MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, AUGUST 1, 2025

8:30 A.M.

1215 0 STREET, 11TH FLOOR

CLIFFORD B. ALLENBY BUILDING

MEETING ROOM 1181

SACRAMENTO, CALIFORNIA 95814

AND

ZOOM ONLINE MEETING PLATFORM

Reported by:
Peter Petty

APPEARANCES

COMMITTEE MEMBERS

Catherine Hess, PhD Dr., Chair

Larry Dickey, MD, MPH, Vice Chair (Via Zoom)

Maria Dinis, PhD, MSW (Via Zoom)

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS

John Schaeuble, PhD, MS

Dr. David Lang (New Member, not yet sworn)

Dr. Lemeneh Tefera (New Member, not yet sworn)

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Sheryl McCarthy

Karima Muhammad

Nicholas Zadrozna

CalHHS

Maggie Schuster, Attorney

APPEARANCES (CONT.)

ALSO PRESENT

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Consultants Present

Joshua Fedewa, Advarra Consulting

Cheryl Byers, Advarra Consulting

OTSI

Deanne Wertin, Chief Deputy Director

Mark Owens, Chief Counsel

PUBLIC

None Present

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Dr. Ashish Deshmukh, University of South Carolina

Ms. Ella Starr, University of South Caroline

Ms. Alina Xu, Social Finance, Inc.

Dr. Christopher Anderson, PHFE WIC

Dr. Kelsey Pukelis, Harvard University

Dr. Laura Carper, Texas A&M Texarkana

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P R O C E E D I N G S

CHAIR HESS: Welcome everyone. And I will officially call the August 1st CPHS meeting to order.

Could I ensure that all remotely participating members turn on their cameras, please. It looks like they are on. Thank you very much.

Sussan, could you do a roll call?

MS. ATIFEH: Sure. But I think I saw Dinis, didn't I?

DR. RYKACZEWSKA: Not yet online.

MS. ATIFEH: Yeah, we're waiting for Dr. Dinis.

CHAIR HESS: Okay, we are still waiting for Dr. Dinis. So, should we hold off for a minute or two?

VICE CHAIR DICKEY: Do we have a quorum?

CHAIR HESS: Do we have a quorum without --

DR. RYKACZEWSKA: We do have a quorum.

CHAIR HESS: Okay. If we have a quorum without Dr. Dinis, then we can go ahead with roll call.

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

CHAIR HESS: Present.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

DR. RYKACZEWSKA: Oh, we cannot hear you, Ms. Lund.

MS. ATIFEH: We cannot hear you.

COMMITTEE MEMBER LUND: Can you hear me now?

(Collective yes)

MS. ATIFEH: Thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, a quorum is established.

CHAIR HESS: Great. Okay, well, I have some kind of exciting news to start with today. So, as you all know, since the departures of Dr. Bazzano and Dr. Delgado we had some vacancies on the board. We started the recruitment process earlier in the year, following the processes outlined in our policies and procedures, and with Agnieszka's support, Dr. Dickey and I reviewed candidate nominations and submitted a list to the secretary for review.

And last week, the secretary appointed two new members to the board. We have --

DR. RYKACZEWSKA: They are both here.

CHAIR HESS: -- both members today, new members, joining us by Zoom today just for introductions. They'll both officially be sworn in at the October 2025 meeting.

So, I'll start with Dr. David Lang. Dr. Lang is currently the Research Manager at the Cradle to Career California program and a post-doctoral research fellow at Stanford.

He currently leads the development and maintenance of a longitudinal data system linking K to 12 postsecondary workforce and other life outcome data.

He has extensive experience with data governance and has led large-scale research studies on the impacts of educational policies, including assessing the impact of 60 million dollar -- $16 million worth of pandemic relief funds on student degree process -- progress. Sorry, I can't talk today.

Dr. Lang also has experience with sensitive populations, including children, individuals with disabilities, students eligible for free or reduced-price lunch, and other vulnerable groups.

So, welcome Dr. Lang. If you would like to come off mute and make any comments.

DR. LANG: Thank you. That was a wonderfully kind introduction. I am looking forward to working with you all and helping support safe, responsible, scientific research

for the State of California. Thank you.

CHAIR HESS: Thank you. We look forward to having you join the board officially in October.

And our second new board member, Dr. Tefera -- Tefera -- can you please -- I want to make sure I'm getting that correct.

DR. RYKACZEWSKA: I saw a nod.

CHAIR HESS: I got it right? Okay.

DR. TEFERA: Agnostic, both works. You're fine.

CHAIR HESS: Okay. So, Dr. Tefera currently serves as the Chief Medical Officer and Deputy Director of Clinical Innovation at Department of Health Care Access and Information, so HCAI.

He's also a practicing emergency medicine physician with over 25 years of clinical experience. He's held multiple faculty appointments and has been a part of multiple clinical research teams.

Dr. Tefera also served as Senior Adviser and Medical Officer at the Centers for Medi-Care and Medicaid Services, shaping policies that promoted patients' safety and hospital quality improvement.

His expertise in research-related healthcare affordability, behavioral health economics, and emergency medicine will contribute to the diverse healthcare research studies submitted by CPHS.

And welcome. And I'll give you an opportunity to say hi to the board and introduce yourself.

DR. TEFERA: Yeah, good morning. Thank you for the introduction. Lemeneh Tefera, Chief Medical Officer and Deputy Director at the Health Care Access and Information.

It's a pleasure to join the Committee and I really look forward to serving along with the members, and contribute to, you know, thoughtful assessment of submitted protocols to promote research in the State of California.

Yeah, look forward to getting to know folks over time. And feel free to reach out if there's an opportunity to catch up in either Sacramento, or the East Bay, where I usually reside.

CHAIR HESS: Thank you. And thank you, again, to Dr. Lang.

Do we have any questions for -- about the process of the new board members? No.

DR. RYKACZEWSKA: Welcome.

CHAIR HESS: Yeah. Just welcome. We look forward to your swearing in, in October.

And is there any public comment from members of the public on this item?

DR. RYKACZEWSKA: If you have a public comment, if you could please raise your virtual hand. Noting that we have no members of the public in the room. Giving folks a

second. I am not seeing any virtual hands.

CHAIR HESS: Okay. Well, Dr. Lang and Tefera, you are welcome to stay on the call and observe. You can also -- I realize you are both very busy, so there's no need to stay on if you don't have time this morning. But you are welcome to continue to join us.

And that, I will turn it over to Agnieszka.

DR. RYKACZEWSKA: Thank you so much. So, for Agenda Item B, the administrator update. There're a few updates --

COMMITTEE MEMBER DINIS: Sorry to interrupt. Sorry to interrupt. Did you all take roll already, roll call?

DR. RYKACZEWSKA: We did already take roll. But noting, also, that Dr. Dinis has joined.

COMMITTEE MEMBER DINIS: Yes, okay, thanks. Sorry about that.

DR. RYKACZEWSKA: Thank you, Dr. Dinis.

So, for the administrator update I do have several updates, starting with an update around CDII. So, in late June CDII Director John Ohanian shares with the board that he would be transitioning out of his role at CDII starting today, August 1st. And that as part of this transition CalHHS is undertaking a strategic reorganization to better align CDII's critical work stream.

Starting with the Committee for the Protection of Human Subjects, knowing that that's of most interest to this group, but also the CDII Insights Lab, will be transferring to the Office of Technology and Solutions Integration, also known as OTSI.

CDII and OTSI have worked closely together over the last several years, but especially most recently on the IT and Data Strategic Plan, where we're really outlining strategies for positioning the CalHHS data ecosystem to really be leveraged in a way that best benefits Californians, while also making sure that we're protecting their information. So, really finding that balance there.

And so, we're really excited to be continuing that work even more closely as we move forward.

And in the spirit of even more introductions today, I'd like to introduce Deanne Wertin, who is with us today. She is OTSI's Chief Deputy Director, as well as Deputy Agency Information Officer, as well as Mark Owens, OTSI's Chief Counsel.

So, Deanne, I'll hand it over to you.

MS. WERTIN: We are really excited. Today, August 1st, is when CDII is joining us officially. But I imagine there might be some questions about that, and why OTSI, and what does that mean for the CDII and for CPHS.

And so, I'll probably start with the most

important thing is that right now, through the transition, it's business as usual. There're no changes to how we're working with the board or anything related to that.

So, that's the bottom line as we transition over. Today, folks continue in their same roles, doing the same work that they're doing.

I did think it would be helpful, though, to share a little bit about OTSI and what we do, and why we understand that agency thought this was a good match. We only learned about it recently, as well, but it makes a lot of sense to us when we think about the work that we do.

So, OTSI, it was called OSI until a couple years ago. You may have heard about OSI, if you were working within this.

But OTSI was established in kind of current form about 25 years ago. It's our 25th anniversary for OSI and OTSI. And even before then this group and this organization, under a different name and different alignment, was talked with planning and delivering our agency's, Health and Human Services Agency's most complex and critical projects' IT solutions.

And over the years that is including, and continues to include solutions like Cal HEERS, the Electronic Benefit Transfer Solution, the Statewide Eligibility System, SAWS. We oversee that work, working

with the consortia. And most recently and in continuation, but the Child Welfare Solution.

So, these are big solutions that hold critical data that we build in partnership with our sponsors, with Department of Social Services and Department of Health Care Services.

And in that role, clearly, we are tasked with understanding and protecting that data, security and privacy protections for that data that's going through those systems.

That's something we do well. We have an agency information security officer, as well as an OTSI security officer that's focused on ensuring that the systems that we build do that on behalf of our sponsors.

Sponsors own the data. We manage the systems on their behalf, and we work very closely with them to make sure we protect that information.

There's another side to OTSI that's more recent, we established it about three years. And that's the side that says, yes, we do end-to-end solution delivery, but that's not all we can do. We can also help departments when they just need support with some of their projects, when they just need us to come help identify and build a data architecture for them, for solutions they're building, or a project manager, or a business analysis, whatever it is.

It's essentially an internal consulting organization leveraging the same knowledge and expertise that we provide through the large projects to department, to help them with the work they're doing.

Most relevant to this group, again to ensure that we're building systems that are safe and secure when it comes to data and protections accordingly.

Within that group, and it's the group that I lead -- and I should have started by saying Adam Dondro, the Director of our department, really wanted to be here today. He's, I think, just about off to Greece for a couple of weeks, with a pre-established vacation he had. So, I'm stepping in for him.

But that part of the organization, when we joined that part, which was a bit of a merger of Adam and I, and some other functions, a couple of years ago, we were tasked, really, with creating OTSI as an organization that leads across agency, and IT, and data.

So, it kind of expanded that role from specific projects to this broader idea of driving consistency and quality into the way that we develop IT and data solutions.

With that we published, in March of last year, the IT and Data Strategic Plan. I'm not sure if you've had a chance to review that. We did it in partnership with CDII and with John Ohanian's team.

And that plan lays out a vision for a future where we have person-centered services that are interconnected, and ensure that we understand the needs of individuals, we meet those needs, and we use the information that we gain through that process to understand how we can improve our policies in general. Right. How can we improve our programs.

Now, with that, of course, there's a data. There's a fair amount of data in play with that. So, we're bringing together kind of the best of the two organizations in terms of understanding the data, understanding the technology to develop and deliver on this mission.

I love the way that Dr. Tefera said, it was very focused on safe, responsible data usage and research. So, it's a great fit, right.

One of the big things that we were talking with an individual the other, he said, you know, recently the concept of consent has really blossomed, right. We're hearing it all the time now, which is a great thing, right. This idea of consent as we work on this solution, this idea of going a step further with that in terms of the ethical and safe use of data.

So, we think it's a good match. And as I said, we're bringing that organization and through the transition nothing really changes.

Questions?

COMMITTEE MEMBER KURTURAL: I guess, who's our agency counsel? Because before we would have the two counsels of agency.

MS. WERTIN: Yes. So, during this transition -- Maggie, I think, is even on the phone, right?

DR. RYKACZEWSKA: She is, virtually.

COMMITTEE MEMBER KURTURAL: Okay. Okay.

MS. WERTIN: Nothing changes with that, so that continues.

COMMITTEE MEMBER KURTURAL: Okay.

MS. WERTIN: And hi, Maggie.

MS. SCHUSTER: I'm going to continue supporting the Committee. I'm working with Mark Owens to explore the wonderful asset, and I'll help transition over. But I'm staying here for now, so you'll see more of me.

MS. WERTIN: Yeah, and I would like to turn it over to Mark. He can speak more to his function, and his role with the project, itself.

MR. OWENS: Yeah. Yeah, thank you. Mark Owens, again, Chief Counsel at OTSI.

In support of all of the things that Deanne just mentioned, we have a team that I've formed over the years. I've been practicing for 30 years, and I've been counsel for OTSI before it was OTSI, or before it was OSI, back when it

was the Health and Human Services Data Center. So, this is a long time ago.

And over these years I've built a team of now seven attorneys. And our philosophy is accessibility and service. That's what exist for.

And so, I and my team of attorneys are now available to all for whatever you need, whenever you need it. And that's my commitment to you. So, that's us. Glad to be here. Thank you for inviting me today.

CHAIR HESS: Thank you.

COMMITTEE MEMBER VENTURA: Thank you.

MS. WERTIN: Mark's team is tremendous at helping us with our -- ensuring in our contracts, and the individuals that are working on our projects, because we do use a fair number of vendors, also comply and align with the same vision that we have around the systems and the data. So.

Any other questions? Yes, sir.

COMMITTEE MEMBER SCHAEUBLE: Actually, two.

MS. WERTIN: I'm coming up to the table, then.

COMMITTEE MEMBER SCHAEUBLE: I don't think they're hard ones, but anyway.

MS. WERTIN: Sure.

COMMITTEE MEMBER SCHAEUBLE: So, just for clarity, Maggie's said hello here, and we've worked with Jared in the

past, and I'm not sure where Jared fits into the picture, if he does.

MS. WERTIN: Jared has retired.

COMMITTEE MEMBER SCHAEUBLE: Oh.

MS. WERTIN: Or left state --

MR. OWENS: Well, he's moved to the UC system, so.

MS. WERTIN: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Okay. Well, the other question was you said no changes at the present, does that say anything about thinking in the future that there are changes of some sort in the works?

MS. WERTIN: I don't even thing we're prepared at this point, on day one, to know that. There is no strategy today. We're like it's the same for the present. But everything changes down the road.

Maggie's been doing a great job in supporting and I think that's been comfortable for you. We would never do anything like that without working with this team and making sure folks had an understanding as well.

MR. OWENS: We will bring you along with any changes that occur, and they won't be made unilaterally.

MS. WERTIN: So, for the other functions that we have, for the Insights Lab, and the Data Hub, one of the great things about CDII coming over is that we have like sister functions in our organization that we're allowed to

take this small group of people and integrate them with a larger group that has some of these, you know, standardized practices and things in place. CPHS is clearly different. So.

Does that lead to a third question?

MR. OWENS: It looks like there's going to be another question.

COMMITTEE MEMBER SCHAEUBLE: No, I don't think so.

MS. WERTIN: Yeah, okay.

DR. RYKACZEWSKA: Thank you, Dr. Schaeuble. Any questions from our online members? I always try to remember our online folks, too.

I'm not seeing any.

CHAIR HESS: Well, thank you. Thanks so much, Deanne, we're really excited to continue this work.

MS. WERTIN: Yeah, we're excited as well.

CHAIR HESS: Public comment?

DR. RYKACZEWSKA: I'm not done with my item, yet.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: So, that brings me to my second set of introductions. So, at the last meeting I did share that in order to align with best practices we were seeing to do a review for CPHS policies and procedures just to ensure that they're up to date, that they're reflective of any regulatory changes, and reflect best practices, as well.

And so, to support these efforts we sought to procure consultant services from experts in OHRP, FDA, and State Human Subjects Research Regulations to help us along in this review.

And I am -- oh, and the intention of this is to help us review those CPHS policies and procedures, and to make recommendations to the board and the secretary as a review and considerations in terms of that new potential revision.

So, with great thanks to Dr. Hess, who served on the review panel, and to Dr. Dickey for his subject matter expertise, we have procured the services of Advarra Consulting. And we wanted to take a moment today to introduce the team that will be working with us.

So, online today we have Joshua -- Joshua, I'm sorry, I'm going to butcher your name this morning. But Joshua Fedewa, Cheryl Byers, and Corinna Cuevas.

So, Joshua, I'm going to hand it over to you to get -- to help us get to know the team.

MR. FEDEWA: Wonderful. Thank you. And I know Cheryl will do her own introduction. It's great to be here with all of you and I'm excited to work through this.

My name is Joshua Fedewa. It's no problem that you got that wrong because nobody ever gets it right.

I have been here with Advarra as the Director of

Consulting for just over a year. Prior to being with Advarra, I was a director at two major academic institutions, one in Michigan and one in Texas. And I've been with institutions doing regulatory work for 15 years.

So, I'm excited to work with all of you to work through assessing correct policies and procedures, and where efficiencies can be gained, where compliance can be tightened, and just really make sure that everything is working as well as it possibly can.

And with me, I also have Cheryl. And Cheryl, I'll kick it over to you for a quick introduction on your side.

MS. BYERS: Thanks Josh. Hi, everyone, it's really great to be here with you all today and hear about the transition. I know we've heard a little bit about that, so it's really -- it's really terrific to hear the new department, I guess, that CPHS will be in. So, that's exciting.

My name's Cheryl Byers, I'm the Senior Vice President for Advarra Consulting. I've been in research and primarily research, compliance, and administrative roles for 26 years, now. I started my career at Wake Forest School of Medicine. And then, moved down to Tampa, Florida, where I currently live. And worked at the University of South Florida, also Moffitt Cancer Center in various regulatory oversight roles.

So, really excited to be with all of you and to help you out with this project.

I've been with Advarra now for five years. And we have -- in addition to myself and Josh, we do have Corinna Cuevas, who works on our team. She's going to be the project manager. She's not able to be with us today. But we also have a number of consultants that we work with that has human subjects research experience. And so, maybe at some point in time you'll be able to meet those individuals, as well.

So, thanks for having us.

DR. RYKACZEWSKA: Thank you.

MS. BYERS: Happy to answer any questions everyone may have.

DR. RYKACZEWSKA: Thank you both. And I just do want to note we are very early in discussion in terms of how to approach this work. And we'll be sharing further details in terms of that as we actually get started. But really wanted to at least start today with introducing Joshua and Cheryl, so that you wouldn't be surprised if and when they reach out to you, you'll be familiar with the names.

But, please, if there's any questions for Joshua and Cheryl.

VICE CHAIR DICKEY: I just want to say the timeline is over the next year, isn't that correct?

DR. RYKACZEWSKA: That's correct.

Any additional questions? All right, and I'm not seeing any questions from our virtual members, either.

So, with that I wanted to see if there is any public comment. If you have any public comment, if you could please raise your virtual hand. Noting no members of the public in the room. And I am not seeing any virtual hands.

So, with that, I will end, close out my item.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: Back to you, Dr. Hess.

CHAIR HESS: Back to me. So, review and approval of meeting minutes from the April 5, 2025, full board meeting. Actually, do any board members have any comments on that, on those meeting minutes? No.

VICE CHAIR DICKEY: Well, right, but Dr. Schaeuble had some comments.

CHAIR HESS: I believe, Sussan, did we send out the updated version with --

MS. ATIFEH: Yes.

COMMITTEE MEMBER SCHAEUBLE: I think that was June, actually, rather than April.

VICE CHAIR DICKEY: Oh, June.

CHAIR HESS: Yeah. Is there any public comment on the meeting minutes from April 5, 2025, full board meeting?

DR. RYKACZEWSKA: If you have a public comment, please raise your virtual hand. Noting no members of the public in the room. And I am not seeing any virtual hands.

CHAIR HESS: Okay. Is there a motion to approve the April 5th meeting minutes?

COMMITTEE MEMBER LUND: I'll approve.

VICE CHAIR DICKEY: I'll second.

MS. ATIFEH: Okay. I start with Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Thank you.

Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

CHAIR HESS: Okay, moving on to the approval of meeting minutes from the June 6th full board meeting.

DR. RYKACZEWSKA: So, noting that we did update them with Dr. Schaeuble's feedback. Thank you, Dr. Schaeuble.

CHAIR HESS: Any additional board comments?

Hearing none, is there any public comment on the June 6th full board meeting minutes?

DR. RYKACZEWSKA: If there are any public comments, please raise your virtual hand. Noting no members of the public in the room. And I am not seeing any virtual hands.

CHAIR HESS: Do we have a motion? Would someone like to make a motion>?

COMMITTEE MEMBER KURTURAL: I'll make a motion to approve.

VICE CHAIR DICKEY: I'll second.

CHAIR HESS: Everyone's so shy about motioning.

(Laughter)

MS. ATIFEH: I start with Dr. Dinis? Oh, you are muted.

COMMITTEE MEMBER DINIS: Sorry, what was the question?

MS. ATIFEH: You --

DR. RYKACZEWSKA: Approval of whether you approve the June 6th meeting minutes.

COMMITTEE MEMBER DINIS: Oh, sorry, yes. Yes, okay, sorry, yes approve.

MS. ATIFEH: Okay, thank you.

Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

DR. RYKACZEWSKA: Thank you, Sussan.

And if I could just, for second, share my appreciations to the team. I know in the last year we've had a lot of meetings, more than typical with a lot of the ad hoc meetings, and lots more meeting minutes to put together. And we are finally caught up completely, and just appreciations to the team for their hard efforts on that.

MS. ATIFEH: And thank you for all of your support. Thank you.

CHAIR HESS: Thank you.

VICE CHAIR DICKEY: Agnieszka, do you want us -- sorry.

(Committee members say thank you)

VICE CHAIR DICKEY: You told me about all the work the staff has done --

DR. RYKACZEWSKA: Oh, happy to share that, too. So, for those curious on the work of our staff recently, of course with the transition we have them preparing all of our

both electronic and physical files for the move, as well. And we actually had over 200 boxes of physical files, historical documents in our basement. And we needed to review them to ensure that we were keeping what we needed to retain per retention policies but processing the things that were already passed the retention policy period.

And so, in the last month, in actually less than a month staff have reviewed all 200 boxes and narrowed it down to 30 of documents that we need to still retain because studies are either still active or within the retention period, if they've closed.

And in that process, they've also documented electronically what each box contains, where each study can be found, who's the PI, what's the study title, so that we can really quickly start to pull those documents if there's questions about a study. And even this week we actually already saw that coming to fruition where there was a question about a historical legacy project. And we were able in seconds to say, okay, that's in box 10. And it was a 7-pound file from what I'm hearing.

CHAIR HESS: Wow.

DR. RYKACZEWSKA: So, I'm just really grateful to the staff, one, for the behemoth work there, but also because of the way that we've organized it now, I think for many of these legacy projects we'll have a much easier time

finding those historical documents that have -- that are in physical form, now. So, definitely great work.

(Applause)

DR. RYKACZEWSKA: And, in particular, I'm going to call out Nick was leading the team through the process and project managing this. So, good job, Nick.

MR. ZADROZNA: Thank you.

COMMITTEE MEMBER VENTURA: Nice job.

Is there any transition -- or plan to make them electronic, so that --

MR. ZADROZNA: You mean scan them?

COMMITTEE MEMBER VENTURA: Scan them, so that it's not, you know, hardcopy.

DR. RYKACZEWSKA: For now -- right. For now, we are focusing just on the move. I think we -- we're going to look into I think long term plans. But even so, just having the physical copies, I'm hesitant to destroy anything until the retention period has truly passed. And we'll definitely look more into it.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm just curious, what was in and what happened to the other 170 boxes?

DR. RYKACZEWSKA: So, what was in those documents were studies that may have already been closed. So, a lot of these documents came from previous board meetings, where

we often had printed every single protocol that we would review, and all of the materials for each of the studies.

Now, we treat them electronically through IRBManager and we sent out, virtually, the protocols for your review. But previously, all of those had been printed.

And I believe, Dr. Schaeuble -- or I'm sorry, Dr. Dickey, you said 10 copies each meeting?

VICE CHAIR DICKEY: We used to require researchers to submit 13 copies. And so, members would come to meetings without about this high of -- I remember Dr. Lowe would come with a suitcase.

DR. RYKACZEWSKA: So, that's what the documents were, were past agendas, things like that. And so, we were following the retention policy, which states, if I remember correctly, that it is active plus three years to retain physical documents.

And so, the way we looked at that is we first checked whether the study was still active. If it is still active, it is being retained.

If a study was closed, we then checked whether three years had passed from closure. If it had, at that point the document was eligible to be shredded. Now, we still have many of the documents within our IRBManager, so those documents, many of them have been transferred over, anyway. But at that point we have met the retention policy

for those projects.

COMMITTEE MEMBER SCHAEUBLE: So, what would happen to things like past board discussions of policy matters that may have been sometime in the past by now.

DR. RYKACZEWSKA: Active, we would still retain them. So, if it is still reflected in our policies and procedures, then we would still retain then.

If, since then, the policy has changed --

MR. ZADROZNA: And when it comes to the board meetings, for the transcripts and meeting minutes we kept them up to eight years, for those ones. So, we have all the way up to 2018 that we're holding onto right now regarding that concern.

COMMITTEE MEMBER SCHAEUBLE: Thank you.

DR. RYKACZEWSKA: Any other questions? All right.

CHAIR HESS: Okay, we are ready to move on. So, we have today two amendments and two new projects.

I believe we are starting with an amendment reviewed by Ms. Lund. Do we have the PIs on? We do. Okay, Ms. Lund, would you like to introduce the project and the research team.

COMMITTEE MEMBER LUND: Sure. Thank you, Dr. Hess.

Who do we have from the research team? I know Dr. Graboyes is not with us today.

DR. DESHMUKH: So, I'm Ashish Deshmukh. I'm MD on the project. And we also have Ms. Ells Starr, who is our research coordinator.

COMMITTEE MEMBER LUND: Great. Thank you so much.

Just to let the Committee know, this amendment is before the Committee because there were some significant changes to some human subjects' aspects of the project in the amendment that I thought the Committee should have the opportunity to review and vote on.

The project protocol, I had questions and was revised based on my questions. So, I no longer have any concerns or questions about the amendment, itself.

So, if I could turn it over to Dr. Deshmukh to describe the amendment, exactly what you're asking to change, and then I'll open it up to the Committee for any questions.

Dr. Deshmukh.

DR. DESHMUKH: Thank you so much. We really appreciate the opportunity to present our project and the amendment. So, I have a few slides that I have prepared. Maybe, if it's possible for me to share the slides, please.

COMMITTEE MEMBER LUND: Sure. That would be fine.

DR. DESHMUKH: Okay. Just confirming you can see the slides.

CHAIR HESS: We can.

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER LUND: Yes.

DR. DESHMUKH: Thank you. I'll just give a brief context of our project. Evan and I, we have been very fortunate to receive this new (indiscernible) grant from the National Cancer Institute.

And the objective of the project is to optimize the demand for human (indiscernible) viruses associated with oropharynx cancer in older adults in the United States.

So, this is our team. Evan and I, we are co-leading this project and have a phenomenal team of investigators and research staff, Talia (phonetic), and Ella. And as I said, Ella is here to (indiscernible) --

So, some moderation (indiscernible) -- HPV associated with oropharynx cancer. Oropharynx cancer among men has been recognized as the fasted rising cause of cancer incidents and mortality in the U.S. It's now more common than cervical cancer, which was traditionally HPV associated with the recognized cancer.

What we're expecting in the future year, so this is our work, which is confirmed by studies from the National Cancer Institute, is that the incidence of oropharynx cancer is expected to increase among older adults in future years.

And so, as well, and so if we look at the (indiscernible) -- the reflective the number of neuro

findings in cancer cases that will occur among older adult population in future years, and this is expected to develop over the next 15, 20 years.

So, the overall object of our project is that the motivation for this is that understanding of care, treatment following oropharynx cancer, it has excellent survival and good prognosis. It can cause liver (indiscernible) chronic toxicity. For example, feeding tube dependence and (indiscernible), altered speech, stroke, depression, et cetera. And subsequent decrease in health-related quality of life.

So, measuring health-related quality of life in patients and their outcome, following the findings of cancer patients is (indiscernible) --

However, when we look at these situations, patients (indiscernible) -- that they don't and aren't willing to make (indiscernible) -- versus treatment toxicity have not been fully characterized in this population.

And it's critical for us to measure these patients and their outcome because the comparative effectiveness of different treatments have not been made, and certain treatments are associated with more toxicity.

So, the critical goal, currently, is how we can reduce toxicity of treatments, yet maintain survival benefits. And so (indiscernible) conclusion for patients in

terms of treatment varieties and preferences.

So, the object of this study is to measure patients and their outcomes, critical to inform preference, concordant decision making.

These are some of our key outcomes that we're measuring, treatment varieties and preferences. We're assessing these outcomes using Chicago HNC Priority Scale.

We have now added two instruments, EQ-5D-5L and MDASI.

Lastly, given the feedback that we received from our advisory board, which has representation of nationwide experts and patients, toxicity and survival preferences. This is something that we previously planned to measure using Standard Gamble method, which allows us to identify utilities of health-related quality of life and demographic insights where there is related differences in priorities, if possible.

So, amendment to our project, and this is a brief summary. We have now added two new baseline assessments for participants to complete, EQ-5D-5L and MDASI. We also made changes to study procedures in that we are now recording the teleconference (indiscernible) -- and we are telling patients regarding measurement of these outcomes.

And these teleconferences now will be audio recorded and (indiscernible) recorded for quality assurance.

And participants will complete MDASI and the EQ-5D-5L as part of the study assessment.

To reflect these changes, we have made some updates to study protocol and our consent form. And script and methods have been updated to reflect these amendments.

So, just to give a brief summary of what EQ-5D-5L is, it's a well-validated measure of health status and quality of life. It is comprised of the following five dimensions, mobility, self-care, usual activities, pain, discomfort, and second depression.

And each dimension has five responses. So, right next to it we have included a screen shot of the instrument and how exactly patients would respond to the survey.

And then, we have a scale there that asks to rank their quality of life or health on scale 0 to 100.

MDASI is MD Anderson Symptom Inventory, (indiscernible) survey. It's a cancer-specific validated inventory used to measure positive severity frequencing impact of endemic (phonetic) cancer-related symptoms.

Highest scores indicate worst severity and higher frequency of symptoms interference.

So, this is the summary of what we have done. And I'm happy to take any questions you may have. Again, thank you so much for your (indiscernible) -- I'll stop sharing my screen.

COMMITTEE MEMBER LUND: Great. Thank you for that discussion. So, I'll open it up to the board, are there any questions or comments?

COMMITTEE MEMBER JOHNSON: I have a question. Could you describe more what the plans around quality assurance are for your recordings? What does that mean?

DR. DESHMUKH: Yes. So, measuring utility scores through the Standard Gamble Method. And Standard Gamble, it's an extremely complex measurement in which patients are asked to make (indiscernible) in quality of life and survival.

And given that there's several questions that we're measuring, and utility scores need to be recorded confidentiality, just to prevent human error we are measuring -- recording the capture on the survey.

Ella, is there something that you would like to add?

MS. STARR: I was just going to add that we, because I and the other coordinators on the study, when we do interact with patients, we always make sure, before we even start the recording, we ask them if it's okay. It is in the ICF, and we go through the ICF with them beforehand as well, in all of them. If they say no, we won't record them. But all of them have been happy to record their sessions during it.

DR. DESHMUKH: And that's right. And we have two sites, currently. And in those kind of things (indiscernible) -- that's standard Gamble assessments in some ways in South Carolina. And we can take it -- and we have a group for the state registries and IRBs to conduct surveys in and out of state, and Kentucky.

So, from our experience in these assessments so far, the response is positive.

CHAIR HESS: Dr. Johnson, were you --

COMMITTEE MEMBER LUND: Thank you. Any other questions or comments?

CHAIR HESS: I was just going to ask a clarifying question from Dr. Johnson. Were you referring to this statement in here, the teleconference session will be audio and screen reported for quality assurance purposes?

COMMITTEE MEMBER JOHNSON: Yeah.

CHAIR HESS: What --

COMMITTEE MEMBER JOHNSON: So, what does that mean? Is that just going back to the transcripts to verify what they said or is that quality assurance for training purposes? Like what -- what are you doing with that recording?

DR. DESHMUKH: Yeah. So, I think what we experience is that because is utility assessment, as I said it's a complex procedure, sometimes there may be human error

in recording those utility assessments. And to prevent that human error, we would like to ensure that we review the videos and make sure that the utilities that are recorded by a (indiscernible) -- that they match with what patients are referring to. That could, we just hope, include the validity of the assessment and accuracy.

COMMITTEE MEMBER JOHNSON: Okay.

COMMITTEE MEMBER LUND: Great, thank you. Anyone else, any other questions or comments?

VICE CHAIR DICKEY: I have a question. It's not necessarily related to the study. But what's the theory as to why this is increasing so much in older people, older adults.

DR. DESHMUKH: Sure. So, we have speculations for this. And Human Papilloma Virus is the necessary cause of (indiscernible) associated cancers. So, when we look at the epidemiology of HPV, it truly started increasing in the blood cohorts of individuals who were born in the 1950's and 1960's. Likely because of sexual revolution and changes in sexual behaviors.

VICE CHAIR DICKEY: Oh.

DR. DESHMUKH: So, as a result of that, the incidents first started to increase in those who are in their forties. And now, as (indiscernible) -- the increases are occurring in individuals who are in their 50's and 60's.

But we expect, and we are seeing now, with the introduction of HP vaccination the individuals are seeing decline in HPV cancer, thankfully.

VICE CHAIR DICKEY: Thank you.

COMMITTEE MEMBER LUND: All right, any other questions or comments?

All right, Dr. Hess, I think I'm ready to make a motion. I move --

DR. RYKACZEWSKA: Sorry, if --

COMMITTEE MEMBER LUND: -- I move to approve the amendment, minimal risk, with the existing timeline for the study.

CHAIR HESS: Do we need a -- we need public comment first.

COMMITTEE MEMBER LUND: Oh, sorry.

CHAIR HESS: That's okay.

DR. RYKACZEWSKA: If you have any public comments regarding this amendment, if you could please raise your virtual hand. And noting no members of the public in the room. And I am not seeing any virtual comments.

And I could also just make a request for the research team, if you could send us your slides so that we can share them with the board after this meeting and post them publically.

DR. DESHMUKH: Certainly.

DR. RYKACZEWSKA: Thank you. Sorry.

CHAIR HESS: Okay. Ms. Lund, do you want to continue with your motion?

COMMITTEE MEMBER LUND: Yeah. So, I think my motion was approval, minimal risk, timeline consistent with the original timeline for the study.

CHAIR HESS: Okay. Anyone second?

COMMITTEE MEMBER JOHNSON: I'll second.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

CHAIR HESS: Great. Thank you.

COMMITTEE MEMBER LUND: Thank you, Dr. Deshmukh. You'll get a letter with the board's findings. And I appreciate the time today that you and your research team has given us.

DR. DESHMUKH: Many thanks. Thank you so much.

Really appreciate the dedication to research.

CHAIR HESS: Okay. Moving on to our second amendment. This one is Dr. Johnson's project. Is the research team -- they are present?

DR. RYKACZEWSKA: They are present.

CHAIR HESS: Okay. You can take it away.

COMMITTEE MEMBER JOHNSON: Sure. I believe Mr. La Rocque is not here today. Is Ms. Xu or Ms. Ivey present?

DR. RYKACZEWSKA: I believe I see Dr. Xu.

DR. XU: Sorry, this is Alina Xu. I'm one of the co-PIs on this project. And my colleague, Amber Ivey, is also on the line.

COMMITTEE MEMBER JOHNSON: Great. So, just to put --

DR. XU: Good morning.

COMMITTEE MEMBER JOHNSON: Good morning. Just to put this into context, we previously approved this study. This was related to a project we heard earlier this year on alternative responders to police encounters, people in crisis. It's sponsored by the Crisis Grant.

So, the research team is back as an amendment. Two were kind of smaller things that I think would have been fine to not bring to the full board. They were just approving the Spanish version of the consents, which Dr. Ruiz has done that. And an additional field on their survey

that they were originally -- that they've already received approval. It wasn't outside of the boundaries, and I felt comfortable with that submission.

There was a new procedures that was put forth of administering in-person -- or virtual interviews with people who had previously received the services and completed the surveys. So, that new consenting procedure is why I requested full board review.

Ms. Xu, would you please summarize just kind of what that amendment looks like for the board and then we can move on to the feedback.

DR. XU: Sure. Thanks so much, Dr. Johnson.

So, as Dr. Johnson mentioned, the version of the study that was previously approved focused on two procedures involving human subjects.

One was submitted service delivery data collected in the course of crisis response, including things like timeliness of response, additional services, and referrals provided to clients.

The other procedure previously approved involved completing client satisfaction surveys.

And so, this new amendment focuses on adding a procedure which is client interviews. And we would select clients for follow-up interviews on the basis of their responses to the client satisfaction survey.

So, the survey includes a question asking clients if they're willing to be contacted for a follow-up interview to provide more insight into their experiences receiving alternative crisis response services.

And so, in the interview they have an opportunity to consent to be contacted for that interview. And if they agree to be contacted, they would provide their name and email address, or phone number.

And so, the interview procedure we're proposing is to reach out to clients who agree to be contacted. They would then be able to view a consent form for the interview and work with us on scheduling that interview.

And based on Dr. Johnson's feedback, we've been thinking through some approaches that would address some of her questions. So, happy to quickly walk through those potential changes as well.

COMMITTEE MEMBER JOHNSON: Yeah. So, I think I had flagged a couple of things. One, given the nature of the topic that you're going to be interviewing on, interviewing your participants on, I thought it would be good for them to see, at least like preview some of the questions, since you're going to be interviewing them about traumatic experiences, and as a way to reduce that potential triggering. If you would be willing to share your questions at the point of consent and then having more of a buffering

time between when the participants are consented and when they're interviewed, so that they can fully think about if they want to discuss that traumatic event in more detail with you.

DR. XU: Yeah, I think that makes a lot of sense and our team has discussed this. So, in the interview consent form we can include a preview of the types of questions we would ask. And can also note there would be these two interviewers in the interview.

We definitely want to provide sufficient information to make the client feel more comfortable with or more familiar with what the interview will entail, so they can make an informed decision about participating.

COMMITTEE MEMBER JOHNSON: Yeah, and I was satisfied, and I think it's a good idea, to also reiterate to the participant at that time that if they don't feel comfortable answering any of the questions, they're permitted to skip or end the interview.

DR. XU: Uh-hum.

COMMITTEE MEMBER JOHNSON: The other issue is after -- after the interview is completed, they plan to upload the transcripts to a Dovetail program, which is a qualitative analysis software that would analyze the transcripts. Dovetail is not a HIPAA compliant software use, so I raised issue with this. And if -- you know, what

process can the transcripts go through prior to being uploaded? What is their license or what is the payment around Dovetail that they would have, you know, the ability to kind of do an auditing trail, or who would have access to that? Like, does Dovetail use the transcripts for their own, you know, modeling.

So, I think that that -- it sounds -- looking at Mr. La Rocque's email, that you're still exploring alternative tools. Could you elaborate on where you're at with that decision?

DR. XU: Sure. So, we are exploring alternative tools. And appreciate the flag about HIPAA compliance. I think one example of a tool we're exploring is Dedoose, which has much of the same functionality as Dovetail, in terms of qualitative data analysis. It is HIPAA compliant and is designed to pass muster in terms of data security.

So, that's one hypothesis. And once we kind of complete our exploration, we can share details on which tool we would be using and the different measures that the platform takes to protect data.

And I think just some of the criteria we'd be looking at, when we're reviewing software is, I think first, Dr. Johnson, you'd mentioned we should disclose to interview participants that we would be uploading information from the interviews to an external program.

We'd also want to make sure the platform doesn't use any of the data for its own purposes. And we would be sure, if we go with a platform like Dovetail, that we would go through a process of scrubbing the interview data to ensure no HIPAA identifiers are in the interview transcripts.

However, our preference is to use a platform that's HIPAA compliant to avoid that manual step of data scrubbing, which would also be prone to human error.

So, I think our next steps are to continue exploring platforms such as Dedoose, that are HIPAA compliant, and we can update the protocol with our preferred approach.

CHAIR HESS: Are these cloud-based programs, then?

COMMITTEE MEMBER JOHNSON: I think Dovetail is.

CHAIR HESS: Okay. But Dedoose can be. Dedoose is a cloud based, I think, as well.

COMMITTEE MEMBER JOHNSON: Yeah, I have no idea if it is.

CHAIR HESS: Okay. I don't know if this board has any concerns about potentially sensitive information being uploaded to like a cloud server on -- hosted by a third-party platform, rather than -- because that would be external to their data security. Their data security letter wouldn't cover anything that's an external platform.

COMMITTEE MEMBER LUND: So, I have a question. Just to your point, Dr. Hess, they're doing this work under contract with CDSS, I understand. So, can they not use -- I'm sure that CDSS has access to confidential data storage and data uploading protocols. Would it not be possible to work with them to make that happen?

VICE CHAIR DICKEY: I don't think it's a data storage issue. It's an analysis --

CHAIR HESS: Uh-hum, too.

VICE CHAIR DICKEY: -- tool that's being used. It's sort of like AI, right. And is this the future? I mean in the past, you know, people do interviews, and the research staff analyzes it, and it stays within the -- within the research team.

But now, we're getting into a whole new world here.

COMMITTEE MEMBER KURTURAL: Do we have information on the external system on whether it's like FedRAMP certified, like are they using AWS or, you know, a HIPAA compliant like software that complies with NIST. And I know that sounds really, really technical, but there is a security standard in general for systems that maintain any sort of healthcare data.

And, you know, if we have verification that they system that they're using, the outside entity is using is

FedRAMP certified then, you know, I would be okay with that. But it's just -- you know, we probably need to find that out if you're going to put it on an external server.

VICE CHAIR DICKEY: So, we need that number with the data security.

COMMITTEE MEMBER KURTURAL: Yeah. Because there's like a minimum standard, you know. And I'm not a security expert by any means, but there is like a standard like certificate that they get in certain systems that hold like sensitive data.

And, you know, most of the systems, they're -- they work with Amazon, the AWS, you know, and it's like a layer of security. And that's fine, you know. From a security perspective it's just -- I know it's super technical.

But is there any way you could -- you could tell or amend, or follow up with us that the external system you're using, you know, complies with those standards?

COMMITTEE MEMBER JOHNSON: I think that's what they --

DR. XU: Definitely. So, I believe, and I can confirm that Dedoose has a certification that is HIPAA compliant.

COMMITTEE MEMBER KURTURAL: Okay.

DR. XU: And just a couple of details about their

systems. They maintain audit trails of all system access. They have strict protocols for breach notification. They have different types of access controls.

So, it seems to have an additional layer of security that other qualitative data analysis platforms don't have.

But these are all good questions to look into and we can -- once we have aligned on a platform that is HIPAA compliant, we can update with kind of all the different security measures they take.

And just in response to an earlier question about our collaboration with CDSS, so all of the other data that will be generated through the study will be stored on CDSS SharePoint servers. And we previously received approval for kind of the protocol for moving and storing data on SharePoint.

So, it's true that because we would like to use software to do qualitative data analysis it is kind of a different system that we would be transferring data to.

VICE CHAIR DICKEY: It's like the tool is a member of the research team.

CHAIR HESS: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Just a couple of general thoughts. We're seeing more and more often the desire to use some kind of content analysis tool for

purposes of qualitative analysis of data. So, this is certainly something we've had in the past and, apparently, are going to see a lot more of in the future.

And regarding your earlier question about the cloud data storage aspects of such tools, that seems a particularly important issue for us to have some understanding of what the provisions are that are -- that are used by those tools.

And I'm finding it a little difficult to think about approving the procedures that are outlined here without knowing what the outcome is of identifying a particular tool that really is going to be used and what the security provisions of it are. That seems to put us in a rather difficult place, I would think.

COMMITTEE MEMBER JOHNSON: Yeah, I agree. I'm not sure if I'm comfortable without -- given that your team still needs to kind of discuss and identify the software that you plan to use, I don't know if I would be comfortable putting forward a motion of deferred approval at this time.

I don't have issue with their other -- like the Spanish consent portion of the survey, and the additional fields. Like, can I split a motion to approve that and table the portion of the new --

CHAIR HESS: Do you feel like the software issue needs to come back to the full board for consideration or --

COMMITTEE MEMBER JOHNSON: I would feel comfortable with that. Yeah, I don't think that I would feel comfortable with like a subcommittee of me, unless like whoever our new person, expert AI person is on the subcommittee as well. I would like to bring that to the -- back to the full board once they figure out and have the detail. I think that would also be a good thing for us to discuss, as it's also becoming a growing issue that we're going to see additional research team's request.

CHAIR HESS: Okay.

VICE CHAIR DICKEY: I think you can make a motion for whatever you.

CHAIR HESS: Yeah.

COMMITTEE MEMBER JOHNSON: I feel so empowered.

(Laughter)

COMMITTEE MEMBER JOHNSON: Okay. Well, I will make a motion for approval of the Spanish consent and the additional fields to the survey, minimal risk, with the existing timeline approval.

And I also make a motion to table the decision regarding the approval of the new human subjects procedure for the virtual interviews, with an understanding that your team will discuss further the software that you intend to use and present that to the board in October.

DR. RYKACZEWSKA: Should we treat that as two

separate motions?

COMMITTEE MEMBER LUND: Should we have public comment, first?

CHAIR HESS: Yes. Yes, we should.

VICE CHAIR DICKEY: You're going to have to repeat that.

CHAIR HESS: We've got it written down, you're okay.

Is there any public comment on this project?

DR. RYKACZEWSKA: Should we do it on the first motion, the approval of the consents and the --

CHAIR HESS: Oh, that's right, the public comment has to be on the individual motions.

DR. RYKACZEWSKA: Motions, uh-hum.

CHAIR HESS: So, is there public comment on the first motion, which is approval of the Spanish consent forms and the additional fields to the survey, and this is deemed minimal risk, within the existing timeline.

DR. RYKACZEWSKA: If you have a public comment, please raise your virtual hand. Noting there are no members of the public in the room. And I am not seeing any raised hands.

MS. ATIFEH: Agnieszka, I just wanted to clarify, in IRBManager I cannot see any way for one project to process with --

VICE CHAIR DICKEY: To have two motions.

CHAIR HESS: To have two motions. Okay, then the --

COMMITTEE MEMBER SCHAEUBLE: Back to the drawing boards.

DR. RYKACZEWSKA: Dr. Johnson, can we make sure I captured the last part of the second component, to table the decision --

COMMITTEE MEMBER JOHNSON: To --

VICE CHAIR DICKEY: For approval of the interview analysis tool.

COMMITTEE MEMBER JOHNSON: He can make the motion.

For the approval of the interview analysis software to be used.

CHAIR HESS: Do we want to table to the October --

COMMITTEE MEMBER JOHNSON: Yeah, table to the October --

COMMITTEE MEMBER HESS: -- 2025 meeting.

VICE CHAIR DICKEY: Or whenever they can come back, because it may take longer than that.

COMMITTEE MEMBER KURTURAL: Like should we clarify what they have to do when they come back? Like do they need to --

VICE CHAIR DICKEY: Well, I don’t think it has to be in the motion, though.

COMMITTEE MEMBER KURTURAL: Okay.

VICE CHAIR DICKEY: But we can talk to them about it.

COMMITTEE MEMBER KURTURAL: Okay.

VICE CHAIR DICKEY: I'll second that.

CHAIR HESS: Yeah, since we're tabling it, that gives you the opportunity to work back and forth with them on --

DR. RYKACZEWSKA: Did we want to specify the timeline?

COMMITTEE MEMBER JOHNSON: No, I know that they are talking with other stakeholders as well. I mean, I anticipate it to come back in October. I know that this is important for them to get going.

DR. RYKACZEWSKA: Motion is up. Any public comments, given that we revised the motion? If you could please raise your virtual hand. I'm not seeing any virtual hands.

CHAIR HESS: okay.

DR. RYKACZEWSKA: So, we need a second.

VICE CHAIR DICKEY: I seconded.

MS. ATIFEH: Dr. Dickey.

CHAIR HESS: Dr. Dickey seconded.

DR. RYKACZEWSKA: Okay.

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

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

CHAIR HESS: Yeah, we can. Can we take a five-minute break and reconvene -- actually, let's say at 9:45.

(Off the record at 9:39 a.m.)

(On the record at 9:45 a.m.)

CHAIR HESS: We are back on the record.

Sussan, can we take roll call again?

MS. ATIFEH: Sure. Okay, so Dr. Hess?

CHAIR HESS: I'm here.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Here.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Yes.

MS. ATIFEH: Okay, thank you.

Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

DR. RYKACZEWSKA: Oh, Ms. Lund, you're muted.

COMMITTEE MEMBER LUND: Here.

MS. ATIFEH: Okay, thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Here.

MS. ATIFEH: Okay, the quorum is established.

CHAIR HESS: Okay. Moving on to our new projects. I just closed out the agenda, so hold on, let me look at the paper copy.

DR. RYKACZEWSKA: This was a tabled from last time.

CHAIR HESS: This was tabled from last time. And, Mr. Lund, are you planning on recusing yourself for the discussion on this project?

COMMITTEE MEMBER LUND: Yes, I'm recusing myself. So, I'm going to leave the virtual room. If someone would just please send me an email when you're ready to resume with the next project. Thank you.

CHAIR HESS: Will do. Thank you.

So, Dr. Johnson, do you want to take over?

COMMITTEE MEMBER JOHNSON: Yup. I can see Dr. Anderson. Welcome back.

So, this was the study that we had discussed in our last meeting with PHFE WIC, with the change in the WIC formula that is occurring today. And their study has changed somewhat.

Originally, they were going to be collecting surveys and measurements of infants on measurement cards that they were sending out. They have removed the measurement cards from the procedure. And it is two surveys occurring at three months and nine months.

Dr. Anderson, do you want to describe, in more detail for the board, kind of what the protocol looks like in its -- in its current form. I know we've had a couple back and forths.

DR. ANDERSON: Absolutely. Thank you, Dr. Johnson.

So, our study has been simplified. The California WIC program has changed WIC infant formula contracts today. And current with that change, so from one manufacturer to another, PHFE WIC has implemented two policies related to infant formula issuance practices.

For people who are not familiar with the WIC program, the infant food packages, mothers who report not fully breast feeding are issued infant formula for their

infants to sort of ensure adequate nutrition intake during the first year of life. So, through 13 months of age.

Our goal is to ensure that all the kinds are sort of being given the greatest opportunity to thrive during that first year and get healthy food and grow.

And something we have been concerned about is cow's milk-based infant formulas that have the lactose reduced and replaced with a glucose carbohydrate.

And so, the infant formula policy changes at PHFE WIC are related to that. We're moving to issuing a lactose-based infant formula as the default in the absence of an indication for a non-lactose formula in the first month.

And then, if the mother wants the glucose-based formula, she can switch to that in the second month.

The second policy was training our staff about this new policy and the infant formula change that happened.

So, all of that has taken place starting today. And we are hoping to collect data from PHFE WIC participating mothers, who have an infant who is receiving infant formula from our program. We intend to collect data around three months of age and nine months of age, because that's before complimentary foods and beverages are generally introduced and then after, but still while children are being given breast milk and infant formula.

And our hope is to sort of identify with sort of

dietary assessment and other relevant variables to really assess whether these policy changes have our intended impact of encouraging greater uptake of lactose-based formula and lower uptake of glucose-based formula. And then, whether that's translating into healthier diet more generally.

And, finally, whether we're seeing a reduction in rapid infant weight gain, because childhood obesity is a really large challenge for our participants in rapid infant weight gain. So, that's a change of over two-thirds of the standard deviation in weight for age before two years. There's a really strong risk factor for that.

So, that's sort of what we're trying to assess and the time points.

The survey at three months postpartum is pretty simple. It shouldn't take more than 30 minutes. The one at nine months postpartum is a little more involved because we've included a 24-hour dietary recall for the infant. So, it still should be a pretty simple dietary recall because they're not getting that much in terms of different foods. But that one, we really want to do a good job of assessing what they're eating, complimentary food and beverage wise.

And so, I think I've addressed it, but I'm not entirely sure I hit everything. But I'm going to pass it back to Dr. Johnson.

COMMITTEE MEMBER JOHNSON: Yeah, I think that was

a good summary of where it's currently standing.

So, I'm looking at the minutes from last meeting, just to kind of touch base on everything. One of the main issues that we flagged was the lack of clarity and transparency in the consent form of notifying the participants that the main focus of the study is to evaluate changes in the type of formula that is going to participants.

I do feel that that has been added to the consent. There's also -- so, the consent form clearly outlines that they are studying a policy change, when the policy change took place. And then, they're also providing additional information, should the participant seek that out, in a very clear, manageable way to get to that information.

We had some discussion on including that in the consent form. Dr. Anderson and team had concerns of making the consent form too long for the participants, that that would discourage them. So, we thought that just providing them on, you know, if -- here is the information, here's how you would get it, this is the specific change that is occurring, and should you want more. So, they have their additional information included in their procedure. It was added earlier this week. So, I'm not sure if that gets to everyone.

But I'm satisfied with the description of the

additional information.

I think the other issues were around the measurement card but given that that's been removed from the procedure entirely, that is no longer applicable.

And I think in general they've added things to the survey about skipping questions. They've added transparency in their recruitment and consent about who they are and why they're being contacted.

They've also permitted participants to say not to contact them for research purposes and that that doesn't impact their WIC participation overall.

So, I think I'll open it up, now, to the board if you had additional questions or comments.

DR. RYKACZEWSKA: Checking also online with Dr. Dinis, just making sure. I'm not seeing a virtual hand, so I'm assuming -- okay.

COMMITTEE MEMBER JOHNSON: So, there is -- I wanted to, yeah, we flagged that the consent, the Spanish consent forms, we wanted to wait to see if there would be any requested changes by the board before they were reviewed by Dr. Ruiz. But given that there are none, but they still need to be reviewed.

I'm ready to make a motion.

CHAIR HESS: Uh-hum.

COMMITTEE MEMBER JOHNSON: For deferred approval,

given the final approval by Dr. Ruiz for the Spanish consent and recruitment forms, minimal risk, one year.

VICE CHAIR DICKEY: Second.

MS. ATIFEH: Okay.

DR. RYKACZEWSKA: Just a moment, one year -- so I can put the motion up on the screen for everyone to see.

CHAIR HESS: We need to ask for public comments.

DR. RYKACZEWSKA: And we need to ask for public comments.

CHAIR HESS: Are there any comments from members in the public.

DR. RYKACZEWSKA: Noting there are no members of the public in the room. There we go. If there are any public comments online, if you could please raise your virtual hand.

COMMITTEE MEMBER JOHNSON: It's Spanish consent and recruitment.

CHAIR HESS: And recruitment, thank you.

COMMITTEE MEMBER JOHNSON: Or you can just say Spanish materials.

DR. RYKACZEWSKA: I will put Spanish materials.

I am not seeing any virtual hands.

CHAIR HESS: Okay.

MS. ATIFEH: Okay. Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

Oh, and just a moment. Yes, we need actually six approvals, and we have six.

CHAIR HESS: Yes, okay.

MS. ATIFEH: Yeah, the motion passed.

CHAIR HESS: Can we take to minutes to bring Ms. Lund back.

DR. RYKACZEWSKA: Thank you, Dr. Anderson.

DR. ANDERSON: Wonderful. Thank you all so much.

COMMITTEE MEMBER JOHNSON: Thank you.

VICE CHAIR DICKEY: It's like Coca-Cola shifting from cane sugar to --

COMMITTEE MEMBER JOHNSON: Yeah.

VICE CHAIR DICKEY: Or it's this change is from corn sugar to cane sugar.

COMMITTEE MEMBER JOHNSON: The better sugar.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: We're giving just a few minutes for Ms. Lund to return.

CHAIR HESS: I texted.

DR. RYKACZEWSKA: And there she is.

CHAIR HESS: There we go. Ms. Lund, are you back with us?

VICE CHAIR DICKEY: No, she had that on.

CHAIR HESS: Yeah, we can give her a minute.

VICE CHAIR DICKEY: She said to email her or --

DR. RYKACZEWSKA: I said email.

CHAIR HESS: Yeah, I texted as well, so she should get one or the other.

DR. RYKACZEWSKA: I also know my email tends to take just a minute to get out there.

CHAIR HESS: Yeah.

DR. RYKACZEWSKA: And if there's an attachment, it's game over.

Ah, there she is.

CHAIR HESS: Okay, great.

DR. RYKACZEWSKA: Welcome back, Ms. Lund.

CHAIR HESS: Okay. I believe we are onto our second and final new project. Is the research team with this project -- I do see them so --

DR. RYKACZEWSKA: And this also was tabled at the last meeting, and we are returning to this one.

CHAIR HESS: Yeah. Dr. Ventura.

COMMITTEE MEMBER VENTURA: Yes. Good morning, Dr.

-- is it Pukelis?

DR. PUKELIS: Yes, Pukelis.

COMMITTEE MEMBER VENTURA: Pukelis, okay, thank you.

DR. PUKELIS: Good morning.

COMMITTEE MEMBER VENTURA: Good morning. And Dr. Carper is also, I see, on the meeting.

DR. CARPER: Good morning.

COMMITTEE MEMBER VENTURA: Good morning.

Okay, so this project is Understanding Enrollment in Public Benefit Programs: Evidence from Disaster Supplemental Nutrition Assistance Program or D-SNAP and SNAP.

I will turn it over to Dr. Pukelis to give a brief introduction of the proposal. Go ahead, Dr. Pukelis.

DR. PUKELIS: Sure. Yeah, I can give a brief overview of the project again, and then I'll talk about how we're in the process to responding to the comments that came up last time.

So, as a reminder, extreme weather events have become more frequent in intensity due to climate change and California is a disaster-prone state.

And at such critical moments food assistance can address the key needs and may prevent short-term disaster and these hardships from resulting in long-term

consequences.

So, for our project, to shed light on the role of food assistance in disaster recovery, we plan to conduct a study of the Disaster Supplemental Nutrition Program, or D-SNAP for short and related disaster food assistance policies.

So, our study objective includes understanding individuals' experiences apply for and using program benefits, including shedding light on the mechanisms and barriers of enrollment programs, like SNAP and D-SNAP.

We're also interested in understanding the impacts of participating in disaster food assistance programs on outcomes such as health and economic wellbeing.

And we're also interested in the relationship between previous enrollment in Disaster SNAP and future enrollment in SNAP.

To answer these questions we use qualitative methods, including sealed observations in interviews. The human subjects in our research include applicants and administrators of D-SNAP, where SNAP called it an actual disaster.

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

Our study also includes conducting field

observations of Disaster SNAP application sites, where we'll be focused on collecting information on the general qualities of this space, such as how crowded it is, and we may also take photographs of the sites.

The potential risks of the research may involve the following. For the interviews, potentially feelings of discomfort or stress in experiences using these programs, or experiences following an actual disaster, possible breach of confidentiality. And there's also the possibility of social harm if one's participation status or beliefs were revealed to other people.

And our research study procedures (indiscernible) potential risks in the following ways. Participant responses to interviews will be kept confidential and conducted in spaces that the interviewees are comfortable with. Questions that touch on potentially sensitive subjects can be skipped. They can revoke consent to participate in the research at any time. Notes from field observations with not include personally identifiable information. And any photos we take during field observations will either exclude faces or obscure them before we include them in any public facing research materials.

And we hope that our research will generate insights to inform policies surrounding disaster food

assistance.

So, now, I want to switch gears and talk about some of the progress that we've made based on the comments from the last session. So, there's sort of three categories of these.

The first was a suggestion to expand the set of participants eligible to participate in the study from those only able to speak English to those speaking Spanish.

So, we, yeah, made contact with one of Dr. Carper's colleagues who -- who we plan on bringing into the project, to help conduct Spanish interviews. So, we plan on for those, so expanding eligibility to people who speak Spanish. And then, this new study member and me will participate in those interviews together, is our plan.

And the second category of things is so, this is made aware in the protocol, and I believe we talked about this last time, but I'm currently an employee at CDSS, California Department of Social Services, that runs SNAP and Disaster SNAP in the State of California. But I'm conducting this research in my capacity as a research fellow with Harvard, and the Taubman Center for State and Local Government as an extension of my -- I recently graduated from (indiscernible) --

So, to be clear, the research is being conducted in my capacity as a Harvard affiliated researcher. And so,

I understand that they're both in the initial review of the protocol and recently there's -- it would be helpful to have some clarification about that status.

So, I spoke with my supervisor at CDSS and so, we're planning on writing an MOU to clarify where the data is housed. That it's Harvard research and the data security, and storage, and all that sort of thing will be under that institution's control and the data will not be housed or accessed at CDSS.

So, we're working on drafting something, an MOU to also include in this protocol as reference.

And then, the last category is things that we discussed last time were consent form edits, which we will plan on including -- sorry we didn't get those in, in time for review here, but those will include -- include contact information for IRB in case that participants have questions about their rights. Clarifying in the consent form that participation in this study would not affect whether participants could access benefits, including SNAP and Disaster SNAP.

And then, we may include additional language based on that conversation in the MOU about potentially disclosing my employment status at CDSS, if they feel that's necessary.

So, I'll stop there.

COMMITTEE MEMBER VENTURA: Thank you for that

summary. One of my -- I especially want to highlight your point number two about clarifying your role, your affiliation. Because when I first reviewed this, you know, seeing that this is a Harvard -- for the rest of the Committee, this is a Harvard funded study. We've clarified that the data will be housed and owned by Harvard University. And this work is separate from Dr. Pukelis' role, new position within CDSS.

So, this is still, as she described, work to complete her fellow -- fellowship work.

My question was around the only other CDSS individual named in this protocol is your supervisor, I believe, as the administrative contact.

And now, given that context, that this is a Harvard study, not being completed in your capacity as CDSS, I wonder, I ask this of the board, is this still under our purview?

VICE CHAIR DICKEY: Technically, I don't think it is.

COMMITTEE MEMBER VENTURA: Uh-hum.

VICE CHAIR DICKEY: But I understand there's a letter of support from CDSS.

DR. PUKELIS: Uh-hum.

COMMITTEE MEMBER VENTURA: Uh-hum.

VICE CHAIR DICKEY: So, it sounds like they're

aware that she's coming to the board. It's one of those situations where we can review it for CDSS's request.

COMMITTEE MEMBER VENTURA: Uh-hum.

VICE CHAIR DICKEY: We don't have to because it's not under --

COMMITTEE MEMBER VENTURA: Their study, right.

VICE CHAIR DICKEY: -- covered in our FWA.

Is it being reviewed by the IRB at Harvard?

DR. PUKELIS: Yes. Both at Harvard and then at --

COMMITTEE MEMBER VENTURA: Texas.

DR. PUKELIS: -- Laura Carper's institution, Texas A&M as well.

COMMITTEE MEMBER VENTURA: Right. So, this was reviewed initially by Dr. Azizian for the June meeting, tabled and brought to me. So, it's now been reviewed by several of us. And we've -- Agnieszka and I, just also for the Committee's awareness, we consulted with CDSS's ISO team.

Because my concern was, when I saw that data was going to be stored on a cloud, again Harvard's Google Drive, and Dropbox, I paused. But this is Harvard's data, they're storing it.

VICE CHAIR DICKEY: Correct.

COMMITTEE MEMBER VENTURA: They've classified it as level three, security level three. They have all their

protocols.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: So, I don't think -- like I said, it's Harvard's data. So, I don't see --

CHAIR HESS: Are they requesting -- is there an IPA consideration for us?

COMMITTEE MEMBER VENTURA: No.

VICE CHAIR DICKEY: No, it's not our data. But, you know, the question is are SNAP recipients, you know, protected under us. In general, we don't consider Medicaid recipients to be protected. But sometimes departments ask us to step in if they think it's a vulnerable class, and they would like us to look, just do another look. So, I mean we -- it sounds like they're aware of the project, they're supporting it and --

COMMITTEE MEMBER VENTURA: Right.

VICE CHAIR DICKEY: -- it might be -- it sounds like they want us to review it. I don't know.

COMMITTEE MEMBER VENTURA: Okay. So, we'll just --

VICE CHAIR DICKEY: We can review it, I guess.

CHAIR HESS: Yeah. I mean, if that's the consensus of the board for us to review it, but it doesn't seem like we have purview here.

VICE CHAIR DICKEY: Yeah, purview in that we --

CHAIR HESS: Ms. Lund?

COMMITTEE MEMBER LUND: Yeah. It doesn't seem to me, after we've sorted out the affiliation and the relationship of the PI to CDSS and Harvard, it doesn't seem to me that we have purview. And I'm reluctant to step into projects where other IRBs have reviewed, who do have purview. I know there's a letter of support from CDSS, but do we have a request from CDSS for us to be an IRB of record for this project?

Otherwise, I don't share the opinion that we should be reviewing this.

CHAIR HESS: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Well, I would find it troublesome to review it, too, in a situation where we're being told that the data are entirely under the control of another institution and where we don't have, really, any direct knowledge of what the security provisions are for the data, other than whatever statements we're receiving from the researchers doing the project.

It seems to me it's really an uncomfortable circumstance for us to try to decide to review a project under those circumstances.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: And to build on Dr. Dickey's comment, just to clarify, so one of the areas through which

CPHS has purview currently is if, for example, one of our departments under our FWA has -- oh, I'm losing the technical term for this.

But the typical example we give is patients at state hospitals, where they are in the care of the state. And so, that's very clear with Department of State Hospitals. But then, when we start transitioning over to many of the program recipients typically, I would say we don't, unless there is an explicit request.

I have not received an explicit request from CDSS. Dr. Pukelis, have you gotten any indication from CDSS that they would like us to review this?

DR. PUKELIS: Yeah, I'm not sure how to answer that question. I originally like was directed to also have this IRB team review it in addition to Harvard. But I think that was based on my supervisor's understanding that it was required. So, potentially -- I'm not exactly sure how to change, based on the conversation and knowledge that you all have about the purview of this board.

And I would say, yeah, because I think they didn't have much experience referring things to the board before. So, I'm trying to answer, but that's the context.

VICE CHAIR DICKEY: So, and not necessarily for this project, but for other projects, it's sort of the general principle by which we operate. It seems like

something maybe we need to tighten up.

Because we have had projects, like from Social Services, for kids who are in foster care, say -- they've wanted us to review the project, and we have. But we didn't get like a delegation agreement from them.

Is that something we should be doing? I think the policies and procedures say it's for subjects that are in the custodial care of the state.

DR. RYKACZEWSKA: Custodial care, thank you.

VICE CHAIR DICKEY: So, this is one of those issues that are new contractors will solve for us, right.

CHAIR HESS: I guess we could make a motion to basically state that we don't have purview and then vote.

COMMITTEE MEMBER VENTURA: Sure.

CHAIR HESS: Although, I would remind the research team that if the project evolves and any data is going to be used from the state through CDSS, through your -- you know, any connection or capacity you have in your role with CDSS that you would need to come back for IPA approval for that.

But otherwise, would you like to --

COMMITTEE MEMBER VENTURA: Okay, this is a weird one. So --

CHAIR HESS: Wait.

VICE CHAIR DICKEY: Well, or if it changes such as she's doing it as an employee.

CHAIR HESS: Yeah. Yes.

COMMITTEE MEMBER VENTURA: Yeah.

VICE CHAIR DICKEY: As part of her official duties.

COMMITTEE MEMBER VENTURA: Right.

CHAIR HESS: Uh-hum.

COMMITTEE MEMBER VENTURA: Public comment, or no?

CHAIR HESS: We should make a motion and then we'll have public comment.

COMMITTEE MEMBER VENTURA: Motion. Okay, gotcha.

CHAIR HESS: Yeah.

COMMITTEE MEMBER VENTURA: So, I'll make a motion to dismiss this protocol from review from CPHS or --

VICE CHAIR DICKEY: Or I think the motion would be this is not in our purview.

COMMITTEE MEMBER VENTURA: Okay, not under our purview, okay.

CHAIR HESS: That we -- yes.

COMMITTEE MEMBER VENTURA: This protocol is not under our purview, and so we will not be reviewing the protocol.

CHAIR HESS: Yeah. Are there any -- is there any public comment on this motion? None in the room. Any online, please raise your hand.

DR. RYKACZEWSKA: I am not seeing.

CHAIR HESS: Not seeing any. Do we have a second for the motion?

VICE CHAIR DICKEY: I'll second. I think I'm seconding everything.

CHAIR HESS: Yeah.

MS. ATIFEH: Okay. Dr. Dinis?

COMMITTEE MEMBER DINIS: 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. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Will the researchers be receiving a letter stating that we had no purview?

MS. ATIFEH: Yes, no purview.

CHAIR HESS: Okay. So, you'll get a letter officially from us. Thank you for your patience.

DR. PUKELIS: Okay, thank you.

CHAIR HESS: Hopefully, it makes the project a little bit easier for you.

DR. PUKELIS: Yeah.

VICE CHAIR DICKEY: You mean, the more IRBs, not the better.

(Laughter)

COMMITTEE MEMBER JOHNSON: Yeah, three IRBs. That's a lot.

DR. CARPER: Thank you for you all's time.

VICE CHAIR DICKEY: It used to be like 10 or 12, yes.

COMMITTEE MEMBER JOHNSON: Good luck.

CHAIR HESS: Okay, I think that is it for our projects.

I will now ask for are there any Committee members questions or comments on Agenda Items I through O on the agenda? Do you want me to list off what those are?

DR. RYKACZEWSKA: It might not hurt.

CHAIR HESS: Okay, so that Items I through O would be our second review calendar, new projects, projects requiring continuing review, amendments, projects with requests for CPHS to rely on another IRB, exemption, non-research approvals, or final reports.

DR. RYKACZEWSKA: And I do want to note that for the new projects and amendments these are specifically that were reviewed through expedited review and did not meet the criteria for full board review.

CHAIR HESS: No comments from the board.

Are there any public comments on Agenda Items I through O.

DR. RYKACZEWSKA: If you have a public comment, please raise your virtual hand. Noting no members of the public in the room. And I am not seeing any virtual hands.

CHAIR HESS: Okay. Moving on to the next item. Are there any public comments for any items that were not on today's agenda?

DR. RYKACZEWSKA: If you have a public comment, please raise your virtual hand. Again, noting no members of the public in the room. And not seeing any virtual hands.

CHAIR HESS: Okay. So, our next CPHS full board meeting is scheduled for Friday, October 3rd.

And thank you, everyone, for participating today. I will adjourn today's meeting at 11:21 a.m.

VICE CHAIR DICKEY: Ten.

CHAIR HESS: 10:21 a.m.

(Thereupon, the meeting was adjourned at 10:21 a.m.)

--oOo--

REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 14th day of August, 2025.

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I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber. And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

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