSKA: As part of the research team?

DR. REMY: Yes.

COMMITTEE MEMBER LUND: But I will note that the protocol was expired at that time. So --

DR. REMY: It was, but we -- nobody was working on it. They were gone.

COMMITTEE MEMBER LUND: -- no one should have been touching the data all.

DR. REMY: As of June 30th they were gone. Everybody was gone except for me and Jennifer.

COMMITTEE MEMBER LUND: Right. And your protocol was expired, so no one should have been touching in the

data, including you and --

DR. REMY: All I did, I wanted to save it, so I downloaded it from the server back onto my computer.

COMMITTEE MEMBER LUND: So, Dr. --

DR. REMY: Nobody used it in any way.

COMMITTEE MEMBER LUND: Yeah, so Dr. Remy, I think my concern and perhaps the concern of Committee members, is your statement that you wanted to save it. If you did not have a valid protocol with CPHS, you were out of compliance both with CPHS and with your data use agreement with CDPH because that is based on the fact that there is an approved CPHS protocol in place.

So, when you say you wanted to save the data, yes, I understand how important these data are, but you were even out of compliance with state law. Why did you not report this situation to CDPH and to CPHS?

DR. REMY: I didn't know that. I thought that what we were doing -- and Jennifer and I were looking to find a new principal investigator to take over because both Jennifer and I had to retire. And so, we were looking for a new PI, which we fortunately had found.

COMMITTEE MEMBER LUND: So, CPHS sent you multiple requests to find out what the status of this project was in regard to your continuing review, and then I believe last August we sent a letter saying, we haven't heard from you,

what's the status of this project. And we didn't get any responses to any of those communications. Why not?

DR. REMY: I didn't have any -- any UCSF email.

DR. RYKACZEWSKA: And we only had the UCSF email contact as part of the information that was submitted as part of the protocol.

COMMITTEE MEMBER LUND: Okay.

CHAIR HESS: Did those emails also go to the responsible official?

DR. RYKACZEWSKA: They did.

CHAIR HESS: Who was, presumably, still at UC?

DR. RYKACZEWSKA: I believe so. Dr. Mahoney, can you confirm that you were at UCSF last August?

DR. REMY: Dr. Mahoney?

DR. MAHONEY: Yeah, I'm on. Yeah, no, I actually can't confirm that I received an email back in August. I started receiving emails this year. I was the -- on record, I suppose the responsible official back in August, but I don't recall receiving any emails related to this matter until this year.

COMMITTEE MEMBER KURTURAL: Has anyone reported this to the University of San Francisco's IT team, to the CISO?

COMMITTEE MEMBER LUND: No, that could be a suggestion that comes out of this meeting. So, no further

action has been taken at this time. This body can decide what action or sanctions should be taken. I am like really concerned about, you know, the situation. And I don't know if these researchers have other projects with us, but I'm very concerned about their attitude towards the data and towards the rules.

DR. REMY: Hello?

COMMITTEE MEMBER LUND: Yeah, we're -- we're waiting for I believe Agnieszka's looking something up.

DR. RYKACZEWSKA: Yeah, I'm trying to look back at the email communication. Can you just give me a few minutes?

COMMITTEE MEMBER LUND: Yeah. So are there any other questions or comments from board members?

COMMITTEE MEMBER VENTURA: One of my concerns, once it's downloaded to a PC that is not secure, even though --

DR. REMY: It is -- it was secure.

COMMITTEE MEMBER VENTURA: We have no way of verifying that. It's not on a secure network. And so, you say it was downloaded to your personal PC, but we don't know if anyone -- we can't track --

DR. REMY: It was not my personal PC. It was not my personal PC. The computer belongs to University of California.

COMMITTEE MEMBER VENTURA: But even so, if there are no login requirements to access that PC and no system in place where we can see who might potentially access it -- I mean, you're telling us it was shut down and in storage, but we just have no way of verifying if it was ever accessed by anyone --

DR. REMY: It was never accessed by anyone. It has two passwords to log on to it. It required two passwords. And it was in my office, that no one ever came in. And when I left the house, the computer was always turned off. And no one ever got into the house except me and my husband and, well, you know, when we had company. But nobody ever, ever worked on my computer except me. And it was not -- it was not "my personal computer", it belonged to the University of California, San Francisco.

COMMITTEE MEMBER AZIZIAN: Yeah, in addition to the compliance problems, I wonder if the researchers also see breach of confidentiality of the data with the programmers who later on, that there was no approval, they were transferring the data. I mean, do you see that as a breach of confidentiality?

DR. REMY: No. There weren't -- I was the programmer that was -- that was transferring the data. No one else, except me, transferred it. We had no programmers left when I did it. No other programmers transferred the

data. Only me.

COMMITTEE MEMBER LUND: So, Agnieszka's still looking something up. We're on pause for a moment, while she --

DR. RYKACZEWSKA: Sorry.

COMMITTEE MEMBER LUND: It's okay. It's okay, this is important.

COMMITTEE MEMBER VENTURA: I have another question, Dr. Remy. Was -- did you get UCSF approval to download it to the UCSF PC or did you -- let me just -- yeah, did you get UCSF approval to do that?

DR. REMY: Well, Jennifer and I had talked about it and we thought it was the thing to do.

COMMITTEE MEMBER VENTURA: But no UCSF official approval to download the data and store it on the UCSF PC?

DR. REMY: Well, no. No, no one other -- we had never really spoken about the data with anybody except me and Jennifer. I mean, and the programmers that I supervised, but they were gone. We didn't have any other programmers. There's was nobody to talk about it. And it was to get it off and to save it. And the university had even disconnected me -- once I downloaded, I was disconnected from UCSF, so there was no way that anybody at UCSF could ever look at the data again. And that was why we tried to -- you know, we finally found someplace to take it

and we're happy that it's in a safe place.

DR. RYKACZEWSKA: I would like to confirm that the email that was sent from CPHS on August 8, 2024 did include Dr. Mahoney, informing the research team that the CPHS statement for birth and death data, and that related to that, and in that statement we do note that they have to renew their annual approval.

Additionally, we sent another email that also included Dr. Mahoney, in October, letting the researchers know, again, that their approval was expired, that all research activities associated with the project were required to cease immediately upon expiration. And that to ensure compliance they needed to submit their continuing review. Well, first stop all research activities and submit a continuing review. And we gave them deadlines to do that.

So, Dr. Mahoney, you did receive those emails. I see on the records that you were listed as part of the "to" line.

DR. MAHONEY: Well, thank you for looking at it. But I also just wanted to express my appreciation for the staff. Everybody has had to go above and beyond to address this matter and I really regret that.

From the perspective of receiving those emails as a department chair, we have over a hundred faculty who are all conducting research and I receive -- I'm copied on a

number of notices that I briefly look at. And the thought process that I go through is, is there an active PI who is going to be able to respond to this. And at that time there were both Dr. Remy and Dr. Rienks were working at UCSF. Well, at least I know that Dr. Rienks was. And so, I largely just assumed that she would take care of the matter. And I regret all of the additional, yeah, just administrative support that you had to provide. Especially me, as chair, who is very distant from the specifics, and I have appreciated being able to kind of be brought in and support as much as I can. Thank you.

COMMITTEE MEMBER LUND: So, if the responsible official isn't responsible, who is?

DR. MAHONEY: No, I absolutely agree that at that point, especially after the second one, you know just looking back, that would have been a time to, you know, kind of bring the team together.

I will note that Dr. Rienks has experienced a significant personal issue in her life and then, you know, just trying to take that into account there were delays in being able to respond, you know, rapidly to this matter given the very significant personal issue that she is going through even currently. So that -- so, that probably affected the communications.

But again, I agree that ultimately somebody -- the

buck needs to stop with somebody and this was an unfortunate outcome of what ended up being a constellation of missteps, it turns out.

COMMITTEE MEMBER KURTURAL: Well, I think someone needs to be alerted at UC to conduct some sort of a fact gathering investigation, and determine if there was a breach and whether notices have to be sent out.

COMMITTEE MEMBER VENTURA: I agree.

COMMITTEE MEMBER KURTURAL: And if you haven't done it yet, you need to do it like immediately.

COMMITTEE MEMBER VENTURA: Right. With other breaches of confidentiality researchers have to notify individuals whose data might have been compromised. And I think that's the right -- especially because so many protocols was not followed. One, downloading the data, that should have never happened without official approval or just, I mean it was expired so it should have just been shut down.

COMMITTEE MEMBER KURTURAL: And there's no (indiscernible) access, you know, controls when you -- even assuming you had approval there's nothing, there's no sort of rule-based access approval to that computer. We just have no idea without more facts.

COMMITTEE MEMBER LUND: So, we probably need to request an audit of access to the data and what happened

during the download. Because it sounds to me like the download wasn't even done in an encrypted, secured way.

COMMITTEE MEMBER KURTURAL: That could be a problem.

COMMITTEE MEMBER LUND: So, yeah, I would think that at a minimum --

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER LUND: -- we could request that from the university.

COMMITTEE MEMBER KURTURAL: Yeah, we need to -- that's why their IT team needs to be alerted, IT security team.

COMMITTEE MEMBER LUND: Uh-hum. Okay, are there any other suggestions? I'm at a loss. I mean, frankly, I think this is huge. And I don't have a suggestion about how to make this right. So, I'm open to other suggestions from the Committee about next steps.

DR. RYKACZEWSKA: If it's helpful to know, we also have Dr. Okumura, who has been identified as -- should this work continue, as the new PI, on the line in case there's anything in terms of the new project application that we would want to note, as well. Just noting that, as well.

COMMITTEE MEMBER VENTURA: Well, I wonder similar to notifying UCSF IT security, has CDPH also been, yes, notified?

COMMITTEE MEMBER LUND: They have worked with us closely on a lot of the resolutions that we've talked about here.

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LUND: They're aware of the situation. They gave their permission to store this security at UCSF for the time being until we can come up with a solution for the next project.

COMMITTEE MEMBER VENTURA: Okay. So, for now, no one's supposed to be accessing the data.

COMMITTEE MEMBER LUND: Correct.

COMMITTEE MEMBER VENTURA: It's just being stored securely.

COMMITTEE MEMBER LUND: Correct. And that's like in all caps, continuing review approval.

COMMITTEE MEMBER KURTURAL: Yeah, UC has the obligation to take the reins --

COMMITTEE MEMBER LUND: I agree with that.

COMMITTEE MEMBER KURTURAL: -- and do their investigation and provide substitute notice on the website, as well as mailing out notices.

COMMITTEE MEMBER LUND: Yeah, so, and a report back to us on that.

COMMITTEE MEMBER KURTURAL: Uh-hum.

COMMITTEE MEMBER LUND: Yes. And I will say in

regard to the new project application, because this was approved so long ago laws have changed, and certainly security requirements have changed. So, I would expect that the new application would be in some places some -- fairly different from what the originally approved project was.

And that, as we always do, we'll work with CDPH VSAC on the approval, because they're the ones who are really up on their current laws.

Some of the data that they may have, we'll have to see what they propose in the new project application, because it's been so long and because laws have changed may not be allowable under new statutes. And we'll have to work with CDPH on that. So, I'm not sure. We would certainly require some of the security protocols that were approved for that -- the existing application would not have been approved, you know, currently. The world has changed dramatically over the time period of this study.

It's one of the things that I'm concerned about with, you know, every time we have one of these legacy projects that comes up we do find that there can be problems in regard to security and in regard to law change. And you guys know that I -- that's one of my soapboxes that I will not get up on at this moment.

So, and I believe Dr. Remy said that she's retired. Dr. Remy, do you have any other outstanding

research projects that are open with this Committee?

DR. REMY: No.

COMMITTEE MEMBER LUND: Okay. Does Dr. Rienks?

DR. REMY: No.

COMMITTEE MEMBER LUND: Okay. So, and of course we have projects with UCSF, which is I think in light of your suggestion, Ms. Kurtural, especially import that they be aware that there was a problem with this one so that they can be vigilant. And we would ask them to be vigilant about any other projects.

Are there any other suggestions as part of this adverse vent that the Committee would like to make?

COMMITTEE MEMBER DINIS: More of a question on my part. But I will say that they do the investigation and they find there was no breaches of confidentiality, no breach of confidentiality, then what do we do from there?

COMMITTEE MEMBER LUND: I'm not sure there's anything we can do.

COMMITTEE MEMBER DINIS: Okay, yeah. That's what I would say.

COMMITTEE MEMBER LUND: You know I mean --

COMMITTEE MEMBER DINIS: I mean, hopefully, there isn't, right, you know.

COMMITTEE MEMBER LUND: Right, yeah. No, let's hope. I mean, you know, if these investigators still had

open projects with us, I would seriously request that the Committee reexamine those. But since they don't, that's a moot point. So, I don't think there's anything else, Dr. Dinis.

COMMITTEE MEMBER DINIS: Okay.

COMMITTEE MEMBER LUND: Okay, are we ready for a motion? Public comment?

CHAIR HESS: Yes. Are there any -- first of all, are there any last comments from the Board. Any of our remotely attending board?

If not, then are there any comments from members of the public, either in person or online?

MR. ZADROZNA: No comments in person.

CHAIR HESS: Thank you.

DR. RYKACZEWSKA: Thank you, Nick. And I am not seeing any hands, any virtual hands being raised. But I'm just going to give it one more moment here. No virtual hands raised.

CHAIR HESS: Okay. Do we have a motion?

COMMITTEE MEMBER LUND: Yeah. I'm reading my notes.

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: So, I think my motion is the Committee accepts the adverse event report. The Committee will alert someone at UC -- I'm going to say the

head of UCSF IT department.

COMMITTEE MEMBER KURTURAL: How about the information -- the chief information security officer.

COMMITTEE MEMBER LUND: Chief information security officer. Thank you. All right, so CPHS will alert the chief information security officer at UCSF, will describe the problem to them, and will ask them to determine if there was any --

COMMITTEE MEMBER KURTURAL: To commence an investigation.

COMMITTEE MEMBER KURTURAL: To commence an investigation to determine if there was a security breach.

COMMITTEE MEMBER KURTURAL: Correct.

COMMITTEE MEMBER LUND: And if any data were exposed, any personally identifying data were exposed. To take action necessary, if data were exposed, to send notices. And to report back to CPHS and CDPH on their findings.

And yes, please, modify as necessary.

COMMITTEE MEMBER KURTURAL: I would say -- instead of saying to take action necessary, I would say to take action to report -- to notice -- hold on -- to notice individuals affected and report the incident to any -- to the federal and state authorities, as required by law.

COMMITTEE MEMBER LUND: Thank you.

DR. RYKACZEWSKA: Okay, I'm just making sure that this is correct. You said instead of to take action --

COMMITTEE MEMBER KURTURAL: Uh-huh, to take action to notice --

DR. RYKACZEWSKA: To take action to notice, okay.

COMMITTEE MEMBER LUND: That sounds like a specific legal term.

MS. ATIFEH: To notice to individual --

COMMITTEE MEMBER LUND: I would keep the report, Agnieszka, but to report back to CDPH and CPHS, I think.

COMMITTEE MEMBER KURTURAL: Yeah, that's a good idea. I would do that.

MS. ATIFEH: And there is a "to" before individual.

DR. RYKACZEWSKA: Notice individuals, or should there be a "to" there.

COMMITTEE MEMBER KURTURAL: Oh, yeah.

DR. RYKACZEWSKA: I think we'll let this sit for a moment.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER LUND: Okay, that looks good to me.

COMMITTEE MEMBER KURTURAL: Okay.

CHAIR HESS: Who second?

COMMITTEE MEMBER KURTURAL: Oh, I'll second.

CHAIR HESS: Oh, and do we have any sort of timeline in there?

COMMITTEE MEMBER LUND: Oh, a timeline.

CHAIR HESS: So, they're continuing review runs out on June 1st.

COMMITTEE MEMBER LUND: Right. I think this is independent of the continuing review, yeah.

CHAIR HESS: Okay. Okay.

COMMITTEE MEMBER LUND: Yeah. Yeah.

COMMITTEE MEMBER KURTURAL: Yeah. Well, notice needs to be provided to the security officer relatively immediately.

COMMITTEE MEMBER LUND: Okay.

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: Do you want to say immediately?

COMMITTEE MEMBER KURTURAL: Yeah.

CHAIR HESS: Yeah.

COMMITTEE MEMBER LUND: Okay. Immediately. Before or after, I don't care about the (indiscernible) --

Okay.

MS. ATIFEH: Okay, so roll call?

CHAIR HESS: Okay, we have a motion. Is there a second.

MS. ATIFEH: Yes, Ms. Kurtural.

COMMITTEE MEMBER KURTURAL: I'll second.

MS. ATIFEH: Okay, I will start with Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Right, approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Okay. Thank you to the researchers for speaking with us today. You should be receiving an official letter pertaining to this adverse event from the board. Please reach out to us if you have any questions or if there's any clarifications needed.

COMMITTEE MEMBER LUND: Could we get the correct contact information for Drs. Remy and Rienks?

DR. RYKACZEWSKA: I do have that now.

CHAIR HESS: We have that, yeah. So, we will be

in touch. Thank you.

DR. MAHONEY: Thank you.

DR. REMY: Thank you.

CHAIR HESS: Okay. Next we -- Dr. Dickey, we need to bring Dr. Dickey back, because the next one's his project.

For the record, Dr. Dickey has rejoined the meeting. And, Dr. Dickey, your amendment project is up next.

VICE CHAIR DICKEY: Right. I'll be right there.

CHAIR HESS: Yep. Do we have the researchers on?

DR. RYKACZEWSKA: Dr. Wellner is on the line.

CHAIR HESS: Okay. So, we have Dr. Wellner on the line. Is that the only member of the research team who will be joining?

Oh, we've got -- okay, we have Dr. Modjeski as well.

DR. MODJESKI: Yes, Denise Modjeski. I'm the project manager here on this study and several other studies. I'm at USC.

THE REPORTER: Can we get her volume turned up.

DR. MODJESKI: (Indiscernible) -- from Michigan.

CHAIR HESS: Welcome. And Dr. Dickey, do you want to --

VICE CHAIR DICKEY: Yeah. So, this is an

amendment and I really didn't have --

CHAIR HESS: Oh, the volume.

VICE CHAIR DICKEY: I didn't really have any real concerns about it. It's just that it's an example of where they're adding another arm, another intervention of the survey. And rather than just approve that on myself, alone, I thought we should get in the habit of hearing these things with the Committee.

So, could you go ahead and describe the -- actually, first, describe the existing project and then how the amendment changes it.

DR. WELLNER: Sure, I'm happy to. Thank you so much for the invitation to come today. So, we have a R37 grant from NCI that is funding the project. So, based on understanding surveillance needs and survivorship care needs of patients diagnosed with early onset colorectal cancer. So, that's patients younger than 50 years at diagnosis.

And so, we're partnering with three SEER Cancer Registry sites (indiscernible) one of them. And we are using both SEER Cancer Registry data to understanding to understand patients' risk of recurrence. But then, also doing a survey of 3,000 patients with early onset colorectal patients to understand their care needs across a number of different domains.

THE REPORTER: I'm sorry, could you turn --

DR. WELLNER: Then we're going to fuse all that information together to create recommendations for risk stratified survivorship care pathways. And so, this approval today for you is a supplement that was funded off that grant, which is adding a survey for the patients' primary care supporter.

And so, what we want to do is be able to augment our recommended care pathways to both (indiscernible) patients and their care supporters. Because, you know, there's literature in other cancers that suggest that these care supporters have a lot of supportive care needs, but we really know very little about the care needs both of the patients, the younger patients with colorectal cancer, but also their care supporters. And so, we're proposing to add a care supporter survey.

And so, let me stop there and see what other questions you have.

VICE CHAIR DICKEY: I guess I could say how are the care supporters identified?

DR. WELLNER: So, we are -- so, as I mentioned, we're surveying 3,000 patients. And on the patient survey we ask them if they have a primary care supporter and their relationship to that care supporter. And so, of those respondents who say they do have a care supporter, we're

going to sample a total of 800 across sites, only 300 in Los Angeles. To then send through the patient a packet with a survey for their care supporter.

VICE CHAIR DICKEY: So, this, the subjects are identified by your existing subjects.

DR. WELLNER: Yes.

VICE CHAIR DICKEY: And they're actually involved in the process of giving them the surveys.

DR. WELLNER: Absolutely, yeah. Because we don't know who the care supporters are, we don't have their contact information. We have to work through the patients, who've already participated in the patient survey, to have them pass off the surveys to their care supporter, or send us a contact information of the care supporter and we can mail it directly if they don't live them. And so, we've used this method in other studies we've done of care supporters in older cancer patients in different cancer sites. And so, it works quite well. And so, we're proposing to do that here.

VICE CHAIR DICKEY: And can you tell us about any informed consent issues.

DR. WELLNER: So, I don't expect any informed consent issues. We're going to to, you know, ask for a waiver of informed consent, considering the completed survey to be consent.

The aim two of this proposal is also -- or protocol, excuse me, is also proposing to interview 15 care supporters and 15 patients to understanding more about their barriers to accessing these survivorship and supportive care services. And so, we'll be sampling amongst those who respond to the patient survey in the parent study or the care supporter survey, and we'll obtain verbal consent for those interviews at the time of the interview.

VICE CHAIR DICKEY: So, I can't remember, did you provide the script for the interviews?

DR. WELLNER: I'm not sure. Denise, do you recall if we gave the interview?

DR. MODJESKI: We did not. So, that is something that we could add, if you would like that.

VICE CHAIR DICKEY: Yeah, I think before we approve that part of it, we would need to see the interview guide.

DR. WELLNER: Okay, yeah, no problem, we have a draft of that.

VICE CHAIR DICKEY: And the type of questions you're asking in the survey are -- are they very personal, are they --

DR. WELLNER: You know, we're really asking them about their access to supportive care services. And understanding unmet needs across a number of domains,

similar to what we are -- the same domains that we're asking about in the patient survey, which has already been approved.

So, you know, there's -- I think, you know, there's some questions about mental health. But, you know, we have plans in place and there's clear guidance given to the participants that they do not have to answer. And everything's voluntary to answer. They do not have to answer any questions they don't feel comfortable answering, et cetera.

VICE CHAIR DICKEY: Right. Okay, I've looked at the survey. I thought it was okay. But I don't have any other concerns, other than about the interviews. Se need that script. But open it up to the Committee for questions.

Seeing no questions -- do we need to ask for public comment?

CHAIR HESS: Yes.

DR. RYKACZEWSKA: Well, first, are there any questions from the virtual Committee members? Just making sure I didn't miss anything.

I am not seeing any comments from the virtual Committee members.

CHAIR HESS: Okay.

COMMITTEE MEMBER SCHAEUBLE: Well, Dr. Dickey, I might add a script for the interviews and they mentioned

verbal consent for those interviews as well. So, it seems like we should see both of those at the same time.

VICE CHAIR DICKEY: Right, sure. Okay.

CHAIR HESS: Okay. Any comments from members of the public who are present, either remotely or in person?

DR. RYKACZEWSKA: I am not seeing any virtual hands. Nick or Francis, anybody in the room?

MR. ZADROZNA: No public comments in person.

DR. RYKACZEWSKA: Okay.

CHAIR HESS: Okay. Dr. Dickey, would you like to make a motion?

VICE CHAIR DICKEY: I would. I'd like to move approval of the amendment -- well, deferred approval of the amendment contingent upon submission of the interview guide and the consent script for the interviews to be reviewed by a subcommittee of myself, if that's okay.

And that's it.

CHAIR HESS: Is there a second?

COMMITTEE MEMBER JOHNSON: I will second.

CHAIR HESS: Dr. Johnson. All right.

MS. ATIFEH: Okay, I start with Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approved.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, motion passed.

VICE CHAIR DICKEY: So, thank you for coming to us. And you'll receive a letter regarding this, but feel free in the meantime to -- I guess they'll get their amendment back through system and then they can submit the --

CHAIR HESS: Yeah, yeah.

DR. WELLNER: Thank you.

CHAIR HESS: Thank you.

DR. MODJESKI: Thank you.

CHAIR HESS: Okay. Moving on, we have -- Ms. Lund, do you have an amendment?

COMMITTEE MEMBER LUND: Yes.

CHAIR HESS: Let's see, we have Dr. Miller, it

looks like.

COMMITTEE MEMBER LUND: Oh, I think we're ahead.

CHAIR HESS: We are a little ahead of schedule, I think. Welcome Dr. Miller. Ms. Lund, do you want to --

COMMITTEE MEMBER LUND: Yeah, thank you. Good morning, Dr. Miller, thank you for being with us today.

DR. MILLER: Thank you, Ms. Lund.

COMMITTEE MEMBER LUND: Yeah, so for the Committee, this is an amendment for a project that we've previously approved. The Committee is seeing this amendment at full board because there were significant changes to portions of the study that involve direct interaction with human subjects, the questionnaires, the consent form, recruitment materials, and so forth.

So, I've reviewed this and I had questions, which Dr. Miller and her team have responded to. So, I'm wondering, Dr. Miller, if you would just describe the amendment for the Committee.

DR. MILLER: Yeah, absolutely. Thank you all so much. So, first of all this is a National Cancer Institute funded randomized controlled intervention. We're trying to determine the efficacy of an intervention to improve self-management of survivorship care among 300 young adult survivors of childhood cancer.

So, this is being conducted at two sites, both at

Rutgers and using recruitment through the New Jersey State Cancer Registry, and the -- at USC, in L.A., through the Los Angeles Cancer Surveillance Program and the California Cancer Registry.

So, I am the site PI at USC. And so, what this amendment does is we first of all are making a few changes in personnel. One of our COIs retired, we've added a new one.

We have added measures to our participant surveys. We make revisions and edits to the participants' eligibility screener that we are using to identify who is eligible to move forward to be recruited to the study. And we make revisions, as well, to the informed consent.

Those edits are to harmonize it with USC's standards and form for the informed consent form. And we've also made some edits to some participant-facing materials, such as the recruitment flyer. I believe that was previously approved. And we've added a participant's website.

And I think that is it. Thanks.

COMMITTEE MEMBER LUND: Great, thank you. So, my -- when I reviewed your amendment request, the only thing that popped up for me, and I'm wondering if you would discuss it for the Committee, is that you've added a lot of questions the questionnaires. And at first, those did not

seem to be related to the stated goals of your study. So, I'm wondering, especially use of cannabis, mammography screening, ECGs. So, I'm wondering if you would speak to why those are in there and how they're related to your intervention that you're trying to evaluate.

DR. MILLER: Yeah, absolutely. Thank you. I realize we probably should have provided more context, so I appreciate your question.

So, those health behavior and preventive screening questions really derive from the intervention itself. Because what we're trying to accomplish is to help young adult cancer survivors engage in ongoing cancer-focused survivorship care with their doctors.

And through that care they receive counseling that can be anything from, you know, medical issues all the way to lifestyle behaviors. That's an important part of counseling that childhood cancer survivors receive.

So, in our intervention, which is a six module online -- like an app. The sixth one goes over lifestyle things such as, you know, smoking, use of substances to try to help counsel, you know, these young adult cancer survivors to make healthy choices regarding, your know, they're preventive screening behaviors, their lifestyle behaviors.

So, that is why we're asking those questions.

It's really to understand. It's not to, you know, just understand what they're doing in their sort of usual course of, you know, their daily activities. It's more to see, you know, what they're learning about healthy lifestyles and the need for preventative screenings through the intervention.

COMMITTEE MEMBER LUND: Great, thank you. And I did want to ask you a little bit about the consent form changes. And what I just heard you say in your remarks is that you have aligned the consent form with what is common practice for the USC IRB.

And this is always an issue for us when we have to work with two IRBs because we don't want to ping pong researchers back and forth, you know, because -- and the USC IRB is responsible for the study as well.

So, I just have a couple questions, if maybe you could speak to the board. You removed the bullet points at the beginning. And it's kind of standard practice, especially the guidance from OHRP is to provide something at the beginning of the consent form that very clearly states, you know, what the -- what the participant could expect, and then you get into the details in the body of the consent. So, I'm wondering why you removed the bullets, if you could just speak to that.

DR. MILLER: Sure, yeah. I'm looking at the consent form right now. And I believe that what we have

done, instead, is to -- let's see. Yeah, I mean, honestly, Ms. Lund, I think the reason we did that was because of the issue with the, you know, standard consent form for USC, to harmonize it with the way that informed consents are typically done at USC.

And so, I'm trying to see if we have -- I think we do give, obviously, the bill of rights. But, yeah, we could restore that. I don't think USC prohibits us from doing that. It's just that they have standardized -- they have a standardized form that we've harmonized it with.

COMMITTEE MEMBER LUND: Yeah, I'm just --

DR. MILLER: USC has ceded to CPHS, so --

COMMITTEE MEMBER LUND: Okay. So, I'm just -- from the perspective of the participants who are reading and trying to understand the consent form, the consent form is a little long, right, so there's a lot of information.

And I do think that it's helpful at the very beginning if they just have a very quick like, you know, here are the things I need to be concerned about with the study and then more detail to follow.

If you would be willing to restore that, I personally think it would be helpful, if others on the Committee agree.

DR. MILLER: Yeah. You know, it's interesting. I have to double check with them. I'm looking at the no

markup and I think -- oh, yeah, no, it does take it away. Yeah. No, we can certainly restore those. That is not an issue at all.

COMMITTEE MEMBER LUND: Great.

DR. MILLER: And honestly, I don't -- you know, I don't really have a better explanation for taking this away, besides the fact that I think we were just, again, adopting USC's form. But we have ceded to CPHS, so those could be restored.

COMMITTEE MEMBER LUND: Okay, great. Thank you. And the reading level seems just a little high with the revision. Have you checked the reading level?

DR. MILLER: We have checked the reading level and I think it is a little bit high. I think it's at the 10th grade reading level.

COMMITTEE MEMBER LUND: Uh-hum.

DR. MILLER: You know, one of the -- obviously, the issues we have is with the randomized controlled trial, and the randomization, you know, that we are having to put a lot of this information in. But I do believe we did check it through the Flesch test and I believe it's at the 10th grade reading level.

COMMITTEE MEMBER LUND: Okay. All right, thank you.

Other Committee members comments, questions?

COMMITTEE MEMBER SCHAEUBLE: Laura? I don't remember, Laura, was there a third comment that I sent you or --

COMMITTEE MEMBER LUND: About the data use. Do you want to talk about that?

COMMITTEE MEMBER SCHAEUBLE: I don't have notes in front of me to do it.

COMMITTEE MEMBER LUND: Okay. So, Dr. Schaeuble had a comment. And he doesn't have his notes. So, if you don't mind, I will pass his comment on.

"I'm always concerned about future use of data, described at the bottom of page 5 of the consent form, especially given the length of the form."

He would like to request that the following phrases be emphasized in bold, or underlined, or all capped, some way of emphasizing the phrases.

The phrase, "without obtaining additional informed consent from you."

The phrase, "we plan to keep your data and/or biospecimens indefinitely."

And the phrase, if you are not comfortable with this, you should not participate in this study."

Do you think it would be possible for you to emphasize those three points in the form?

DR. MILLER: Yes, absolutely. So, just one

question. Yeah, that's fine. Will you all give the notes to us back from that?

COMMITTEE MEMBER LUND: Yes.

DR. MILLER: Because I just want to make sure I'm capturing that accurately. We certainly can highlight or bold those phrases.

COMMITTEE MEMBER LUND: Absolutely. We can give you the specific phrases. You don't have to take good notes here.

DR. MILLER: Okay, great. Just to make sure.

COMMITTEE MEMBER SCHAEUBLE: That would be much appreciated.

DR. MILLER: Yeah, and that -- yeah, no, no problem. To address that, I will just say the primary reason for that due to the funding from National Cancer Institute, which requires this in terms of childhood cancer. So, that's -- those -- that language comes from the requirements of NIH.

COMMITTEE MEMBER LUND: Thank you for that.

COMMITTEE MEMBER SCHAEUBLE: I think the reviewers here understand those circumstances. But the consent form is quite long and those particular points seem to be especially salient for what participants might be concerned about. And that was the reason for asking you to provide some emphasis about them.

DR. MILLER: Yeah, we certainly can. Thank you. I think that's a good idea.

CHAIR HESS: Yes?

VICE CHAIR DICKEY: I just want to say, in terms of the bullets at the start, I think maybe -- what would you say if the USC IRB said no. I mean, could we make that a recommendation as opposed to a requirement.

COMMITTEE MEMBER LUND: Sure, I'm okay with that. Would you be okay with that? Dr. Schaeuble also had that concern.

COMMITTEE MEMBER SCHAEUBLE: Yes. Although I think Dr. Miller said that she -- that it was not a problem as far as USC was concerned.

VICE CHAIR DICKEY: No.

COMMITTEE MEMBER SCHAEUBLE: So, I'm not sure it's really an issue here.

VICE CHAIR DICKEY: Well, I hope not, but she can't speak for their IRB.

DR. MILLER: Well, I -- one thing I will point out, thank you, is that USC has ceded the IRB.

VICE CHAIR DICKEY: Oh, ceded. Oh, okay.

DR. MILLER: So, it is okay.

VICE CHAIR DICKEY: All right. Okay.

DR. MILLER: We're harmonizing the form because there is, of course, still a oversight in terms of whether

or not there is, you know, adverse reporting. That does still go to USC IRB and also to CPHS. But this is a ceded study, so that should not be an issue.

VICE CHAIR DICKEY: So, they don't --

DR. MILLER: Because it's Cancer Registry, we are able to make these changes. So, CPHS would have the last word on it.

VICE CHAIR DICKEY: All right.

COMMITTEE MEMBER LUND: Okay, great.

VICE CHAIR DICKEY: Well, we got the last word.

COMMITTEE MEMBER LUND: Okay. Wow, that almost never happens.

(Laughter)

COMMITTEE MEMBER LUND: Anybody else?

Public comment?

CHAIR HESS: Yeah, any comments from our remote board members?

DR. RYKACZEWSKA: I am seeing no raised hands.

CHAIR HESS: Okay. Any comments from members of the public, either remote or in person?

DR. RYKACZEWSKA: Nick and Francis, any in person?

MR. ZADROZNA: No comments in person.

MR. BROWN: Ditto.

DR. RYKACZEWSKA: Thank you.

CHAIR HESS: Do we have a motion?

COMMITTEE MEMBER LUND: Okay. So, and in making my motion I want to say, Dr. Miller, I know that you all are under time constraints. So, I'm going to say deferred approval, but we can turn that around as soon as you get the changes to us. So, there should -- the different approvals shouldn't imply to much of a delay.

DR. MILLER: That's great.

COMMITTEE MEMBER LUND: So, I recommend deferred approval pending the following changes. Restoration of the bullet points at the beginning of the informed consent form. And emphasizing three phrases at the end, or on page 5 of the consent form.

Do we have to do those here or can we just send those to her?

DR. RYKACZEWSKA: We can send those to her.

COMMITTEE MEMBER LUND: Okay. We will send you the exact text to be emphasized.

And I think those were the only two stipulated changes for approval.

VICE CHAIR DICKEY: Second.

MS. ATIFEH: Okay, Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approved.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

COMMITTEE MEMBER SCHAEUBLE: I think there were

three, the number three before the phrases. There were three.

DR. RYKACZEWSKA: Three phrases?

COMMITTEE MEMBER LUND: Yeah, three phrases.

VICE CHAIR DICKEY: I guess we didn't ask the public, did we?

CHAIR HESS: We did.

VICE CHAIR DICKEY: Did we?

CHAIR HESS: We asked for public, yeah.

VICE CHAIR DICKEY: Nothing.

CHAIR HESS: Uh-hum.

MS. ATIFEH: Okay. Let me start again. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

CHAIR HESS: Thank you, Dr. Miller. You'll be receiving a letter.

DR. MILLER: Thank you so much.

CHAIR HESS: Yeah, thank you.

COMMITTEE MEMBER JOHNSON: Can we take a quick break? I'm next up.

CHAIR HESS: Yeah, we can. Can we take a five-minute break?

COMMITTEE MEMBER LUND: Yeah, we're an hour early.

CHAIR HESS: Yeah, we're early. Okay.

(Off the record at 9:58 a.m.)

(On the record at 10:05 a.m.)

CHAIR HESS: Welcome back, everyone. So, I think we're moving on to our first new project of the day. And do we have the researchers on?

DR. RYKACZEWSKA: I do believe so, yes. They are here.

CHAIR HESS: Okay. Dr. Johnson, do you want to --

COMMITTEE MEMBER JOHNSON: Sure. So, Mr. La Rocque. So, just to provide some background, this study went through multiple iterations of kind of where it

currently exists. Before I have Mr. La Rocque go through those specific details, there's two main parts of these research activities.

One that is mandated in statute that CDSS is collecting data. And then the research team, the main thing that we will be evaluating is for under the Common Rule for human subjects of a survey follow up.

So, Mr. La Rocque, if you want to introduce your research team and then provide a short description of the study proposal as it currently stands.

MR. LA ROCQUE: Thank you, Dr. Johnson. I'm Matthew La Rocque. I work with Social Finance and I'm a member of the research team for this study. I'm also here with Alina Xu, who is the Co-PI on this study. We're happy to answer any questions you have after I provide a brief introduction.

But just for a little bit of background, the California Crisis Act Statute, that's AB 118, created the Community Response Initiative to strengthen Emergency Systems Act Grant Pilot Program.

And this grant program funds community-based organizations in four different jurisdictions across California to create or expand crisis response pilots to lessen the reliance on law enforcement agencies as the first responders in a crisis situation.

In accordance with that law, AB 118, the California Department of Social Services, that's DSS, is working with our organization, Social Finance, to conduct a descriptive study of the four pilot programs. And we're trying to understand things like client satisfaction, whether individuals who are receiving these crisis response services are satisfied with those services, whether pilots are implementing their programs as intended, what pilots are learning from this process, and how community-based emergency response programs can be supported or expanded in the future.

And these are the sorts of things the statute requires learning about through this evaluation.

We are collecting -- I should say we're accessing two different types of data that will involve human subjects throughout this study.

The first we are terming service delivery data that pilots collect on their own during emergency dispatch and response, and they're submitting that data to CSS.

The second is the survey data that Dr. Johnson mentioned, that Social Finance collects from clients after they consent.

I want to say just a couple words about both types of data. The service delivery data sites are collecting and reporting, that includes information such as how long

clients waited before the crisis response team arrived, and any services that the response team is providing in that time, such as referrals to services that clients can access after their response.

Service delivery data is mandated by state law and CDSS, not Social Finance. So, sites report that data to CDSS and Social Finance is receiving its state data.

We have tried to understand the sources of these data and three of the four pilots involved in the study have informed us that their service delivery data comes from sources that are protected by HIPAA. CDSS is responsible for receiving and storing that date. So we, as the research team, are not responsible for those data collection practices or their HIPAA compliance.

However, we are committed to accessing that data that the state collects in a HIPAA compliance way, which we've detailed in our application.

In addition, we are -- we also included a request for a HIPAA waiver to ensure that we can access that data properly for the evaluation.

In terms of the survey data, we are getting that from adults who receive crisis response services and a follow-up visit from pilots. Subjects will need to fill out a consent form before they actually fill out the survey. And both of those are written processes that would be

conducted through Qualtrics.

I'll pause there and welcome any questions from the Committee.

COMMITTEE MEMBER JOHNSON: Yeah, and I'll just add that there is not overlap between the service delivery data that you'll ultimately be accessing and the survey data follow up information. So, there is not a way to link those two sets together.

I didn't have any major issues with the request for the HIPAA waiver. I also thought the consent form was clear and straight forward.

There are some relatively minor inconsistencies in the application of, you know, if people are being contacted via email or text, which we discussed yesterday. And clarifying things, like if you're collecting things via Microsoft forms versus Qualtrics. So, just a little clarification is needed within the proposal, I think, to really solidify how information is being transferred to you would benefit.

But those were my main issues with the study as it currently stands. And I'll open it up to anyone else who has comments or questions.

VICE CHAIR DICKEY: I just wanted to say with regard to the HIPAA waiver, they have specified name, telephone number, email address. I assume that's all of it.

Our letter that we send to them granting that needs to specify those variables. In the past we've just said you get a HIPAA waiver and not specifying exactly what. So.

CHAIR HESS: What it's for.

VICE CHAIR DICKEY: Hum?

CHAIR HESS: What it's for.

VICE CHAIR DICKEY: Yeah.

CHAIR HESS: Shouldn't it, like specify we're giving you a HIPAA waiver for these --

VICE CHAIR DICKEY: Exactly. It should say exactly what it is.

CHAIR HESS: Yeah.

VICE CHAIR DICKEY: There's a format that they want us to do it in, so --

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: That's new, yes?

VICE CHAIR DICKEY: No, it's been there all along, but we haven't been doing it.

COMMITTEE MEMBER LUND: Ah, okay, that's why I didn't know.

(Laughter)

COMMITTEE MEMBER LUND: So, that would be the service delivery data and not the survey data --

COMMITTEE MEMBER JOHNSON: That's correct.

COMMITTEE MEMBER LUND: -- would be the HIPAA. So, probably all of the data fields that are in the service delivery data should specified, then, in the HIPAA waiver. Yes?

VICE CHAIR DICKEY: Well --

CHAIR HESS: Or only the ones that they are asking.

VICE CHAIR DICKEY: I think it's only the ones that they're asking, that they didn't obtain themselves, that they're getting from us.

COMMITTEE MEMBER LUND: Ah, I see. Okay.

CHAIR HESS: Any comments from remote staff?

DR. RYKACZEWSKA: I'm not seeing any virtual hands from our virtual Committee members.

CHAIR HESS: Okay. Any comments from members of the public, remote or in person?

DR. RYKACZEWSKA: Nick, Francis?

MR. ZADROZNA: No comments in person.

DR. RYKACZEWSKA: Thank you, Nick. I am not seeing any virtual hands at this time.

CHAIR HESS: Okay. Dr. Johnson, are you ready to make a motion?

COMMITTEE MEMBER JOHNSON: Get clarification.

CHAIR HESS: Yeah.

COMMITTEE MEMBER JOHNSON: So, for the HIPAA

waiver request, it's just that they include the service delivery data variable fields that they're --

VICE CHAIR DICKEY: That they specified in the protocol.

COMMITTEE MEMBER JOHNSON: Okay.

CHAIR HESS: But that's on our side.

VICE CHAIR DICKEY: It's on our side. We're only approving the waiver for those variables.

COMMITTEE MEMBER JOHNSON: Okay. So, then I think just the issues are just very minor, consistent -- like inconsistencies with the application.

So, I will make a motion for deferred approval, minimal risk, one year, pending minor modifications for inconsistencies with confirming how information or when information is exchanged following the consent for the survey data. And clarifying that this is taking place in the format that you suggested with Qualtrics and not Microsoft Forms, to be reviewed by a subcommittee of me.

DR. RYKACZEWSKA: I was trying to be really fast about it, but I think I missed pieces.

COMMITTEE MEMBER JOHNSON: All right, let me see what you've got. Yeah, it's clarifying that this is -- that the data are being collected in Qualtrics and not Microsoft Forms, as is in the application. To be reviewed by a subcommittee of me.

CHAIR HESS: Is that it?

COMMITTEE MEMBER JOHNSON: That's it.

COMMITTEE MEMBER LUND: I'll second.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approved.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

COMMITTEE MEMBER JOHNSON: Okay. Thank you Mr. La Rocque and Ms. Xu. We'll be issuing, after you submit the amendment and I'll process that relatively quickly since they're relatively small changes. And good luck.

CHAIR HESS: Thank you.

MR. LA ROCQUE: Thank you so much.

MS. XU: Thank you.

CHAIR HESS: Okay, moving on, California Long term Services and Supports Financing Initiative, Dr. Shugarman.

DR. SHUGARMAN: Hi. How are you doing?

CHAIR HESS: Hi. Is the rest of your team here?

DR. SHUGARMAN: They are. Yes, and I'll just introduce myself and then I will -- I'll ask my colleagues to introduce themselves and state their role.

My name's Lisa Shugarman. I'm a Senior Fellow at NORC, at the University of Chicago. And I am the project director for this survey that is the subject of our conversation today.

And I'll pass it over to my colleagues, whoever wants to introduce first.

MS. MCCABE: I'll jump in. Hi, everybody, my name is LeeAnn McCabe. I'm a Client Services Senior Manager for the AmeriSpeak team. And AmeriSpeak is the probability panel on (indiscernible) that we'll be using as the sample source to collect data. And I'll be working very closely with Xueyin. And I will pass it to her to introduce herself.

MS. YANG: I am Xueyin. Yes, and I will just work closely with Lisa and LeeAnn on this project for like (indiscernible) -- product execution, data collection, and

data processing. Yeah, and look forward to this meeting.

CHAIR HESS: Thank you.

COMMITTEE MEMBER VENTURA: Wonderful. Good morning, Dr. Shugarman. This is Dr. Ventura. I was primary reviewer on this and so we've communicated a bit on some of the revisions I requested.

Can you please share with the board a brief summary of the project, the main components and then we'll continue from there.

DR. SHUGARMAN: Yes. Yeah, happy to. So, the project that we're engaging with you on are we are going to be pursuing two surveys. For today, we're just talking about the first survey that we want to pursue.

And this is going to be using NORC AmeriSpeak Panel. This is a national panel that's been in operation for many years and is used for a number of different survey purposes.

Our intention is to focus on, within that panel, California residents that are 50 years of age and older, that have already been identified and consented into the panel.

And the members of the panel, just as background, receive requests for survey participation on a number of different topics all throughout the year. And they agree or -- consent or decline participation in any given survey, as

they choose.

This survey would be focusing on respondents' concerns that are related to retirement and plans for long-term care, planning and financing. This is part of a project that is -- a larger project that is being funded by the California Department of Aging. And we're working with University of Massachusetts, Boston, and CDA on this work.

We will be focusing in on questions around how they plan for aging, if they already caring for a loved one who is -- who needs long-term care, how that -- how they're engaging them, and how they are thinking about their own plans.

It's approximately a 12-minute survey and they will be provided, I believe, a $4 or $5 incentive for participation in the survey.

Participants can refuse to answer any question in the survey. And our intention is that this will be the first of two surveys and we will submit an amendment to the IRB request for the second survey, when that is ready to be delivered.

Does that give you enough of a background? I can go into some of the -- some additional details, if you need it.

COMMITTEE MEMBER VENTURA: Is that enough? That's okay for the Committee. Since I've thoroughly reviewed it,

I could just go into my primary concern. Okay.

My primary concern has to do with the informed consent. First, you know, in your submission you had indicated that informed consent to participate in the panel and to receive survey invitations as part of this AmeriSpeak -- bigger AmeriSpeak panel project.

But I think those are two separate issues. Participating in the panel is one thing and consenting to that, but consenting to participating in the survey for research is a different issue for me.

I thought that the informed consent was, first, you know, at a higher reading level. I think it was at the 12th grade reading level. And so, when I asked Dr. Shugarman to reduce that, I was told that they can't make a change to the consent because it was approved 10 years ago. Is that correct?

DR. SHUGARMAN: This is Lisa. I'll just jump in with a little more detail and clarify.

COMMITTEE MEMBER VENTURA: Sure.

MS. MCCABE: So, the informed consent for the panel did start, and it has been modified over the last 10 years, and that is for the respondents to join the panel.

We typically go for -- it depends on our clients. And some clients do require an informed consent for their survey specifically, some do not. And the ones that do not,

we work with NORC IRB on a waiver of informed consent. But we are happy to put in an informed consent for this survey specifically that can give a brief -- we already have a brief intro and we can add to that just reminders of data privacy and get informed consent that way for this survey.

DR. SHUGARMAN: Just to take a step back, if we can. The consent language that we shared with you was the consent language for participation in the panel. It was not the consent language for participation in the survey.

The survey consent language was embedded in the survey itself, and allows them to participate or not.

COMMITTEE MEMBER VENTURA: Yeah.

DR. SHUGARMAN: And so, we're relying on the language that is at the front of the survey is for consent to the survey.

So, there may have been some confusion. We were -- we offered, for your information, the consent process for the panel. But because we're not consenting people to participate in the panel in order to participate in the survey, and these are members that are already consented to be part of the panel.

What we're concerned about is if you're comfortable with the language that is the survey itself to consent.

And to LeeAnn's point, if the language in the

front matter of the survey is not sufficient for consent. We can add additional language there. But it would not involve us revising the consent process or language that's used to participate in the panel.

Does that make sense?

COMMITTEE MEMBER VENTURA: Understood. Is that good with --

CHAIR HESS: Do we have a copy of the language?

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER JOHNSON: Of the survey?

CHAIR HESS: Yeah.

COMMITTEE MEMBER VENTURA: Yeah.

CHAIR HESS: I didn't see that. Oh, it's on the survey.

COMMITTEE MEMBER VENTURA: The survey.

VICE CHAIR DICKEY: The survey.

DR. SHUGARMAN: It's embedded in the survey itself. So, they are invited to participate. And by their continuing with the survey, they're agreeing to participate. And if that language at the front end needs to -- if you feel that there needs to be some strengthening of that language, we can add additional language up front there.

But I really just want -- what I was trying to communicate before, Dr. Ventura, in the communications that we had prior to today, and what I'm trying to convey now is

that the process for consenting to the panel is something that is not -- we cannot modify that for this project.

COMMITTEE MEMBER VENTURA: Sure.

DR. SHUGARMAN: Because the panel is operated and governed by a different IRB and it's a different process. Because we are not adding new members to the panel in order to -- in order to engage in the survey. We are working with the panel members that have already consented to that.

COMMITTEE MEMBER VENTURA: Understood. I just -- we're only reviewing the consent process for the research, participating in the survey itself. Which I didn't think was sufficient. I think there was -- the statement, "You may choose not to answer questions you don't wish to answer." But I think there wasn't a description, a summary of the types of questions that they would be asked. How long. You mentioned it's a 12-minute survey, but in the email and phone scripts there wasn't a mention of how long the survey would take and the incentive to participate.

So, I think there are some places that we can provide participants just a little bit more information about what they're agreeing to participate in.

Dr. Schaeuble, was there anything else?

COMMITTEE MEMBER SCHAEUBLE: I know I suggested to you some specific things about consent --

COMMITTEE MEMBER VENTURA: Yes.

COMMITTEE MEMBER SCHAEUBLE: -- at the beginning of the survey.

COMMITTEE MEMBER VENTURA: That's right.

COMMITTEE MEMBER SCHAEUBLE: And again, I don't have the notes that I sent to you, so I hope that you have them there.

COMMITTEE MEMBER VENTURA: I do. Yeah. It was just, again, to explain a little bit in more detail just the types of questions that they're going to be asked. I believe that, you know -- let me find their topics. At least the topics of retirement and, you know, healthcare into retirement and --

CHAIR HESS: And financial concerns in retirement.

COMMITTEE MEMBER VENTURA: Financial concerns, yeah.

CHAIR HESS: Yeah.

VICE CHAIR DICKEY: Right now it just says health concerns, right.

COMMITTEE MEMBER VENTURA: Health concerns, yeah, and nothing about finance. So, I think that needs to be clearer that they'll be answering questions about those topics.

DR. SHUGARMAN: Okay.

COMMITTEE MEMBER VENTURA: And in the email and phone scripts that you submitted, it just states that a new

survey -- we have a new survey for you. But again, no details about the length it will take to complete, the types of questions that will be asked of them. So, I think that you should provide them that information.

DR. SHUGARMAN: Okay. How --

COMMITTEE MEMBER SCHAEUBLE: I'm trying to recall, is this the project where people have to, in effect, decline twice if they don't want to answer a question?

VICE CHAIR DICKEY: It says here, "If you skip a question, you'll receive a reminder prompt asking you to complete the question."

COMMITTEE MEMBER SCHAEUBLE: Yes, so it is. And if you're putting that kind of burden on participants, I think that needs to be very clear in the consent information that --

DR. SHUGARMAN: There's language in --

COMMITTEE MEMBER SCHAEUBLE: -- you do absolutely have the right to decline to answer a question, even though you will be reminded before you try to go ahead to another question. That was not really clearly stated.

DR. SHUGARMAN: There is a --

COMMITTEE MEMBER SCHAEUBLE: Also, any of the questions that might be considered particularly sensitive by participants, if when you're describing topics for the survey if you could also describe any topic areas that they

might likely consider more sensitive than other parts of the survey, that would be sort of a common thing to do in consent at the beginning of a survey.

DR. SHUGARMAN: Sorry, so just to clarify that what you're suggesting is that there would be -- at the front end of the survey there would be language that says there may be questions here that are considered sensitive, just to give them an awareness of the questions that we're asking. Did I hear that correctly? I want to make sure I got that.

COMMITTEE MEMBER SCHAEUBLE: Yes. And if you can, I would suggest including one or two examples of parts of the survey that you, yourselves, know might be considered more sensitive by some people.

DR. SHUGARMAN: Okay.

CHAIR HESS: And Dr. Schaeuble, in response to your first comment, so are you suggesting they add language like you may be prompted to answer a question more than once, but you may skip that.

COMMITTEE MEMBER SCHAEUBLE: Well, the typical thing is that, you know, the people can simply decline to answer a question and they aren't prodded to do something other than that.

VICE CHAIR DICKEY: Can I just read what they have to the Committee?

CHAIR HESS: Uh-hum.

VICE CHAIR DICKEY: It says, "If you skip a question, you will see a reminder prompt asking you to complete the response. You may, of course, choose to continue to the next question or complete the question before proceeding.

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: Yeah, that was going to be my comment is if they're letting them know we're just making sure you didn't unintentionally skip a question.

COMMITTEE MEMBER VENTURA: Yeah, got it.

COMMITTEE MEMBER LUND: Yeah, so I'm fine about that.

DR. SHUGARMAN: Right. So, is that language sufficient. We did anticipate that in our -- in the way that it was drafted. So, it's just creating awareness for them that they will be asked to confirm that they don't want to enter it, and they can skip it. And we also have a refuse to answer -- there are questions where there is a refuse to answer, or decline to answer on some of the questions, but not all.

CHAIR HESS: I think that's sufficient.

COMMITTEE MEMBER VENTURA: Uh-hum.

CHAIR HESS: Okay.

COMMITTEE MEMBER JOHNSON: And I do want to say

for the Committee, I feel like this is kind of an unusual situation because we don't usually have a pool of research subjects who are familiar with being research subjects, right. So, they know in advance that they have been, you know, recruited to this pool and they may have done other research studies. So, they're kind of -- they're not naïve to the process.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: You know, I won't say experienced, but familiar with what might happen. So, I feel like the burden is not -- the bar is not quite as high in that set of circumstances.

VICE CHAIR DICKEY: I agree with you. It says they get AmeriPoints if they complete it. What are AmeriPoints.

DR. SHUGARMAN: AmeriPoints is our incentive process. And so, 1,000 AmeriPoints is equivalent to one dollar, and we have a system where they get banked and they are able to go into that system and redeem those points for things like gift cards. It's mostly e-gift cards that people choose. There are other options available through that system. Like, just to explain, our panels take our surveys, you know, a few times a year they are invited to do different surveys and are familiar with the processes.

VICE CHAIR DICKEY: Okay.

DR. SHUGARMAN: And if they have any questions, we have a full support team that they can call into, as well.

VICE CHAIR DICKEY: Any airline flights involved in this?

(Laughter)

DR. SHUGARMAN: That would be quite a lot of points. I don't think so.

COMMITTEE MEMBER VENTURA: Any other comments about the informed consent from Committee members.

COMMITTEE MEMBER SCHAEUBLE: Is it common practice in your surveys to not allow participants to simply go ahead to the next question without some kind of prodding?

DR. SHUGARMAN: Again, we do so many surveys a year. It is common to have prompts on questions that are extremely important to the research. We try to limit those prompts to limit the burden on our panelists. So, this one, having a prompt on every question isn't incredibly unusual, but it is not something that happens on every single survey.

Again, having I think that note in the beginning of our letting our panelists know there will be a prompt, but you can move forward will not be -- we've done things very similar in the past and we always give them the heads up in the beginning. And they're all aware of if they don't feel like participating any longer, they can end the survey at any time.

MS. MCCABE: And just to underscore that the design for the survey was at the request of the client, which is California Department of Aging.

COMMITTEE MEMBER VENTURA: Okay. And then, I just wanted to point out to the Committee that there were Spanish materials submitted along with this application, but I didn't review any of that. And so, after revisions are made to the consent that we find adequate, then it will go under review of all the Spanish materials submitted by Dr. Ruiz.

One other minor point, under "storing identifiers", in IRBManager it's indicated that "Identifiers will be stored separately from analysis data, but only de-identified data will be sent to the University of Massachusetts."

And that's the first place where UMass is brought up. No research personnel are listed from UMass. So, can you please explain their involvement in this and why data would be sent so them?

DR. SHUGARMAN: So, they are receiving the de-identified data. They are serving as both a part of a larger research team and as sort of the program office for California Department of Aging for all of the elements of the larger work in which our survey is contributing.

So, they are our immediate clients, in that our contract is with UMass Boston. It came from California

Department of Aging to UMass to manage, as like a program office. And they will also be receiving the de-identified data for them to do analysis and connect with the other parts of the project that we have no role in.

Does that help?

COMMITTEE MEMBER LUND: So, here's my question. This -- the way that the protocol then is structured is for approval of data collection only, and not any use of analysis of the data. So, right, so if they're going to collect the data and then pitch it over the fence, we need a protocol that also provides a description of how those data will be analyzed and used, and what their final product is, and yeah all of that.

So, yes, this is for data collection bit then, you know, if Aging is paying UMass to do data analysis and, you know, research, then we need a protocol that describes that so that we can approve that piece of it. In my opinion.

COMMITTEE MEMBER AZIZIAN: It may be also necessary to establish that in the consent form, that the data is being shared.

COMMITTEE MEMBER LUND: Yeah. And whoever -- UMass, whether the data are de-identified or not, it doesn't matter. Right. If they're being used for research. So, that can either be part of this application, an expanded application where that's mentioned here, or maybe we need an

application from UMass to get permission to do the analysis and research work.

CHAIR HESS: Do we need a data security letter from UMass, as well.

COMMITTEE MEMBER LUND: If it's going to be there, I would think so.

DR. SHUGARMAN: Is it possible that the application -- so, there are two -- there's sort of two steps in the analysis process. There is -- NORC will be responsible for an initial analysis of the data, high level descriptive analysis, and we can incorporate that into this application.

But the purpose and intent of analysis that UMass Boston might have, we're not privy to that. So, I'm wondering if that requires -- if that can be engaged in its own application and potentially be considered -- it could be considered exempt because of the nature of the data. And if we separate that because it's their -- what they're going to do with the data, not us, I'm wondering if that can help expedite us getting approval for the data collection, itself.

The concern is, is that the project is already behind schedule. This is not your problem. This is ours. But the project is behind schedule because of the IRB -- the IRB review that we're waiting for that, so that we can even

collect the data.

And I'm wondering if it's possible for us to separate those out. And then, UMass Boston can pursue their own IRB application for use of the data.

The only thing I'm wondering about is because the data are not California Department of Aging data, they're AmeriSpeak data, if that matters in the consideration here?

COMMITTEE MEMBER LUND: Well, if we have purview, we have purview.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: So, I'm wondering, my concern is the data release to UMass. So, I would be willing to consider the merits of the data collection aspects of the protocol, but not approve the release of the data until we have something from UMass.

VICE CHAIR DICKEY: Well, but I think that could be an amendment of this. I mean we could just approve this up to this point. And any -- before they share it with UMass they need to come back to us with an amendment.

COMMITTEE MEMBER VENTURA: Right, the specifics of what de-identified -- the variables that will be released.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: Yes.

COMMITTEE MEMBER VENTURA: The -- I know you have a data transfer agreement, but --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: -- all of the analysis plans, everything that you UMass --

COMMITTEE MEMBER LUND: Yes, data security.

COMMITTEE MEMBER VENTURA: Yes, all of that. I would be okay with an amendment following this.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: But just being clear that if we approve this portion it's for data collection, everything that you are planning to do as you described the descriptives that's fine, but not beyond that. Not the data transfer to UMass until we review that portion, phase two, or whatever you want to call it of your research.

VICE CHAIR DICKEY: Yeah. We have lots of projects like this where there's somebody else is going to do the analysis.

COMMITTEE MEMBER VENTURA: Sure.

COMMITTEE MEMBER SCHAEUBLE: Yeah, and so --

DR. SHUGARMAN: Okay. And so, would the amendment itself, though, be completed by UMass Boston?

VICE CHAIR DICKEY: No, I think it would be you.

COMMITTEE MEMBER VENTURA: No, it would be you.

VICE CHAIR DICKEY: But by you, but you can include them as CO-PIs.

COMMITTEE MEMBER VENTURA: Yes, like research

staff or something like that.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER VENTURA: Named research staff.

COMMITTEE MEMBER LUND: Yes, who is receiving the data, who will be responsible for it at UMass, and all of the, you know, the specifics about data security at UMass before transferring it.

CHAIR HESS: Yeah, we're wondering if it should be separate. Because once the data is transferred from NORC are they really the responsible official for any data breaches or anything, or does that responsibility lie with UMass. I would think it would lie with UMass. And so, my suggestion would be we approve this, but then we basically notify, I don't know, Department of Aging that UMass puts in --

COMMITTEE MEMBER LUND: Although, if UMass comes on as CO-PI, then they are equally responsible for data security and data breaches, and so forth, that happen on their end.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: So, that would -- I'm just thinking it becomes extremely complicated if you ask for a brand-new application from UMass --

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: -- since it builds on this

one.

CHAIR HESS: Yeah.

COMMITTEE MEMBER LUND: So, I would want a way to make UMass a responsible party. Because certainly any breach that happens at UMass is not the fault of NORC.

CHAIR HESS: Yeah.

COMMITTEE MEMBER LUND: And if they are a CO-PI, I think legally that establishes a responsible party.

VICE CHAIR DICKEY: Right. Yeah.

COMMITTEE MEMBER LUND: Sorry, laughing from hunger.

(Laughter)

DR. RYKACZEWSKA: So, just to make sure I'm following here, so we could approve for the data collection piece with what they have, assuming that the board supports that, and then they would submit an amendment that could potentially add UMass as CO-PIs for whatever else UMass is doing with the data, but that can come as a phase two type.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: Correct.

VICE CHAIR DICKEY: And that's not saying that UMass wouldn't have to go to their own IRB, but that's something they have to deal with, with their own IRB. But for our purposes --

COMMITTEE MEMBER SCHAEUBLE: The other thing I'm

thinking here is that if there is the potential likelihood, even, for the data to be transferred to UMass, the participants in the survey should be --

VICE CHAIR DICKEY: They need to know that.

COMMITTEE MEMBER SCHAEUBLE: -- should know about that now.

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER SCHAEUBLE: Because it's not going to be possible to come back to them later.

COMMITTEE MEMBER VENTURA: Yeah.

VICE CHAIR DICKEY: Right. So, something you introduce at the start about that we may share your --

COMMITTEE MEMBER SCHAEUBLE: So, part of your consent at the beginning of the survey should acknowledge that an initial analysis will be done by NORC, but there's a strong likelihood of later analysis of the data at University of Massachusetts.

COMMITTEE MEMBER LUND: The de-identified data will be shared.

COMMITTEE MEMBER VENTURA: Yeah.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER VENTURA: Those are my main concerns. If the Committee has no other questions maybe --

VICE CHAIR DICKEY: I just want to point out this would be a waiver of written informed consent. We're still

getting -- we're giving them, informing them, we're just not getting it written.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: That will be part of the motion.

CHAIR HESS: Okay. Any last comments from members of the board, remote or in person?

Any comment from members of the public, remote or in person?

MR. ZADROZNA: No comments in person.

CHAIR HESS: Okay, great. Do you want to make a motion?

COMMITTEE MEMBER VENTURA: Okay. So, deferred approval, minimal risk, one year, pending the following modifications to the consent form.

DR. RYKACZEWSKA: Consent section.

COMMITTEE MEMBER VENTURA: Consent section, yeah.

VICE CHAIR DICKEY: Yeah, consent section of the survey.

COMMITTEE MEMBER VENTURA: Since it's going to be a survey. More description of the types of questions being asked. The length of time to complete the survey. And I think incentive that they receive the AmeriSpeak box, or whatever it's called.

DR. SHUGARMAN: AmeriPoints.

COMMITTEE MEMBER VENTURA: AmeriPoints, thank you. Certainly, language around University of Massachusetts involvement.

VICE CHAIR DICKEY: Potential.

COMMITTEE MEMBER VENTURA: Potential that their data will be shared with the University of Massachusetts.

DR. RYKACZEWSKA: That's a hard word to spell. UMass.

(Laughter)

DR. SHUGARMAN: UMass is just easier to say.

DR. RYKACZEWSKA: Yeah.

COMMITTEE MEMBER VENTURA: Involvement for data analysis. And the Spanish review of all material is pending. Oh, I'm sorry, and the waiver of written informed consent.

VICE CHAIR DICKEY: Just it's a waiver of -- we're granting a waiver of written informed consent.

COMMITTEE MEMBER VENTURA: Yeah, we're granting.

DR. RYKACZEWSKA: Would that go in the beginning, and waiver of written informed consent.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: Could we say explicitly no approval for data to be transferred --

COMMITTEE MEMBER VENTURA: That's right. Until an amendment is submitted.

COMMITTEE MEMBER LUND: -- until an amendment is submitted and approved.

COMMITTEE MEMBER VENTURA: Right.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: To be reviewed by a subcommittee?

COMMITTEE MEMBER VENTURA: To be reviewed by myself.

VICE CHAIR DICKEY: We trust you.

COMMITTEE MEMBER VENTURA: Oh, and then Dr. Ruiz for the Spanish component.

CHAIR HESS: Do we have a second.

COMMITTEE MEMBER AZIZIAN: I'll second.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis?

DR. RYKACZEWSKA: Dr. Dinis is offline.

MS. ATIFEH: Okay. Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Great. Thank you, NORC team.

DR. SHUGARMAN: Thank you.

CHAIR HESS: We'll be in touch.

MS. MCCABE: Thank you.

DR. SHUGARMAN: All right, thank you much.

CHAIR HESS: Thanks.

All right, moving on. Do we want to take a break before --

VICE CHAIR DICKEY: This might take a while.

CHAIR HESS: Okay. Can we -- we're going to take a break for five minutes. We'll return at 10:55.

(Off the record at 10:50 a.m.)

(On the record at 10:57 a.m.)

CHAIR HESS: We're back, everyone. So, the next item on the agenda is a new project we are being asked to consider. It is the Health Care Payments Data System operations. So, we're being asked -- or, effectively we are reviewing the database itself under the Common Rule.

And we have a large contingent of the HCAI HPD team here with us. Do you want to, everyone, go around --

oh, it's Dr. Dickey. Sorry, I was just jumping in. Go ahead, Dr. Dickey.

VICE CHAIR DICKEY: Oh, that's okay. They can introduce themselves, please do.

MR. VALLE: Sure. Well, let me just say first than you to the Committee, and Chair Hess, and Vice Chair Dickey, we appreciate the opportunity to be appearing before you today.

I'm Michael Valle, Deputy Director for Information Services at HCAI. And I'm joined by, yes, a large contingent. But I'll go ahead and introduce everyone.

James Yi is a Senior Attorney with HCAI and staffing our program.

Dionne Evans-Dean is Chief Data Programs Officer, and her role is the management and administration of HPD database, and other HCAI databases.

Chris Craig is Chief Risk Management Officer, and he oversees all cyber security and data privacy programming for the department.

And then online we also have two members, who we may call on to answer questions, if needed. Dr. Chris Krawczyk is Chief Analytics Officer and he oversees all HCAI analytics and public reporting.

And Wade Iuele is HCAI HPD Project Manager, who's on the call as well.

And again, we just really appreciate the opportunity to be here.

VICE CHAIR DICKEY: Yeah, and you guys dress better than we do.

(Laughter)

COMMITTEE MEMBER LUND: We're volunteers.

(Laughter)

VICE CHAIR DICKEY: We appreciate it.

So, I'm the primary reviewer on this, but there have been a lot of reviewers on it up to this point. So, we've had meetings with you guys, including Agnieszka, and Dr. Hess, and Jared, and Maggie. So, we've tried to work through some of this before getting here.

So, as you know, this is a huge project, a very important project, with a $22 million BCP behind it. And so, it's very important.

Before we go forward, maybe Agnieszka, could you show that slide? We're not used to reviewing databases themselves, or registries. In fact, we have. We may not realize it, but like the Parkinson's Registry was a case where we approved the registry itself, not individual projects that come from it.

Yeah, so this is guidance that OHRP put out in 1997, actually. And it talks mainly about tissue depositories, but it also talks about data. And if you go

down further, at the very bottom sort of the takeaway is, it states that "The IRB should review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provision to protect privacy of subjects and maintain the confidentiality of data."

It can also review sample collection protocols, informed consent documents.

And it also makes the statement, "Certificate of Confidentiality should be obtained."

But like I said earlier, I looked into this, I went on the NIH website and it said for these types of registries they do not issue Certificates of Confidentiality. So.

But this is from 1997, but it's still in place. And we've had communications only last year from OHRP saying that registries should be reviewed by the IRB of the institution. But that the individual releases from that registry subsequently are not reviewed by the institution's IRB, but by the receiving institution's IRB. But we have the Information Practices Act that says we still have to review those releases under the Information Practices Act.

So, just so we're all on the same page about this, it's great.

You know, you may say there's a lot of registries

that we have that we didn't review in the past, and I suspect most all of those were established before 1997, before OHRP made this guidance. But it's something that we should be cognizant about going forward that we should be doing the same thing for other registries in the future, as what we do for this.

So, this is -- the protocol may look like it's just a request for a waiver of informed consent. But in fact it's a request to approve the registry as a whole. And that includes the policies and procedures of the registry.

And it's an interesting issue on that, which we'll discuss, which is that they feel they can't share certain details with us because it would -- we have to be public and it would compromise the safety of the registry if all the details were shared with us.

And so, there's two big issues there, the policies and procedures and the informed consent issue. And I guess with that caveat or introduction can you guys take it away.

MR. VALLE: Sure, happy to do that, Dr. Dickey, and we have a slide deck as well. And I also believe that Committee members received what we title The Data Management Plan as part of our project submission, which we consider to be some of the policies and procedures for the database, and we're happy to respond to any specific questions and provide additional information about them, should that be needed.

I'll start with a brief presentation on behalf of HCAI. Can you please go to the next slide. And with an overview, again briefly, about the history of the Health Care Payments Data Program, which is an administrative database comprised of healthcare claims that providers bill to insurers, and are subsequently issued for payment.

For nearly a decade, state policymakers had discussed how to build in California what is called an all-payer claims database. California's all-payer claims database, or ATCD. We call it the Health Care Payments Database, HPD. Twenty other states have similar databased.

And over time, nearly a dozen bills were introduced but ultimately failed in the California Legislature until the passage of Assembly Bill 1810 in 2019, which instructed HCAI to study the feasibility of establishing an all-payer claims database in California and to convene a committee of stakeholders and experts, and to submit a report to the legislature about how to operate an all-payer claims database in California.

Based on the findings and recommendations of that committee that were included in that report, the legislature subsequently enacted AB 80, which gave HCAI enabling authority to establish the database.

If you go to the next slide, you'll see some of the intent language from the California Legislature about

the HPD. In creating this database, the legislature acknowledged the substantial public interest of addressing healthcare cost. So much that in AB 80, that established the HPD, HCAI was given emergency regulatory authority, recognizing the rapid development and use of the database was necessary to, what the statute says, "Avoid serious harm to the public peace, health, safety, or general welfare."

And I'll just, if I may, share a survey that was conducted by CMS that showed per capita healthcare spending in California grew by nearly five percent from 1991 to 2019. Also, the administration for Health Research and Quality conducted a study that showed family deductibles, what consumers pay out of pocket for healthcare in California, have more than quadrupled during the same time period at a rate of more than 10 percent per year.

A survey conducted by NORC, at the University of Chicago, shows that half of Californians say they or family members skipped care and in the past year due to cost And many of them said it made their condition worse.

The legislature also recognizing, as reflected here, that our efforts to control cost must not be at the expense of quality or access, and not further disadvantage vulnerable populations.

I'd like to note that the legislature recognized, as reflected here, as well that our -- sorry, that

healthcare data is reported and collected through various and disparate systems. That's in Section B. And that creating a mechanism to aggregate and use this data will help to reduce disparities, improve public health, and oversight of the healthcare system, among other benefits.

If you go to the next slide, please, I'd also like to point out also in the legislature's intent language that the purpose of this database is to encourage data users to develop innovative approaches that may have the potential to deliver better healthcare and to impact the social determinants of health, recognizing that novel, innovative approaches may be needed to bend the cost curve and improve care for all.

If you go to the next slide, I'll just draw back to the legislature's acknowledgement that healthcare data is reported and collected through various disparate systems. Not all of them reflected here. But like all all-payer databases and like all administrative databases, the HPD collates information that was intended for one purpose, paying healthcare providers, and used it for another purpose in research and analysis.

When a patient enrolls in health coverage and sees a provider, the provider then bills the patient's insurance company. And to do so, they must submit a claim for payment that includes information about the treatment, the diagnosis

for which the treatment was performed, as well as information about the patient.

When you look across the state of the healthcare marketplace as a whole in California, that produces hundreds of provider organizations billing dozens of health plans for millions of patients, with separate data feeds for each of the various commercial insurers. Then HCAI collects Medi-Cal information from the Department of Health Care Services, and Medicare fee for service information from CMS.

Which results in the collection of approximately 1.3 billion healthcare claims record per year, for nearly the entire insured population, within which individuals and their records may be present amongst multiple health insurance products, or data sources as people change coverage throughout the year, turn on or off Medi-Cal, or the Covered California Exchange, or are duly eligible for multiple types of health insurance.

The payers, these commercial plans, and Medi-Cal, and Medicare abstract those individual records into a package of relational flat files that is consumable, and able to be organized by the HPD database.

The collation of this disparate data sources then run through a matching algorithm that merges the datas that can be crafted on a routine, periodic basis into an analytic dataset suitable for analysis and use, and to meet the goals

and the intent set out by the legislature.

I also wanted to mention, and you'll see it here, and James will get into it a bit later, this system involves an important privacy protection called the HCAI Secure Data Enclave that allows HCAI to control external users' access to the data and revoke it remotely, and destroy data once projects are deleted. And we have a slide in this deck in the appendix, if you'd like more information about that.

So, with that, I'll turn it to James Yi, HCAI counsel, to discuss this particular project and lay out our key points for your consideration.

CHAIR HESS: Question.

COMMITTEE MEMBER LUND: I have a question.

MR. VALLE: Yes. Go ahead.

COMMITTEE MEMBER LUND: I have a question. The box on the lower right says that HPD research and analysis is used to inform policy decisions regarding et cetera. It's kind of a passive voice there. Could you tell me who is using it and since it's not built yet to do these specific things how do you know that that's what it's going to be used for?

MR. VALLE: Member Lund, thanks for asking that question. The HPD is -- has been created. It started collecting data in 2022. Since then we're continuing to collect data on a monthly basis.

Since that time HCAI has produced five public reports, de-identified information from that database. We're actively monitoring the use of those reports. I can cite one by the Legislative Analyst's Office about prescription drug cost, comparing the relative difference between branded versus generic drugs.

And we think there's going to be many, many more uses by policymakers and others of that data.

In December of 2024, we began the data release process, which allows external entities, such as researchers, to request access to the data. So, it's timely for us to be appearing before you today.

COMMITTEE MEMBER LUND: Okay, great. So, if you built it and you're already using it, what's, you know --

VICE CHAIR DICKEY: They haven't released anything, yet.

COMMITTEE MEMBER LUND: Ah, okay.

VICE CHAIR DICKEY: They've taken requests.

COMMITTEE MEMBER LUND: Okay. Thank you. You anticipated my question.

COMMITTEE MEMBER VENTURA: I have another question about the data enclave environment. So, is the idea that approved users will access the data there, do all analytics in that space? Is data ever downloaded, say, to a --

MR. VALLE: And Dr. Dickey, happy -- would it be

good now to get more into the details of that, and we have a slide if we fast forward to the end.

VICE CHAIR DICKEY: Sure.

COMMITTEE MEMBER VENTURA: Sure.

MR. VALLE: And thank you for the question. The statute actually envisions -- and I think two more at the very, very end, and kind of the appendix. But the statute envisions a creation of this secure data enclave. It refers to it as the secure research environment. You see some details on it, on the right.

What this allows to do is provision data for external users on HCAI servers, allowing external researchers to connect to that data system through a remote connection. And this is envisioned to be a major protective control of data privacy in the HPD program.

The HPD statute prefers the use of the enclave as the primary way the HPD data should be used. And it states that HCAI should be limiting direct transmission outside the secure environment.

Just a few more technical details, if you'd like. The system allows HCAI to create virtual desktop environments. And these environments resemble what you would see on your computer, on Microsoft Windows. It's not physical hardware, it's a virtual machine. And on that machine are preloaded statistical analysis software such as

SAS, and Stata, and SQL, R, and Python.

The enclave is then populated with the data elements the requester has been approved to access. HCAI creates a separate desktop environment for each project in the enclave and only approved users have access to their project space. And all of those project spaces are segregated from one another.

Within this environment all of the activity can be logged and monitored. No data can be removed from the enclave until it has been completely de-identified per agency policy, and after inspection by HCAI staff.

The enclave virtual environment is then destroyed upon the completion of the project or researchers access can be controlled or terminated for cause.

And this is similar to a process that is run by CMS in something they call the Virtual Research Data Center, for researchers that are accessing Medicare claims data.

So, we're happy to be sort of following their lead and following their best practice in the implementation of the Step system.

COMMITTEE MEMBER SCHAEUBLE: So, what would be the exceptions to this more secure process that would instead involve downloading data directly to researchers, since you're saying this is a preference, but not a requirement.

MR. VALLE: That's a great question, Dr.

Schaeuble. So, we have a -- I think we go into that in the slides --

VICE CHAIR DICKEY: Yeah, go for it.

MR. VALLE: -- if that's okay. I'm sure we'll answer that question. If not, I'll be happy to follow up with you.

COMMITTEE MEMBER SCHAEUBLE: Okay.

MR. VALLE: But Agnieszka, if we could maybe go back to slide six or so, and I'll ask James to walk through this portion of the presentation.

MR. YI: Yeah, and just on that note, we have a whole regulatory scheme that we passed about data release, and it talks about those requirements for direct transmission, where someone can get the data themselves versus enclave access. And so, we can talk about that more later on.

And so, as Dr. Dickey said, we are coming here for Common Rule approval. We believe that probably the biggest -- the biggest element that's probably going to be discussed a lot is about informed consent. Because we are requesting a waiver of informed consent from the Common Rule.

And so, that's why a lot of this presentation will be focused on informed consent.

And so, based on that if we can go to slide 9. And so, I think there's a threshold question of, you know,

why we're asking for an exemption from informed consent under Common Rule. And I think probably one of the biggest questions is, you know, is that justified. You know, would we deserve to get that.

And I think this slide talks about how the HPD system and the statutes that created the system, how they were developed. And so, we believe that the whole development of the HPD complies with the basic principles of the Belmont Report in the sense that the creation of the HPD was a public process.

There as a statute before that created what we call the HPD review committee, which was a public committee that was created, it had many stakeholders, including stakeholders who represented consumers and the public. We wanted a wide variety of stakeholders and the statute provided that.

And we had several meetings for a year talking about privacy, confidentiality, security, the uses of the HPD, and these were open public meetings. So that anybody could come in and state, you know, concerns or what they wanted to see in the HPD.

And what this led to was the actual implementing statutes that created the HPD itself. And that went through the political process. It went through our legislature, or governor, it went through all of our elected officials,

essentially.

And so, if we can go back to slide six. So, this, we are asking for the use of -- there is an informed consent waiver provision in the Common Rule for public benefit and service programs conducted by the government.

And so, we're asking that CPHS invoke this provision and give us a waiver of informed consent. And if you can see, there's a citation to it, to the specific federal regulation about that.

If you go to the next slide.

COMMITTEE MEMBER LUND: Could I just ask you a quick question about that slide?

MR. YI: Yes.

COMMITTEE MEMBER LUND: So, the waiver of informed consent, yes, for research involving public benefit and service programs conducted by or subject to the approval of state government.

So, do you envision that these data will only be used -- will only be used for research involving public benefit and service programs? Or when you release these data will they perhaps be used for other research purposes?

MR. YI: This database, the intent, if you read the intent language it goes beyond research. It could be used for other -- what the legislature wanted was for the data to be used for, I guess, for innovation in the

healthcare system and the market. And so, statute does allow for a limited data to be released for non-research purposes.

COMMITTEE MEMBER LUND: Uh-hum.

MR. YI: And so, there is -- research is a big component of this, but there's also uses that may not be research.

But I guess the issue for us is that the definition of research for in the Common Rule is pretty broad.

CMS, I believe, when they defined research they say that they defined it very broadly in order to release the data to us.

COMMITTEE MEMBER LUND: Uh-hum.

COMMITTEE MEMBER KURTURAL: I'm sorry I didn't review the law before we got to this meeting on this new program. But there's no required by law provision and, you know, for the HPD, so there's nothing requiring the information to be exchanged, the claims data?

MR. YI: Oh, it --

MR. GOLDMAN: No, they're required to both receive the information from the payers. They're also required to disclose it under the conditions described in the state.

COMMITTEE MEMBER KURTURAL: Oh, I'm just wondering if we even need a waiver of HIPAA consent.

MR. YI: Oh, so --

VICE CHAIR DICKEY: It's not HIPAA consent, it's a waiver of written consent.

COMMITTEE MEMBER KURTURAL: I mean, yeah.

MR. YI: Yeah, HIPAA does not control this database --

COMMITTEE MEMBER KURTURAL: Right.

MR. YI: -- because California law states that the plans, they have to give it to us. They're mandated by California law to provide the data to us.

COMMITTEE MEMBER KURTURAL: Got it. It's not a business associated to care services.

MR. YI: No.

VICE CHAIR DICKEY: But their statute also says that they have to come to us for research.

COMMITTEE MEMBER KURTURAL: Uh-hum.

MR. YI: For certain --

VICE CHAIR DICKEY: In addition to the Common Rule.

MR. YI: For certain types of data releases.

VICE CHAIR DICKEY: Yeah.

MR. VALLE: Should we go to the next -- the next slide?

MR. YI: And so, this slide is about one of the elements in the Common Rule for this exemption. And I just

wanted to point out that the HPD has already received Medicare data, Medicare claims data from CMS.

CMS, they released that data under HIPAA, under the research exemption under there.

COMMITTEE MEMBER KURTURAL: Okay.

MR. YI: And, essentially, that exemption has the same requirements as the Common Rule exemption. And so, just wanted to put that out there.

But we believe that it is pretty clear that the HPD does support public service or benefit programs to research regarding -- it's generally about healthcare in the State of California.

CMS, they also provided us funding for the HPD. And they noted that they believed that it does serve to benefit Medi-Cal, Medicare, and Covered California.

COMMITTEE MEMBER KURTURAL: Okay, thank you.

MR. YI: And so, that's one of the reasons why they approved that funding.

And as you can see from the slide, I believe as of 2024 we've collected about 33 million persons in California. About 22 million of those were getting services under public healthcare programs.

And so, one of the purposes of HPD, as stated, was to aggregate all of this data around the state so that policymakers could get a good sense of what's going on.

Next slide, please. Probably the second criteria in this exemption is whether the research could be practically carried out without waiver of informed consent.

And we believe that it cannot be. To get informed consent for 30 plus million people, it's not practicable in our view.

When CMS gave us their Medicare data, this was an element that they also had to review. And we explained to them that we didn't seem it's practicable for the six million Medicare members that we were getting.

And it seems like the same reasoning applies for the HPD database as a whole

And another aspect of HPD was that when it was being developed was that if you look at the statute, it states that HPD shall collect data on all California residents to the extent it's feasible and permissible under law.

And I think we'll get to other parts of the statue later on, but the general idea was that the HPD would collect all data without consent feature in the statute itself.

The public policy reason for that was we did want individuals to be able to exempt themselves and so basically destroy the integrity of the database if too many people exempted themselves from data collection.

The other issue is that one of the legislative purposes of HPD is to help disadvantaged groups in California to get their data. And so, there was also a fear that, as we saw during the COVID crisis, certain groups in the United states were pretty untrustworthy of the government. And so, the fact that we didn't want those people, their data to be lost in the system.

COMMITTEE MEMBER AZIZIAN: Can I ask a question? With respect to the database being as comprehensive, earlier you had a slide that had Medi-Cal, Medicare, and then something which was framed as private or commercial.

So, just walk me through this. If I were to go to my dentist and had some type of a procedure, would that fall under that? I mean, is that --

MR. VALLE: Well, it's interesting. Thank you for the question. Interesting you used the example of your dentist because we have -- there's actually separate provisions --

COMMITTEE MEMBER AZIZIAN: I see.

MR. VALLE: -- for dental claims data collections that's just beginning. But if you go to your primary care provider, most likely we are collecting that record. There are some exceptions to that. There's a federal preemption for self-insured entities that cannot be overseen by California State law, and they're overseen by federal law

that represents some lives.

And then, we also have an exemption for small health plans. So, health plans with fewer than 40,000 covered lives are not required to provide data. But I believe have 90 plus percent of the insured population included in this, 80 percent.

MS. EVANS-DEAN: Ninety-seven.

MR. VALLE: Ninety-seven.

COMMITTEE MEMBER AZIZIAN: And then, what is exactly -- what is being collection is conditions, variables, like what is exactly falling under that?

MR. VALLE: Yeah, thanks for that question, too. So, there's a healthcare claim data format that's governed by national data standards bodies, (indiscernible) standard bodies that includes the information you just described, information necessary to pay a claim.

Certain data elements from that have been identified in what's called the APCD Common Data Layout, which is a separate national framework that's specifically designed for all-payer claims databases. And so, it includes those data elements that are necessary for sort of this type of administrative research and analysis, the condition, and diagnosis. And then information about payment, the allowed amount, the charge by the provider, the allowed amount by the plan, the paid amount by the plan, and

the out-of-pocket cost by the consumer. That information about the consumer as well from the enrollment file that plan has.

COMMITTEE MEMBER SCHAEUBLE: So, what if information, if any, would be excluded at that point?

MR. VALLE: That's a great question, Dr. Schaeuble. And we may not have specific information on that in the slide deck, but the data release program, and we will talk about it, now that I'm remembering, has several conditions for the request for information. Including that the minimum data necessary to perform any sort of particular research or analysis is provided, and that may be a subset of the data that's available in the database itself. And we -- I can't remember if we get into that in the deck, but would be happy to share more about that.

COMMITTEE MEMBER SCHAEUBLE: Okay. But I don't think that was the question I was trying to ask. Is all of the information from claims submissions included in the database or are some pieces of information considered not appropriate and, therefore, not included in the database?

MR. VALLE: Yeah, it's a good question. And in terms of the reasoning why, I think I'll ask Wade Iuele, if he's on the call.

I'll start off to say that the purpose of abstracting from the claim is really to make all of those

records efficient and effective for research. That receiving all of the information on an individual claim would be -- would be more information that you need and would not be structured in the right way for data analysis.

But I don't know if we can unmute -- Wade, do you want to share more about the -- I think Dr. Schaeuble's question is about sort of the transformation from what's on the 837 to common data layout format.

THE REPORTER: Can I just get a quick spelling for Wade Iuele?

MR. IUELE: It's I-U-E-L-E. This is Wade.

The layout we're using, the all-payer claims database common data layout was designed specifically for APCDs. So, it has less information than an 835 and 837 file format. It's data that APCDs need so we can get all of that data and use it all to make the HPD analytic dataset.

VICE CHAIR DICKEY: So, APCDs is a term that I don't know that you've used before, but it stands for all-payer data, I guess.

But can you say more about other states and how they're doing this. California is not alone, right.

MR. VALLE: No, we're not. As mentioned, over 20 other states have all-payer claims databases. Actually, next month we'll be convening in Austin, Texas to talk about the administration of these databases. The common data

layout that Wade described is governed by a national consortia, the National Association of Health Data Organizations. And Dr. Krawczyk, who's on the line, is a board member of that organization.

But if there's more that you'd like about the transformation, if you will, and the data elements that are in the common data layout, I'm happy to provide that.

COMMITTEE MEMBER SCHAEUBLE: Well, what I'm trying to get a sense of is the kind of information that would not be included in the database versus the kind of information that automatically is transferred into the database. And in particular, if there are certain sensitive kinds of information that are not incorporated into the database, or not. I don't think I can tell from what you've said so far.

MR. CRAIG: Mike, would you like me to?

MR. VALLE: Yeah, please, Chris.

MR. CRAIG: Thanks for the question. So, to your point and as Wade mentioned, for the common data layout, those of you who are familiar with X12 transactions, from an administrative simplification point of view the primary source of the data elements in the common data layout are sourced from X12 transactions.

The key elements maybe that you might be thinking of, direct identifiers, are included in the CDL. We also get codes on diseases and conditions. There is information

such as address, race, and ethnicity, other demographics included. But there -- it's not a complete transcription of the X12 claims.

There are certain elements -- you're asking me to dig deep from my days as a HIPAA administrative simplification expert. There are elements such as paperwork elements, and other pieces that are not included. But it does give a fairly comprehensive picture for the basis of payment, and the patient, and the provider perspective for the service delivered.

Is that -- without looking at the -- pulling up the CDL layout, which is available to us going from memory, does that address your question?

COMMITTEE MEMBER SCHAEUBLE: Well, I think what you're telling me is that pretty much everything is there except maybe the text of comments from a physician or something of that sort.

MR. CRAIG: There is a -- there is a fair amount of information in the CDL, yes.

COMMITTEE MEMBER SCHAEUBLE: Okay. I'll leave it there for now.

MR. CRAIG: Okay.

VICE CHAIR DICKEY: Do you want to continue with your --

MR. YI: Yes, I just want to know that through our

regulatory process we adopted the common data layout. And I believe you can still see that on our website, if you're curious about all the data elements that we do collect.

And so, going on to the second element of this informed consent waiver, it's whether the HPD can be practicably implement. Oh, the slide before, please. Be carried out without waiver of informed consent.

And we believe it cannot be just because of the mass of people involved. And also, the fact that we want that complete data for, basically, all of the residents of California in order for the government, and others, to be able to have good data to use for policy.

So, if we go to slide 10, I believe. And so, the legislature, when they enacted the HPD statute, recognized that it's a lot of data and a lot of censored data, as Dr. Schaeuble's question referred to.

And so, the HPD statute, itself, has many privacy safeguards within it. What Mike explained earlier about the secure research enclave, that's one of the big pieces that HPD statute requires.

And this is -- as Mike explained, it's a controlled environment to prevent the release of this sensitive information to the public.

But there are other privacy controls or protections within the HPD statute. This slide talks about

Article 8 of the Information Practices Act. This is interesting in the fact that under normal Information Practices Act anybody can ask a state agency are you collecting information about me. And then, they can review that information and ask for corrections, if that information is incorrect.

The legislature, for HPD, exempted HPD from that requirement. And this goes to the theme of the fact that the legislature was basically taking the individual out of the HPD system. Such as, you know, similar to informed consent.

And the individual can't even ask HPD, you know, whether they're records are in HPD. That's what Article 8 of the IPA, the Information Practices Act, allowed individuals to do.

Although the legislature exempted the HPD from this, they also added protections in the HPD.

The HPD is for analyses about the general population as a whole, not about individuals. And the statute literally states that.

It also states that information in HPD cannot be used for individual decisions for healthcare payment or anything similar to that.

DR. RYKACZEWSKA: Which slide should we be on.

VICE CHAIR DICKEY: Sorry to interrupt.

MR. YI: That's okay.

DR. RYKACZEWSKA: Should I go back?

VICE CHAIR DICKEY: I don't know.

MR. YI: Yeah, and that is actually slide number 12. Sorry, I'm getting ahead of myself.

DR. RYKACZEWSKA: Thank you.

VICE CHAIR DICKEY: Oh, okay.

MR. YI: And so, if you look at this slide, this slide talks about many of the protections that HPD statute has. And as discussed earlier, the HPD statute contemplates releasing this information outside of the state to private users.

And HPD statute has a whole legislative scheme about release of data to these private users. There's many steps and many criteria that these users have to establish in order to get confidential information.

HPD statute also differentiates from limited data, from research identifiable data and requires much higher standards for research identifiable data.

As noted earlier, also HPD data can be released through the enclave or directly transmitted to outsiders. Again, HPD statute requires a more heavy lift for an individual to get direct transmission of HPD confidential data.

HCAI developed regulations for the application

process and the reasons why certain applications would be denied. One of those requirements is that if somebody wants to get direct transmission of the data they have to establish why they can't use the enclave.

Another protection, if you look at the last bullet point, HCAI -- HPD has a separate committee called the HPD Data Release Committee. For the most sensitive data requests, HCAI is required to send these requests for review for the Data Release Committee. And if the Data Release Committee does not approve the request, we cannot release the data.

On top of that, HPD statute also requires some of the most sensitive research requests to go to CPHS for review under the IPA.

And on top of that, for Medi-Cal data our regulations also require that data to go to DHCS for their review and approval.

And so, there are a lot of checks and balances built into the system by statute and also by our regulations.

COMMITTEE MEMBER LUND: Who decides what the most sensitive data are that would get -- data requests are that would get sent to CPHS?

MR. YI: That is controlled by statue.

COMMITTEE MEMBER LUND: Okay.

MR. YI: Statute requires research identifiable data for research to go to CPHS.

COMMITTEE MEMBER LUND: Identifiable.

VICE CHAIR DICKEY: Just identifiable.

MR. YI: And our regulations require custom limited datasets for research to go to CPHS as well, because of a quirk in the statute.

COMMITTEE MEMBER LUND: And by limited datasets, do you mean this is the same way that the HCAI data around hospitalizations and so forth are limited datasets?

MR. YI: Correct. HPD uses the definition of limited datasets from HIPAA.

COMMITTEE MEMBER LUND: Okay.

MR. YI: So, if you look at the third bullet point, that statute also requires HPD to have data use agreements with outside users. And also, ties it with some of the criminal sanctions from the IPA, any violations of these data use agreements.

And if we go to the slide before. I think a big concern has been raised, I think part of the IRB review includes the security and privacy policies that we have as part of the HPD.

This slide talks about how the HPD has gone through many reviews for its privacy and security controls.

The California Military Department performs a

security assessment on the HPD system. We have to go through the California Department of Technology, the CDT, which oversees the HPD project and the system.

And a requirement to get annual data from CMS, we have to fulfill their security requirements as well, which they look over and approve.

And so if you go to slide 13, I think that's basically the end of the presentation about the security, privacy, and the informed consent exemptions under the Common Rule. This slide is just about CPHS's role under HPD law regarding HPD data releases to outside entities.

And so, this talks about, this cites to some of the legal provisions that talk about CPHS's role. And it also discusses the data requests which CPHS would be involved in.

The next slide.

MR. VALLE: So, with that we'll again say thank you for the opportunity. And as your deliberations continue, we're standing by to answer questions today. We welcome feedback on the data management plan that we shared, or any other questions about our data policies and procedures.

And then, when the time is right, we'd like to talk about how the HCAI and CPHS can work together around processing those research identifiable requests, or anything

else that HCAI can do to be of assistance to the Committee.

VICE CHAIR DICKEY: Thank you. So, at this point we're looking at the database itself, not these individual requests, which we will deal with in the future.

So, as I said at the start, I think there's two big issues. This issue of policies and procedures. And I guess the question is for that you've given us a healthcare payments data system data management plan. It's, I think, an abbreviation of your data management plan. And a copy of your data use agreement document. This is with CMS I think, right?

MR. VALLE: Yes.

VICE CHAIR DICKEY: But you have data use agreements that people would have to sign with you to get the data, right?

MR. YI: Yes. Currently, we don't have one executed as of this moment. We have been working on a template with DHCS. And that might be good to go pretty soon.

VICE CHAIR DICKEY: Okay. Well, that might be useful for us to see when you have it.

But in general I think what the Committee needs to sort of decide is given the fact you've got the California Military Department, which I really don't know what it is. Is this the National Guard?

But the California Department of Information Technology has reviewed this and will review it on an ongoing basis, is that right?

MR. CRAIG: That's correct. I can answer questions on both. So, the HPD platform as a state system and as a federally funded system, is subject to the standard controls for all state systems.

We have an entire chapter within the state administrative manual that is focused on information security programs, has about 70 different sections that are each subject to auditable controls.

The department generally, and including the HPD system, must abide by the National Institute of Standards and Technology's Special Publication 800-53. I promise I will not nerd out too much about security for this body. But that document, which is required for state and federally funded system, has 20 information security control families in it, with over a thousand individual auditable security controls. From everything from access management to training and techniques for staff, and workforce. It's a very comprehensive and landmark security control set for system of this type.

We also are subject through the California Military Department to, as we mentioned, independent security assessments. Those include both risk assessment of

systems, and configurations, and organizational practices, as well as technical testing of systems. That happens every two years. We are in the middle of our biannual assessment right now. The technical testing completed in March and we are waiting the out brief for the risk assessment.

The HPD system was also independently penetration tested, which means we hired somebody to pretend to be a threat actor to try to hack the system. We did that in December and got a report out for that in order to meet our requirements from CMS for federal funding.

The CDT audits that Dr. Dickey mentioned, they happen every four years, with a check and review every two years, and that is happening in August.

COMMITTEE MEMBER KURTURAL: I have just a technical question.

MR. CRAIG: Sure.

COMMITTEE MEMBER KURTURAL: I'm assuming that HCAI got an RFP out for a contractor to develop the system, or is this in-house?

MR. CRAIG: I'll let Mike speak to that.

MR. VALLE: Yeah, I'm happy to answer that question. So, we -- actually one of the recommendations from the review committee of stakeholders and experts that we convened in 2020 was to implement a modular system. So, to not rely on any one vendor for the implementation of the

HPD system. So, that's what we've done.

We have a platform vendor, whose responsibility is to collect the commercial data, the commercial claims data from commercial health plans. And, I mean, some components of the HPD system also reside within HCAI's local environment that we maintain ourselves such as the master person index and other components.

COMMITTEE MEMBER KURTURAL: But overall HCAI is the main administrator on the entire system.

MR. VALLE: Correct.

COMMITTEE MEMBER KURTURAL: And there is no other outside agency, outside businesses or anything like that, that would have the same controls?

MR. VALLE: We have a technology partner, like I described, that's collecting that data and also running the research data enclave.

Chris, do you want to describe OnPoint's --

MR. CRAIG: Yes. So, contractually we bind all of our vendors to something like a five-page security agreement above and beyond the IT general provisions that tend to apply to all state IT systems.

Included in that, because it is federally funded, there are considerations for federal requirements on information security. We have frequent, I mean weekly meetings with all of our technology partners including not

just operational considerations, or on system performance and data movement, but also security considerations. And we have very tight integrations among all the security teams.

Obviously, since this is a public setting I cannot get more into some of the details of that. But speaking as the Chief Risk Management Officer, I will just say from a personal note I watched the work of this Committee for a non-HPD work, and I very much appreciate the work that you do.

This is one of the most secure platforms that I have ever worked on. And I have done a lot of statewide health IT.

COMMITTEE MEMBER KURTURAL: Appreciate it. Thank you.

COMMITTEE MEMBER LUND: Will these data be shared with any other states?

MR. YI: We have not gotten a request and I don't believe that would be -- I mean, I guess we haven't really addressed that question, but I don't belief it's likely or a possibility.

COMMITTEE MEMBER LUND: Okay, that's different than no. I guess I would have a concern. This is a huge database and I sent Agnieszka the common layout so that everybody can take a look at all of the data fields that would be here. And you weren't here earlier in the meeting

for my expressed concerns about sharing data with other states on, for example women's reproductive history and so forth.

So, I'm just concerned about you're still in process, I understand you're still in development and a lot of these things are still being worked out. But I just personally express concern that these data might be shared with other states and misused.

MR. YI: Oh, that is a concern that, you know, that was brought up. We have -- we have regulations about how entities can request data. And there is a regulation about how, you know, the reasons why we would deny data.

And one of the reasons is if it threatens the health and safety of the individuals.,

And so, there has been discussion internally about, you know, sensitive procedures, like reproductive health. And so, those -- you know, we would -- we evaluate every application very closely. And if we have good reasons to deny it, we will.

And so, that is definitely a concern that we are aware of.

COMMITTEE MEMBER LUND: Okay.

MR. GOLDMAN: And with respect to identifiable information we have good reason to deny it, and we'll have that opportunity, too.

COMMITTEE MEMBER LUND: Because from what I'm understanding, our review of this database is under the Common Rule.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: But subsequent research studies that would come to us would be IPA.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: Yeah. So, okay, I'm back to the loop of what we discussed earlier.

MR. CRAIG: Might I make one remark? I believe you said one of the concerns that you mentioned was sharing with other states' reproductive data. Did I hear that correctly?

COMMITTEE MEMBER LUND: Well, I'm concerned. I gave reproductive data as an example. But I am concerned about a number of -- this is highly identifiable and very detailed information on medical history and billings.

And so, I am concerned with sharing that information with states, yes.

MR. CRAIG: Okay. Yes. I just wanted to make the point specifically about reproductive data. Obviously, HPD statute is not the only law that we follow when considering data release. There are laws on the books in California that severely limit the sharing of reproductive health information health information with other states. And that

is something that I look at when I'm performing my data release reviews. And we also follow IPA quite closely, as was already mentioned.

So, yes, that is a definite consideration for that. Because of the risk of harm from a data release is a very important consideration for us.

COMMITTEE MEMBER LUND: Because I would suggest that there are data fields that are not protected in statutes that are still risky. Any information on gender identity, and transition surgeries, and there may be information in some of these databases on country of birth. So, I am just -- I'm just expressing concern.

MR. CRAIG: Yes. And I hear you one hundred percent.

COMMITTEE MEMBER LUND: Sorry. I can't see him if I'm here.

VICE CHAIR DICKEY: So, can you keep DOGE from getting in --

(Laughter)

MR. CRAIG: I am not a lawyer. I should just say I'm not a lawyer.

MR. VALLE: We have several.

COMMITTEE MEMBER AZIZIAN: Mental health would be, you know, incorporated in this as well, right?

MR. VALLE: If it generates a claim under

insurance. Of course, a lot of mental health is paid, you know, out of pocket.

COMMITTEE MEMBER SCHAEUBLE: I'd like to offer a couple of low level thoughts and a couple of higher level thoughts, and see what you might say about any other. I mean, this is obviously a tremendously important project and I'm super glad to see the implementation of a secure data enclave as a way of protecting data, and providing it to researchers.

Looking at the application as it was provided to us, it's hard for me to look at the application without trying to think about the implications that go beyond just the question of the database itself, without thinking about how the database will be used. Because, I mean let's face it, the database isn't any good to anybody until it's used by someone for some purpose.

VICE CHAIR DICKEY: Just to try to -- if you look at what the Common Rule, the slide we showed that said, and we need to look at use and issues. So, it's not just the database, but also how it's used.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I think that hopefully makes some of my thoughts relevant.

A couple of the low level thoughts, again just looking at the application, it said at the beginning no vulnerable populations were involved, and then later on said

something like, well, given California's population there will be vulnerable sub-populations included, but they're not being targeted.

Well, really, I think the more direct thing would be to acknowledge up front that even just starting from the stand point that a significant part of the database is Medi-Cal data, that pretty much says right away that vulnerable populations are a part of what we're looking at here.

Similarly, in another vein, the description of risks seems to try to say that there's very little risk related to the information in the databases -- in the database, yet. We've got all kinds of claims going into it. As was just asked a moment ago, mental health claims are part of that, gender-affirming care. I'm sure there are lots of others we could toss out.

And, well, I guess especially with what has been happening in our country in recent months, I think people are getting more and more concerned about the nature of the information in databases that if it ever were compromised in some way could lead to rather serious problems for individuals.

So, those were two thoughts at a lower level about looking at the application form.

At a higher level, I thought in reading your description of procedures that it implied there was perhaps

some discretion on your part about when CPHS review might be sought in connection with data releases to researchers. And at the same time I was sort of hearing a few moments ago comments to the effect that it was pretty much laid out in enabling legislation. And I guess I thought you were saying only the following things, because of the legislation, would be projects that would come to CPHS, and other things, I guess regardless of any circumstances, would not.

So, I'm hoping you might clarify that a little bit.

It seems to me, from what I'm seeing of the situation, that you probably are anticipating that in many instances research that would be done with the data would be done with some kind of a de-identified data where you are not contemplating any review by CPHS.

And I don't know, but I'm wondering if that might even be the majority of instances of data usage.

And then, one final thought is I know we're -- and I understand that so many of you are so heavily involved in all of the technical aspects of how the data are secured and protected. But I had the occasion a few months ago to try to do a little bit of looking into some of the research on de-identified data, and what are the possibilities and probabilities of de-identified data being re-identified in some way.

And what I was seeing in a lot of that research was that it was a lot more possible than many people in the general public might have assumed to be the case.

In one of the articles I was looking at, the conclusion they drew was that the results of the study they did our results rejected claims that, first, re-identification is not a practical risk. And second, sampling or releasing partial datasets provides plausible deniability. Moving forward, they questioned whether current de-identification practices satisfy the anonymization standards of modern data protection laws, and emphasize the need to move from a legal and regulatory perspective beyond the de-identification release and forget model.

And I'm wondering in all of this in what way you are dealing with, or trying to deal with, or if it can be dealt with the apparent risk that taking the identifiers named in HIPAA out of data, and assuming that that protects them from re-identification may not in fact end up doing that.

So, that's sort of a series of things to try to probe your thoughts on.

VICE CHAIR DICKEY: Do you guys want to take them one by one or --

MR. VALLE: Sure. And I'll start, Dr. Schaeuble.

Thank you so much for that. Let me just start with the de-identification policy for public information that HCAI follows, which was established by the Health and Human Services Agency. And I understand, actually, that the agency is in the process of revising that standard. That may be something this Committee has an interest in. But that's what's applied to our public information.

And then, I apologize if our application was not clear. James, I might ask you, if you would, to walk through the statutory delineation between access to the standard limited dataset and the identifiable data that, as I think you correctly mentioned, is required to be reviewed by this body, or it's listed researchers.

MR. YI: Yeah, I can clarify that. It's confusing for us, as well, because just the way that statute separates everything out. The statute makes differences between limited versus research identifiable data. And then, there's another dichotomy about enclave access versus direct transmission. And there are different requirements for different things.

And so, statute lays out that release of any research identifiable data goes -- needs, requires CPHS review and approval for that data to be released. And so, that's enclave access and direct transmission.

Through the regulatory process, we also included

custom limited data via direct transmission also goes through CPHS approval based on a legal interpretation of our statutes.

Otherwise, for limited datasets through enclave does not require CPHS review. And standard limited datasets by direct transmission does not require CPHS review. And this is all based on statute.

COMMITTEE MEMBER KURTURAL: Are you concerned about what data de-identification methodology that they're using? Like one question I had is the -- your interpretation of de-identification aggregate, or are you going to be publishing individual record data and using the safe harbor? Could you talk more about that?

MR. YI: Oh, yeah. So, HPD statute says the only public data products that can be released must be aggregated.

COMMITTEE MEMBER KURTURAL: Okay.

MR. YI: And must be de-identified. And so, any record level data cannot be publicly released.

COMMITTEE MEMBER KURTURAL: Okay.

MR. YI: That's by statute. And through regulation what we did was we adopted the agency de-identification guide as a way -- as the standard for, you know, outside researchers to de-identify the data. And we made that very specific in regulation. And that we will

check whether it was officially de-identified before it is publicly released.

COMMITTEE MEMBER KURTURAL: Well, that might answer a question Dr. Schaeuble, did the --

COMMITTEE MEMBER SCHAEUBLE: Well --

COMMITTEE MEMBER KURTURAL: No.

COMMITTEE MEMBER SCHAEUBLE: Let me be sure that I'm understanding the language that's being used here.

When you say publicly available data, releasing data to a researcher, is that coming under the phrase publicly available?

MR. YI: Oh, yeah, in -- the way I'm using it, it would not. That is a controlled release that's governed by regulations, and statutes --

COMMITTEE MEMBER SCHAEUBLE: Okay, I didn't think so. All right. Well, let me give an example of a kind of situation that I think would be troublesome for the Committee.

A researcher asks for a limited dataset, not only wants to analyze information in that limited dataset, but wants to try to link data in that dataset to information from other sources using some kind of probabilistic matching of people from the two sources, your source and whatever else they're trying to acquire information from.

What I'm hearing from you is from your perspective

your releasing a limited dataset does not come under our review. If we did know about it, we might be concerned about the implication of trying to link that data to other information that might be considered even more sensitive, and less well controlled, or whatever.

Am I describing a situation that could happen?

MR. YI: It could happen. In our data release application requirements we ask what the intention is about linking data to other datasets. Because that is a concern that we have thought about.

Unfortunately, we are bound by our statutory mandates. And so, I think that's an issue that we can further discuss.

But we also have our HPD Data Release Committee, and we have statutory discretion to refer cases to them, that otherwise would not be under their review.

And so, the department is aware of that issue. We are thinking about it and there are avenues to get your other outside review of that, of those requests as well.

And I don't know if that --

COMMITTEE MEMBER SCHAEUBLE: And in the situation I described, are you saying you believe you do or do not have the ability to refer such a project to CPHS as well. Because it sounded to me like you were saying maybe you think you cannot.

MR. YI: I don't -- I don't think anything prevents us. But I think statute basically states CPHS has a certain amount of decision making authority over these requests, or certain requests.

And so, if we did refer it to CPHS for those limited datasets, you know, we may be able to get your recommendations and review but it wouldn't be control.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, it would be advisory only.

MR. YI: Yes.

MR. VALLE: Can we just take -- I want to just note that we're taking note of the concern, Dr. Schaeuble, and thank you for raising that for us.

COMMITTEE MEMBER SCHAEUBLE: I mean, linkage to other data has been a thorn for the Committee in quite a few of the projects we've dealt with over the years. So, that was the kind of example that I -- I think we would want to have some clear understanding of how you would be approaching it and how we should be approaching it, or if we can approach it or --

MR. YI: And I believe during our meetings with the HPD Data Release Committee that the members have raised similar issues about that, as well.

VICE CHAIR DICKEY: Would permission to do any linking with a limited dataset have to have a part of the

DUA that you would have with them. Do you have a --

MR. YI: It could be. The DUA, the thought is that it could be malleable based on specific use and specific data based on our review. So, it would be a case-by-case analysis for that.

VICE CHAIR DICKEY: Any other questions about the operations and maybe we can get to the informed consent issue, then.

MR. YI: No, I would highly recommend looking at our regulations. It has a lot of detail. It has a lot of requirements. It may be a little hard to read, but I think it would give you valuable insight into how we expect the data release process to work.

COMMITTEE MEMBER SCHAEUBLE: Are you able to give us any thoughts at all about the issue of safe harbor data, even possibly being re-identifiable, and how that has been taken into consideration at all? Because I think all I'm hearing is the technical aspects of securing the database, itself, but I don't know whether or if it's possible for you to deal with the kind of issue that I was raising.

MR. YI: I think that's a difficult question. I think, you know, there has been some conversations about that. And we've been relying on the de-identification standards that HCAI, itself, has to use. And so, we use that, you know, for the public data products in our

regulation.

I don't know to what other extent there's been conversations about that or analysis.

MR. VALLE: As I mentioned, there is a group of people that is evaluating those and trying to understand if they should be changed in any way.

But as James noted, they do apply to all agency reporting of public information.

COMMITTEE MEMBER SCHAEUBLE: It's such a huge database that it makes the kind of thing that's being described in the research seems so much more possible, simply because of the huge volume of information that is going to be in the database about all of the individuals in California. That's why it keeps cropping up in my head as a big concern.

VICE CHAIR DICKEY: Agnieszka?

DR. RYKACZEWSKA: Sorry, can I ask a clarifying question, because I was looking back on the visual that you had in the slide with the virtual machine. Oh, wait, I think it's this one.

So, I just want to check, through these virtual machines the researchers would not have access to all the data. They would only have access to what they've been approved to see. So, it's not that if they've been approved to have either the limited dataset or even the PII data that

they would have everything. It would only be what they've been approved to see.

VICE CHAIR DICKEY: Minimum necessary.

DR. RYKACZEWSKA: Minimum necessary, right.

MR. VALLE: That's correct.

DR. RYKACZEWSKA: Okay, I just -- okay.

CHAIR HESS: And any data linkages, the vast majority of data linkages are going to happen in the enclave, correct?

MR. YI: That's what we hope so.

CHAIR HESS: Okay.

MR. VALLE: And just to add, again this Committee and we haven't talked much about the Data Release Committee that is also established by statute, and there's a commensurate group of experts, healthcare and data security experts that reside on that group. I think we'll rely on these public bodies to help oversee these uses and to set that expectation and precedent with the research community and the users.

VICE CHAIR DICKEY: Having solved that --

(Laughter)

VICE CHAIR DICKEY: -- can we move on to the informed consent?

Okay, Chris, do you have a --

MR. CRAIG: Yeah, really quickly, because the

question about vulnerable populations on the application was raised. That may have just been a clerical problem. And many thanks to Agnieszka and Sussan for helping me complete the application.

In entering data into IRBManager, if you select vulnerable population from the list, you're required to complete a supplement that asks why the population was targeted.

Since by statute, we're obligated to collect data on all Californians, it would have been specious for us to say that we were targeting any of those populations. It was not an intent to mask the fact that there are vulnerable populations in the database, it's just the difficulty with the submission. So, I don't know if that was part of the concern. It was just really hard for us to fill out those supplements in a way that was truthful, when we weren't specifically targeting vulnerable populations.

VICE CHAIR DICKEY: Unfortunately, we didn't get $22 million to develop the IRBManager.

(Laughter)

COMMITTEE MEMBER LUND: Dr. Dickey, could I just make a comment on that?

VICE CHAIR DICKEY: Yeah, please.

COMMITTEE MEMBER LUND: And I do believe under the Common Rule, really the intent of that question is whether

or not the study is targeting vulnerable populations.

VICE CHAIR DICKEY: Correct.

COMMITTEE MEMBER LUND: It is possible to have a study that pulls from a general population pool --

VICE CHAIR DICKEY: Sure.

COMMITTEE MEMBER LUND: -- and also includes vulnerable populations, which I think I would characterize this effort as, rather than specifically targeting vulnerable populations. So, I think that that was --

MR. CRAIG: Yeah, that was our -- that was our intent in the application to clarify that.

VICE CHAIR DICKEY: That's it, yeah. Yeah.

COMMITTEE MEMBER SCHAEUBLE: Well, it seemed to me it was a little bit of both because by definition if you are capturing all of the Medi-Cal data, it looks to me like targeting the Medi-Cal population as part of what the study is doing. So, that was -- that was the lens I was using in looking at it.

VICE CHAIR DICKEY: Sure. So, I just want to -- can we move on to informed consent.

So, there's -- you mentioned the two major criteria for informed consent. And one has to be conducted by the state officially, it has to address public health, basically, issues.

And there is a section in that waiver that says,

also, that if the data was collected and people were asked to provide broad consent and they didn't consent, then you can't waive the informed consent for them.

And you mentioned, to your knowledge, none of these databases were collected where there was broad consent requested. Is that correct?

MR. YI: To our knowledge, there was no effort to get broad consent for this database.

VICE CHAIR DICKEY: Yeah.

MR. YI: At least to our knowledge, I believe.

VICE CHAIR DICKEY: Yeah. So, this whole issue of broad consent and, you know, opting out of broad consent (indiscernible) -- had the issue of opting out, a lot of people to opt out of your database. And we had a discussion about whether you thought that was permissible.

And Jared and Maggie looked into this, and looked at the statutes for us. And I'm going to ask Jared and Maggie to say what you think.

MR. GOLDMAN: Sure. So, I had a chance to meet with the HCAI team and I looked at their statute independently. And it appeared pretty clear to me that he comprehensive nature of the statute, and sort of the call of the mission of the whole HPD is one that does not provide for either obtaining informed consent or providing an opportunity to opt out.

In my view, providing people with that opportunity would undermine the very purpose of the project that the HPD is undertaking.

So, you know, while the statute doesn't say there shall not be an opt out or you -- you know, this does not require informed consent. It's pretty clear to me that it's implicit in the whole statutory scheme that an opt out or a request for informed consent isn't compatible with the statutory structure.

VICE CHAIR DICKEY: Does anybody have any questions about that?

UNIDENTIFIED SPEAKER: No, I think it makes sense.

VICE CHAIR DICKEY: So, if we all accept that, it sounds like we are in agreement with this issue of informed consent waiver.

But then there's the rest of it, there's a part -- we have other questions and concerns about the operations side. And I thought that was too easy, okay.

COMMITTEE MEMBER LUND: So, just understanding and acceptance are two different things. I understand what Jared has just conveyed. I'm not sure that I agree that it was a correct thing for the legislature to disenfranchise people in regard to informed consent for this.

So, I'm not saying that I necessarily object, but I just wanted to be clear about the semantics of the

situation, in that I think it's a little much of a -- too much of a gloss to say that, okay, we're all good with the informed consent.

VICE CHAIR DICKEY: No, I just meant legally.

COMMITTEE MEMBER LUND: Yeah. I understand what was said and don't disagree with that interpretation.

VICE CHAIR DICKEY: But how about the rest of it. Do we have more questions about operations that we need to know more about before we would feel comfortable approving it?

COMMITTEE MEMBER LUND: Are we going to be asked to approve this today or could we ask for more time? Because I really feel like this is a lot. And thank you, so much, for all -- this has been super, super helpful. It's been a deep dive, it's been very informative. I appreciate all of the information. But I think that it's a lot to digest and I'm not sure that I'm ready to vote today. And I would certainly defer to the rest of the Committee.

VICE CHAIR DICKEY: No, I understand that. But do you have other questions?

COMMITTEE MEMBER LUND: I do not have other questions.

VICE CHAIR DICKEY: About operations. But you want time to think about other questions.

COMMITTEE MEMBER LUND: Correct, I think that's

where I would fall.

MR. YI: And we have many, many public documents about the HPD. We have, I think there's at least three legislative reports. We have our rulemaking files for all our regulations. If the Committee wants anything, you know, we would be happy to provide all that.

COMMITTEE MEMBER AZIZIAN: So, you may have answered this already, but I keep going back to what is being exactly collected. And I understand the demographic information, the diagnostic codes. Periodically, there's also physician's notes that may have very specific information about an individual. Would that also be part of -- or, no, it's not --

MS. EVANS-DEAN: No. Only claims and encounter data is included.

COMMITTEE MEMBER AZIZIAN: Understood.

VICE CHAIR DICKEY: So, all those pictures you doctor puts in your medical charts --

MR. VALLE: We don't want 'em.

MR. CRAIG: Yeah, there was some effort -- I mean, EHR technology is quite sophisticated these days. The purpose of the database is mainly about payment and services provided. So, the detail -- like, and I plugged it a little bit earlier. And so, another example I thought of, I don't think that we get units, for example, although we might.

But some of that higher level detail that you might find in a medical record is not submitted.

COMMITTEE MEMBER SCHAEUBLE: I'm not clear on what you just mentioned.

MR. CRAIG: Oh, dispensing units for -- I was going from memory. I don't know that we get dispensing units for drugs.

COMMITTEE MEMBER SCHAEUBLE: Oh, okay.

COMMITTEE MEMBER LUND: Dosage.

MR. CRAIG: Yeah, dosage.

MR. VALLE: I'll just add, we are -- we do have a budget request, as Dr. Dickey mentioned. Since 2018 we've been spending a one-time $60 million appropriation, but we're requesting $22 million to continue the operation. Which we think is actually a fairly efficient use of funding for all of the types of analyses and cost savings that could be produced by this database.

Actually, there's an example using our hospitalization database for Covered California saved $20 million in one year showing the risk mix of their population versus what the carriers were saying. So, we think there's going to be a broad applicability.

And also, you mentioned IRBManager. We've produced our own workflow for data requests that will come to HCAI. And we would, of course, be happy to share that

with this Committee, if that would ever be of interest or use.

VICE CHAIR DICKEY: But you're not using IRBManager?

MR. VALLE: We're not.

(Laughter)

CHAIR HESS: Thank God for that.

COMMITTEE MEMBER SCHAEUBLE: I'm curious, can you say a little more about the hospital savings that were --

MR. VALLE: Yeah, absolutely. So, we have a hospital discharge database as -- as, I think, no it's a similar information in terms of the discharge record that's an abstract from the patient's record. And we provide that to Covered California, so they see things like emergency department encounters, and characteristics about the patients.

And so, during the COVID-19 pandemic there was a special enrollment session. And so, you had this cohort of people that were applying to join the Exchange, and then Covered California's in negotiations with the individual carriers about what the cost should be to managed care for those individuals. And they used certain algorithms to be able to show the risk mix and health of that population was better -- was better than the baseline, and that assisted their negotiations. And they produced a report and they

submitted it to the legislature about that use of the data.

COMMITTEE MEMBER SCHAEUBLE: So, kinds of things that were found that led to the potential cost savings?

MR. VALLE: Like lower emergency department encounters, lower readmissions, just a healthier population mix for the individuals that were -- the cohort of people that were in enrolled. And I'd be happy to provide the details of the report if that would be of interest.

COMMITTEE MEMBER SCHAEUBLE: Comparing regions of the state or comparing -- when you say lower, lower for what group than some other group?

MR. VALLE: The cohort of individuals that during the special enrollment period that was open to the pandemic were apply to join the Exchange.

COMMITTEE MEMBER SCHAEUBLE: Oh, okay.

VICE CHAIR DICKEY: So, I'm kind of hearing that this may be a little too much for members to swallow all at once. Is that right? I hear people saying yes. But we've kind of resolved this issue of informed consent. Is that true?

Anybody have -- I just want to have a good voice, one takeaway from this, which is that we believe Jared and we believe their lawyers that informed consent -- we can't grant that.

And how would you guys feel about coming back to

the next meeting and, in the meantime, dealing with any of these operational concerns that some of the people have?

MR. VALLE: We completely respect the deliberations and decisions of the Committee. And as was mentioned, we'd be happy to share information, talk to members, whatever would please the Committee.

CHAIR HESS: I think we have a couple options on that. Either we could bring this back on the June meeting agenda, or if the Committee agrees, we could schedule an ad hoc meeting in May, mid-May.

VICE CHAIR DICKEY: May.

CHAIR HESS: Just to focus on the HPD project.

COMMITTEE MEMBER LUND: It's already the 25th of April.

CHAIR HESS: Yeah, so it would just -- it would be like three weeks out. I don't see a lot of enthusiasm for that. And what our meeting is likely to be very early in June, right.

COMMITTEE MEMBER LUND: It's the 7th, I think, isn't it.

VICE CHAIR DICKEY: It's only six weeks off until the next meeting.

CHAIR HESS: Yeah, June. And we think we'll have a quorum for that meeting. We don't anticipate any --

DR. RYKACZEWSKA: We have not inquired about

quorum yet, on that meeting.

CHAIR HESS: Okay. I think it's fine to discuss this in June, then, and let the Committee have time to review everything that needs to be reviewed, and have the Committee feel comfortable with an approval.

COMMITTEE MEMBER LUND: So, do we need a motion to table it and do we need public comment before we do that.

VICE CHAIR DICKEY: Oh, yes.

CHAIR HESS: We do need public comment. So, I will will invite any members of the public, either in person or remotely, who would like to comment on this to please speak up.

MR. ZADROZNA: No comments in person.

DR. RYKACZEWSKA: Thank you, Nick. I'm giving it just one more second for any virtual hands. I'm seeing none.

VICE CHAIR DICKEY: Okay. So, I'll make a motion to table and revisit this issue at the June meeting. And do you guys have any concerns about that?

MR. VALLE: Again, we respect the decisions of the Committee, of course. I will just say, since we opened the application portal in December we've had 12 requests for data. They're not all research identifiable datasets. But I can say the research community is certainly eager to begin the process that they know will take a significant amount of

time, and there's many check points along the way. And just wanted to share that with the Committee, as well.

VICE CHAIR DICKEY: Well, luckily, you don't have to wait two months.

CHAIR HESS: How shall we know any Committee members that want further documentation and information?

VICE CHAIR DICKEY: Yeah.

CHAIR HESS: Should that come to you, Dr. Dickey, and then you can reach out to the HCAI team?

VICE CHAIR DICKEY: Ah --

CHAIR HESS: I could do it. It doesn't matter.

VICE CHAIR DICKEY: Yeah. How about Agnieszka?

DR. RYKACZEWSKA: I can take it on. Yes, you can --

VICE CHAIR DICKEY: What if you submit your questions to Agnieszka and she'll forward them on to the appropriate person there.

CHAIR HESS: Yes.

VICE CHAIR DICKEY: I'm no longer a state employee so --

(Laughter)

CHAIR HESS: I just thought that would be easier than people throwing individual questions at the HCAI team.

VICE CHAIR DICKEY: Yeah.

CHAIR HESS: So, we could kind of maybe collate

some of the questions and requests for further information. So.

VICE CHAIR DICKEY: Yeah, I mean, as you get them I would just send them as soon as you can to them, so they'll have time to deal with them, you know.

DR. RYKACZEWSKA: And just noting, we did share the link that was on --

COMMITTEE MEMBER LUND: Thank you very much.

DR. RYKACZEWSKA: -- about the materials you guys mentioned, as well.

VICE CHAIR DICKEY: Okay. So, I made a motion there.

COMMITTEE MEMBER LUND: Second.

THE REPORTER: Who seconded?

MS. ATIFEH: Ms. Lund.

THE REPORTER: Thank you.

MS. ATIFEH: Okay. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: And Dr. Ruiz?

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: We'll be in touch.

MR. VALLE: Thank you so much.

CHAIR HESS: Thank you very much.

MR. VALLE: Okay, thank you.

CHAIR HESS: I think that was our last new project. Okay, so we can move on.

Are there any Committee members' questions or comments on Agenda Items I through O?

Any public comment on Agenda Items I through O?

MR. ZADROZNA: No public comment in person.

DR. RYKACZEWSKA: And I am not seeing any virtual hands.

CHAIR HESS: Okay. Are there any public comments for items not listed on the agenda?

MR. ZADROZNA: No public comment in person.

DR. RYKACZEWSKA: And I am looking for a virtual hands. I'm seeing no virtual hands raised, either.

CHAIR HESS: Okay. So, our next full board meeting will be June 6th.

And if there's nothing else, I adjourn this

meeting at 12:32.

(Thereupon, the meeting was adjourned at 12:32 p.m.)

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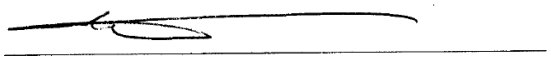
REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 9 day of May, 2025.



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I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber. And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.
IN WITNESS WHEREOF, I have hereunto set my hand this 9th day of May, 2025.

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