MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, JUNE 6, 2025

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AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

COMMITTEE MEMBERS

Catherine Hess, PhD Dr., Chair

Larry Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Nicholas Zadrozna

ALSO PRESENT

CalHHS

Jared Goldman, General Counsel

HCAI

Michael Valle, Chief Information Officer

Chris Krawczyk, PhD, Chief Analytics Officer

Dionne Evans-Dean, Chief Data Programs Officer

James Yi, Attorney

Wade Iuele, HDP Consultant

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Ms. Alma Torres-Nguyen, Kaweah Health

Ms. Abigail Ramirez, CDPH

Dr. Christopher Anderson, Public Health Foundation Enterprise (PHFE), WIC

Dr. Kelsey Pukelis, Harvard University

Dr. Joelle Atere-Roberts, Mathematica

Dr. Dana Peterson, Mathematica

I n d e x

CHAIR HESS: I will first ask if remotely participating members can please turn their cameras on, if they are on already. They all are.

And, Sussan, could you start the roll call?

MS. ATIFEH: Sure. Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Present.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Present.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: And for the record, Dr. Dinis and Dr. Ventura are not attending this meeting today. So, a quorum is established.

CHAIR HESS: Okay, we have established a quorum.

I don't have any other opening remarks, other than we still are not able to discuss the findings of the subcommittee. Thank you very much. We don't really have any updates other than that, so I'll turn it over to you.

DR. RYKACZEWSKA: Thanks. So, I have several administrator updates to give today. I'm going to start with a recruitment update. So, as we all know, we have two openings on the board at this time.

And I am excited to share that we have received applications from four candidates to join the Committee. These are currently being reviewed by the Chair and the Vice Chair.

And then, per the policies and procedures once these are reviewed the next steps would be for the Chair to provide a prioritized list of candidates to the secretary, who would then appoint the members based off of those.

So, any questions there in terms of that update? Not hearing any, I will go on then to my next update, which is an update on the adverse event investigation.

So, at the last meeting we reviewed an adverse event and part of our motion was to notify the chief information security officer at UCSF, and to ask them to investigate whether there was a security breach and whether any personal identifiable information was exposed.

We received an update, just earlier this week,

from the chief information security officer at UCSF that they have concluded their investigation. They report that they have verified that the data was encrypted and that they found no indication of unauthorized access.

They did submit a report to us. I will just note it was marked as confidential, so we have not shared that out. But if members have questions, need additional information, please reach out to me and I can make connections or share additional information. But wanted to at least follow up on that motion and make sure that I was keeping the board informed of the findings.

And then, my final update today is related to the review of the CPHS Policies and Procedures. So, in alignment with best practices we are seeking to do a review of our policies and procedures to make sure that they're up to date with any regulatory changes, and that they reflect best practices.

To support these efforts, we are seeking to secure consultation services from experts in OHRP, FDA, and State Human Subjects Regulations, and who have experience in IRB administration and operating procedures.

The intention is for the consultants to review our policies and procedures, as well as any other supporting documents, and to make recommendations to the board, and for the secretary's review and consideration. So, they would

bring them back to you to -- with suggestions and recommendations.

I'll also note that what we -- it might be separate, but related, we additionally sent out consultation services for an expert in AI, and data security. However, we were not able to identify a consultant that met those -- or had that experience and expertise, so we're going to go back to the drawing board. But we did at least try to secure those services, hearing the board's needs for services related to that. But we're back to the drawing board to figure out what our next steps are related to them.

And those are the updates.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: Any questions?

CHAIR HESS: Sorry, I just stepped in.

DR. RYKACZEWSKA: I'm not hearing any questions.

CHAIR HESS: That's okay. We can move on to review and approval of meeting minutes. So, I move -- okay, public comment first. I'll almost jumped the gun there.

So, are there any public comments on the meeting minutes from the January 10th Subcommittee meeting, the Framework Subcommittee?

Don't see comments in the room and I am not seeing any online. And I'll just also note we did not receive any feedback from board members, as well.

CHAIR HESS: Okay. So, then I ask for someone to make a motion to accept those, then.

COMMITTEE MEMBER AZIZIAN: I'll make the motion.

MS. ATIFEH: All right. Dr. Azizian makes the motion.

COMMITTEE MEMBER AZIZIAN: Yes.

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

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund? Oh, you are muted.

COMMITTEE MEMBER LUND: Abstain.

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: Okay, the motion passed.

CHAIR HESS: Thank you. So, now we'll move on to review and approval of the meeting minutes from the March 7, 2025 full board meeting.

Are there any public comments on the March 7th full board meeting minutes?

DR. RYKACZEWSKA: And if you have any public

comments, please raise your virtual hands. There's none in the room. I'm not seeing any online.

CHAIR HESS: Okay. Would someone like to make a motion to approve the March 7th meeting minutes?

COMMITTEE MEMBER KURTURAL: I'll make the motion.

MS. ATIFEH: Carrie Kurtural making the motion.

COMMITTEE MEMBER JOHNSON: Jonni Johnson seconds.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: 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: Abstain.

MS. ATIFEH: The motion passed.

CHAIR HESS: Okay. I think that's it for our meeting minutes. And we can move on four minutes ahead of schedule to our first project. We're going back to --

COMMITTEE MEMBER LUND: Yes. This is an amendment. Thank you, Dr. Hess.

The board has previously approved this project. And the researchers are asking for -- in this amendment for some expansion to the population from which they will be selecting to recruit people.

And they're also asking to recontact individuals who were originally contacted to ask some additional questions.

So, I wanted to bring it to the board because I felt like the expansion and the recontact were significant enough, and from a human subjects perspective, that I wanted to give everyone the chance to review and ask questions before approving.

So, Ms. Torres-Nguyen, do I have your name correctly, would you like just briefly describe your project and the amendment that's being presented to the board.

MS. TORRES-NGUYEN: Yes. Good morning, everyone. I'm working very closely with the other principal investigator, who is Abigail Ramirez, and so she will go ahead and provide that summary.

MS. RAMIREZ: (Indiscernible) -- our project today. I wanted to just give a general overview of the changes because they're quite -- there's just a few of them. And so, I'll give a general overview and then there are some partners, program partners that are online, that can help provide additional details.

So, I wrote a brief summary for all of you, and I'll start there. So, as Laura mentioned, we did change -- we made changes to the population. So, the target population for the study has been expanded to include any patients assigned to Kaweah Health via Tulare County Medi-Cal Managed Care Plan with asthma or chronic obstructive pulmonary disease, or COPD.

This change was made because the original target population, or ECM patients in this case, did not yield enough eligible participants for weatherization and energy services referrals.

Patients who previously met the inclusion criteria within the ECM program will remain in this pilot study. The goal is really to broaden the pool of potential eligible participants and enhance the study's reach and impact.

And then, I just wanted to provide a little bit more details about the information we've found and why this certain population did not yield sufficient eligible weatherization patients.

So, Kaweah Health developed an initial master list of 157 ECM patients who met the initial eligibility criteria. However, upon contacting these patients it was observed that many of them were ineligible for weatherization and energy services due to their housing status. We found that many of them were homeless or in

transitional housing. They lived in multi-family homes or apartments.

Additional barriers, such as patients' relocation, prior weatherization services with the five-year period. So, under the guidelines, if you've received weatherization under five years you can't -- you have to wait after that to reapply.

Additionally, a response -- some of them were unresponsive to contact attempts. There's also lack of an interest or folks express anxiety about program participation, as well as disenrollment from ECM program. And this further decreased the eligibility pool.

And so, as a result only 21 of the 157 patients, which is about 13.4 percent, were potentially eligible for weatherization services, with 13 ultimately deemed ineligible by Proteus for weatherization services.

The remaining eight completed the original approved intake survey and are paused in weatherization proceedings through -- until approval for additional baseline collection via amendment intake survey.

So, this required us to change some of the documentation and some of the timeline, as well. So, the timeline for collecting data after weatherization services was adjusted 6 to 12 months, for both the comparison and treatment group, to gather more information after the

intervention.

The consent -- the consent form, HIPAA form, and questions were also amended to include the expanded population. The intake and post-survey were updated with additional questions based on research on weatherization impact on health. So, those were the changes you'll see on that intake form.

These changes aim to capture data crucial for evaluation, for evaluating the intervention's full effect.

Eligible patients who completed the original survey will be contacted by CHW between June and December of 2024 to offer the option, so this is optional, to answer additional survey questions. The option also includes to share the consent form with them or review the consent form with them and walk them through any questions that they might have, as well.

We will not be reconsenting the eight households awaiting weatherization eligibility determinations since they were originally consented, and the services of weatherization have not changed. And this is also based on the guidance that we received from the Committee, stating that if there's no substantial changes to the services and folks were already consented that reconsenting is generally not required.

So, this is the summary of the changes that we

made to the protocol, and we're happy to provide additional details to the Committee.

COMMITTEE MEMBER LUND: Great. Thank you, very much, for that summary. I had a few questions that I put in IRBManager, that I thought were adequately addressed.

I felt like their strategy for reconsenting the eight individuals, that was fine. I didn't have any issues with that.

The additional questions don't seem to be of a sensitive or particularly confidential nature.

And I didn't see any reason to object to the expansion of the population, the recruitment population. So, all my questions were addressed.

So, I would open it up to the board, if there's anyone with a question for the researchers at this time. No hands, no questions.

DR. RYKACZEWSKA: There are no questions in the room and none online, either.

COMMITTEE MEMBER LUND: All right. Dr. Hess, community comments?

CHAIR HESS: I was about to ask. Are there any public comments on the amendment?

DR. RYKACZEWSKA: There are no members of the public in the room. If you would like to make a public comment, please raise your virtual hand. I am not seeing

any virtual hands raised.

CHAIR HESS: Okay. If you're ready to make a motion.

COMMITTEE MEMBER LUND: Okay. I move approve, minimal risk, and all other timelines remain the same for this research project.

CHAIR HESS: Can we get a second?

COMMITTEE MEMBER JOHNSON: I'll second.

CHAIR HESS: Dr. Johnson seconds.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: 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: Okay, the motion passed.

CHAIR HESS: Okay. Thank you, Ms. Lund and everyone on the research team.

MS. TORRES-NGUYEN: Great, thank you.

MS. RAMIREZ: Thank you so much.

CHAIR HESS: Okay, we are running a bit early. The standby time for the next project was 9:00.

Okay, so we are just talking about a project that was reviewed by Dr. Johnson. I believe, Ms. Lund, you were going to --

COMMITTEE MEMBER LUND: Yes, I am recusing myself.

CHAIR HESS: (Indiscernible) -- and recuse herself from this project. So, I will let you take over.

COMMITTEE MEMBER JOHNSON: Great. Okay, so Dr. Anderson, before I ask you to introduce yourself and your team, and give a short summary of the study, I wanted to provide the Committee with a bit of context around this study.

There is somewhat of a time constraint. The researchers were notified relatively not too long ago about approval of a change in infant formula that was going to occur. They're now submitting a study for review to contact WIC recipients who are going to be receiving that formula before and after the change occurs.

If you reviewed this study prior to Monday, the study also contained a component that involved sampling of WIC staff. That portion of the study has been removed. It is now going to be submitted as a separate submission. So, we're only reviewing the human subjects aspect for WIC

recipients.

We also met with the research team earlier this week, Dr. Hess and myself, to go over some outstanding issues. And the research team still wanted to move forward with potentially presenting this to the board today, to get feedback on it.

But I'll raise the issue that I'd like feedback from the board, if you have it today, and I'm still wondering if I'll be recommending deferred approval or tabling the issue to be reviewed in August.

Dr. Anderson, if you can please introduce yourself, your team, and give the Committee a short overview, particularly with emphasis on the time constraints that your team is focusing on.

DR. ANDERSON: Thank you, Dr. Johnson. So, my name is Christopher Anderson. I'm an Associate Research Scientist with PHFE WIC, which is a large, local agency with a program in Southern California.

My research team involves myself and the Director of Research and Evaluation at PHFE WIC, Dr. Shannon Whaley, who is unable to join us today.

And so, some additional background on this project. The WIC program provides infant formula to participating infants whose mothers are unable to fully meet the child's nutritional needs via breastfeeding.

The state level WIC programs provide infant formula via contracting processes, with individual manufacturers. And those contracts are renewed roughly every three years, but different states have different timetables.

California's infant formula contract that's currently in place went in August of 2022. And PHFE WIC was planning to do a local agency policy change in which we did a staff training about the types of infant formula that we provide to infants. Those types can be cow's milk based, or soy based, and they can include reduced (indiscernible) -- starch and different modifications. There are generally four infant formulas provided through the formula contracting process.

PHFE WIC is implementing a policy change which will involve making the cow's milk based non-lactose reduced formula the standard issued in the first month for all children who don't have a prescription or medical indication for a specialty formula.

We are -- the agency is doing this because there's a building body of evidence that the lactose-reduced formulas, with added corn syrup solids are associated with elevated obesity risk among formula feeding infants.

So, before that policy change can happen, the agency will also be doing a staff training. We had

anticipated these policy changes happening between October and December of 2025. But because the state WIC agency is changing formula manufacturers in the contract which will be implement in August of 2025, our timeline got moved up by over three months.

And so, we have submitted a proposal to the IRB, in the hopes of getting the ball rolling on getting feedback so that we can, hopefully, be prepared to start collecting data early in the month of August.

So, our plan is to collect survey data from caregivers of infants when the infants turn three months of age, and again when the infants turn nine months of age. These are planned to be online data collections. They will include a brief survey and a dietary recall to get a sense of, you know, maternal perception of infant feeding and then, actually what is being fed to the infant in the preceding 24 hours.

We also are hoping to collect anthropometric data on these individuals. And that will either be via the participants coming to a WIC site to have measurements collected or by having their healthcare provider fill out a card with the data of length and weight measurement, and the length and weight measurements, themselves, and then return that via the postal service to PHFE WIC.

So, obviously, we're working on a more abbreviated

timeline than we had anticipated, but we're hopeful that we can make the best of this situation and start making progress towards having a compelling study that will adequately address evaluating this sort of important public health challenge in the WIC program.

COMMITTEE MEMBER JOHNSON: So, I'll ask if the Committee has any questions based on the procedure, the general procedure of the study that was just presented, or the information that is in IRBManager describing the procedure.

So, I added comments in the application, particularly around the consent form. One of my concerns with the consent form is that it doesn't mention anywhere that there's a change in formula. Are recipients being notified that they are receiving a change in the formula?

DR. ANDERSON: So, we are unable, at the behest of the California Public Health WIC program, we were requested not to provide any statement about upcoming formula policy changes for study participants, as educating the participants about the infant formal contract change in August is anticipated to be a substantial staff burden. And as PHFE WIC is the largest local agency program in the state, they did not want us to sort of muddy the waters of their messaging around that policy change.

So, we certainly are amenable to providing

additional language about there being, you know, changes to the formulas that are provided by WIC, but we will need to clear that language with the CDPH WIC program because we do not want to complicate WIC programmatic efforts about maintaining a smooth transition between the formula contracts.

COMMITTEE MEMBER JOHNSON: Well, yeah, I think the consent form needs to at least be more transparent that there is at least some change going on with the new formula. Right now, it's just kind of saying that you're interested in infant consumption of liquid. So, I think that that transparency can be improved.

I think it would be good to have that conversation with -- it's a bit uncomfortable for me to approve the study with people not really having full awareness that their very recent newborns are going to be receiving a change in formula. So, I would like to kind of discuss that with this other.

I'm not sure how your typical studies go, but do you have anything in place for contacting parents who have lost an infant in the time period that you'll be contacting them?

DR. ANDERSON: So, parents who have lost an infant, as in the infant is deceased, or have lost custody of their infant? Could you provide a clarification there?

COMMITTEE MEMBER JOHNSON: The infant is deceased.

DR. ANDERSON: So, if an infant is deceased that will be flagged in our WIC programmatic data. So, generally, in the State of California a very high proportion of our infant participants, their mother participated during the pregnancy. We then contact after the expected delivery date to attempt to enroll the infant in the program.

That is the point at which we anticipate, and this is standard WIC program, not research at all, we would anticipate identifying most of the decedents, if any, in this study population, potential study population.

COMMITTEE MEMBER JOHNSON: Okay, if you can add that. I didn't observe in your application that you have access to that information or show that there was a plan in place that you contacted a parent above that.

DR. ANDERSON: Yeah, so we would only be contacting parents who had enrolled an infant in the WIC program and were issued infant formula for that infant. And so, a negative birth outcome that involved the expiration of an infant, those would not be included in our population to whom we could reach out for participation in this study.

We certainly -- I have been at PHFE WIC for six years and I have not encountered an example where we did try to contact and enroll a caregiver of an infant in the study, and that infant was deceased. The administrative data has

generally pre-excluded those from our samples.

COMMITTEE MEMBER JOHNSON: Okay. I think it would be good to add that to your application, that you will be using the initial administrative data to protect against that, to screen out bereaved parents.

The Spanish materials need to be attached to your protocol for all the surveys that you'll be administering.

I think we also need to discuss, probably more offline, the recruitment materials that we addressed on Monday, with discussing how you obtain their information.

There's a portion in your questionnaire that ask if they are the current caregiver. And if they are not, you request names and contact information of the current caregiver. What do you intend to do with that?

DR. ANDERSON: We would intend to then reach out to the current caregiver of the child. That is relatively standard for our approaches when we're trying to do a population-based recruitment of study-eligible WIC participants.

We very (indiscernible) -- through our administrative data, someone who is not currently the caregiver of their infant.

As an example, we did our 2020 Los Angeles County WIC survey, in which we completed over 6,750 surveys with WIC participants, and we had three total current non-

custodial individuals who we contacted in the recruitment.

So, again, the administrative data is updated regularly because the WIC benefits are being provided to the infant via their current caregiver. So, the current caregiver is generally the one reflected in those data that we would be using for recruitment purposes.

COMMITTEE MEMBER JOHNSON: I think it's an ethically gray area to be collecting contact information for someone that isn't originally in your sample. And if it's a relatively low number, of 3 out of 6,000 plus, I think, I don't see why that should be included. I mean, the time, I think, to collect information on whether it's the current caregiver, and it's not, then if you don't proceed. But I'm not seeing justification for collecting contact information for a person who's not in your pool.

We can discuss that as a committee, or I don't know if others want to weigh in on that.

But would you be -- is that something that you feel that you need to -- that you must include, given the 3 to 6,000 ratio?

DR. ANDERSON: No. I think from a statistical perspective it is a negligible proportion of the study population and we would be open to removing that language and including that as sort of a termination, sorry, you're not eligible, instead of collecting information that the IRB

feels is not appropriate.

COMMITTEE MEMBER JOHNSON: I think the remaining flags that I have in IRBManager are -- were about sort of procedural inconsistencies, or some redundancy with data that are collected, that you seem to have administrative data that would document that information. But I think that those are things that we could work out in a back and forth.

I'll open it up to the Committee, now, if you have additional questions or concerns.

CHAIR HESS: My suggestion is that we (indiscernible) -- because I think that could be a real sticking point. So, effectively, the consent form does not include a reason for why infants are being enrolled in this study, correct. They're not being told that it's because of a change in formula, which is the reason for the study.

COMMITTEE MEMBER JOHNSON: Right.

CHAIR HESS: So, I understand CDPH not wanting that to be a part of the consent, but I guess I think it's only fair for us to discuss it now, if it's something that the board didn't think that they could approve, either now or at a later date. Like, I would have hesitations over a consent form that include the reason for the study. And I wonder -- to approve. Yeah, and I wonder if other board members feel the same.

Because if they do, that might be something that

they've -- we need to really push back at CDPH on, potentially, the researchers do.

COMMITTEE MEMBER JOHNSON: Okay.

VICE CHAIR DICKEY: May I ask a question? What is the reason that they don't want to reveal it?

COMMITTEE MEMBER JOHNSON: Can you elaborate on the -- on CDPH's preference to not disclose the formula change.

DR. ANDERSON: So, I would not say that CDPH does not prefer to disclose the formula change. They have requested that our data collection not compete with their communication with WIC participants about the upcoming formula change.

CDPH does a very laborious process about communicating about the infant formulas. Because starting in August they will be providing different contract infant formulas to all participants who receive formula in the state. And they do not want us to generate additional confusion by potentially communicating to participants in advance of that formula change.

Now, we anticipate our data collection not beginning until after that formula change, so that is certainly something -- in August. So, we certainly could circle back with CDPH and say, look, the formula contract changed on August 1st, so the participants should all be

aware of it at this point. And we can hope to say we're looking to study, sort of in light of recent changes to infant formula benefits, and that would not, should not compete with their messaging.

But I think their concern is generating additional man hours of communication with WIC participants due to, say, recruitment and consent materials that might confuse participants when compared to the communications they're getting from the WIC program about their benefits.

COMMITTEE MEMBER KURTURAL: The contract -- this is Carrie Kurtural. The contract with the new supplier, is it in effect right now or is it in effect in August?

DR. ANDERSON: It goes in effect in August.

CHAIR HESS: Okay. Well, I think that if it's not yet in effect yet and, you know, you probably wouldn't want to say anything for the fact it's -- the consent form needs to be updated in August.

COMMITTEE MEMBER JOHNSON: Yes.

VICE CHAIR DICKEY: So, they would come back to us for approval of the consent form in August.

CHAIR HESS: It almost feels like we need to table that. It seems like they're going to need a couple of months of time to deal with it.

COMMITTEE MEMBER JOHNSON: Okay. Are there --

DR. RYKACZEWSKA: Just to note, for context we do

have an August 1 meeting would be our next meeting, for the timing.

COMMITTEE MEMBER KURTURAL: Yeah.

COMMITTEE MEMBER JOHNSON: Did anybody have additional comments? Otherwise, I would be ready to make a motion.

CHAIR HESS: Okay.

COMMITTEE MEMBER JOHNSON: I make a motion that we table decision on this study to our August 1st meeting. And I'll -- Dr. Anderson, I request that you work with CDPH on developing language, particularly around the consent form with improving the transparency to potential participants about what the study is looking at. And we can work together to address the remaining issues in IRBManager. And present to the Committee again in August.

COMMITTEE MEMBER JOHNSON: Is there a second?

VICE CHAIR DICKEY: I'll second.

CHAIR HESS: Dr. Dickey seconds.

COMMITTEE MEMBER JOHNSON: Okay.

VICE CHAIR DICKEY: Do we have public comment?

CHAIR HESS: Do we have any public comment on this project.

DR. RYKACZEWSKA: If you have any public comment, please raise your virtual hand. Not having any public members in the room, members of the public. And nothing in

the virtual room. Okay.

MS. ATIFEH: I'll start with Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Yes, approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund? Oh, sorry, Ms. Lund is not here.

Dr. Palacio? 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: Thank you, Dr. Anderson.

DR. ANDERSON: Thank you.

CHAIR HESS: Thank you for your very careful explanation of the process.

Okay, so moving on, I'm going to take a moment to ask Ms. Lund to rejoin us.

COMMITTEE MEMBER LUND: I'm back.

CHAIR HESS: Welcome back.

Okay, do we have a researcher from our next study?

DR. RYKACZEWSKA: We do.

CHAIR HESS: Okay, Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: Good morning. I don't see the researchers on. Could you hear me?

DR. RYKACZEWSKA: Coming on video right now.

DR. PUKELIS: Are we up next? Sorry, I didn't look at the schedule.

CHAIR HESS: You are.

DR. PUKELIS: Okay, great.

COMMITTEE MEMBER AZIZIAN: Good morning. Is it officially now Dr. Pukelis or is it still Ms. Pukelis.

DR. PUKELIS: Doctor now.

COMMITTEE MEMBER AZIZIAN: Congratulations. The proposal came and you were a PhD candidate, so almost congratulations. It's a pleasure to see you here.

I'm Allen Azizian. I'm a Committee member. Background psychologist. And I have the pleasure of facilitating this conversation around your protocol.

As far as I understand, the protocol is about, broadly about eligibility or participation in Supplemental Nutrition Assistance Program, which I think to most people is known as food stamp. Would that be correct to say?

DR. PUKELIS: Yes, that's fine.

COMMITTEE MEMBER AZIZIAN: I'm glad that I learned the official name so, you know, I can formally refer to it.

And what I would like to ask you to do is provide an overview of the project. Committee members already had

the opportunity to review your proposal, so it would be more like a Reader's Digest version of your research objectives, and data collection methodology, interactions with human subjects, and any potential risk to human participants. And then, they'll start from there.

DR. PUKELIS: Okay, great. I'll also just make you aware that my Principal Investigator, Dr. Laura Carper, is also on the call, if you have other questions.

But with that, I'll dive right into the summary. So, extreme weather events have become more frequent and intense due to climate change. And California is a disaster-prone state, issuing over 150 disaster declarations with FEMA, the Federal Emergency Managed Fund agency, since 2015.

At such critical moments, food assistance can address acute needs and may prevent short-term, disaster-related hardships from resulting in long-term consequences.

And to shed light on the role of food assistance and disaster recovery, we conduct what we understand to be the first study of the Disaster Supplemental Nutrition Assistance Program, or D-SNAP, and related disaster food assistance policies.

Our study objectives include the following. First, we're interested in understanding individual experiences applying for and using program benefits. And we

would like to shed light on the mechanisms and barriers of enrollment in programs like Disaster SNAP and SNAP, including stigma, and the costs of learning about programs, and how to apply to them.

Second, we're interested in understanding the impacts of participation in disaster food assistance programs on outcomes, including health and economic wellbeing.

And third, we're interested in the relationship between previous enrollment in D-SNAP and future enrollment in SNAP.

So, to answer these questions we use qualitative methods, including field observations and interviews. Human subjects in our research include applicants and administrators of Disaster SNAP, or of SNAP following an actual disaster.

Participation in our study involves one interview about one's experiences applying for or participation in or administering these programs.

We also would like to conduct field observations of Disaster SNAP application sites. And we're interested in collecting information on the general qualities of this space, such as how crowded it is, and we also would like to take some photographs of the sites.

So, as an overview of the potential risks of

participating in this research, in the case of interviews they may include feelings of discomfort around discussing experiences using these programs, or in recalling experiences surrounding a natural disaster. A possible breach of confidentiality. And there's also the possibility of social harm if someone's participation status or beliefs were revealed to other people.

And our research study procedures aim to minimize these potential risks in the following ways. Responses to interviews will be kept confidential and conducted in spaces that interviewees are comfortable with. Questions that touch on potentially sensitive subjects can be skipped and respondents can revoke consent to participate in the research at any time.

Notes that we collect from field observations will not include any personal identifiable information. And any photos we would take during field observations would either exclude faces or obscure them in any public facing research materials to maintain subject anonymity as much as possible.

So, that's an overview and we hope that the insights gained from this research would help inform policies surrounding disaster food assistance programs.

COMMITTEE MEMBER AZIZIAN: Thank you very much for that. And if I may ask you to expand a little bit more about your sample, broadly just so people are informed,

there are three types of, I guess, participants. It would be those who are participating or are interested to become part of the program. There are the administrators, people who run these programs, I suppose. And then, the field observation.

And I think it would be helpful if you expand how you plan on recruiting and interacting with those three different types of participants in some ways.

DR. PUKELIS: Yeah. So, for the administrators, we're planning on getting contact information through connections I now have with the state. I meant to mention this beforehand, but now that I'm -- this research is an extension of my PhD, but I will be -- I am an employee with CDSS, California Department of Social Services.

And so, obtaining contact -- one way of recruiting the administrators will be through obtaining contact information of different administrators of disaster staff, as well as potentially -- as well as being on application sites and talking to people, in their downtime, outside of their job duties to sort of get real time understanding of how they're administering these programs.

For the applicants, our current main way of recruiting them is also at the application sites. And we're also, to the extent possible, like getting in touch with people to reach out to us if they'd like to participate in

the interview afterwards, and over Zoom.

And then, yeah, I guess recruitment for the field observations is more or less self-explanatory.

COMMITTEE MEMBER AZIZIAN: And that takes me to the next question for consent process. So, as I understand this correctly, you'll be onsite, on various programs. People are coming there to complete their application or ask questions, and you're planning on approaching them and inviting them to participate in the study.

There is also an incentive for them, correct?

DR. PUKELIS: Yeah, we would like -- we're offering participants $25 for participation in an interview, which we expect to last 30 to 60 minutes.

And we're offering this to all participants, including both participants and administrators. But we also give like administrators the opportunity to decline the participation incentive or compensation if it -- it naturally might conflict with the duties of their job.

And I just want to clarify that the reason for writing it in that way, which may be potentially odd, is this was a sticking point when we were discussing with Harvard's IRB when it came to compensation for different types of participants.

COMMITTEE MEMBER AZIZIAN: Would you might expanding a little bit more? Like when you approach a

person who's participating over there, is there a particular announcement, flyer, or something that's given to them, and maybe a little bit more about the consent process in terms of what they're offered and --

DR. PUKELIS: Yeah.

COMMITTEE MEMBER AZIZIAN: -- where you plan to do the interview, equally, would that be on the site, actually?

DR. PUKELIS: Yeah. So, we would -- we would approach them. We have a recruitment script that's a part of the -- included as part of the protocol. And we also have a flyer with some basic information about the nature of the study.

And then, the participants would have the option of either conducting the interview there with us, directly onsite. In which place, we would find a place that they're comfortable with, semi-private, you know, to make sure that their responses are more or less private. Or, they have the option of reaching out to us afterwards and conducting an interview remotely or over the phone.

So, I mean, I think this preserves the opportunity to conduct it in an environment that they're -- that they would be most comfortable with.

And then, in terms of consent, we would conduct the consent process at the beginning of whatever the interview stage was, whether they wanted to do that remotely

or onsite.

COMMITTEE MEMBER AZIZIAN: Thank you. Let me see if any of my colleagues have any questions or comments.

VICE CHAIR DICKEY: I have a minor thing about the consent form. You probably need to add something that says whether you participate in the interview or not, it's not going to affect their ability to access the applicant (phonetic) in the future.

DR. PUKELIS: Yeah, I think that's a great addition, especially in this instance. I can add that.

VICE CHAIR DICKEY: And then, also at the end you have how they can reach out to you. But you need to also include an IRB that they can contact if they have concerns.

DR. PUKELIS: That's --

VICE CHAIR DICKEY: Now, it could be the Harvard IRB, if they want, or it could be us.

DR. PUKELIS: Okay.

VICE CHAIR DICKEY: But that needs to be there. An IRB they can contact about their rights as research subjects.

DR. PUKELIS: Uh-hum. Happy to add that, too. And just clarify, this is added to the consent form is your suggestion, is that right?

VICE CHAIR DICKEY: Right.

DR. PUKELIS: Yeah.

COMMITTEE MEMBER AZIZIAN: In the protocol, there was another way there that said that the consent could be obtained either verbally, or then you have included a form in there. And I was wondering if the verbal thing was just something left over or are you trying to replace that with an actually written consent form? I think it was referred as an oral consent.

DR. PUKELIS: I believe our online plans are to record consent verbally.

VICE CHAIR DICKEY: In here it refers it as a script, it doesn't say it's a full -- so, this is going to be read to them, right, and they're going to --

DR. PUKELIS: Yes, we would read the -- we would read the consent.

VICE CHAIR DICKEY: Yeah.

DR. PUKELIS: To them and then get a verbal yes and make note of that. In the -- and that is -- I say that based -- because we -- based on the remote nature of interviews that I've had experience within the past, we would have copies of the consent information to give to participants in person, to read through, or have a copy of it, supplement --

COMMITTEE MEMBER AZIZIAN: I'm wondering if you think that having a written consent form actually it would be more beneficial for the participants. I mean, just

picturing that people are there to ask questions about the program or any other types of things, and there's awfully a lot, actually, components in the consent form. Who to contact, the incentive component of it. And it just sounds to me, it may be an overwhelming experience for someone over there that people approach them as researchers, and they're trying to get an oral consent from them that has -- oh, and that has an incentive component to it, and I think that it would naturally attract people.

But providing them with a written consent form may help them to make that decision, and then also what to do in case that they want to reach out to someone.

DR. PUKELIS: Sure. I'm -- I think it would be fine for -- we'd be happy to modify to do a written consent in the in-person.

Yeah, the only thing I'm thinking about is if people opted in to doing a remote version of this, I'm just thinking out loud about what type of consent might be most appropriate, whether written, electronic, verbal. And if you have thoughts about what might be best.

COMMITTEE MEMBER AZIZIAN: That's why I was asking about the approach in recruiting the participants. I would think that if you're onsite recruiting people, something that could be provided to them that could have the consent form, and they could somehow send that to you, or some other

type of mechanism that you find fits.

DR. PUKELIS: Yeah. Yeah, I think we could do electronic version in the case of the remote to make it consistent across.

COMMITTEE MEMBER RUIZ: I have a quick question. This is Dr. Ruiz.

DR. PUKELIS: Uh-hum.

COMMITTEE MEMBER RUIZ: So, are you planning to use the same consent form for the 20 SNAP participants and also for the administrators, or is it going to be different?

DR. PUKELIS: The consent is slightly different between -- they're separate between the participants and administrators. A lot of the content is similar, but some of it is different because of the nature of, you know, the types of questions that we're going to ask them are slightly different.

COMMITTEE MEMBER RUIZ: Okay. Thank you.

COMMITTEE MEMBER AZIZIAN: Well, I guess having both versions of that written forms of it, it would be helpful. And then, the other part of this is also when you're on the site, I would assume, particularly in California, you may have people there who are bilingual. And having it -- have you thought -- do you have any reactions to that or thoughts? Are you going to exclude, for instance certain people, or how are you planning on

managing that?

DR. PUKELIS: Yeah. So, I guess, first, to your earlier point about different consent forms, I believe both of those types are currently in the protocol.

In terms of language, our eligibility includes people who are comfortable speaking English. I have thought about this. I speak some Spanish, but I don't believe I'm comfortable enough speaking in Spanish fluently to conduct an interview like this. So, it is something that I've thought about, and I'll try to make these sorts of perspectives as representative as possible, given those constraints.

COMMITTEE MEMBER LUND: So, this is Laura, and I have a question. So, the kind of program this is, you would expect that there's a high proportion of non-English speakers, yes. So, it does raise an ethical issue. If you're doing this English-only, you know, it's not fair to the non-English speakers in regard to any policy implications that your findings might have because they're not based on the full population.

So, I'm wondering if there's a way around that. I'm concerned about that. With this population, and especially in California, you're going to have a lot of people who are not represented in your study, who will potentially be harmed by policy actions based on your

conclusions that they weren't part of.

DR. PUKELIS: Yeah, thank you for raising that, and heightening it. I think that, again, thinking out loud here, I wonder if there's a way for our team to get in contact with someone who is more comfortable with Spanish, and translating materials into making sure that -- in order to help be able to conduct this. That's something that I would, yeah, be happy to explore. Yeah, to address and make this study and its potential findings more equitable for all (indiscernible.)

COMMITTEE MEMBER AZIZIAN: Any other questions or comments?

So, would you be open to potentially deferring this and having you think about this, exploring the possibility of also making the program available, the research, to Spanish speakers. And then, for us to review this in our August meeting. Would that be fair to do that?

DR. PUKELIS: Yeah, that sounds okay to me.

COMMITTEE MEMBER AZIZIAN: Yeah. There were a few minor things, but those are just suggested comments and I'll send that to you over email, and feel free to decide as you find fit on various aspects of it. But I don't want to take too much of the Committee's time. And again, those are just basic recommendations.

But I think those are the core issues that we

have, the written consent and making it eligible, also, for non-English speakers.

DR. PUKELIS: Okay.

COMMITTEE MEMBER AZIZIAN: So, with those, we can review this again in our August meeting.

DR. PUKELIS: Okay, thank you very much for all of your comments and engagement.

COMMITTEE MEMBER AZIZIAN: Thank you, very much, too.

COMMITTEE MEMBER LUND: Dr. Azizian, Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Yeah.

COMMITTEE MEMBER LUND: We need a formal motion to table in order to postpone this project to August.

COMMITTEE MEMBER AZIZIAN: Well, then I make a motion to table this in -- to declare this to the August meeting.

COMMITTEE MEMBER SCHAEUBLE: I second.

COMMITTEE MEMBER LUND: This Laura, I second.

MS. ATIFEH: Who seconded?

CHAIR HESS: I think Dr. Schaeuble was first.

MS. ATIFEH: Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: That's fine, I seconded it.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: 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: The motion passed.

VICE CHAIR DICKEY: I just want to ask a question. When you say translations, do you expect them to have staff members that can do the interviews and --

COMMITTEE MEMBER AZIZIAN: Well, I think that they will have to explore the -- yeah, it sounds that that would be necessary for the research team. I don't know if Dr. Pukelis, herself, can do that or may have to have a research team member who can actually conduct the interviews in Spanish.

COMMITTEE MEMBER SCHAEUBLE: I think she did say she would explore trying to find a person who could do that.

CHAIR HESS: Before we move on, we did not ask for public comment on this project.

DR. RYKACZEWSKA: If there is any public comment,

could you please raise your virtual hand, given we have no members of the public in the room. Giving it a moment for any virtual hands raising. Seeing none.

CHAIR HESS: Dr. Dickey.

COMMITTEE MEMBER SCHAEUBLE: Sure. So, this is the evaluation of the California and Children and Youth Behavioral Health Initiative of Caregiver, Youth, and Youth Adult Focus Groups.

And there's another one coming after that. Ms. Kurtural is the reviewer, which has to do with the study of certified wellness coaches.

Who do we have from the research team?

DR. ATERE-ROBERTS: Hello, my name's Joelle Atere-Roberts. I'll be representing the research team for this first protocol.

VICE CHAIR DICKEY: Did we speak?

DR. ATERE-ROBERTS: Yes, we did.

(Laughter)

VICE CHAIR DICKEY: I said, is this the voice that I remember.

DR. ATERE-ROBERTS: Yes, that's me.

VICE CHAIR DICKEY: Before you get going, let me just sort of give an introduction. This is funded by the Health and Human Services Agency, evaluating a number of initiatives that have taken place around the state regarding

youth behavioral health.

This is a little -- this is a very broad project. Originally, when it was submitted, it was sort of like an outline or a this is how we're going to do these different studies in different counties. And it lacked the definition of what the programs were exactly that were going to be evaluated or the questions that might be asked regarding those programs.

But subsequently, they've added in the program names and some potential questions for each program.

So, why don't you take it away and give us an overview better than my overview.

DR. ATERE-ROBERTS: Sure. Sure, I'd be happy to. So, as part of the larger CYBHI evaluation our team at Mathematica will be conducting focus groups, specifically for youth and families, in order to gather more information on the specific experiences of participants in California's Behavioral Health System.

So, our primary objectives here are first to gather information on how participants have leveraged CYBHIA funding, particularly for impact, and also to try and eliminate any perceptions on remaining gaps in the overall programming.

So, in terms of our human subjects, they'll be in two groups. So, youth and young adults ages 14 to 25, as

well as caregivers of children and youth ages zero to 25.

The participants will be asked to complete an online screener to collect demographic information to determine their eligibility and to group participants into the focus groups. And these data will be saved on a secure, encrypted server.

And we've also revised the protocol such that the youth can complete the screener for themselves, similar to the young adults and the caregivers completing that online screener.

So, they will also complete a consent form. For the youth, that consent form will be completed by a parent or caregiver. And we revised the consent forms to note particularly how the potential participants have been identified, specific risks and mitigation strategies related to confidentiality, and potential emotional distress that might arise. Some additions about the legal reporting requirements, voluntary participation, as well as 988 and SAMHSA resources that they can reach out to.

And then, lastly, we added some contact information for the CPHS that participants can reference.

They will be asked to provide verbal consent for those 18 and older, and verbal assent for those 14 through 17, as we've noted in the revised protocol, at the beginning of the focus group itself.

And then, they'll participate in a 90-minute virtue session where they'll answer questions related to their perceptions and experiences with CYBHI programming. And as Dr. Dickey, we've added some additions on those specific programs, as well as some sample questions.

And then, we'll also be offering the potential for additional sessions in Spanish to accommodate caregivers whose primary language is Spanish, and we'll be collecting that information as part of the screener.

And then, at the end of the sessions all participants will be compensated with $50 electronic gift card.

So, in terms of recruitment, we'll be planning to partner with community-based organizations who receive funding from CYBHI to recruit participants. So, this will include sharing a recruitment flyer, email, as well as the link to the online screener with their existing networks.

However, the CBOs will not have access to any of the data that's collected in the screener. And we've also revised the protocol such that CBOs will not actively be participating in the listening sessions, themselves.

So, in terms of psychological risks, specifically, that we considered, our mitigation strategies include again providing contact information for 988 services, as well as SAMHSA treatment services. And we also plan to tailor local

resources specific to each county that we will conduct the listening sessions in.

All facilitators will be trained by an in-house mental health professional, on our team, in trauma-informed and youth-centered approaches to conducting focus groups, which involves creating a safe environment, respectful environment, and recognizing signs of distress.

And then, our facilitators will, of course, emphasize that participation is completely voluntary and that participants may choose to skip, pause, or withdraw from the group at any time without consequence.

And then, in terms of loss of security and confidentiality, participants will not be asked about their specific diagnoses or sites of care, and we'll only be using participant's first names throughout the focus groups.

And we, at Mathematica, use secure servers, a firewall, and computers that are password protected, with full encryption services to be able to store any of the video and audio recordings that contain PII.

And then, at the end of the study we'll, of course, destroy all related video and audio recordings.

And so, to sum up, ultimately the goal of the evaluation is to inform future decision making by policymakers based on what CYBHI has accomplished and hearing what CYBHI has accomplished directly from its

intended beneficiaries, who are the youth and families of California.

So, I will pause there for any follow-up questions.

VICE CHAIR DICKEY: Wow. I just want to say I think you did a really good job of revising stuff and really appreciate the effort you put out. (Loss of audio).

CHAIR HESS: Have lost.

VICE CHAIR DICKEY: -- projects that are considered to be above minimum risk.

DR. ATERE-ROBERTS: Oh, excuse me, Dr. Dickey, do you mind starting over, we lost the audio in the room for a moment.

VICE CHAIR DICKEY: Oh, okay. Can you hear me, now?

DR. ATERE-ROBERTS: Yes, we can hear you now.

VICE CHAIR DICKEY: This is really just for the Committee's information. We've previously had a project where we talked about the need to have, for wards of the state needing to have advocates appointed by the research team. And I looked at that more and it's really projects that the Committee might consider to be above minimum risk. And those, we are required to have an advocate, other than a parent, et cetera, appointed for each kid.

I don't consider this to be above minimum risk,

but the Committee, we need to make that determination.

And the questions that you have provided, specific for each program, might those change as time goes on.

DR. ATERE-ROBERTS: Sure, it could be potential for them to change, but our plan was always to submit an amendment with the specifics of the protocols that we'd be conducting before we actually conduct the focus groups.

But the changes that might happen would just be variation between the specific programs that are being conducted in each county, where there could be variation county-to-county. So, we would just have, potentially, different specific questions around those services that we ask in a county.

VICE CHAIR DICKEY: But we would get any amendments that --

DR. ATERE-ROBERTS: Right. Yes, that is our plan.

VICE CHAIR DICKEY: I'll open it up to the rest of the Committee for questions.

COMMITTEE MEMBER KURTURAL: Yeah, I think --

VICE CHAIR DICKEY: No, no.

COMMITTEE MEMBER KURTURAL: Since I reviewed the other project and I'm noticing some parallels between the two, I want to make sure to remain consistent with more on privacy, so comments in the last time.

And now, I didn't have time to read your parental

consent form. But, for example, in the other one it didn't -- I know you're going to use first names in the interviews. I just want to, for awareness purposes, that's still personal information.

And so, you know, if we could get a blurb in the consent to get the parents' consent to utilize the child's first name, that would be great.

And then, also, I do think that there could be -- because it is so open ended, especially when you're doing an interview, you don't know what's going to come out of the interviewee's mouth. And like what they're going to say about the (indiscernible) program, and if they're going to say anything confidential or not, and how you're going to publish that information.

So, I don't see your methodology here on how you would suppress small cell sizes if, you know, you had to from the information you gather from your interviews.

So, I would just ask if that could be aligned with the second project by Dr. Friend, both Mathematica projects. Just, I think you had said you wanted, on the other one, to suppress under 10, which is fine, you know.

VICE CHAIR DICKEY: Okay. So, you had suggestions to make it parallel.

COMMITTEE MEMBER KURTURAL: To make it parallel for the consent form, parent consenting --

VICE CHAIR DICKEY: That we use the first name.

COMMITTEE MEMBER KURTURAL: For use of first name, because you are going to use that. And then, the other one is just describe your methodology on how you would suppress small cells.

DR. ATERE-ROBERTS: Absolutely. So, in the revision to the consent form we did note in the consent that we will only be using first names in that revision. But we could add some clarity to make sure that we're actually consenting that the parent -- it's clear that the parent is consenting that we will be using that first name. So, we did update that.

In terms of your second question, an important piece for this particular analysis is we plan to report any findings in the aggregate, such that we wouldn't be planning to identify particular individuals in the details of how they identify or any demographic information. But we can certainly add more clarity to that in the protocol, itself.

And I think in the revision we may have added, but I could double check to make sure that that's clear.

COMMITTEE MEMBER KURTURAL: Because only -- I'm not in the portal right now. I have the pdf. doc up.

DR. ATERE-ROBERTS: Okay.

COMMITTEE MEMBER KURTURAL: So, but yeah, that would be great.

VICE CHAIR DICKEY: Okay. So, if they don't have it, they should add something having to do with small cell size.

COMMITTEE MEMBER KURTURAL: Yeah.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER KURTURAL: So, that was my only thing.

COMMITTEE MEMBER AZIZIAN: So, my comment was consistent with the items of information. Nothing else on that, thank you.

COMMITTEE MEMBER SCHAEUBLE: Dr. Dickey?

VICE CHAIR DICKEY: Well, any other comment on this?

CHAIR HESS: You beat me to it.

VICE CHAIR DICKEY: I was going to make a motion, but then we're always behind them.

CHAIR HESS: Public comment.

COMMITTEE MEMBER SCHAEUBLE: Dr. Dickey, I was --

VICE CHAIR DICKEY: Oh, I'm sorry, do you want to make a comment?

COMMITTEE MEMBER SCHAEUBLE: Yes.

VICE CHAIR DICKEY: Oh, I'm sorry.

COMMITTEE MEMBER SCHAEUBLE: Or a question, actually. I'm recalling, if I'm recalling accurately, that you asked a question in the protocol regarding questions

about gender identity and sexual identity, and I think your question was would be the child be told what the parent said. And I don't know whether there was a response to that or not.

VICE CHAIR DICKEY: Yes. I'll let her respond to that.

DR. ATERE-ROBERTS: Yes.

COMMITTEE MEMBER SCHAEUBLE: And there's some follow up.

DR. ATERE-ROBERTS: Yes, thank you for following up there. In our revision, we did change our protocol such that the youth would be completing the online screener for themselves. So, it would no longer be such that the parent would complete it on behalf of the youth, it would be the youth disclosing an optional field to disclose their sexual orientation or gender identity.

COMMITTEE MEMBER SCHAEUBLE: Okay, good. I have some thoughts that are maybe not directly related to this particular project, but more of a concern that I'm beginning to ponder here. The categories or labels provided for gender and sexual identity are numerous and very specific. And this is -- this is one example of several kinds of data that we see pretty commonly that could be considered rather sensitive information.

The thing that's roaming around in my mind and I

just want to mention this to the Committee because it's sort of bothering me. If six months ago anyone had suggested to me that there was a potential risk to participants of a government agency trying to compile a list of people who fall into categories that they no longer are supportive of, in some way, I would have thought that was a pretty crazy idea.

But at this juncture, I know longer think that it's totally out of the realm of possibility, which makes me begin to ask, when these questions come up in a project, is the information being gathered because it is central to the research questions that are being studies, or is it being gathered perhaps more to provide demographic information about the sample that's involved in the study. In which case I would, at least in some instances, wonder whether it's prudent to ask the question in as much detail as it's being asked.

So, I'm just raising that, as I said, a concern that might or might not apply in this study, but I'm seeing it as something that I feel that I'm going to have to ponder when we look at projects in the future here.

And if the rest of you think I'm way off base in asking about that, that's okay, but --

VICE CHAIR DICKEY: Speaking for the rest of us, I don't think you're off base, no.

But I'd like to ask the researcher as to how do you respond to that?

DR. ATERE-ROBERTS: Certainly. And this is definitely a concern that we keep in the top of mind as we're considering our research questions.

I think in the case of our specific protocol part of who we're trying to uplift are the specific high needs beneficiaries of CYBHI. And as a part of that, we're elevating LGBTQ+ youth and families as a part of those high needs populations. Such that part of our research question is to understand are there any gaps that we need to be addressing, specific to this population, that they might raise in the listening session.

I think in this case with ours, where our research question is tied to the demographic question that could be sensitive, potential -- potentially we could make it an optional question such that it wouldn't be required to fill out, if people or youth were uncomfortable.

But I think our intention here was to capture this demographic information as it relates to our specific research question and not just to describe our sample population.

VICE CHAIR DICKEY: So, this is collected in the screener. Does it not say in the screener that answering these questions is optional?

DR. ATERE-ROBERTS: I'd have to revisit the screener, itself, but I believe there are certain questions that are optional. While certain things like age, which we'd need to be able to sort people into the focus group, would be required.

VICE CHAIR DICKEY: Do you feel that it would be acceptable to make the question about gender identity, those two questions optional?

DR. ATERE-ROBERTS: I think that's certainly something we could definitely do in this case.

VICE CHAIR DICKEY: Would that help out?

COMMITTEE MEMBER SCHAEUBLE: I think that would be a good thing to do.

VICE CHAIR DICKEY: And I have to confess that some of the categories I don't know the meaning of. But I feel like maybe it's because I'm not with it. But is there -- is there an opportunity, you know, when they're answering those questions, if somebody doesn't understand exactly what each category means, that they can ask and find out?

DR. ATERE-ROBERTS: Certainly. There would be -- we could add contact information, if it's not already included, in the online screener for follow-up questions that we could field, specific around the categories that are listed.

VICE CHAIR DICKEY: Okay. Any other comments or

questions from the Committee?

COMMITTEE MEMBER LUND: Dr. Dickey, it's Laura. I just have a comment/question related to that last point. My question or the researcher is, is it your belief that the audience who would be looking at these categories would understand them all?

DR. ATERE-ROBERTS: I would like to believe so, particularly for the youth. There may be some variation in understand for, potentially, the caregivers. But we could certainly revisit the list to see if there's any narrowing that we might consider doing.

I think that the reason and the rational for the granularity is wanting folks who do understand the variation between the different terms to feel like they're seen and heard. And so, we were leaning more into having more categories, than less, in that regard.

COMMITTEE MEMBER LUND: Thank you.

VICE CHAIR DICKEY: And as I understand it, you're not posing those questions to the caregivers anymore, right?

DR. ATERE-ROBERTS: We wouldn't be posing them to the caregivers on behalf of the child, no, that's correct.

VICE CHAIR DICKEY: Exactly. Right.

COMMITTEE MEMBER SCHAEUBLE: Caregivers don't see responses of the child, do they?

DR. ATERE-ROBERTS: No.

COMMITTEE MEMBER SCHAEUBLE: Okay.

CHAIR HESS: Ready for public comment?

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Okay. If there is any public comment, please raise your virtual hand. There is no members of the public in the room. And I do not see any virtual hands.

VICE CHAIR DICKEY: So, I would like to move approval contingent upon -- one-year, minimum risk, contingent upon one --

MS. ATIFEH: Deferred approval.

VICE CHAIR DICKEY: Deferred or contingent approval.

MS. ATIFEH: The same thing.

VICE CHAIR DICKEY: It's the same thing, isn't it. Making the screening questions about gender identity optional, one. Two, providing resources for respondents to have their questions clarified regarding the gender identity issues.

MS. ATIFEH: Categories.

VICE CHAIR DICKEY: Categories. Three, inserting language regarding how you will be using -- dealing with small cells.

Am I missing -- you had another one.

COMMITTEE MEMBER KURTURAL: Confirm that parents

are consenting for interviewers.

VICE CHAIR DICKEY: Yeah. And if you haven't done it already, put something in the consent form for the parents regarding the use of first names.

And five, that any changes, subsequent changes in the questions for specific programs will be submitted as amendments for approval.

Is there a second?

COMMITTEE MEMBER SCHAEUBLE: I'll second it.

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: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Okay. Thank you to the research team.

DR. ATERE-ROBERTS: Thank you so much.

CHAIR HESS: And we will move on to our next new project. I believe there's some overlap on the research team on this one, so do we have everyone from --

DR. PETERSON: We do.

CHAIR HESS: Okay.

DR. PETERSON: Thank you.

COMMITTEE MEMBER KURTURAL: All right. Well, good to see you, Dr. Peterson. My name is Carrier Kurtural, and I reviewed your project.

I did not have an opportunity to talk to you face-to-face, but you got my comments, and you revised your protocol a bit to address some of the privacy issues.

For the board this, interestingly, is an agency project similar to what Dr. Dickey just reviewed. It's an interesting project with youth and utilizing wellness coaches throughout the state. And a lot of money was allocated to this by agencies to various employers who employed wellness coaches to serve youth, I believe in their teens through the age 25, which is a really important policy.

This kind of fell into into an interesting bucket because the question initially was, you know, is this quality assurance, which would be exempt from research or is this something that requires full board review.

I found that it needed a full board review

because, yes, it is evaluating the quality assurance of this initiative from agency. However, there is interviews, one-to-one interviews that are being conducted with youth. There is a recruitment process involving a $25 gift card, and they're also getting some HCAI data, as well, to review demographics and other information on recipients of the behavioral health services.

So, I'll leave it to you, Dr. Peterson, to kind of give an overview of what you're accomplishing here in this process.

DR. PETERSON: Thank you for that overview and the opportunity to share about our study.

So, as with these projects, this is part of the larger evaluation that Mathematica is conducting of the CYBHI. And this particular study is a small, I would say, descriptive implementation study of certified wellness coaches, or I'll just refer to them as coaches for the rest of this discussion.

And we're looking to include in our sample six to eight organizations as the primary focus that received certified employer -- they're called employment -- employer support grants, so that they can bring on coaches into their workforce.

Coaches are a new profession that are helping California's overall capacity to support behavioral health

and wellbeing of children and youth, as pursuant to the CYBHI evaluation of authorizing legislation.

And the objectives of the study are, one, to identify effective strategies for integrating this new role into school and community-based health teams, behavioral health teams, to examine how its introduction is influencing the access and delivery of behavioral healthcare to youth, and to uncover ways to strengthen implementation so that other organizations that want to bring on coaches in the future have something to learn from.

So, we also want to document, by talking to youth and all the respondents, early perceived benefits of working with coaches in these new contexts.

So, the study will involve data from two sources, as were described by Dr. Kurtural. One is a set of de-identified, and aggregate administrative data on scholarships that were given by HCAI to folks that are pursing this role, a certification of people who have been certified into the new role. And then, also the employer grants that were provided.

And we'll obtain these data from HCAI. And as per the request, after your review of the initial protocol, we've uploaded a list of the variables, and our justification for their use, and also a letter of support from HCAI for this part of our application.

And again, these data will all be de-identified and aggregate, and they'll help us answer our research question around reach, statewide, of the scholarships, certification, and the grants.

The second source of data for our interviews -- for our study are interviews. And we're proposing to do quad interviews, I'm calling them.

So, for each of the six to eight organizations that we'll be working with, we'll talk to the person who can speak most to why and how they applied for the employer support grant, so that's kind of our starting point.

And then from there, we'll snowball into talking to a supervisor of the coach or coaches at that site, a coach, him or herself, and at least, you know, one teen, 14 to 17, who has interacted with a coach at that site.

Teens, the teen interviews will be 30 minutes, the adult interviews are 60 minutes. Teens will be offered an incentive, a $25 gift card. We'll not contact any youth until we have parental consent.

We appreciated your feedback on the reading levels of our consent forms and have worked to lower those. We were able to get the youth recruitment flyer down to a reading level of five. We had a little more difficulty lowering the reading level for the adult and parent consents, because some of the words are just that we must

use, like Children and Youth Behavioral Health Initiative, or certified wellness coach. Or, particularly, a section at the bottom of the consent that talks about reaching out to me, if you have questions, or to the, you know, California Committee for the Protection of Human Subjects. It raises that score a bit.

If I take out that last paragraph, I can get those down to, you know, in the five range. But with that paragraph there, they're in the six, grade six range.

Also, in response to the comment you made on the previous discussion, study with the youth, focus groups, too, we did add a request, a specific request for parents to consent to us using their first name in the interviews.

The risks to the study are pretty minimal, from our perspective, we hope you agree. First, we can confirm you asked a question about presenting identifiable information in our reports, and we will not do that. All quant data will be in aggregate. As I mentioned, we'll suppress any cells under 10.

Though recordings might include first names, none of our, you know, reports will do that. And we're presenting the qualitative data thematically, in aggregate as well. Not kind of vignettes of a particular individual.

The risk is very low for adult participants. We're asking just about, you know, why and how they're using

coaches and integrating them into their workplaces.

For youth, the ages 14 to 17, the risks might be slightly higher. We will ask youth questions about their perceptions of working with a coach. We're not asking them to identify their own, you know, particular reasons for working with a coach. If they choose to self-identify it, we are. But our questions are more about how this new service has benefitting them and how they interact with that coach.

As Joelle mentioned in her presentation, you know, as we're saying to all interview participants can skip, or decline any question. They can stop an interview at any time.

We, too, like with the youth focus groups, if something were to come up in the youth interviews that we thought might be concerning, we will share, you know, 988 and SAMHSA, find treatment services if needed.

Also, as Joelle shared, you know, we have -- we're saving all data, contact information separate from the data on our secured, and password protected servers. Everything will be destroyed when the study is over.

And I think I'll stop there and see if you have any additional questions for me.

COMMITTEE MEMBER KURTURAL: Okay. I just wanted to let everyone know that I did review the revised consent

forms and they are -- I appreciate you taking a second stab because they were at the college level. And so, it's nice when you're dealing with the general population even -- and, you know, I'm sensitive with utilizing -- especially on the assent forms of the teenagers. But I thought they looked good, and you did a great job on that.

And I don't have very many follow up. You've really, you know, addressed the confidentiality. I just want to forewarn, like I did on the last one, you don't know what's going to come out of the interviewee's mouth when you're doing these sorts of interviews, and to be cognizant when you're doing your reports. Because you're certainly, yes, you're utilizing first names that obviously won't be published, but I always have fair warned researchers on the characteristic information, because you just don't know what they're going to say.

But other than that, I'm actually fine with just one-on-one.

DR. PETERSON: Thank you.

CHAIR HESS: No comments from the board?

Public comments?

DR. RYKACZEWSKA: If you have a public comment, please raise your virtual hand. Acknowledging there is no members of the public in person. No virtual hands have been raised.

CHAIR HESS: Okay. If you're ready to make a motion.

COMMITTEE MEMBER KURTURAL: Yes, I make a motion for minimal risk, one year approval on this project.

VICE CHAIR DICKEY: Second. Dr. Dickey seconds.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz? Dr. Ruiz?

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Okay, the motion passed.

CHAIR HESS: Okay. Thank you very much.

DR. PETERSON: Thank you for your time.

CHAIR HESS: We're going to take like a five-minute break to let folks settle.

(Off the record at 10:18 a.m.)

(On the record at 10:24 a.m.)

CHAIR HESS: Welcome back, everyone. I want to state for the record that Dr. Ruiz has had to step away from

the meeting for some office things.

Dr. Dickey, okay.

VICE CHAIR DICKEY: Sure. So, this is revisiting the issue of the Healthcare Payer Payments Database, or Data Systems. It's good to see you all again, thanks for coming.

As you remember, at the last meeting we basically put off deciding this to give Committee members the time to more thoroughly consider the issues and pose any questions that they had.

And we received one question, which I'll read. It's a question from Laura. And I'll just read it, the way it was worded.

"They've asked for a waiver of informed consent. Can they please clarify this requested waiver covers the creation of the database only. If the data are used for research, the research would have to come through this Committee and either CPHS, if reviewing under the Common Rule, or another IRB with purview would review the researcher's request for the informed consent waiver in each specific instance."

So, you guys had a chance to look at this and I'll turn it over to you to respond to that.

MR. VALLE: Well, thanks, Dr. Dickey, and thank you, Committee members for having us again. I'll just briefly introduce the members of my team that are here. I'm

Michael Valle, Deputy Director of Information Services at HCAI.

James Yi is to my right, staff counsel at HCAI.

To my left, who appeared virtually in our last meeting, is Dr. Chris Krawczyk, Chief Analytics Officer for HCAI.

And then, virtually, Chris Craig, Chief Risk Management Officer over the state on all privacy and security matters is on the line.

And Dionne Evans-Dean, Chief Data Programs Officer.

Just a check point of order is if Cal HHS counsel is present?

VICE CHAIR DICKEY: Yes, they're also on.

MR. VALLE: Great. Fantastic. That's good to know. And they may wish to opine on this question, as well, but I'll start with James YI, HCAI counsel.

MR. YI: Hello. So, that is true, this approval of a waiver of informed consent is for the creation of the database itself. Regarding research, HPD statute states that for limited datasets in the enclave, which is our virtual data environment, that does not go to CPHS. But for research identifiable data, which is the most personal data, that does go to CPHS.

VICE CHAIR DICKEY: And it goes to CPHS for a

review under the Information Practices Act.

MR. YI: Correct.

VICE CHAIR DICKEY: But if it were research that were funded by or being conducted by the agency, then it would come to CPHS for not only the Information Practices Act, but the Common Rule. Is that correct?

MR. YI: Are you talking about other state agencies within Cal HHS?

VICE CHAIR DICKEY: Yes. I don't know, you probably can't answer that because that's really a question for Jared.

MR. GOLDMAN: I can answer that. That's correct.

VICE CHAIR DICKEY: Maybe repeat what I said because --

MR. GOLDMAN: Sure. So, maybe starting at the beginning, the waiver of informed consent that we're considering today is related to the protocols, the policies and procedures of the HPD. Any PII related disclosures that's tied to research going through the HPD would come to the Committee under the IPA.

However, if there was research that was being conducted by a Cal HHS entity, that would come back to the Committee, also, as a Common Rule review.

COMMITTEE MEMBER LUND: So, thanks, Jared. I think just to clarify, my question wasn't necessarily about

under what circumstances it would come back to use for review. And thank you for clarifying it would come back if we have PII under the IPA, and if it falls under one of the agencies doing research it would come back under the Common Rule.

My question is more specifically about the waiver of informed consent. So, the protocol that we're being asked to consider has a waiver of informed consent. And I just want to clarify and make sure that I understand correctly. That waiver is for the creation of the database.

My question then becomes if a researcher, regardless of whether we have purview as Common Rule, or some other IRB has purview of Common Rule, for each research project for which a waiver of informed consent would be appropriate, is a separate waiver of informed consent considered for those specific instances of research?

Or does this waiver that we're approving as part of this protocol cover any research going forward using this database?

MR. GOLDMAN: This waiver only covers the creation of the database. Any research project being conducted by another researcher, if they're covered by the Common Rule, would have to get IRB approval and a separate waiver of informed consent.

COMMITTEE MEMBER LUND: Great. Thank you, that

was my question. Thank you for clarifying.

MR. GOLDMAN: Yup.

VICE CHAIR DICKEY: Are there any other questions from the Committee regarding this or any other issue?

CHAIR HESS: Is that waiver of informed consent that would be required under the Common Rule review, that is only for PII being released. And is that PII being shared out or would a waiver of informed consent also be required if the researcher was proposing to use the data exclusively within the HPD enclave?

MR. YI: So, HPD statute basically states once CPHS review is required under the IPA. And for limited datasets in the enclave, there is no CPHS review for research projects, according to HPD statute.

And this is just about IPA review, correct, not Common Rule?

CHAIR HESS: No, this was referring to Common Rule review.

MR. YI: Oh, okay. I think our sense has been that Common Rule review would be up to the researcher to determine. There are no requirements in HPD statute about Common Rule, complying with Common Rule because it is a federal requirement for most researchers.

VICE CHAIR DICKEY: So, if a researcher comes from, say, University of California, and comes into your

enclave and is working with identifiable information, we would have to review that under the IPA. But what about their IRB having to review that under the Common Rule that's working in your enclave?

MR. YI: I think our position is that if their research is -- if Common Rule applies to their research, they would have to do that. That's their obligation. Their institution's obligation and their own.

VICE CHAIR DICKEY: So, regardless of where they access identifiable information, they would have to get permission from their own IRB under the Common Rule. I mean, you can't speak for their IRB, I know that, but --

CHAIR HESS: Well, putting it into sort of perspective of this IRB, if we had an application under the Common Rule from a researcher or a group within the agency, we would have to issue, in every instance, in order for their research to go forward, a waiver of informed consent.

Right? Because there's no way around that.

VICE CHAIR DICKEY: Right. No, if it's covered by the Common Rule, we'd have to do that again.

CHAIR HESS: Okay.

VICE CHAIR DICKEY: Is that right?

CHAIR HESS: Regardless of whether or not they were using the data within the enclave or using the data external, we would still have to issue that waiver of

informed consent any time we did a Common Rule of this data.

VICE CHAIR DICKEY: It would be a part of the review, yeah.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: And then, if we don't have Common Rule purview -- this is me, putting the pieces together. If we don't have Common Rule purview, but their research is still subject to the Common Rule and it's their institution, in that case they would be asking for that waiver of informed consent from their own institutional IRB. But again, from what I'm understanding, essentially if Common Rule applies to their research, you would be looking for them to make sure that they --

MR. YI: I don't know to what extent we would be looking, because that would be that researcher's institution's obligation. Because some institutions, they voluntarily comply with the Common Rule, even if it doesn't technically apply to them. And so, it could be an internal policy matter for them, or it could be a federal requirement for them.

COMMITTEE MEMBER LUND: So, if somebody, when people are allowed to access these data, is somebody going to be checking to make sure that researchers have received the appropriate approvals?

Like, if it's a Common Rule, if it's a research

project that's subject to the Common Rule, that's not an optional thing. Somebody -- some IRB has to look at that. And the institution's IRB might look at it, and sometimes we know from experience with data-only projects, they call it exempt, or their requirements are not as stringent as the requirements we might impose if we were the IRB of record. You know, that's not something we can do anything about.

But is there going to be somebody on your end checking to make sure that researchers have done their due diligence on this, or do you just give them the data and trust that they've done what they're supposed to do?

MR. YI: We're constrained by what HPD statue and our regulations state, and currently there are no requirements that we double check whether they complied with their Common Rule obligations.

But again, that can be a complicated question because it depends on the researcher and the institution, whether the Common Rule applies to their research or not. I mean, there are a lot of exemptions. Also, there's the funding requirement or the requirement that the research be supported by the federal government. And that could also depend on which federal agency is supply the support.

And so, it can become a very complicated question that the research and the institution, itself, it's their obligation to meet.

VICE CHAIR DICKEY: But you would be --

COMMITTEE MEMBER LUND: So, there is no process for making sure that -- you're talking about a massive database, and when they're going to be accessing PII, and the project falls under the Common Rule I'm very concerned that, you know, one of the things that we experience on this Committee is that not all researchers are as well informed, as others, about what their responsibilities and requirements are. And that's one of the things that we often help them with as part of the process.

And so, if you're just opening up your database and, you know, it's like, okay, well, we'll trust you guys, it strikes me as having greedy kids with their hands in a candy jar. I'm sorry, I just -- this concerns me.

MR. YI: There are very stringent requirements to get the data. If you look at our regulations, there are -- I think for each application there's 20 things that have to be approved. Statute, itself, talks about requirements for the researchers to get the data. And there are even more stringent requirements for the research identifiable data.

There are also options to get this data directly transmitted and those requirements are even more stringent than those.

And so, our staff, and possibly our Data Release Committee, they will be vetting the researchers and the

institutions regarding how they protect the data, how they use the data, and whether the use of the data is consistent with the principles of HPD statutes.

VICE CHAIR DICKEY: And also, you won't be letting them access it until we've approved it under the IPA, because that's in your statutes.

MR. YI: That depends on the mode of access and who the researcher is.

VICE CHAIR DICKEY: Well, no, if it's identifiable data it doesn't matter the mode of access, we have to approve it under the IPA.

MR. YI: For limited data, which we consider identifiable, that can be released in the enclave, in the secure research environment without CPHS review, at least under the HPD statutes.

COMMITTEE MEMBER KURTURAL: Have you guys looked at the federal HIPAA statutes and what you (indiscernible) -- provide limited data?

MR. YI: What was that?

COMMITTEE MEMBER KURTURAL: So, there are requirements under federal law, under Title 45, Code of Federal Regulations Part 164 or 162, that have a certain amount of requirements on what you have to do to provide even a limited dataset for any reason.

So, when considering all of this did you look at

those laws? I mean, is there going to be data use agreements between you and the researcher, is that what you're doing? Did you double check that it complies with HIPAA regulations for limited data use or --

MR. GOLDMAN: I don't believe HCAI's a covered entity under HIPAA.

COMMITTEE MEMBER KURTURAL: Yeah, but don't they collect information, Jared, from HIPAA covered entities?

MR. GOLDMAN: That wouldn't matter. A lot of people collect information from HIPAA covered entities that aren't necessarily HIPAA covered themselves.

MR. YI: The HIPAA connection is severed, since we collect the data under the required-by-law exception.

COMMITTEE MEMBER KURTURAL: Oh, it's under the required-by-law section. Okay.

MR. YI: But to answer your question, when they were drafting the HPD statutes they did consider the HIPAA requirements. And so, data use agreements are required for all users and all staff, who have access to the data. And so, it's more stringent than the HIPAA requirements.

COMMITTEE MEMBER KURTURAL: Okay.

COMMITTEE MEMBER SCHAEUBLE: You've mentioned different sets of requirements for different kinds of data releases, and maybe it was in the information given to us, but I don't recall seeing that. Is there a summary that has

been provided of what specific requirements would apply to researchers for the different kinds of data releases that are possible, going to be possible with this?

MR. VALLE: Dr. Schaeuble, maybe I could suggest, we do have some slides, that if that would please the Committee, we'd be happy to present them and illustrate those different types of datasets, if you'd like.

COMMITTEE MEMBER SCHAEUBLE: That would help, but I'd like to see it in printed form, as well, to be able to look at it more thoroughly.

And related question, repeatedly referring here to the statutes that you're working with, are those a flood or a ceiling on what is required for data releases? Do the statutes say that this is the minimum of what must be done, or do they prevent any higher level of review that this Committee, or some other committee might think is appropriate for the circumstances?

MR. YI: I believe HPD statute does have the floor -- is the floor. They have several requirements that we have to implement, but it is the floor.

Basically, my promulgating the regulations we added to those requirements. And we had to -- when formulating our regulations, we had to talk to our Data Release Committee and our Advisory Committee by statute. And so, we did consult with them when we created the

regulations and the requirements to get the data.

MR. VALLE: And I think, just to add, that beyond that both the Data Release Committee, this Committee, and the HCAI Director have broad purview in circumstances where a data release could be denied. James, correct me if I'm wrong.

COMMITTEE MEMBER SCHAEUBLE: Well, I'm asking, of course, because as Laura has been saying here, there are concerns, obviously, about circumstances in which maybe higher level of review than what the statutes indicate is a minimum would be appropriate, at least from our point of view, in looking at research situations. So, I think it's relevant from that angle.

MR. VALLE: Great. And just on that news, anything we could do to help the Committee, when they requests, about the considerations you may wish to apply to the research requested, I think we have an opportunity for collaboration between the department and the Committee.

But to Dr. Dickey and the Committee, if it would be helpful, we could kind of shift over into more sharing information, but please --

VICE CHAIR DICKEY: Yeah, I think that I'm a little bit confused about, you know, there's information that you consider to be identifiable where we wouldn't be doing a review, in limited datasets. Whether we'd consider

that identifiable or not is a really good question.

So, maybe you could, I think, go through the different things.

MR. VALLE: Sure, happy to do that. So, I'll turn it over here to Dr. Krawczyk. And, Agnieszka, can you handle the slide deck.

DR. KRAWCZYK: We can actually, this is just some background of the underlying data files that particularly are relevant to the conversation. These are the datasets that are available for request, there are four of them.

The standard limited, again this is a pre-built record level that has the four files that were in the previous slide available. That's just, again, the underlying structure of the database.

And it will include the data from commercial payers and from Medi-Cal. This does not include certain CMS data, per the agreements that we have with them. All direct identifiers for patients, providers, and plans are removed. That's all direct identifiers.

Standard limited plus, you basically take that standard limited, but then you add in the direct identifiers for the providers and the health plans.

Custom limited is basically customized datasets with direct identifiers removed. But then, the request process, itself, determines what's going to get approved for

the release. And so, that's where -- you know, it essentially operates kind of a minimum data necessary, where we only make available and release the data that we feel is necessary to satisfy the use of the data, taking into consideration privacy, security, confidentiality, sensitivity of the data. And also, the mode of access for the data.

And then, there's the research identifiable, which is record level. And it could include some of that additional Medicare data under a separate approval from CMS. But this is where the direct patient identifiers there.

And if we go forward some slides, we kind of break down direct identifier a little bit further.

So, again, standard limited, if you go back one, on the lower left corner is, again, noting that all direct identifiers for the patients, providers and plans are removed. These data are available for use in the enclave or direct transmission. But again, per statute, we are to limit the direct transmission of these data, and we're to promote the use of the data in the enclave because of, again, additional protections that we have over how the data are being used. But also, observing and approving what does and what does not go out. Nothing can go out of the enclave even in de-identified form, without an HCAI approval of that product.

The standard limited plus is where we add in identifiers for health plans and providers. But this is only available in the data enclave. We are not going to allow these data out for direct transmission. This, again, is to afford the opportunity for us to have review of what the requesters are using these data for. And again, that requirement, even for anything de-identified, that we would have to review before this information goes out.

Included in here is also the consideration for sensitive procedures and conditions, both administration by the provider, but also the occurrence of among the patient. And that's, again, a higher level of screening, higher level of review, higher level of control.

Go to the next slide, please. This is where we get into the research identifiable. And this is where you see that for us the research identifiable is first name, last name, physical address, member's social security number, and the data of birth.

This is available for direct transmission. However, there is an extremely high bar for receipt of direct transmission. Essentially, the question that has to be answered is what can the data enclave not facilitate in your use of these data. And they have to be able to answer that question.

So, again, the more restrictive that we got -- the

more, I guess, specific and identifiable the information gets, or the more sensitive, the more restrictive our review is going to be. And that's, again, getting at regulations and statute establish the floor, but we have purview to, per their request, consider the level of review and the level of information that's needed, and also how will that data be accessed and utilized.

This data also is required to go to our DRC, anything research identifiable. To go back, the other datasets depend upon the mode of access. Anything direct transmission has to go to our DRC. But any request we have the option to request our DRC to review and making of a recommendation, as well.

CHAIR HESS: So, within these sorts of four levels of data releases, what's the threshold for an IPA? This is Catherine Hess. So, what triggers an IPA review for our Committee?

VICE CHAIR DICKEY: Yeah, what triggers us.

CHAIR HESS: Yeah. At level is that required?

VICE CHAIR DICKEY: Do you want to go, James.

MR. YI: Yeah, it's for research identifiable data in the secure research environment.

VICE CHAIR DICKEY: Okay, go back to the --

DR. KRAWCZYK: I was going to go forward.

CHAIR HESS: So, this is the only dataset that we

-- release request that we would get to review under IPA.

MR. YI: Yes, under HPD statute it states research identifiable data that's directly transmitted or --

VICE CHAIR DICKEY: Or in an enclave.

MR. YI: Correct.

COMMITTEE MEMBER KURTURAL: I just want to make a comment from more a legal perspective. I understand that you get data from HIPAA covered entities under required-by-law section. I don't know if that's required by law under federal law or state law.

But that being said, even if HIPAA doesn't apply to you, it still applies to us in the sense that we're the ones that approve research for HIPAA waivers.

So, I do think that there is a laundry list of what creates a limited dataset. And, for example, this research identifiable dataset, that's correct. But there's also medical record numbers, there's, you know, Medi-Cal IDs, any other IDs. There's a laundry list of things that have to be included here. And I'm only seeing a few things listed.

I don't know if we can -- we can talk more about that because in my perspective you're -- the researchers have to move forward, and you can't approve something that is going to be releasing stuff beyond what is considered federally a limited dataset.

And so, I want to make sure that this section that triggers our review has all the identifiers in there. And there are additional things, like phone numbers, email addresses.

VICE CHAIR DICKEY: You mean, all the identifiers in the HIPAA Safe Harbor?

COMMITTEE MEMBER KURTURAL: It's not all the identifiers in there, it's a specific, more limited. That's what I recall a limited dataset. I can get you a code section so you can know what I'm talking about, if you just give me a minute.

MR. VALLE: Much of what --

COMMITTEE MEMBER KURTURAL: I think -- I see what we're trying to do and I'm gonna -- I'm trying to get to yes, but I also want us to be within the legal boundaries. And if I was OCR, for example, or something like that or, you know, I forgot, whoever -- any other federal agency that has, you know, control over us to review what we're doing, that we need to be in the confines of what that is.

And when a clear boundary of when something has to be triggered. So, if you get a request in and you're reviewing it, you're like, all right, this is beyond a limited dataset, right, kick it over to us for review.

So, I just want to make sure and double check that --

MR. VALLE: Absolutely.

COMMITTEE MEMBER KURTURAL: -- that you got everything listed. Because I'm not seeing like emails, phone numbers, account numbers, that sort of thing.

MR. VALLE: So, I think I'd ask the Committee, we don't have that in this, prepared here, but I think we could prepare it. I'm bringing up other materials that we've published online or that the team could surface.

So, I suppose the question would be should we work to assemble that, to be able to have that discussion? We'd be happy to do that and could break now, in order to do it. We'll continue on with other discussion. I can ask my staff to make sure that that information's available for the Committee today.

MR. YI: Do you want to know what's in the standardized limited datasets?

COMMITTEE MEMBER KURTURAL: No, it's really the research identifiable datasets. So, when you get a request from a researcher and you're looking at it, and let's say they're asking for email addresses, I'm just throwing that out there, of a recipient of services, and you're looking at this on your end. I mean, you shouldn't be approving that, right, because you know that that's going to involve PII and it has to go through an IPA, you know --

MR. YI: So, one of the requirements for the data

application is we do have a data element matrix. They have to, at least for the custom limited data requests, or the research identifiable, they have to justify each data element for minimum necessary. And also, they have to list them out.

I'm just wondering if your concern is that what we put in our standard limited datasets, which are going to include -- are within the bounds of the HIPAA limited datasets, that's the question.

COMMITTEE MEMBER KURTURAL: Correct.

VICE CHAIR DICKEY: Can you show us what's in the limited dataset? Maybe those elements aren't in there. I don't know, we'll see.

DR. KRAWCZYK: And what's available for request under research identifiable. Many of the variables that are being pointed to don't exist in the database.

VICE CHAIR DICKEY: Yeah, that's --

DR. KRAWCZYK: And/or aren't eligible for request. And that's what we listed here are the ones --

COMMITTEE MEMBER KURTURAL: Oh, okay.

DR. KRAWCZYK: -- that are eligible for request, that are listed as identifiers.

VICE CHAIR DICKEY: Because they may not have --

DR. KRAWCZYK: But email address, Medi-Cal record number, none of that is available for request.

COMMITTEE MEMBER KURTURAL: You don't have it in the first place. Okay. It would be good to know those details.

DR. KRAWCZYK: And then, what is eligible for request is on our website and we can pull together that info, so you can see exactly for each data file type these are the data available. And that's what we did is we basically pulled out from that and listed here what would be of interest to the Committee, which are the identifiers across all the datasets.

And the only place that those identifiers exist is the research identifiable or under custom, but they would be limited to these being available that are shown on this slide.

MR. YI: Yeah, we could also provide to you with the -- we used the APCD CDL format to collect the data. It's a national standard for collecting this type of data from health plans. So, that has tables of all of the data elements that are supposed to be submitted to us.

And then, we also have a data submission guide for the plans, that also specify what data they're supposed to send to us.

VICE CHAIR DICKEY: So, can -- sorry. Can you give us a list of all of the elements that are in the limited dataset, so that we can whether there's any that we

think shouldn't be in there?

MR. VALLE: Absolutely, Doctor. So, I think what I could ask is if I could huddle, maybe with my staff, it would be perfect to recess, then we could figure out the best way to present that today, because we would like to do that today.

If that makes most sense, I could ask my team to do that while we continue the conversation, or whatever would best please the Committee.

COMMITTEE MEMBER KURTURAL: If we could get a rundown, that would be great.

VICE CHAIR DICKEY: We're scheduled to one.

CHAIR HESS: I mean, how much -- if we were to take a break, how much time do you think your team would need to compile that?

MR. VALLE: Five minutes.

CHAIR HESS: Oh, okay. Oh. Like only five minutes, that's okay.

MR. VALLE: I just want to make sure we're able to bring up the right information.

CHAIR HESS: Oh, Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Well, going back to something I was asking a few minutes ago here, what would really be helpful for me, and I think for other Committee members also, would be to see, side-by-side, the scope of

the data that's available in each of the four categories, and for each of the four categories the requirements which you would have in place for researchers to have access to that data. Because I'm not getting the big picture look as well as I would like to, and I think that's the kind of thing that would be really helpful to me, if we could see such a thing.

MR. VALLE: That sounds great. So, I'll ask for an extra five minutes to do that, also.

CHAIR HESS: Yeah.

MR. VALLE: Okay, my proposal to the Committee, ten minutes, allow me to discuss with my team, and we'll find the right content and to display it pretty well, so we can continue the discussion.

Does that sound okay?

CHAIR HESS: Yeah. WE will take a ten-minute break and reconvene at -- I'm going to say ten after 11:00.

MR. VALLE: Great. Thanks so much.

(Off the record at 10:58 a.m.)

(On the record at 11:14 a.m.)

MR. VALLE: Great, thank you. So, I'll say thank you, again, to the Committee for the accommodation.

So, what we'd like to start is with the global variable grid, of all the variables in the database, and within that showing the differentiation between which

variables are included in the standard limited dataset and which variables fall outside the standard limited dataset.

CHAIR HESS: Perfect.

MR. VALLE: And which, then, would become research identifiable request that would be subject to the purview of this Committee.

That's where we'd like to start and then, of course, to go to other places as well.

VICE CHAIR DICKEY: Sounds good.

MR. VALLE: Wade Iuele is contract project manager with our team. He is on the virtual call. If he's given screen sharing permission, he'll share his screen and then Dr. Krawczyk will walk through it.

DR. KRAWCZYK: Okay. So, actually, before we do the screen share, just starting again with the four types. The standard limited and the standard limited plus were created based off of the HIPAA definition of standard limited. So, for that purpose there's nothing identifiable in those. Okay.

So, when you look at the variable grid we can't show that there's identifiers in those, because there's no identifiers in those. So, we'll certainly hand it over. We can show you exactly what the contents are in the standard limited and standard limited plus, but there are no --

COMMITTEE MEMBER KURTURAL: Identifiers.

DR. KRAWCZYK: -- identifiers. It is based off the standard limited, the HIPAA standard limited.

COMMITTEE MEMBER KURTURAL: Okay.

VICE CHAIR DICKEY: Can you show us?

DR. KRAWCZYK: We can come back to that. Wade has the filter on the custom and on the research, so let's go there now next because --

COMMITTEE MEMBER KURTURAL: Wait a second. Are we allowed to comment on this.

VICE CHAIR DICKEY: Zip code, you're going to comment on zip code, I think.

DR. KRAWCZYK: Okay, so let me give a little framing on this, now, what's being shown. Not to confuse, again, the four file types.

I just was addressing that there's no identifiable data in custom limited, custom limited plus. Those were developed off the HIPAA definition of a standard limited.

Now, when it comes to custom and research identifiable, that's where there is the opportunity to request direct identifiers.

What Wade is demonstrating here is what we call our variable justification grid. This is what the requester will use to give us a justification for each variable that's available under custom limited and research identifiable to justify, again, minimum data necessary.

Now, if we filter, then, to from the justification grid, is this identifiable data. That's what Wade is showing now. Okay. So, these are all the variables available to request that under HIPAA are identifiable.

Now, what you'll also see, though, is this doesn't have, for example, you know, patient email, because we're not collecting it, it's not available.

COMMITTEE MEMBER KURTURAL: Right.

DR. KRAWCZYK: These are only the variables available to request that HIPAA considers identifiable.

COMMITTEE MEMBER KURTURAL: Now, this first one you have here, believe it or not, I don't have any questions on the zip code, Dr. Dickey. But the first one for --

VICE CHAIR DICKEY: Policy number.

COMMITTEE MEMBER KURTURAL: -- for policy number. Is that considered to be a health plan beneficiary number? Because isn't that an insurance number, connected to a client or --

DR. KRAWCZYK: And I just want to make sure, folks in the room, if we can speak up because specific questions like that we're going to be deferring, also, to Wade and to Chris Craig, and some others. And just, sometimes, the audio doesn't fully come through for them. So, could you repeat the question.

COMMITTEE MEMBER KURTURAL: Sure. And for the

report, this is Carrie Kurtural asking about the first line there. It would be line 17 in your Excel docs. You have, insured group or policy number. Is that a number that's an insurance plan beneficiary number? And what do you mean by encrypted, also under custom limited?

MR. IUELE: Hi, Wade Iuele here, Project Manager for HPD.

This entire list of fields is the whole set of lists in the data. It's a long list. I'm scrolling here to show you that it's a big list. We're going to filter through to get to the HIPAA limited fields.

But this one, in particular, is the subscriber's group policy number, the policy number under which the subscriber is covered. And you can get the specific number in a research identifiable if you're approved to get access. But for a custom limited dataset, the only thing that would be available would be an encrypted version of that. So, you couldn't actually use that information in the real world to find that policy number, but you could get the cohort of people that are covered under that policy, if that was approved as well.

So, this grid of stuff is encrypted and not available in the limited column. But is available to request, and if authorized, you'd be able to access in this column.

COMMITTEE MEMBER KURTURAL: Okay. And then go down, there's a couple others that were under custom limited, and I wanted to just see them.

MR. IUELE: Do you have a specific one that you're looking for? I'd be happy to take you there.

COMMITTEE MEMBER KURTURAL: Just whatever is under custom limited marked with a Y.

MR. IUELE: Okay. So, I can just show you those.

COMMITTEE MEMBER KURTURAL: Okay, (indiscernible) -- and then, provider's submitter claim control number. What is that, submitter claim control number, under 185?

MR. IUELE: The submitted claim control number I think is to manage claims where there's a primary and a secondary payer.

COMMITTEE MEMBER KURTURAL: Oh, okay. Okay. So, and then to reiterate, if something is research identifiable, that's something that would go to us for review?

MR. IUELE: Correct.

COMMITTEE MEMBER KURTURAL: Okay, great.

I don't have any more questions on those.

MR. IUELE: Thank you.

VICE CHAIR DICKEY: Do you need to see the list for the limited or you're just going to trust them.

COMMITTEE MEMBER KURTURAL: Might as well, we're

here.

VICE CHAIR DICKEY: Do you have the list for the limited?

MR. VALLE: Wade, did you hear? The question is, I think, to confirm that none of the HIPAA identifiers are included in the limited dataset. Is there a way to demonstrate that for the Committee?

Sorry, Wade, you're on mute.

MR. IUELE: Okay. Sorry about that. Unmuted, now. So, if you have numbers or identifiers, or things from that slide that you want me to check, just holler out what they are and I'll pull them up on the list.

MR. VALLE: Other direction. Wade, could we go the other direction, can we show what is included in the standard limited dataset. I think that will just give the Committee some assurance, just comfort that there's no HIPAA identifiers included in the it.

DR. KRAWCZYK: So, that would be the application grid on our website, Wade.

MR. IUELE: Oh, the other grid.

DR. KRAWCZYK: Yeah. So, back out from the custom and research and go to the standard limited justification grid. The challenge is I don't think the filtering is available to say -- because it doesn't exist.

VICE CHAIR DICKEY: Right.

MR. YI: Also, just want some clarification here. There are two lists. There are the Safe Harbor HIPAA identifier list versus the limited data direct identifier list.

COMMITTEE MEMBER KURTURAL: Yes.

MR. YI: And so, limited data is still considered PII. It's identifiable. Just to make that clear.

And so, when we say identifiable, we mean directly identifiable.

COMMITTEE MEMBER KURTURAL: To reiterate on that, that's why I didn't question the zip code because it doesn't include zip code in that. So, providing a zip code is still okay under federal law.

VICE CHAIR DICKEY: If it's a five-digit zip code.

COMMITTEE MEMBER KURTURAL: If it's a five-digit. Yeah.

VICE CHAIR DICKEY: Are we waiting for --

DR. KRAWCZYK: Well, I think that's the question, again, do you still need to see it. Because the file, itself, just it doesn't list any identifiers. So, again, what Wade did there is he filtered is this available, yes or no, based on the identifier column.

COMMITTEE MEMBER KURTURAL: Oh.

DR. KRAWCZYK: We don't have that column in that spreadsheet because there's no variables that were

considered as identifiers under HIPAA.

COMMITTEE MEMBER KURTURAL: Right.

DR. KRAWCZYK: So, the spreadsheet just doesn't have the same functionality. But you can look and see. Like, for example, I mean, you know, there's just no name, there's no address. There's no date of birth. We like, you know -- that kind of stuff what's listed in there.

COMMITTEE MEMBER SCHAEUBLE: Would it show us, though, the scope of the medical information that's available in the file?

DR. KRAWCZYK: It's based on, for example, like ICD codes.

MR. IUELE: Sorry about that. It's all in the -- it's all in this file, that I think's in the chat. But I'm showing it now, if you wanted to ask specific questions or if you wanted me to scroll through.

VICE CHAIR DICKEY: These are all the elements that are in the limited?

COMMITTEE MEMBER KURTURAL: What's internal member ID?

MR. IUELE: I can tell you. So, inside the database, inside the dataset, the standard limited dataset, it's multiple tables. There's the eligibility table, the medical table, the pharmacy table, and the provider table, and then some reference tables.

The internal member ID is something that we can use to longitudinally track, a person without identifying them, across years, across submitters, to find the claims for that person and cross them together. So, it's just a way to join across tables in your coding.

MR. VALLE: And it's an HCAI generated.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER KURTURAL: Like a -- okay, gotcha. Okay.

MR. IUELE: There we go, maybe that's easier. It's more helpful. Yeah, so this is -- you can see all the member fields here, city, state, zip, five digits only, race fields, ethnicity fields, language.

That's the eligibility table. Is there anything specifically you wanted me to zoom in on the eligibility fields?

COMMITTEE MEMBER KURTURAL: No, I'm good.

MR. IUELE: And then for the medical -- oh, it's a little small.

COMMITTEE MEMBER KURTURAL: Thank you.

MR. IUELE: For the medical it's similar. So, these are -- this is claims data, so these are all claims. And you can see that there's what you would expect to be in the claims data. Pay dates, admission and discharge dates, codes for billing procedures.

COMMITTEE MEMBER KURTURAL: I'm confirming under limited dataset I think it's okay to use ages.

MR. IUELE: The amounts, the payment amounts.

COMMITTEE MEMBER KURTURAL: A quick question. You might have went through it really fast, it doesn't have date of birth, right? I'm just wondering.

MR. IUELE: Correct. It just has age.

COMMITTEE MEMBER KURTURAL: Okay.

MR. IUELE: But I can show you. If my filters will work. Oh, I need to enable that. You want to look at birth. No matches. Age, that's it. They have age in months, as well.

COMMITTEE MEMBER KURTURAL: Okay.

MR. IUELE: You also wanted to check on the medical table? And probably see similar for the drugs. That's the drug information and provider information.

COMMITTEE MEMBER SCHAEUBLE: Can you remind us, again, what is added in the expanded limited set that's not in the basic limited set?

MR. IUELE: Yes, there's standard limited and standard limited plus. And you can see here, on this data dictionary that I've linked in the chat, there's a column here that shows you what's in the plus that's not in the standard limited dataset. And it's the identifiable provider information. Payer and provider information is not

included. Identifiable provider information is not included in the standard limited dataset, but you -- if approved for standard limited plus, you could pull that.

COMMITTEE MEMBER KURTURAL: And I think that's okay because it's a provider address. It's not like a residential address. All right. Is there anything else?

VICE CHAIR DICKEY: I guess the question is, is there anything else that the Committee members need to see, would like to see.

COMMITTEE MEMBER SCHAEUBLE: Well, this talks, again, about the different types of data files. Did you come up with something that would show us criteria that you will be using for releases of the different categories of data? That was the other part of the question from before.

DR. KRAWCZYK: This standard limited -- the workflows could possibly help, in terms of the steps that they have to go through. So, if we wanted to go back to the slide deck, I can quickly use those.

Because like standard limited, again, as expected, you know, it doesn't have identifiers. All of the requests are going to have to, you know, fulfill their requirements around security, privacy, that again. And those are standards that we've referenced in the regulations and also as a part of the application.

But if we go to -- just keep going forward until

we get to the workflow slides. This is just how it applies. Actually, go back to -- this is also serving as the workflow.

So, the standard limited and standard limited plus, again, they submit the application. We do our preliminary review. Now, whenever you see something shaded in light blue here, that means that that's a step that is additional or outside of HCAI. Okay.

So, here you'll see that there's Department of Health Care Services review. If they're requesting the standard limited that includes Medi-Cal data, then the request does have to go to DHCS for review. And then, DHCS will do the review under the requirements that, you know, they have to follow.

For example, the use of the data has to provide benefit to Medi-Cal. That's like one of the key questions that they'll be considering.

We could send the request of data to our Data Release Committee, but that's not required. Okay. But, for example, if we do get a request and they want, you know, to do something around, say, provider location, that raises a level of security about the provider, we would send that probably to the DRC for their input. So, it's an optional, but we can send these to the Data Release Committee.

And then, basically, you know, it goes through our

review and our approval.

Standard limited are intended to cover a broad set of use cases. Which is, again, you know, how HIPAA limited data are also intended to be used. But they present low risk for reidentification and/or breach in the use.

Go to the next slide. We're going to get into the custom and the research identifiable. Now here, again, research identifiable required to go to CPHS. So, we, you know, do recommend, again, that the requester draft their CPHS application. Then they do their application to us. They submit it to us on our portal. We will be doing extensive preliminary reviews with them, making sure that, you know, they have given the level of justification necessary, especially for that variable grid that Wade just displayed. They're going to have to give a justification for the use of each and every variable that they're requesting access to.

We also are going to be scrutinizing sufficiency in the methodology that they're going to be using. You know, proposed other linkages and/or bringing in of other datasets, method of access, and so on.

We will also, then, be providing the letter of acknowledgement for them to include in their application to CPHS. Again, if there's Medi-Cal data that's included, it's going to have to go to DHCS. A difference between these and

the other, these requests are required to go to our Data Release Committee. Okay.

We're going to bring back probably from this conversation, also, if they are external to the umbrella of agency there will be a step in here for them to go to their own institutional IRB, if I understood the conversation earlier correctly. Okay.

Internal to agency that wouldn't be a step. We'll have to put a third color on here, differentiating that. But it will say if they're under agency, they're already going to be doing step one. Right.

And then, we essentially do our -- put our review on hold at this point, waiting for all of the different approvals to come in. Okay. So, a recommendation of approval from our DRC is required in order for HCAI to also approve. Actually, they can -- yeah, if they decline, they reverse the authority on that.

VICE CHAIR DICKEY: Right.

DR. KRAWCZYK: If our DRC declines approval, it's a hard stop. CPHS declines approval, it's a hard stop. Those two entities can recommend approval, and we can still decline.

VICE CHAIR DICKEY: Still.

DR. KRAWCZYK: And I think that's key.

VICE CHAIR DICKEY: Can I just ask you a question.

Step one, does it make sense for them to prepare their application to us before they've even prepared their application to you?

DR. KRAWCZYK: I think it's generally like we're just saying work with CPHS, begin your application, work with both, right.

VICE CHAIR DICKEY: I don't know if we want to see them before they're -- I don't want to see them. Do we? I mean, traditionally, for your other databases we don't even look at them until we have a letter of support from you.

DR. KRAWCZYK: Yeah. Part of this is -- and correct me, Agnieszka, others, if I'm wrong. But going to IRBManager, create your account, create your application create your protocol is also an efficiency for later on.

So, one of our requirements is that the individuals listed in our application and the data users listed have to match identically with what's in the CPHS protocol.

VICE CHAIR DICKEY: Right.

DR. KRAWCZYK: And so, it's really, you know, I think -- like for example, if we did our initial review --

VICE CHAIR DICKEY: Okay.

DR. KRAWCZYK: -- and then they down the road, right, start their CPHS application and protocol, and at that point in time they've added a user --

VICE CHAIR DICKEY: Right.

DR. KRAWCZYK: -- that then wasn't in ours, we've got to bring their application back in our process. So, the more that again -- and it's not to say that both are going to be official, right. But the both -- but the extent to which the requester is concurrently beginning these processes, the better, the more efficient I think, also, for the different committees working together.

MR. VALLE: But I'll just add, we are in, you know, complete deference to this Committee, what they'd like to see and, obviously, those conversations can continue, as well.

VICE CHAIR DICKEY: I mean, I'm just trying to figure out the workflow on it. But Agnieszka, you're probably better at --

DR. RYKACZEWSKA: I think this approach would be very similar to what we're already doing with CDPH VSAC. It does resonate with me.

But I would also note, I think there's also two pieces here. One is the database, itself, needs a sense of the database itself. And then, I think there's also the individual requester process.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: And I guess most --

VICE CHAIR DICKEY: This is for the individual

requester.

DR. RYKACZEWSKA: Yes, this is for the individual requester process. I think our focus so far has been on the existence of the database, itself. And one question that I have is whether the individual requester process needs to come back to this Committee once they've kind of refined these steps, too, separate from the existence of it.

VICE CHAIR DICKEY: So, as I understand it, you guys have a lot of individual requests piling up, right.

DR. KRAWCZYK: Thirteen. Oh, about thirteen -- but not, again, 13 total. It terms of custom and research, I think probably about half, half and half, like from standard limited.

DR. RYKACZEWSKA: And that's just -- not too muddy the waters, I think this process is important to discuss. And like I said, to me this is very similar to what we're already doing with CDPH VSAC.

I think on one hand, one of the advantages there is that we're frontloading expectations for the researchers that they are going to have to go through all of these steps and processes, and they're starting to familiarize themselves with the application, what they need to be providing. I think it's potentially some early opportunity for us to screen and flag with them, if there's something they're missing.

VICE CHAIR DICKEY: Is there something we could do where they start the process, but it doesn't go to the reviewer until you guys have decided that it's gotten the approval from DRC?

DR. RYKACZEWSKA: I think the -- let me state an assumption here. We wouldn't start the official review process until we've received your letter of acknowledgement. So, what I think you're saying in step one is that they start drafting the application, but they wouldn't actually fully submit it for our review until we have that letter acknowledgement letter of support.

VICE CHAIR DICKEY: But we don't have a function that enables us to stop IRBManager on that. It's something you guys have to do.

DR. RYKACZEWSKA: Right, so we screen oftentimes with -- again, with CDPH, use that example, we'll do some preliminary screening, but we don't assign it to a reviewer until we --

VICE CHAIR DICKEY: Right, that's all I wanted to --

DR. RYKACZEWSKA: -- yeah, until we receive that letter of acknowledgement or letter of support.

CHAIR HESS: Are we requiring any sort of indication or letter from the DRC for our applications?

MR. VALLE: So, I'll ask James, maybe, to talk

about how we are planning to formalize the Data Release Committee's decision through an acknowledgement letter.

MR. YI: Yeah, we still have to talk to the Data Release Committee, but we expect them to have a formal resolution regarding their decisions that outlines what they've approved, and any conditions they've put on.

CHAIR HESS: That's what the board means to make our determination. Because if they can't get that, then our review is kind of nullified, right. If the DRC doesn't release the data then we shouldn't be even reviewing the protocol until that happens.

VICE CHAIR DICKEY: Well, it's -- what do we do with VSAC?

DR. RYKACZEWSKA: So, with VSAC, their statute specifically states that CPHS review comes first. So, they do a preliminary review. Our researchers attach a copy of their application to our application to demonstrate proof that they have submitted an application to VSAC.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: VSAC does a preliminary review, they do give us a letter of support. But before they do their approval, they have to receive our approval letter. And that is because specifically in state statute for CDPH VSAC it's stated that first, it uses the term "first" for CPHS's review as part of the demonstrating there's

scientific, solid scientific interest in the study that's being proposed. So, that process is predefined by statute.

I don't know if --

VICE CHAIR DICKEY: Nothing like that for you guys, though.

MR. YI: Yeah, we have a provision in our regulations about CPHS review. And we basically tell them, you know, you can do it whatever you want.

VICE CHAIR DICKEY: But it doesn't say we have to --

COMMITTEE MEMBER SCHAEUBLE: It doesn't say first, right. Okay, so we can handle it more like we do other situations.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: So, the more typical would be that all of the departmental approvals are completed, or departmental related. I do understand that the DRC is separate from HCAI. But the departmental related or dataset-specific reviews are completed prior to CPHS review.

VICE CHAIR DICKEY: But that, in this case it wouldn't include their Data Release Committee?

DR. RYKACZEWSKA: I think, and HCAI, I don't know if you would be open to this, but I do think there would be value in having DRC's resolution be uploaded as part of their CPHS application, and then CPHS would review.

In part, because then we could see the exact variables that, from what I'm hearing, the DRC has approved. And so, we could make sure that we're aligning on those.

COMMITTEE MEMBER SCHAEUBLE: And it almost seems logical that we would want to know that there is a willingness to release the data before we try to determine, ourselves, other circumstances that we're required to review.

MR. VALLE: And I was just going to add, you know, again, I think HCAI's open. I also think it would be great for the Committee, or perhaps the Chair, the chairship here, to engage with the DRC directly. And we have a chair and co-chair structure as well. Dr. Nuriel Moghavem is our chair. Dr. Miranda Dietz is our co-chair. And they may also have some ideas on how to make this (indiscernible).

CHAIR HESS: Do you have additional questions?

COMMITTEE MEMBER JOHNSON: I have a few questions.

CHAIR HESS: Yes.

COMMITTEE MEMBER JOHNSON: In your application, you mentioned that you will also include Vital Records data, in your database.

DR. KRAWCZYK: Not at the present time. Our database does not include Vital Records. Now, a requester can indicate that they're going to link to Vital Records. That would have to go through the Vital Records process and

get, again, VSAC approval. You know, but that's not our purview, you know, the VSAC approval.

But we, in our database, do not currently have Vital Records available for request.

COMMITTEE MEMBER JOHNSON: If you intend to have Vital Records, is that going to come back to us?

DR. KRAWCZYK: A future point in time, I think. And today, focuses on what we're currently --

VICE CHAIR DICKEY: But that would change the database, and we would have to approve the change.

MR. YI: Also, a large measure for Medi-Cal data that goes through the Department of Health Care Services, as well, and their DRC, their Data Research Committee.

VICE CHAIR DICKEY: Too many DRCs.

MR. YI: Yes.

COMMITTEE MEMBER JOHNSON: I do really appreciate the note that you are also looking at what they're linking with, like with Vital Records. I think that that's a really important piece to be reviewing. Yeah, just appreciation for that.

MR. VALLE: Of course.

COMMITTEE MEMBER SCHAEUBLE: Well, I guess more broadly, if a researcher proposes to link data from your source with data from whatever the other source is, how is that factored into any consideration when you approve a

release of data?

MR. VALLE: I think -- I think we already have a way, Dr. Schaeuble. Chris, do you want to talk about how data linkage is --

DR. KRAWCZYK: Could you repeat that?

MR. VALLE: So, Dr. Schaeuble's asking about the additional consideration that we'll be applying when the requester requests to link data, and from a data privacy standpoint and others.

DR. KRAWCZYK: Yeah. I mean, again, when other data is brought in, you know, we have to first consider the information being requested to facilitate the linkage. Oftentimes, there's identifiable information in there. We have to consider the creation of new information and any risks or concerns that come with the creation of new information.

Also, the mode or mechanism of receiving the data. Again, if they're going to be direct transmission or if they're going to be within the enclave. If they're going to be within the enclave, we have to consider them, also, for example their authority to bring those other data sources into our domain environment. So, we'll looking for things, again, do they have approval from the other data storage for those data to be brought into a developed secure environment.

So, we're often going to be looking, again, at the typical of many data linkages, the viability of the linkage information being requested to facilitate the linkage. The information that's going to be created as a result of the linkage. We'll be looking at the information that's going to be brought in, the authority of the approvals being in place for the use and the bringing in of those data.

We'll be looking at the mechanisms for transmitting. We'll be looking at security of the privacy, if it is not within the enclave. And then, with all of these, what are going to be their mechanisms, again, for de-identification, what products are they going to produce, where are those products going to appear.

And again, most of -- a linkage, you know, steered into the enclave, we'll be able, again, to see anything that goes out of the enclave.

VICE CHAIR DICKEY: But if it's outside the enclave, if it's an actual release, which there won't be many of those, I'm assuming --

DR. KRAWCZYK: Yeah.

VICE CHAIR DICKEY: -- but is there any way you can control the linkage there?

DR. KRAWCZYK: The data use agreements. Ultimately the agreement that's going to be in place, you know, on what they said they were going to link, and what

they were going to do with those linked data.

VICE CHAIR DICKEY: So, they would have to have that in their data use agreement.

COMMITTEE MEMBER SCHAEUBLE: Is this a situation, then, that would trigger CPHS review?

DR. KRAWCZYK: Well, research identifiable data does, you know, trigger the CPHS review. Very few linkages can be done, also, without those identifiers. Certainly, you know, someone can get creative and try and come up with some sort of a, you know, linkage based on other available information. But it's just hard to do a linkage without identifiers. And then, again, as we showed, the researcher identifiers do have to come to CPHS.

COMMITTEE MEMBER SCHAEUBLE: I know we've occasionally seen people trying to link using some kind of probabilistic matching, is the way they usually phrase it, without having direct identifiers, and that's sort of why I was asking.

DR. KRAWCZYK: And again, if they're not using identifiers, you know, they're using indirect and/or the -- they're using the limited dataset and, you know, they want to try and do a linkage on that, one, the limited data wouldn't be coming to CPHS. But we would be looking at it again from, you know, our usual security and confidentiality, what is coming in.

And certainly, making sure that whatever product is done, then, doesn't get somehow, right, linked back using the same mechanism to other identifiable data sources. That would be something that would go in the data use agreement. Reverse engineering, essentially. We wouldn't -- we want to prevent reverse engineering.

COMMITTEE MEMBER SCHAEUBLE: I'm just imagining situations in which your normal practice of releasing limited data without any reference to review from CPHS. There seems like there might be a need, on occasion, to refer a particular study even though it involved only limited dataset, but it had some other considerations in the research study that --

DR. KRAWCZYK: And I think we'd been open to that. What I'm hearing is kind of a referral, Dr. Schaeuble, in these sort of circumstances. And just to add, too, --

COMMITTEE MEMBER SCHAEUBLE: Some flexibility in going beyond the minimum when the circumstance is warranted, yes.

DR. KRAWCZYK: Yeah, I think we would be, you know, tremendously benefitted to avail ourselves of the wisdom of this Committee. And just to add that, also, we can voluntarily request our Data Release Committee to review any request even though they're not obligated. So, that would be something I'd be happy to look into more.

CHAIR HESS: Presumably, like a probabilistic matching, I think would be very difficult to deal with in the enclave, right. Like the software and everything, I think would not be there.

MR. VALLE: And just to -- I wanted to clarify as well, if you look at the last slide, any direct transmission request must go through the Data Release Committee, so that's a must. And then, there's some circumstances where it's voluntary.

VICE CHAIR DICKEY: Right. Can we ask if there's other comments from the public?

CHAIR HESS: Yes. I was about to say are we ready to ask for public comments. Are you ready to make a motion?

VICE CHAIR DICKEY: I am.

CHAIR HESS: Okay. Do we have members of -- first and foremost, are there any other members of the board who have questions or any comments?

And seeing none, I will open it up to any members of the public who are present on Zoom. Could you raise your hand or otherwise indicate if you have a comment?

DR. RYKACZEWSKA: I am not seeing any virtual hands but giving it a couple more seconds here. No virtual hands.

CHAIR HESS: Okay. Dr. Dickey, if you are ready to make a motion.

VICE CHAIR DICKEY: Yeah, I'm trying figure how to work this. But I think the correct wording is that we're -- move to approve the Health Care Payments Database -- well, Health Care Payments Database. This is just the establishment of it. Yeah, approving the establishment of the Health Care Payments Database.

CHAIR HESS: Do we have a second?

COMMITTEE MEMBER KURTURAL: I'll second.

CHAIR HESS: Ms. Kurtural seconds.

COMMITTEE MEMBER SCHAEUBLE: Is there anything that needs to be said or should be said regarding some future discussion with the Committee of these procedural issues that we've spent so much time on?

VICE CHAIR DICKEY: Well, I don't think that's part of the motion. I mean, really what they've applied to us for is the establishment of the database. We're obviously going to work out those details.

COMMITTEE MEMBER SCHAEUBLE: Okay.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: So, when will we see you again?

MR. VALLE: Well, in respect to Dr. Schaeuble's comment, too, I just want the Committee to know that we are available at any point to discuss these matters, whether it's with the entire Committee, or subcommittee, or individual members. I'll make myself personally available, as well as my team. So, perhaps we can discuss what the desires of the Committee are and when to see us again.

CHAIR HESS: Yeah, I think (indiscernible) -- you are a data release committee, just to get a better understanding of how you're reviewing project applications and, yes, the procedures, just so this board has a better sense of what that looks like on the ground.

MR. YI: We do have a Data Release Committee manual that's available. And I would be happy to meet with you, as well.

CHAIR HESS: Yeah, the manual will be helpful as well for us, as reference.

COMMITTEE MEMBER KURTURAL: And, you know, contact between the two, right. Like if there's something that's a

gray area, there's always going to be some sort of gray area.

MR. VALLE: I think I can speak for the Data Release Committee; they would be very happy with that offer. They point to this Committee, and the importance of your work, and so would welcome that.

VICE CHAIR DICKEY: I think it would be probably -- you know, at a staff level it would be good for you to have the --

DR. RYKACZEWSKA: Yeah, we already have monthly meetings with HCAI established, with the CPHS admin team. Yeah, we absolutely do.

I guess, really, as the next step I would propose that maybe the Chair and the Vice Chair can meet with HCAI to, again, go through some of those details of your applications, work through the details and then maybe bring that back as information for the full Committee.

CHAIR HESS: Yeah.

VICE CHAIR DICKEY: Sure. It's going to happen pretty quickly, right? I mean --

MR. VALLE: Absolutely.

CHAIR HESS: Okay. I believe that was our last project. Are there any public comments or questions on agenda Items I through O? Or, Committee member questions, sorry, on the agenda?

Hearing none, are there any public comments on agenda Items I through O?

DR. RYKACZEWSKA: If you have -- if there are any public comments, please raise your virtual hand. Acknowledging no members of the public in the room. I am not seeing any virtual hands.

CHAIR HESS: Okay. Are there any public comments on items not on today's agenda?

DR. RYKACZEWSKA: Again, not seeing any virtual hands.

CHAIR HESS: Okay. Well, then, I will inform everyone that the next CPHS's full board meeting is Friday, August 1st. And I will adjourn today's CPHS full board meeting.

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

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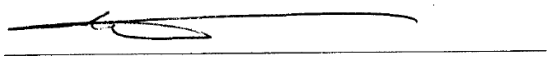

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