MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, MARCH 7, 2025

8:33 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



PETER PETTY REPORTING, CER**D-493
4632 Freeman Way, Sacramento, California 95819
916-889-2803

APPEARANCES

COMMITTEE MEMBERS

Catherine Hess, PhD, Dr., Chair

Larry Dickey, MD, MPH, Vice Chair

Maria Dinis, PhD, MSW

Jonni Johnson, PhD

Carrie Kurtural, JD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna

ALSO PRESENT

CalHHS

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Jared Goldman, General Counsel

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

PUBLIC

Stephen Henry

ALSO, PRESENT

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Dr. Michael Hoyt, UC Irvine

Dr. Jennifer Tsui, University of Southern California

Emily Dang, University of Southern California

Dr. Jessica Schleider, Northwestern University

Gina Misch, Kooth Digital Health

Index

CHAIR HESS: Good morning everyone, welcome. And I will call to order the March 7th meeting of the CPHS.

DR. RYKACZEWSKA: Welcome everyone. Can we do a roll call?

MS. ATIFEH: Yes.

Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Here.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, a quorum is established.

DR. RYKACZEWSKA: So, I believe our first order of business is actually an oath ceremony for Dr. Hess, swearing her in as Chair. So, we're going to go (indiscernible).

(Whereupon Chair Hess is administered the oath of office by CDII Deputy Director Agnieszka Rykaczewska)

DR. RYKACZEWSKA: Congratulations.

CHAIR HESS: Thank you.

(Applause)

DR. RYKACZEWSKA: And from there, we go to the Chair updates.

COMMITTEE MEMBER HESS: Do you want me to -- do we want to comment about the current policies and procedures? I wasn't sure what that was about, actually, when I looked at it.

VICE CHAIR DICKEY: I think it was about keeping to the current policies and procedures until they change them.

CHAIR HESS: Oh, okay. So, since there are some changes happening to our policies and procedures, we have decided that we are going to adhere to the current written policies and procedures until any changes are made formally in our policies and procedures document. Okay.

COMMITTEE MEMBER LUND: May I ask a question about that?

CHAIR HESS: Uh-hum.

COMMITTEE MEMBER LUND: Are the policies and procedures being updated to reflect information that we had gotten from legal about the review process and what constitutes an IPA and what constitutes a Common Rule review?

Because as currently written, it would appear that we only do Common Rule for human subjects contact studies. I believe that that is actually the wording that's used in the policies and procedures, and it turns out that that is in fact not correct. So, is that part of the update?

VICE CHAIR DICKEY: I think what's in the policies and procedures is that chart that is still in there, that CPHS legal created, where it shows the flow chart for the different decisions.

COMMITTEE MEMBER LUND: Right. And so, the document that Agnieszka put together for us actually clarified and corrected some of that. So, I would request that we follow what was provided to the Committee by Agnieszka.

DR. RYKACZEWSKA: I think -- I think that part of it is as we're still discussing these items until the formal change has been fully passed, we have to stick to the written document. And I think that that is -- I don't want

to put words in your mouth. We are still finalizing that. It's still under discussion as we still are going through the regulations discussions.

And so, it's just the clarification that until the formal changes have been passed through the process, and that is one of the pieces that we are examining of whether we're going to change that. But until the formal process is done, I think that's the concern that we don't want to have a lack of clarity of like whether we're following the written or the discussed.

VICE CHAIR DICKEY: And the formal process is the secretary has to sign off on it. So, this hasn't been submitted to the secretary yet.

DR. RYKACZEWSKA: We are finalizing that chart. And in part, because there's still these regulations conversations happening, and so I wasn't sure whether we're ready or not. So, we'll be looking for the board's direction in terms of the actual changes.

And, of course, the changes will entirely be presented to the board first, before we would present it to the secretary.

CHAIR HESS: I don't have any others to share, updates. So, if we can move to administrative updates.

DR. RYKACZEWSKA: Absolutely. So, I have a couple of updates. One is that there was routine audit of the

Committee for the Protection of Human Subjects by the FDA. The last one, just as a fun fact, was in 1993. It had been a while since we had gone through one of these.

There was one observation made that some of the historical rosters were not properly maintained over the last five years. We are addressing this by documenting our administrative procedures or whenever there are any board changes, be it somebody joins or a board member departs.

And part of that documentation will include instructions for how to properly store this historical roster and to update the new roster to make sure that we are maintaining those records appropriately.

And so, that was the only observation made. Otherwise, our documentation was well done, and we will be addressing just this one piece.

The other item that I had is actually about the April meeting. So, we've already identified that we will not have a quorum for our April 4th meeting, and so I would like to propose moving that to April 18th. But wanted to see if the Committee has alternative dates they would put forth, if the April 18th date does not work.

I'm seeing a lot of phones going.

(Laughter)

COMMITTEE MEMBER LUND: That is the Friday before a holiday weekend.

DR. RYKACZEWSKA: I'm hearing not a resounding yes to the 18th.

VICE CHAIR DICKEY: Sounds like it.

DR. RYKACZEWSKA: Is there an alternative date anyone would propose? The 25th?

CHAIR HESS: Does the 11th not work?

DR. RYKACZEWSKA: I can try to make the 11th work. I have a conflict.

CHAIR HESS: Okay, I do, too.

DR. RYKACZEWSKA: Okay.

CHAIR HESS: The 25th.

COMMITTEE MEMBER DINIS: If the 18th didn't work out, what about the 25th?

DR. RYKACZEWSKA: All right, then the new proposal is the 25th of April for our April meeting. Perhaps we could have a motion just to confirm that meeting date?

CHAIR HESS: Do we need to ask for public comment, first?

DR. RYKACZEWSKA: We do need to ask for public comment, first.

CHAIR HESS: Okay. If any -- if members of the public who are present would like to comment on our proposal to move the April 4th meeting to April 25th, now is your opportunity to comment.

DR. RYKACZEWSKA: And I am not --

MR. ZADROZNA: There are no public comments downstairs.

DR. RYKACZEWSKA: Thank you, Nick. And I am not seeing any on the Zoom.

CHAIR HESS: Okay. So, I move that we --

DR. RYKACZEWSKA: I think as Chair, you can't make a motion.

CHAIR HESS: All right. So, does anyone want to make a motion?

VICE CHAIR DICKEY: I'll meet that we meet next time on April 25th.

COMMITTEE MEMBER KURTURAL: I'll second it.

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

COMMITTEE MEMBER DINIS: 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?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

DR. RYKACZEWSKA: Wonderful. Then, those are my administrative updates.

CHAIR HESS: Okay. I assume we're going on to subcommittee updates.

COMMITTEE MEMBER DINIS: Wait a minute. Wait a minute, I may not -- oh, it's April 25th, right.

DR. RYKACZEWSKA: That's correct.

COMMITTEE MEMBER DINIS: Okay, sorry.

CHAIR HESS: Subcommittee updates. Just to let everyone know that the Governor's Office has requested the Committee defer consideration of the proposed IPA regulations until our April meeting. So, we will not be discussing those today.

I don't know if there's any members of the public on who were anticipating that discussion, but that will not be happening at this meeting. And that's all the information we have about that.

We wanted to discuss the training policy. So, as everyone recalls, we have access now to some CITI training through, I think it's OHRP that puts on the CITI training. But we have access to a fair number of modules on the CITI framework.

And we're recommending that we're updating the policies and procedures to require that all new members complete the CITI training in the first six months of their

tenure on the board. So, I'll put that proposal out there and open it up for discussion.

COMMITTEE MEMBER LUND: Can I ask a question?

CHAIR HESS: Uh-hum.

COMMITTEE MEMBER LUND: What about existing members?

CHAIR HESS: Ideally, existing members would also be taking the training, but we haven't discussed like requirements for existing members. I think it's strongly encouraged that existing members would take advantage of these trainings.

I've started them. They're actually pretty full. I hadn't taken CITI training for, you know, a couple, like maybe five years.

But I don't think that we -- unless the -- unless the board feels strongly that we should require existing members to take the trainings.

COMMITTEE MEMBER LUND: So, I've taken them. I've finished doing them. And what I can say is the one, the big one is extremely full. There's information in there that we often discuss here and not everyone is on the same page.

And I truly believe that if we all took that training, that much of the discussion that we have wouldn't occur because we'd all be on the same page about what the requirements are and what we should be considering, and so

on, and so forth.

VICE CHAIR DICKEY: Exactly.

COMMITTEE MEMBER LUND: So, for that reason I, you know, would put it out there that I think should -- and we sit on a board and people's lives are in our hands, as well as people's livelihoods. You know, the researchers and the people whose data, you know, we're here to oversee.

So, I personally would be in favor of requiring it. I know we're all volunteers and I know nobody has the extra time, but I found it helpful, and I think it would be helpful for all of us. So, that's my opinion.

The one training that I would say is not useful for board members is the information security training, because it's not really information security training. It's onboarding new people so that they don't leave their screens open with private data, and so on and so forth. It's the kind of training you would give a new employee.

The one that is also extremely useful is the IRB protocol review training. Everybody, I think, would benefit from that just in terms of what you consider, and how you consider it, and how we have those discussions. So, that's my two cents.

VICE CHAIR DICKEY: So, if it's six months for new members, maybe a year for existing members.

COMMITTEE MEMBER VENTURA: And the certification,

the training is good for several -- is it one time and you're done? Because for researchers it's three years, right.

CHAIR HESS: That's a great question. I don't know what --

COMMITTEE MEMBER LUND: I don't know the answer to that question. I guess it would --

COMMITTEE MEMBER VENTURA: You usually get a certificate of completion, and it says, you know, three years from that date you complete it. And so, I wonder if it's the same for the IRB modules.

COMMITTEE MEMBER LUND: Yeah, I don't know the answer to that. I didn't look at my certificate of completion. You know, it generates it, but I didn't look.

COMMITTEE MEMBER VENTURA: Yeah.

COMMITTEE MEMBER LUND: So.

CHAIR HESS: We can look into that and then, you know, it's not something that I would think we would need to have board members do every three years. But one time, certainly, new board members, or just refreshers, you know, every once in a while.

COMMITTEE MEMBER LUND: If there are major changes. Like when I took my training, it was very interesting because when I started the training and when I finished the training there had been an administration

change. And so, there were a lot of pages on the training that said this training is under review pending changes. So, especially in the DEI section.

VICE CHAIR DICKEY: DEI stuff.

COMMITTEE MEMBER LUND: So, I would say that if there are major changes that members would benefit from a refresher, but that I wouldn't require it.

VICE CHAIR DICKEY: If they do another 2018 update, or something like that, you know.

COMMITTEE MEMBER LUND: Yeah.

CHAIR HESS: It does look like it's three years. So, but, you know, that would be something that we could -- that I don't think we would need to require it every three years. But as we say, just if there's updates.

But I mean I think it's reasonable if new members have six months, but existing members have a year to complete the training. I think, I agree, it's extremely -- they are extremely useful.

So, does anyone else have any thoughts or --

COMMITTEE MEMBER DINIS: Yeah, I've done the training, too. But I think that in the refresher, then the refresher could be more selective. You know, like maybe just a few trainings that people have to do, you know, that are considered more important or something. Because it's a lot of hours to ask everybody to do every three years.

CHAIR HESS: Agreed. I think updates, like refreshers can be as needed. So, do you have any other thoughts? Any other thoughts from the remote board members?

COMMITTEE MEMBER DINIS: Well, I'm sorry, I kept saying -- maybe I was muted. Maybe in the required, every three years, would be like some of the models that everybody should do, and not like the whole 20 hours, your know.

CHAIR HESS: Oh, yeah. Great. But I think we're talking about not -- maybe not requiring board members to do like recertification every three years, but it can be as needed. So, the requirement would be the initial training.

COMMITTEE MEMBER VENTURA: For everyone.

CHAIR HESS: For everyone. And then, as needed beyond that. We could look into whether or not we would require the training again, should there be updates to the Common Rule. Okay.

VICE CHAIR DICKEY: Is this something we need to vote on?

CHAIR HESS: Yeah. So, first I'll open it up to public comment, if there are any members of the public that would like to comment on this.

MR. HENRY: Can I make a comment?

CHAIR HESS: Yes, please.

MR. HENRY: I'm sorry, I don't know how to raise -- my name is Stephen Henry, I'm a physician researcher.

And I would just say that the comments by the board member that people's lives are in their hands is very apt. And as I know that the researchers who apply to your Committee have to generally spend dozens and dozens of hours a year on these trainings, and I think it's really important, part of responsibility for anyone who, you know, chooses to volunteer to CPHS that they maintain regular review and training so that, like they said, everyone is on the same page. And you don't waste time in committees arguing about things because there's differences in knowledge about established federal, and state rules, and practices. Thank you.

DR. RYKACZEWSKA: Thank you.

CHAIR HESS: Thank you.

DR. RYKACZEWSKA: Any other public comments on the zoom? Not seeing any. Nick, any in person?

MR. ZADROZNA: No public comments in person.

DR. RYKACZEWSKA: Thank you, Nick.

CHAIR HESS: Do we have a motion? Does anyone want to make a motion?

VICE CHAIR DICKEY: Why don't you do the honors.

COMMITTEE MEMBER LUND: Okay. I move that CPHS adopt the policy that new members be required to take the initial CITI trainings within six months of becoming a member. And that existing members complete the CITI

trainings within one year from this meeting. And that the board will decide in the future when refreshers are necessary.

CHAIR HESS: That sounds good. Do we have a second?

VICE CHAIR DICKEY: I'll second.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: And I'm just making sure that I've got this motion correctly. Just one moment.

VICE CHAIR DICKEY: So, is this something we'd put in the policies and procedures?

CHAIR HESS: Yeah. Do we want to include that in the motion that --

DR. RYKACZEWSKA: So, I have changed the CPHS policies and procedures. And that -- the last part of that motion, I'm so sorry.

COMMITTEE MEMBER LUND: And that the Committee will decide in the future when refreshers are necessary.

DR. RYKACZEWSKA: We're having all kinds of technical difficulties today. Thinking really hard about this motion. Here we go.

All right, I just want to make sure that I've got it captured. Moved that CPHS policies and procedures be changed, new Committee members complete the CITI training within six months of starting, of joining --

CHAIR HESS: From their appointment to the board.

DR. RYKACZEWSKA: That existing Committee members take the training at least and that the Committee decides in the future when refreshers are necessary.

COMMITTEE MEMBER LUND: Existing Committee members take it within the next 12 months.

VICE CHAIR DICKEY: Yeah, yeah.

DR. RYKACZEWSKA: Do I have that right, now?

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: Yeah.

CHAIR HESS: Do we need to specify forward from what date? From today.

COMMITTEE MEMBER LUND: It is the 7th of March.

CHAIR HESS: We had a second, correct?

MS. ATIFEH: Yes.

CHAIR HESS: Okay.

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: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Okay, great.

VICE CHAIR DICKEY: Speaking of new members, are we going to talk about that?

CHAIR HESS: It wasn't on the agenda.

DR. RYKACZEWSKA: Yeah, it wasn't on the agenda.

CHAIR HESS: We are starting recruiting.

Okay, we have -- can move on to review and approval of meeting minutes. We have three meetings for which we need to approve minutes.

So, we'll start with the October 4, 2024, board meeting. I ask if there's any feedback from the Committee on that, from those meeting minutes?

Hearing none, we will open for public comment. If there is any member of the public that would like to comment on the October 4, 2024, meeting minutes?

MR. ZADROZNA: No comments in person.

DR. RYKACZEWSKA: Thank you, Nick. And I'm not seeing any online.

CHAIR HESS: Okay. So, is there a motion to approve the October 4th meeting minutes?

COMMITTEE MEMBER VENTURA: I move to approve.

CHAIR HESS: Okay.

COMMITTEE MEMBER VENTURA: October 2024 meeting minutes.

CHAIR HESS: Thank you.

VICE CHAIR DICKEY: And I'll second.

CHAIR HESS: Thank you.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Abstain. I was not here.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: The motion passed.

CHAIR HESS: Okay. Moving on to the November 1, 2024, Committee meeting. Is there any comment from the Committee on those meeting minutes?

I'm not hearing any. Is there any public comment from members of the public on the November 1, 2024, meeting

minutes?

MR. ZADROZNA: No comments in public -- or in person.

CHAIR HESS: Okay. Are there any comments on the chat or anything?

DR. RYKACZEWSKA: I am not seeing any on the chat.

CHAIR HESS: No. Okay, I will ask for a motion to approve the November 1st meeting minutes.

COMMITTEE MEMBER KURTURAL: I'll make a motion to approve. Is it November 4th -- I mean, I'm sorry, November 1, 2024, meeting minutes.

CHAIR HESS: Okay, thank you. Is there a second?

COMMITTEE MEMBER VENTURA: I'll second.

MS. ATIFEH: Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: 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?

COMMITTEE MEMBER RUIZ: (No audible answer)

MS. ATIFEH: The motion passed.

CHAIR HESS: Thank you.

Okay, moving on to the December 6, 2024, meeting. Are there any comments from Committee members on the meeting minutes for December 6, 2024? I'm not hearing any.

Again, I will open it up to public comment. If there are any members of the public who would like to comment on the meeting minutes for December 6th?

MR. ZADROZNA: No comments in person.

DR. RYKACZEWSKA: Thank you, Nick. And I am not seeing any on the Zoom.

CHAIR HESS: Okay. We need another motion.

COMMITTEE MEMBER VENTURA: I move to approve meeting minutes from December 6, 2024.

CHAIR HESS: Second?

COMMITTEE MEMBER JOHNSON: I'll second.

VICE CHAIR DICKEY: Two seconds.

MS. ATIFEH: Who seconded?

CHAIR HESS: Dr. Johnson.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Okay, motion passed.

CHAIR HESS: Okay. We are way ahead of schedule.

VICE CHAIR DICKEY: We are.

CHAIR HESS: So, we could move on to the projects that we'll be discussing, but I first want to see if Dr. Michael Hoyt or Marcie Haydon are available and online.

DR. RYKACZEWSKA: I'm not seeing them having joined, yet.

CHAIR HESS: Okay. Do we see any other project -- anyone from the other projects?

Okay. We will take a five-minute break while we reach out to the researchers.

(Off the record at 9:00 a.m.)

(On the record at 9:15 a.m.)

DR. RYKACZEWSKA: We are unmuted, and I think we can resume the meeting.

CHAIR HESS: Okay.

DR. RYKACZEWSKA: And see Dr. Michael Hoyt online. Dr. Hoyt, are you there?

DR. HOYT: Yeah, so sorry to keep you guys waiting.

DR. RYKACZEWSKA: Okay, we're ahead of schedule so that's okay.

CHAIR HESS: Welcome Dr. Hoyt.

Dr. Dickey, do you want to --

VICE CHAIR DICKEY: Sure. Just a preface on this. Some of us have felt that we should maybe be doing full Committee reviews as amendments, particularly when there's significant changes in a project.

And so, I looked at this one and it's -- you know, it's creating a whole different link to the research. And, you know, had some significant changes, and that's how we got here.

After I looked at it more thoroughly, I don't think it's as big of an issue as I thought. But Dr. Hoyt and I have been communicating.

And so, Dr. Hoyt, I think it would be useful if you first summarized your original project and then summarized the changes that you're making to that project.

DR. HOYT: Yeah, great. Thank you so much. So, yeah, we -- the original project was a small pilot study which we were testing a behavioral cancer survivorship intervention for Latino young adults, who had testicular cancer. That was building off of other work we've done with

that population.

And so, we did that pilot study. And we then received some additional funding to extend this work. And so, that's why we put in the amendment to now do sort of a study two, to add on to this work, to test this same intervention with Latinx young men, who've had cancer.

So, moving this from just testicular to other cancer types, but with the same population and the same intervention, and adding a control arm to do this as a slightly larger pilot study.

So, the changes from study one, now, to sort of study two really are about those inclusion criterion. So, broadening them out across diagnoses.

Changing in the design, as I mentioned, just adding a attention mask control. So, the attention mask control is something we've used across many of our studies. It's basically just sort of supportive listening. So, masked in terms of the same amount of time and each of the conditions, one-on-one in the same format that they receive our intervention. So, meeting with one of our interventionists. And it's really just sort of nondirected supportive empathic listening.

VICE CHAIR DICKEY: Can you describe the actual intervention for the group?

DR. HOYT: Yeah, the actual intervention is

focused around skill building and self-regulation, with a focus on pursuing goals after you've had cancer, motion regulation skills. It's a very brief intervention. It's six sessions that we deliver across two months.

They meet one-on-one, we deliver it like this, on Zoom. And there's some like between-session exercises that folks do. There's some like homework exercises and things like that. But it's really based off of what are your values after cancer? How have things shifted? How do you pursue goals? What are the skills that you might need? How do your emotions affect your goal pursuits and maybe get in the way? And different skills in that way.

VICE CHAIR DICKEY: Great. Could you describe the recruitment, and then the screening, and --

DR. HOYT: Yeah. So, the recruitment mirrors exactly what we do in the pilot and what we do in some of our other studies. Recruiting through the California Cancer Registry, we obtain a list of potentially eligible folks from the Cancer Registry. We contact them by letter, telling them very briefly about the study and how to contact us. We follow up with them after a certain period of time.

We also do recruit through our clinics here at UCI, and will also be recruiting -- you know, we send out flyers and information about our study just through like cancer care organizations, and things like that, so that

people can contact us if they're eligible.

When we -- when they contact us, in the lab we do a screening, making sure they're eligible. There's some eligibility criteria, as you probably know. Probably the most notable one is they have to sort of score within -- under a threshold in some of our screening questionnaires. So, there's two screening questionnaires.

One's related to sort of goal skills. And so, if they show that they could benefit from our intervention on that dimension, they could be eligible.

The other is the distress thermometer, so if they have some elevations in their overall distress, they may be eligible for the study as well.

VICE CHAIR DICKEY: Great. Okay, I just want to make a comment that as in your previously approved study, those screening questions are administered before they go through a consent, right. You requested and were given a waiver of informed consent for those screening questions. So, he's requesting the same waiver for this arm.

The questions are pretty, not too -- I don't know if people have looked at them, they're not too sensitive. But I think it's -- the screening questions are mainly to determine that the person needs help. Right?

DR. HOYT: Yeah, yeah.

VICE CHAIR DICKEY: That they're --

DR. HOYT: Yeah, we don't want to give interventions to people who just don't need interventions, yeah.

VICE CHAIR DICKEY: So, they have to exhibit some difficulty dealing with their diagnosis.

And then, there's a consent process that takes place when they go ahead and do the intervention or the control.

One thing I questioned about was are you informing the participants how you got their name or how you contacted them? And I think you said it would be okay -- you haven't been telling them you got it from the Cancer Registry, but that you would be willing to change that?

DR. HOYT: Absolutely, yeah. Yeah, I think that's an important change.

VICE CHAIR DICKEY: And that would go into the --

DR. HOYT: The initial recruitment contact letter.

VICE CHAIR DICKEY: The initial contact, but not the consent. I mean because the consent would be different for different folks.

DR. HOYT: Yeah, exactly

CHAIR HESS: I thought they were required to tell participants that they got their information from --

COMMITTEE MEMBER LUND: There should be a CCR brochures, that's also a requirement.

CHAIR HESS: Yes.

VICE CHAIR DICKEY: It's -- I'm not questioning that.

CHAIR HESS: No.

VICE CHAIR DICKEY: In the past, this is how they -- they didn't have to reveal that.

But what we're hearing here is that you need to put it in the consent, as well as the contact letter.

COMMITTEE MEMBER LUND: I don't think that that's a requirement. What's a requirement is that when you -- when you contact the people that you tell them that you got their contact information from CCR.

VICE CHAIR DICKEY: Okay, so you're saying it doesn't have to be in the consent.

COMMITTEE MEMBER LUND: That would be my take.

VICE CHAIR DICKEY: We often have it in the consent. But this is mixed because there's a lot of -- probably most of your patients are not contacted through the Registry, is that right?

DR. HOYT: It's a mix, yeah. It's a mix. And, you know, it may be that one of our clinicians says, oh, this patient may be eligible, send them a -- please send them an information letter, right. And so, they wouldn't be Cancer Registry folks.

VICE CHAIR DICKEY: I guess the data that we have

program review over is the Cancer Registry folks, right.

CHAIR HESS: Yeah, I think so.

COMMITTEE MEMBER LUND: And I wouldn't have a problem with a contact script that said something like, we either got your information from your physician or from the California Cancer Registry. I mean, you know, I --

VICE CHAIR DICKEY: Or, either, not actually say that they got it from the Cancer Registry.

COMMITTEE MEMBER LUND: Yeah, I would -- for me, I think it satisfies the requirement that they know the source. And if it could be either/or, that's okay with me, as long as they know what source it might have been.

CHAIR HESS: So, they wouldn't have to have two different contact letters for people who are recruited at the Registry versus --

COMMITTEE MEMBER LUND: Yes, that's what I would -- that's what I would say.

VICE CHAIR DICKEY: Okay, moving on. You know, I had questions about, you know, how you scored the screening questions, I couldn't figure out -- but I don't think we need to go into that. I think you know you're scoring them the right way.

DR. HOYT: Okay.

VICE CHAIR DICKEY: And I'd never heard the word "attention match controls", so you explained to me what that

means.

DR. HOYT: Yeah. It really just means that you're giving your control participants the same amount of attention. So, the same amount of time is maybe another way to say it. As opposed to, you know, usual care, where you really aren't giving them anything extra.

But attention match is not uncommon in sort of behavioral intervention study designs because if we give them nothing, chances are our intervention's going to look really good. But we won't know if it's because of the active ingredients of our intervention or just because we spent time with them.

And so, we have a control group that controls, basically, for just spending time face-to-face with them, without giving them the skills in the intervention component study that are in the other group.

VICE CHAIR DICKEY: Do we have the script for the controls? I mean, what do you talk to them about? Football?

DR. HOYT: Yeah. It's very whatever they bring to those sessions. We have -- I mean we train our interventionists and, basically, they're meant to just do active listening. So, they use reflective listening techniques, empathic, you know, sessions with them. But the -- really, the content can be whatever the individual brings

to the session.

What they don't do is exercises, and coping skill training, and emotion regulation work. They don't do any of that.

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

COMMITTEE MEMBER LUND: Having just finished the CITI training --

VICE CHAIR DICKEY: You're dangerous now.

(Laughter)

COMMITTEE MEMBER LUND: Consent is not necessary for screening. So, we don't actually have to have a waiver of informed consent for screening. But what we can do is ask, especially if the screening questions are detailed, or intrusive, or sensitive, we can ask them to have a script to make sure that people are prepared for what they're to be asked.

But technically speaking, they don't need to have an informed consent process for screening, as long as it's just for screening.

VICE CHAIR DICKEY: Yeah, and usually the screening is something, you know, on a demographics order, but these are questions that ask about how you're doing. So, it seems to me a little more sensitive.

COMMITTEE MEMBER LUND: Yeah. I'm not saying I

object. I'm just saying. I'm dangerous now.

(Laughter)

CHAIR HESS: Any other questions, comments from the Committee? No.

Are we ready for a motion?

VICE CHAIR DICKEY: I guess so. I move approval, one-year, minimum risk, with the proviso -- what is, it's conditional approval -- deferred approval.

CHAIR HESS: Deferred approval.

VICE CHAIR DICKEY: One-year, minimum risk with the changes in the recruitment letter to state that they're being recruited because they've been identified as having cancer, either through the California Cancer Registry or another -- another means. And the other means would be clinical contacts?

DR. HOYT: Yeah, so this is provider identified or self-referred.

VICE CHAIR DICKEY: Oh, okay.

DR. HOYT: So, self-referred, they wouldn't get the letter so, yeah.

VICE CHAIR DICKEY: Oh, okay. So, through the California Cancer Registry or your provider.

COMMITTEE MEMBER LUND: Is it one year? Since this is an amendment or is for the term of the study?

VICE CHAIR DICKEY: Well, that's true, amendments

are not full -- well, this is so big of a thing.

When is your renewal going to be? Do we know?

DR. HOYT: Uh, the (indiscernible) --

VICE CHAIR DICKEY: Your continuing renewal.

DR. HOYT: That's a good question, I don't know.

DR. RYKACZEWSKA: I thought it was not in -- I was not anticipating that question, sorry.

CHAIR HESS: I just saw it and --

DR. RYKACZEWSKA: It is August 1st, 2025.

VICE CHAIR DICKEY: Oh, okay. So, it's off a little ways. We probably don't want to reset the whole -- okay, so it's not for one year. We're approving the amendment.

DR. RYKACZEWSKA: Approval of amendment. Okay, let me share a screen just to make sure I've got the motion correctly. So, this will be motion six.

VICE CHAIR DICKEY: And with review by myself as a subcommittee.

Second?

CHAIR HESS: Second?

COMMITTEE MEMBER KURTURAL: I'll second.

DR. RYKACZEWSKA: Okay, here we go. So, we have a second by Ms. Kurtural.

All right, and Dr. Hess?

CHAIR HESS: No, do I vote?

VICE CHAIR DICKEY: No.

DR. RYKACZEWSKA: No. Thank you.

Dr. Dickey, you --

VICE CHAIR DICKEY: I seconded it, so -- I mean, I made it.

DR. RYKACZEWSKA: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

DR. RYKACZEWSKA: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

DR. RYKACZEWSKA: Ms. Kurtural seconded.

Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

DR. RYKACZEWSKA: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

DR. RYKACZEWSKA: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

DR. RYKACZEWSKA: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

DR. RYKACZEWSKA: All right, the motion has passed.

VICE CHAIR DICKEY: I sort of want to ask the Committee, is this an appropriate thing to come back to the full Committee?

COMMITTEE MEMBER KURTURAL: Yeah, I think so because it’s such an expansion of the project.

COMMITTEE MEMBER VENTURA: As you said, it's a new arm.

VICE CHAIR DICKEY: A new arm, yeah.

COMMITTEE MEMBER VENTURA: It kind of changes from the original design. I think that's appropriate.

VICE CHAIR DICKEY: Yeah, okay. Good.

COMMITTEE MEMBER KURTURAL: And I don't think we get that many of these where it's like third and some. We only have three on the agenda.

VICE CHAIR DICKEY: I know. Exactly, we wouldn't have much to talk about today, if we didn't do it.

CHAIR HESS: All right. Okay, Dr. Hoyt, if you're still on, thank you very much. You should be getting --

DR. HOYT: Thank you all so much.

CHAIR HESS: -- contact from us shortly. Thank you.

DR. RYKACZEWSKA: And we are reaching out to the next research teams. So, that's why we might need to take a second break, just to reach out to the team.

CHAIR HESS: Okay, we'll take --

DR. RYKACZEWSKA: Five minutes.

CHAIR HESS: -- five minutes.

(Off the record at 9:33 a.m.)

(On the record at 9:40 a.m.)

CHAIR HESS: Okay. Welcome back, everyone. We

are ready to talk about our next project.

I believe we have Dr. Jennifer Tsui, who has joined us. Yes. Is there anyone else from your research team, Dr. Tsui?

DR. TSUI: Hi everyone. Yes, thanks for putting our project on the agenda today. I think my research team is just joining now. We -- I think here that you all are way ahead of schedule. Our window was 10:00 to noon. So, I'm hoping they can join us momentarily. I see Emily is on, now.

CHAIR HESS: Do you want to go ahead.

COMMITTEE MEMBER LUND: Sure. Hi. Good morning, is it Doctor -- is it Tsui or Tsui?

DR. TSUI: It's Tsui.

COMMITTEE MEMBER LUND: Great. Apologize.

DR. TSUI: Thanks for asking.

COMMITTEE MEMBER LUND: So, Hi. I'm Laura.

DR. TSUI: Hi, Laura, nice to see you in person, sort of.

COMMITTEE MEMBER LUND: Yes.

DR. TSUI: Or over Zoom or, you know, a face to the name, as always.

COMMITTEE MEMBER LUND: So, I just wanted to let the board know that this is been heard as an amendment. We previously approved this project. But I brought it to the

board because it's a significant amendment. When we originally reviewed this project, they had planned to do the 12-month follow up, but they did not have any of the associated materials, consent forms, and questionnaires, and so forth, recruitment materials and that kind of thing.

So, the amendment is to add the 12-month follow up to the originally approved study.

And what I'd like to ask is if Dr. Tsui would introduce anybody else who's on her team, and then explain the amendment to the board.

DR. TSUI: Sure. So, hi, everyone. I'm Jennifer Tsui. I've mentioned earlier I'm Associate Professor at the University of Southern California. I am one of the MPIs on this NIH-funded study. And as Ms. Lund had mentioned, this is an amendment to primarily address edits we were trying to make around the 12-month follow-up survey.

I'd like to introduce one of our project directors, Emily Dang. And I can have Emily introduce herself really quickly.

MS. DANG: Hi, everyone. I'm Emily Dang. Thank you for the introduction Dr. Tsui. I am the Researcher Coordinator at USC, and I work really closely with the other project coordinator at the Columbia University site.

DR. TSUI: And then, just a brief summary, and first I want to say thank you so much for putting this

project on the agenda today, and for the reviewers, primarily Ms. Lund, for going back and forth with us so many times over the last -- Laura, has it been 12 months, 18 months.

COMMITTEE MEMBER LUND: Yeah.

DR. TSUI: A great back and forth around this study. And I can do a 30-second overview of the amendment items we're trying to discuss.

So, this study is based in two sites. It is recruiting cervical cancer patients from both the New Jersey State Cancer Registry and the Los Angeles Cancer Surveillance Program.

The amendment here, and the reason we're going through CPHS is because we recruit through LACSP.

The three amendment items that we have submitted and described in this amendment is, one, the 12-month follow-up survey and all the associated recruitment documents. They so far are submitted only in English. They have been reviewed thoroughly by our research team, as well as our Community Advisory Board, which sits nationally.

And some of the measures in this amendment -- or in the 12-month survey overlap with our baseline survey. Some of our baseline survey items have been removed because we no longer need to follow those items up in the 12-month, and there are new 12-month items that have been added.

In addition to this major amendment, the other two items include an update to our baseline survey, itself. We had previously been approved with some minor edits to our English version of the baseline survey. That occurred on December 23rd. And we are just submitting the Chinese and Spanish translated versions of those edits to our baseline survey.

And then, the last and third minor edit to the amendment is that in our original protocol we said that registry staff would be the personnel on the team to request medical records from physicians associated with these cancer cases. We're expanding that, just due to project resources, logistics, but also including appropriate training. We are also including research staff as part of the process for recruiting or contacting physicians for the medical records we need in phase two of the study.

I would say that's the overview. I'm happy to answer any questions or provide updates to the study, if that will help make any of the board decisions or answer any questions.

COMMITTEE MEMBER LUND: Great. Thank you, Dr. Tsui.

And just for the board, I had a few questions and comments on some things that were minor. Dr. Tsui made changes, just some of the consent form language, and

answered my questions. So, I don't have any concerns to bring to the board about this amendment.

I thought that the follow-up questionnaire was appropriate. I didn't see anything in it that I was concerned about or that would be unnecessary. And the consenting process and the consent form look good to me.

So, I don't have any additional comments about this study, and I would open it up to the board for any comments or questions they may have.

No. Okay. And public comment?

CHAIR HESS: Did we ask for public comment on the previous project?

COMMITTEE MEMBER LUND: No.

CHAIR HESS: Okay. Okay, well, if there's no additional comments from the board, do we have a motion?

COMMITTEE MEMBER LUND: We should really ask for public comment. Are there public comments on this?

CHAIR HESS: Do we have any comments from the public?

DR. RYKACZEWSKA: I am not seeing any online. Nick, any in person? Nich, you're muted, if you're speaking. From my understanding, there are no in-person attendees, so I'm going to say no in-person.

CHAIR HESS: Okay. No public comment.

COMMITTEE MEMBER LUND: All right. Then, I move

to approve the amendment. It's approved and not deferred approval because I didn't hear any additional comments above and beyond the changes that have already been made. Approved consistent with the time of the study. So, we're not adding any additional time. The amendment is just approved. Okay.

VICE CHAIR DICKEY: It can't be that simple.

(Laughter)

DR. TSUI: Yeah, this is the simplest we've ever seen. So, just glad it turned out this way. Kudos to Emily for being great at coordinating all of this.

COMMITTEE MEMBER LUND: So, we need a second and a vote.

COMMITTEE MEMBER VENTURA: I'll second.

VICE CHAIR DICKEY: I'll second. Oh, I'm sorry, you got it.

MS. ATIFEH: Okay. Dr. Dickey?

VICE CHAIR DICKEY: Approved.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Ms. Kurtural?

COMMITTEE MEMBER KURTURAL: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Approve.

MS. ATIFEH: Okay, the motion passed.

CHAIR HESS: Great. Thank you, Dr. Tsui.

DR. TSUI: Okay, do you need any other comments from us or anything else?

COMMITTEE MEMBER LUND: No. You'll get a letter that this was approved. But you've already made the changes, so there won't be any additional changes requested in that letter.

DR. TSUI: Okay, great. Thank you so much.

MS. DANG: Thank you.

DR. TSUI: Have a great rest of your meeting, I hope it all goes just as quickly.

(Laughter)

DR. RYKACZEWSKA: All right, and Dr. Schleider.

CHAIR HESS: Yeah. Okay, do we have Dr. Schleider?

DR. RYKACZEWSKA: Uh-hum.

CHAIR HESS: Okay, who's project, Dr. Ventura's.

COMMITTEE MEMBER VENTURA: Yep. Good morning, Dr. Schleider, is that the right pronunciation?

DR. SCHLEIDER: Yes.

COMMITTEE MEMBER VENTURA: Great.

DR. SCHLEIDER: You got it on the first time.

COMMITTEE MEMBER VENTURA: Thank you. And can you please introduce any of your other team members on the call?

DR. SCHLEIDER: So, I don't see any of them here. I think we were scheduled to have a call time that was a little bit later than this, so I probably beat them. So, it's just me today.

COMMITTEE MEMBER VENTURA: Okay, we're okay to -- okay.

If you can, Dr. Schleider, please provide the Committee a few -- a brief summary of your proposed project and then we'll go from there.

DR. SCHLEIDER: Absolutely. So, I have some slides, if that would be helpful, but I can also just chat. What would be preferable?

VICE CHAIR DICKEY: Whatever she prefers.

COMMITTEE MEMBER VENTURA: Yeah, whatever you prefer. If you have slides, you can share them.

DR. SCHLEIDER: I'll go ahead and share the slides, just so I remember not to miss anything at all.

DR. RYKACZEWSKA: And Dr. Schleider, just as a housekeeping, if you could please email me those slides afterwards, so that we can provide them to the public as well.

DR. SCHLEIDER: Of course. Of course. All right.

All right, does that work?

DR. RYKACZEWSKA: Absolutely.

DR. SCHLEIDER: All right. Well, thank you so much for your time today and for the careful review you've already provided for our proposed project.

I'm Jessica Schleider. I'm an Associate Professor of Medical Social Sciences, Pediatrics, and Psychology at Northwestern University in Chicago.

And I'm collaborating with Kooth, a digital mental health company, who has a contract with the state to deploy their app, Soluna, across the state, to lead an analysis of the implementation of this digital mental health app, which is currently freely available to use across California.

And particularly, my lab studies single-session interventions, which are mental health supports that intentionally involve single-session encounters and make the most impact with that encounter.

So, this is one of the few digital mental health apps out there that include single-session components.

So, we're trying to understand the effects of those single-session components, as well as the overall effects of the app for California young people who access it.

I'm going to skip over some slides just about our lab but, really, we're to talk about the project with Kooth.

But in short, we are a team of 30 investigators here at Northwestern, cross-disciplines, that design, test, and disseminate brief barrier pre-interventions to reduce mental health problems at scale.

Which is the reason we're so excited about working with Kooth on this evaluation project, because they're app really does fall into that brief barrier free.

And I'm just going to skip over some other things about our lab.

So, what we're going to be doing in this project and what we're proposing to do is to evaluate the accessibility, impacts and added value of Soluna's single-session coaching option, which is one of several different digital mental health tools on the app, in combination with Soluna's other supports.

So, we're going to measure young people's use of the Soluna app. We're going to collect data on their emotions, thoughts and wellbeing, as well as the demographics. These outcomes are all really critical, not just to understanding the effects of Soluna and its components on students, but also to parents, teachers and policymakers who may want to make decisions on Soluna's use in the future for California students.

And young people, we're recruiting between 250 and 500 young people. They'll be compensated up to $30 for

their effort on the study, which includes a pre -- a baseline assessment, and then a one- and three-month follow-up assessment to track how they're doing over time.

Participants will be ages 14 to 17. These young people across California all already have access to the Soluna app through the state's investment. They'll have English proficiency, have access to the internet. They will live in California. And they'll have the capacity to consent assessment that we've used in many of our previous digital mental health studies for young people, to evaluate low risk digital mental health tools that are freely available to use.

They will ask youth to evaluate whether they are able to consent independently to take part in the study.

What they will be asked to do in the study? They will be asked to answer multiple choice questions about potential risks of participating and what happens if they no longer want to participate.

And the way the (indiscernible) is extremely important for research like this, because we know that without this kind of waiver youth would be systematically excluded from participating in either resources that could help them, or other kinds of -- or participating in studies like this, simply because they may not be able to disclose, or it may not be safe to disclose mental health concerns to

their families.

This is a quick summary of all of the data that we're going to be collecting through voluntary surveys for study participants. I'm happy to go through any of this in detail, although it's outlined in the proposal.

We're going to be collecting their feedback and demographics.

All of these items and surveys will be conducted through Qualtrics surveys, which will be offered to use in links that they receive through the Soluna app that they already use and have access to.

Our hypotheses for our study are youth with access to Soluna will show reductions in overall stress across a three-month follow-up period. That students with access to Soluna will show reductions in depression, anxiety, hopelessness, mental health stigma, and loneliness, as well as well as increases in perceived social support and quality of life.

That youth will show similar benefits to Soluna regardless of their individual backgrounds or treatment histories.

We predict that more engagement with Soluna, on more occasions, will predict larger improvements in the outcomes noted in hypotheses 1A and 1B.

And we predict that students will find both

individual single-sessions and the overall platform to be accessible and helpful to their wellbeing.

So, alongside this Qualtrics data collection, we've already gotten approval from the state to pursue this secondary analysis, or we've gotten a data sharing agreement approved with the state, rather.

So, we're also interested in -- because, you know, for the Qualtrics survey we're not going to be able to detect users individual patterns of engaging with Soluna itself, we'll just be asking youth to self-report their engagement.

We're also going to be examining secondary data from 3,500 to 4,500 newly registered users of Soluna during the project period. All of them, through the Soluna app, have previously affirmed that, you know, it's okay to use their data for secondary research purposes.

And this data will all be anonymous. So, we will not be linking this data to the data we collect through the Qualtrics survey. This is a separate and complementary secondary analysis effort to better understand how people overall are using Soluna's app.

And we'll be examining uptake in patient and accessibility. And these are not Medi-Cal data from DHCS. However, the data that we'll use is specified to be owned by a contract by DHCS. And so, we've already applied for and

have received approval from DRC for security to use this.

And this is just a quick description of the data components that will be included in the secondary anonymous data analysis which, again, I'm happy to share more about in detail, if you like.

Recruitment. All recruitment will happen through Soluna's platform. Within Soluna's platform, students will receive a message that informs them about the study. People who click on the message will be taken to a webpage on Qualtrics to determine eligibility. If they're eligible, they'll proceed to the baseline survey, which will include all the surveys I already talked about earlier.

Participants who are in the study will receive -- be eligible to receive a $10 gift card after completion of each of the three surveys. So, up to $30 across a baseline, one-month, and three-month surveys. And gift cards will be sent to youth by email.

And it's a minimal risk study. And participants will receive their gift cards within ten days of participating.

This is, as I said, a minimal risk study. Participants may feel potential discomfort because of the length and content of the questions. But they're told explicitly they don't have to answer anything they do not want to answer. And that they can skip any questions at any

time.

We are asking about suicidal ideation over the past month. In certain surveys, I'm a clinical psychologist and my team are all trained in risk assessment and response of adolescents. That's the primary focus of our research in our lab overall.

I'm happy to go over the risk protocol that we've detailed in the application, if it would be helpful, or just answer questions if any remain, given that we've been back and forth a little bit about clarifying some of the features.

And these are just some details about, you know, summarizing the risks and benefits of the study. Really, just hitting on the points that this is going to be -- this study is going to be safe for Soluna users, all measures are validated. And they are going to be helpful for helping us understand how Soluna is benefitting California young people.

The privacy of the information is detailed early in the protocol that we submitted.

This study will not affect the availability of Soluna to anybody who already had access to it.

And there are these benefits. So, Soluna users can receive small gift cards, and they may enjoy even answering some of the survey questions.

I'm happy to discuss data protections. This protocol that we've submitted to you, the identical protocol has already been approved by the Northwestern University IRB. But we have the standard data protections in there that we would use for any project.

And I'm more than happy to take any questions you have about the protocol or our responses to your questions. Thank you for your attention.

COMMITTEE MEMBER VENTURA: Thank you for that explanation to the Committee.

I reviewed this protocol several times, just to try to make sure I understood all the components. But I will start with the issue that gave me most concern --

DR. SCHLEIDER: Okay.

COMMITTEE MEMBER VENTURA: -- which was the waiver for parental informed consent.

DR. SCHLEIDER: Okay.

COMMITTEE MEMBER VENTURA: Because this is a study with minors, 14 to 17, it just gave me pause. And they're asking questions about suicide ideation and other mental health questions. There are some sensitive questions, you know, regarding sexual orientation and gender identification in the surveys. And so, they're sensitive topics.

And so, I just want to ask the other Committee members for their input as far as the request for waivers

for parental consent because of the nature of this research.

DR. SCHLEIDER: And I'm more than happy to share why we prioritize this in 100 percent of identical mental health research with adolescents that we conduct.

But it's obviously a topic that deserves discussion.

COMMITTEE MEMBER LUND: So, the Committee is going to get tired of me, because I'm going to say I just finished the CITI training.

(Laughter)

COMMITTEE MEMBER LUND: That may speak to this in part. First, parents cannot give consent, they can only give permission. So, that's, I think an important distinction about whether parental permission should be required for these individuals to participate in the study.

And I think that's a real question given the sensitive nature of the topics that are being covered.

However, also one of the things that's raised in the CITI training is, does it actually disadvantage the group being studies to require parental permission here.

I think it would not be feasible to conduct this research if parental permission were required. I think a lot of folks would not be willing to participate if they had to tell their parents that they were accessing these services, which I think is something that we have to, as a

Committee, consider.

So, you would have -- you would not, I think, recruit broadly, or as broadly if you made this a requirement of the study.

And are the participants, themselves, harmed if parental permission is not sought. And I don't think they are. They're already accessing this service without parental permission, as I understand it.

DR. SCHLEIDER: Correct.

COMMITTEE MEMBER LUND: So, it just means that they wouldn't be able to participate in the study if you added this additional burden of requesting parental permission.

So, I just throw that out to the Committee to consider whether or not we should waive the parental permission and to enable more people from this group to participate in the research.

COMMITTEE MEMBER KURTURAL: I have a question about the app. The law on the consent side for mental health service side, it's very particular in California on -- and I know we're talking about research, but I just want to understand, you know, how are they getting to the app initially.

So, what type of criteria or screening does the app do for a determination that a child is mature enough,

which is what the code requires for 12 and older, they have to show that the child is mature enough to receive services on the app.

And then, that kind of relates back to the question of are they children under the Common Rule, you know, which ties into the research.

But if you could kind of explain more about that analysis and maybe that analysis is taking place when they sign up for the app before they -- you know, add that's already done and --

DR. SCHLEIDER: Yeah. So, it's not available to young people below a certain age, I believe either 13 or 14. But, you know, in compliance with that law that you're talking about.

But Soluna is not designed as a treatment or a service, so to speak.

COMMITTEE MEMBER KURTURAL: Okay.

DR. SCHLEIDER: It's designed as a support that anybody could use, which is a little bit different from a traditional mental health service.

So, it's proving that all youth could benefit from the coping skills and activities that are included within the app.

But when, at the time of onboarding, there's a similar kind of series of questions that we ask to determine

competence to provide consent, that determine whether or not somebody understands what this is, what it provides and what it doesn't provide, that it doesn't replace, you know, a therapist and other pieces. So, those questions are built in, as I understand it, to the onboarding process of Soluna, and if they're under a certain age they cannot access it, anyway.

COMMITTEE MEMBER KURTURAL: Okay. I think I would want to know more about that, I mean personally, as what type of screening is going on, on the front end to know --

DR. SCHLEIDER: Sure.

COMMITTEE MEMBER KURTURAL: -- that -- you know, I do think that it's interesting that you're defining it not as a mental health service to receive counseling. So, what is it, you know?

DR. SCHLEIDER: It offers many different things for folks at different levels is how I believe Kooth would describe the app.

But this is something that the state has sanctioned of being available to all youth and they will continue to access it, regardless of the study.

COMMITTEE MEMBER KURTURAL: Yeah, I'd want to see that. When you say the state has sanctioned it, like what, is it in law, like literally or, you know, to allow this app to move forward. Or like where is the authority coming

from, I'm just curious?

DR. SCHLEIDER: It's a contract with the state that Soluna has to make this part of sort of their mental health initiative --

COMMITTEE MEMBER KURTURAL: Okay.

DR. SCHLEIDER: -- of making sure care is accessible to all. So, it's a hundred percent funded and backed by the State of California to make this available to all California youth.

I would suggest asking Kooth, since I'm an expert in the study protocol, with respect to, you know, if there are particular questions about their contract with the state.

But I do know that regardless of whether this study occurs, students or youth across the state will continue and already do have access to Soluna.

COMMITTEE MEMBER KURTURAL: Yeah. Yeah, I mean, I just -- I feel like I need more information like about it, about that to know what type of screening. And what type of screening are you doing on the research side? I mean --

DR. SCHLEIDER: Capacity to consent. Again, we're not requiring anybody to have a particular profile or diagnosis.

COMMITTEE MEMBER KURTURAL: Okay.

DR. SCHLEIDER: And I can pull up the criteria for

inclusion, which are the other things --

COMMITTEE MEMBER KURTURAL: That would be helpful.

DR. SCHLEIDER: -- that we assess --

COMMITTEE MEMBER KURTURAL: Okay.

DR. SCHLEIDER: -- to determine eligibility for the study.

COMMITTEE MEMBER KURTURAL: Do you mind if we look at that?

DR. SCHLEIDER: Sure.

COMMITTEE MEMBER VENTURA: Sure.

COMMITTEE MEMBER KURTURAL: Okay.

DR. SCHLEIDER: Let me just go back to that slide. So, we require that folks are between the ages of 14 to 17. We ask them to attest that they're proficient in English. They must have access to the internet, which if they're accessing Soluna, they have access to the internet.

COMMITTEE MEMBER KURTURAL: Right.

DR. SCHLEIDER: They must live in California. And they must pass the capacity to consent assessment.

So, it's designed to be representative of all of the users who are already using Soluna, the app.

CHAIR HESS: That -- oh.

VICE CHAIR DICKEY: No, you go ahead.

CHAIR HESS: I'm looking at your consent and like my understanding is that as minors they cannot consent, they

can only assent. So, yeah, at the very least the consent form would need to be changed to an assent form.

And I think some of the language is a little high. And I think that for especially youth who may -- yes, they may have the capacity to assent, but whether or not they really understand how their data are going to be used, I think it will be beneficial in the assent form to have a bit more explanation of what the study is about and how their data is going to be used. I don't know, if anybody agrees with that.

COMMITTEE MEMBER VENTURA: More details.

CHAIR HESS: Yeah.

COMMITTEE MEMBER VENTURA: More details. I agree.

VICE CHAIR DICKEY: Well, how is the capacity to assent evaluated?

DR. SCHLEIDER: They have to get all the questions right. It's a multiple choice.

VICE CHAIR DICKEY: Unfortunately, I didn't look at the questions.

COMMITTEE MEMBER VENTURA: So, they ask like, you know, are you going to participate in groups. And it's like if they say -- if they answer incorrectly, it's like -- basically, they're quizzed on the consent form information.

VICE CHAIR DICKEY: Oh, what's in the assent form.

COMMITTEE MEMBER VENTURA: Yeah.

DR. SCHLEIDER: Yes, exactly.

COMMITTEE MEMBER VENTURA: That's the capacity to understand --

VICE CHAIR DICKEY: Where the capacity to understand is from.

COMMITTEE MEMBER VENTURA: Yeah. Not, again, understanding how their data will be used, which I think we can ask for a little bit more explanation.

I asked to include, you said the surveys will take 15 to 30 minutes, but in total I want to see like, you know, before they agree to participate in research they have to understand that there will be baseline, one-month, and three-month surveys. So, in total their commitment is maybe an hour and a half or two hours of their time. So, very, just spelling it out very clearly from the beginning what they're being asked to participate in, I think would help.

DR. SCHLEIDER: Sure.

COMMITTEE MEMBER VENTURA: Is the --

DR. SCHLEIDER: And given that each survey is, you know, brief, I don't believe it would be two hours.

VICE CHAIR DICKEY: So, if they're identified at risk for suicide, or something like that, or harming themselves or somebody else --

DR. SCHLEIDER: Yes. Yeah, that would be outside of the study participation, but yeah.

VICE CHAIR DICKEY: Right. But they know that before they participate, that you're going to notify their parents and report the --

DR. SCHLEIDER: That is in the forms that they have to agree to, yes.

VICE CHAIR DICKEY: That's the biggest issue for me.

COMMITTEE MEMBER VENTURA: Well, one of my questions was, so the youth provide a parental contact information.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: And my question was, how do researchers then confirm that that's a real legitimate phone number. And if something, a risk were to be identified --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: -- and they need to contact the parent, do they have the right information.

And Dr. Schleider, your response to that was -- I mean, we can't guarantee that the information provided at all is correct.

DR. SCHLEIDER: That's right.

COMMITTEE MEMBER VENTURA: So, I'm not sure, if that situation were to arise where there is risk identified, how do we know.

VICE CHAIR DICKEY: And if they can't contact the parents --

COMMITTEE MEMBER VENTURA: That's right.

VICE CHAIR DICKEY: -- what's the next step?

DR. SCHLEIDER: So, Kooth has their, and Soluna app have their own risk assessment response team. So, we would contact Soluna and let them know.

So, there are backup options for if we are unable to reach a parent. And if the information is correct, there is a circumstance in which we would not be able to reach the parent because they're not responsive.

So, this is the nature of any online study. We cannot guarantee with a hundred percent certainty that the information we receive is accurate, because we're not physically in the room with them. But I'm happy to look it up further. This is -- really, this is the (indiscernible) that's impossible to meet in an online study that's maximally inclusive to young people without, you know, incurring barriers to participation. That would be extremely exclusive to their ability to take part.

COMMITTEE MEMBER KURTURAL: Yeah. I feel like I need more information about the app in general. Just know what, you know, the family code and health and safety code kind of points on this issue. And I just need to see that contract to have a deeper understanding of how the app

works.

I mean it's -- I'm not -- they have access to the app, so that I mean that it makes sense that your user base that you're reaching out to is going to be the app users.

DR. SCHLEIDER: Yes.

COMMITTEE MEMBER KURTURAL: But I just want to, you know, know a little bit information on that contract because like in what was said and, you know, what was the purpose. It's just not enough information, I think for me, to move forward without.

DR. SCHLEIDER: I'm also trying to contact the member of the Soluna team that was meant to be here. But we were scheduled for 15 minutes from now to start. So, I do wish she were here to answer those questions right now, but I'll see if she's available.

COMMITTEE MEMBER LUND: I'm wondering, it sounds like this might be critical to you in determining whether or not you would be able to vote today, if we could pause until she could get somebody to answer those specific questions.

CHAIR HESS: Break, yeah.

VICE CHAIR DICKEY: Yeah.

CHAIR HESS: I was going to suggest that.

VICE CHAIR DICKEY: We need to give them that chance.

CHAIR HESS: So, would it help if we took like a

15-minute break and then staff from Soluna would be able to join? And then, we could continue the discussion when more of your team is present.

DR. SCHLEIDER: Sure, yeah, at least more of Soluna's team.

CHAIR HESS: Yes, yes. Okay, I think that everyone is on board with that. Okay, why don't we do that. Let's break for 15 minutes from now, so about 10:30, 10:32.

(Off the record at 10:17 a.m.)

(On the record at 10:32 a.m.)

CHAIR HESS: Welcome back, everyone. And I think we have some members of the Soluna team on board to continue the discussion and answer some of the questions that board members have had.

So, Dr. Ventura, do you want to --

COMMITTEE MEMBER VENTURA: Yes. So, we have some questions about the contract between Soluna and DHC -- Department of Health Care Services.

COMMITTEE MEMBER KURTURAL: I can go ahead.

COMMITTEE MEMBER VENTURA: Yeah.

COMMITTEE MEMBER KURTURAL: I kind of -- because this is -- I haven't heard of this app before. So, and I wanted to know on the front end, front end, when you have someone, say, 15 sign up for the app, what type of -- how do you -- what type of screening occurs on the front end to

determine that the minor is mature enough to participate in the app. And if you could please expand upon that, that will be helpful to me.

MS. MISCH: Sure. First of all, you'll see that I put in the chat a link to CYBHI, so it's the Children Youth Behavioral Health Initiative, which is a statewide initiative under Governor Newsom's protocol, which started I believe in 2023. So, it is state funded.

And then, you'll also see the Soluna app website as well, too, which notes as a CalHOPE program. So, again, this is part of the wider initiative that's across California. And we started in 2024, January 2024.

You may have heard of -- oh, my goodness, now why am I blanking. BrightLife or BrightLine kids. They're also the other virtual behavioral health for caregivers, and then children under the age of 13.

So, Soluna is particularly designed to meet the behavioral health needs and support young people in California as a free app. The ages are between 13 and 25.

And we have a digital ecosystem. So, to start with, when someone decides to register for Soluna, they go through the app itself, which is actually anyone can download it via, you know, Apple, or what's it, Android. Everyone uses Android, right. You can download it either way and the registration process requires the age of the

young person. So, the age gates, to make sure that nobody too young or too old try to access, so with date of birth.

And then, secondly, it would be the zip code, again to make sure that they are within California. So, the expectation is with our standards and terms of privacy that they are being honest with that.

When they register, they have access first only to content and tools in which there is no interaction with a human. So, the content is literally articles, or some audio features. A lot of them look like -- you would -- it almost looks like you're scrolling through phone and looking at the conversation back and forth. That's like a graphic. And so, none of that is interfacing with a human person. It's all just content.

And in the tools, again, are things like some breath work types of activities. There is a Starboard, which is kind of like we call our digital fidget spinner because it's kind of neurodiverse. But there are tools that can be used by the individual that have no human interaction, they are just tools and content.

The next level up, which requires -- that would be guest user access. And if the young person's between 13 and 25, then they can access the human interaction pieces of that. Which then, the next level would be coaching. And those coaching sessions are chat based.

We do also offer tele-coaching to those that prefer not to use the chat based. And we also have video coaching.

And with that particular, the sessions are done with a peer, a certified peer specialist who have gone through the California Certified Peer Specialist program, and all of that that entails. And so, those are chat based, tele-coaching or video coaching.

They are sub-clinical, so it is not with a licensed counselor. Although, we do have LCWs and licensed counselors that provide clinical oversight to our peer specialist team and are also available to get on those chats if there was a need to.

We have an extensive human moderated system in which all chats are moderated by a human to look for risk, and we have an extensive (indiscernible) protocol.

And then, in terms of the second way a young person might interact with a human or provide a little bit higher level -- not higher, but a little bit more extensive level of service would be through our peer community forum. And this is an opportunity in which the young person can either respond to a Soluna created poll or reflection.

And so, the polls are literally kind of like what you would expect, like in Zoom (phonetic), where there's a poll and they get to choose an answer. So, that's how they

respond that way.

Or there is a reflection item. So, it might be a question that the young person can respond to. Any of t hose responses are a hundred percent moderated by a human, peer specialist, or licensed counselor that are looking through those, and have an appropriate safeguarding if there's any concerns. As well as they aren't posted live until they are moderated.

And then, the next level would be the young people also have the opportunity to participate in an age-gated, peer community. And I believe the age on this, and don't quote me, I believe it's 13 to 17 and 18 and above. So, we do have two different peer communities where they can write their own content and post it. But again, before it posts, it's a hundred percent human moderated, where a human is looking at it, evaluating it for risk, making sure it's within our policy and protocol before it gets submitted.

That's kind of the levels in terms of direct. Off-platform, we also do have another piece of Soluna, which is our care navigation. And that is particularly for young people who are engaging in coaching and who have need to connect to other services, and they sign up to be able to do so via the app and connect with a live person to get connected to a service within their community, and do like a direct handoff. So, that's another level.

Also, just state that within the State of California, the legal age of consent to treat is 13 -- sorry -- yes, it's 13. We make we have our own privacy officer that in any state that we are in, we always make sure that we are recognizing that consent to treat.

So, a young person has the ability within this age bracket to consent to their own treatment.

But again, I want to just emphasize that the level of treatment here is coaching and that's with a peer specialist. It's not with a licensed clinical counselor, like you would expect in a traditional setting.

So, I know that's a lot of information to throw your way. And I can definitely follow up with the specific contract. We've been working with Autumn and her team for quite some time at the Department of Health Care Services. We meet with them on a monthly basis. It's very well monitored.

And you'll see that Dr. Schleider has a approval letter from DHCS, specifically, and it cites that they have reviewed the project, we've met with them several times, they are well aware of this. And they are very much in favor of having this additional evaluation done by an external expert in the field of single-session interventions in order to be able to get an unbiased assessment of the impact that Soluna is making for young people within

California.

COMMITTEE MEMBER KURTURAL: And is there any way in the screening process in the front end to track if someone lacks capacity to engage with a human? Lacks capacity, you know, to receive any sort of coaching services?

MS. MISCH: And by lacks capacity, can you tell me a little bit more what you mean in terms of are we talking age, are we talking developmental --

COMMITTEE MEMBER KURTURAL: Not age. Talking development. Because I understand the age cutoff is, you know, 13 and higher. So, I'm not concerned about that because there is a way for them to receive services if it elevates to that level.

I'm talking about if someone has, yeah, a developmental disability or an intellectual disability, you know, what is done to assess that?

MS. MISCH: So, the contract with DHCS which, again, I think I can definitely follow up and see what we could share specifically, does require that it would be free to anyone who is 13 to 25. So, there is no gating in terms of developmental. There's no expectations around that.

Again, I want to emphasize that this is sub-clinical. So, the types of tools and information that's being provided would not be at a therapeutic level,

especially within the content and the tools. So, it would very well probably be developmentally appropriate.

COMMITTEE MEMBER KURTURAL: Okay. I'm just trying to wrap my head around this.

MS. MISCH: And I wonder if, particularly for the Northwestern evaluation, Jessica, if we've spoken to anything that you have in terms of the level of consent and any kind of appropriateness. Because I think that might be more of a concern. The app is going to be what the app is going to be.

COMMITTEE MEMBER KURTURAL: Uh-hum.

MS. MISCH: Because of our contract requirements, that we can't change.

DR. SCHLEIDER: That was our reason for including the capacity to, you know, understand the assent form, that those are meant to identify whether somebody has the comprehension to be able to take part in the study.

But they're -- per the state's requirements, the app must be available to all young people per criterion.

COMMITTEE MEMBER KURTURAL: And one of the things, Jessica, that you talked about was the fact that through the app that if there was a sort of risk situation, where the parents had to be notified because there was some sort of mention of suicide ideation, what -- so, what's the sort of policies, you know, on the app side of handing this.

DR. SCHLEIDER: Sure. So, on the app, I think Gina is better positioned to speak to that.

COMMITTEE MEMBER KURTURAL: Yeah.

DR. SCHLEIDER: It's first identified in the Qualtrics survey, then in the protocol that we outlined in the proposal that we submitted that apply. But Gina, if you could speak to the within app --

MS. MISCH: Yeah, which I'm not sure -- I mean I can talk about that, but I'm not sure it's as pertinent as the study itself.

DR. SCHLEIDER: I agree. It's just there were questions about those.

MS. MISCH: Yeah, so let me start with we absolutely, if it's helpful, can follow up in terms of pulling out that specific safeguarding policy that we have with Northwestern, because I realize that there's a lot of materials and we want to make sure that everybody understands that policy.

I can also provide the safeguarding policy that we have in terms of the app itself and what we categorize as risks, and then what the specific action is. Which is usually signposting to a service, depending on the level of risk. And, of course, mandated reporting, then that's required, right, and so we do have a process for mandated reporting.

COMMITTEE MEMBER KURTURAL: Okay. All right, I don't have any further questions on the app side.

MS. MISCH: These are really great questions, though, and I really appreciate this concern. You sure were snaking through things.

I also just want to encourage; I hope that you'll connect on the website that I provided for the Soluna app. We also have another one, the solunaapp.com/impact. If you're looking for printed materials and you're just wanting to learn more about the Soluna app, that's a great place to go.

COMMITTEE MEMBER KURTURAL: Thank you.

COMMITTEE MEMBER VENTURA: Are there any other comments from Committee members, after reviewing all of the application material?

VICE CHAIR DICKEY: I guess the question that I'm -- children who are wards, do you have a special way to deal with them? You know, who are not with their parents, but are wards of the court? Or would you have a way of identifying them?

DR. RYKACZEWSKA: You're muted, Dr. Schleider.

DR. SCHLEIDER: Sorry. We would ask them to provide a phone number for a caregiver or a guardian, so not necessarily a parent but whoever is identified as their legal guardian.

So, if somebody doesn't -- is not placed with their bio parents, then that's the phone number we would request from them.

COMMITTEE MEMBER LUND: But your question is a good one, Dr. Dickey, because that's a little bit different.

VICE CHAIR DICKEY: Slightly different, yeah.

COMMITTEE MEMBER LUND: Wards of the court is a special circumstance. And my understanding is that they have to have permission from the court to participate. They can't just assent.

VICE CHAIR DICKEY: That's my understanding, too. I'm reading the OHRP guidance.

DR. SCHLEIDER: Would they be able to access Soluna, thought?

VICE CHAIR DICKEY: Yeah, they would. The question is could they consent to be involved in the research.

COMMITTEE MEMBER LUND: Yeah, if they're wards of the court they're in the general population, but they are -- they're not incarcerated, so they would be able to access the app the same way anyone else in that age group would be able to access it.

CHAIR HESS: But they'd have to be -- effectively, they'd have to be excluded from the study.

COMMITTEE MEMBER LUND: Correct.

CHAIR HESS: Okay.

VICE CHAIR DICKEY: Yeah, that's --

CHAIR HESS: Screened out.

DR. SCHLEIDER: Okay. That's the way we have it set up now, in order to achieve a representative sample of Soluna app users, we don't ask about that particular -- about that.

VICE CHAIR DICKEY: But I think the --

MS. MISCH: Would there be a possibility of being able to add -- I think, Jessica, you've got gating on there in terms of the caregiver, of adding in something in terms of being able to further define who the caregiver is, and so that if it happened --

DR. SCHLEIDER: Definitely can. Yeah, that's not a problem at all.

VICE CHAIR DICKEY: Yeah, I think, because the rule says that they have to have an advocate appointed by the court.

DR. SCHLEIDER: Okay.

VICE CHAIR DICKEY: And it can't just be the guardian.

DR. SCHLEIDER: Okay.

VICE CHAIR DICKEY: So, if there's a way you could add that into your screening -- or questions, give us the name of, you know, a parent to contact, and are you a ward

of the court or something like that.

COMMITTEE MEMBER LUND: Yeah, I think if there was a way in the screening to basically make wards of the court ineligible for the study, because they -- it's not just that the advocate would have to give permission, my understanding is that the court, itself, would have to give permission.

VICE CHAIR DICKEY: It doesn't say that here. But I don't think you'll want to go through the process of getting an advocate.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: So, I think you just want to exclude them.

COMMITTEE MEMBER LUND: Yeah, I agree.

DR. SCHLEIDER: Exclude, okay. That's not a problem at all, I would just need to know the exact wording that we'd be asked to use, and we can include that as another exclusionary criteria without any issue.

COMMITTEE MEMBER VENTURA: Okay. We'll work on -- we'll provide you the wording as the exclusion criteria for the screener?

DR. SCHLEIDER: Okay.

COMMITTEE MEMBER VENTURA: Were there any other comments? One minor thing is that in the flyer there is a statement that, "No foreseeable risk associated with the project." I think I would feel comfortable if it was at

least minimal risk because there is potential for loss of confidentiality --

DR. SCHLEIDER: Okay.

COMMITTEE MEMBER VENTURA: -- and sensitive questions being asked and just kind of, you know, feelings around that. I know you say that uncomfortable questions might be -- they might feel uncomfortable answering some of the questions, but if it could just be minimal. I think that was kind of a minor point.

DR. SCHLEIDER: Sure.

COMMITTEE MEMBER VENTURA: But the more important thing is exclusion for the screener for wards of the court.

Is there anything else major that I may have missed, or Carrie?

COMMITTEE MEMBER KURTURAL: Okay, so we have a cohort, my understanding it's 250 to 500 is what the goal is. So, that denominator is pretty low, you know, in comparison.

We have protection against small -- I'm sure you're going to public, right. And you're willing to suppress any numbers under five. But you are asking very granular information about gender identity, sexual orientation, and other things like that. And so, I'm thinking that that number needs to be higher.

DR. SCHLEIDER: Sure, we're happy to adhere to

whatever the --

COMMITTEE MEMBER KURTURAL: And, actually, and I know I see Dr. Ventura's note here, no cell size plus than 11.

But because the denominator is going to be so low on this, 250 to 500, I actually suggest using the CalHHS de-identification guidelines.

DR. SCHLEIDER: Okay.

COMMITTEE MEMBER KURTURAL: Because just so many granular questions in your survey. And we're happy to provide a copy. It's a way to statistically mask that's a little more of a -- I don't know, it's a more scrutinized process than just I'm going to mask anything under 11.

And it might be helpful for this one because it's just, you know, I'm sure you're going to want to publish on demographic information and all of that, so.

DR. SCHLEIDER: No problem at all to follow this. That's very helpful to know. I'd love to receive a copy of those guidelines.

COMMITTEE MEMBER KURTURAL: Okay.

MS. MISCH: Dr. Schleider, I can work with you on that. But actually, as part of what we would be requiring as well, too, and have talked through that with DHCS. In particular I worked for a very long time in terms of projects that data de-identification guidelines and know the

scoring rubric on that, we'd be very much able to do that. I was part of implementing these within San Diego County, when I was there at UCSD.

So, I've actually got a copy of the guidelines right in front of me to ensure those -- we would make sure, because this would be important to do, when we're also publishing a manuscript, as well as a report, to use those guidelines would supersede anything, and they're just more rigorous, and careful in terms of the small numbers. But also, with the way things are shared out in terms of demographics, more region, there's just some granularity there that we know really well.

COMMITTEE MEMBER KURTURAL: Great.

DR. SCHLEIDER: That'd be great, thank you, Gina.

CHAIR HESS: Did we want to request that they change the request form to assent.

COMMITTEE MEMBER VENTURA: Assent, yes.

CHAIR HESS: And are there any other changes to the assent form that we --

COMMITTEE MEMBER VENTURA: No, got that, have noted. Oh, well, we're going to make the -- so, they're going to make the language. Should I make the motion or --

CHAIR HESS: No, we can talk about it, because maybe it was just more detail.

COMMITTEE MEMBER VENTURA: It is, so more detail

on like what --

CHAIR HESS: Exactly how the data's going to be used and what the project is, yeah.

COMMITTEE MEMBER VENTURA: Yeah, yeah. So, more detail on that. But also keeping the grade level appropriate. You said it was high.

CHAIR HESS: Yeah.

COMMITTEE MEMBER VENTURA: I checked most of it. I thought it was eighth grade, but I'll check the entire T of the assent form.

CHAIR HESS: I mean with adults we would want eighth grade. But I think with this age group we may even want younger, like sixth grade.

COMMITTEE MEMBER VENTURA: Sixth grade?

CHAIR HESS: Yeah.

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LUND: These are 14- to 17-year-olds. I mean, they will have barely cleared eighth grade by age 14 so --

COMMITTEE MEMBER VENTURA: So, even younger, okay.

CHAIR HESS: With the caveat that we understand that that may -- that's the goal. But it is sometimes difficult to achieve that in a consent form, while still communicating --

COMMITTEE MEMBER LUND: What you need to.

CHAIR HESS: -- the information. So, we should make it clear that that's like if -- get it as low as you can.

COMMITTEE MEMBER LUND: And there are really good references online for assents. Remember, it's an assent form, not a consent form. So, you have a little more latitude in an assent form in terms of, you know, explaining things. And the language can be very basic.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: So, is that something she could review?

CHAIR HESS: Uh-hum.

COMMITTEE MEMBER VENTURA: Yes.

COMMITTEE MEMBER LUND: And I just want to say, I think that the idea of having the quiz is a great one, right. Because it's a way of knowing that they actually read the form, which a lot of times we don't know if they actually do. They read the form, and they actually understand the material that was presented to them before. So, I think that that's a great idea.

CHAIR HESS: Do we have a copy of the quiz, the questions?

COMMITTEE MEMBER VENTURA: Yes. It's all in the one, the Qualtrics survey document, .pdf, it's 54 pages. So, it's everything from the flyer to the consent -- will be

assent, the quiz questions.

And I believe, Dr. Schleider, if they get a certain number wrong on the quiz, they get kicked back. They have to reread the form, the information, and then take the quiz again.

DR. SCHLEIDER: Correct.

COMMITTEE MEMBER VENTURA: I think they have two tries or -- is it two? Okay, I did read that correct.

DR. SCHLEIDER: They have two chances, yes.

COMMITTEE MEMBER VENTURA: Two chances to pass the quiz, to make sure they absorb the information, and then proceed. Okay.

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

COMMITTEE MEMBER VENTURA: Okay. Is it deferred or conditional approval?

VICE CHAIR DICKEY: Deferred.

COMMITTEE MEMBER VENTURA: Deferred, okay.

So, I'll make the motion for deferred approval --

VICE CHAIR DICKEY: One year.

COMMITTEE MEMBER VENTURA: -- one-year, minimal risk, with the conditions that they will make the following revisions.

One, making -- changing the consent/assent form to be assent only.

I'm just going to wait. Two, in the assent form

include more explanation about how their data will be used and what -- and details about what is expected if they participate.

Also, lowering the grade level, reading level as low as possible. Sixth grade is the target, but just simplify language as much as possible.

The other, in the screening criteria there will be exclusion for -- to identify wards of the court -- or wards of the state.

VICE CHAIR DICKEY: Wards of the court.

COMMITTEE MEMBER VENTURA: Wards of the court, okay.

DR. SCHLEIDER: Is that the exact language we should use?

COMMITTEE MEMBER VENTURA: Yes.

DR. SCHLEIDER: Okay. Okay, not a problem.

COMMITTEE MEMBER VENTURA: And then, finally, will revise the masking -- data masking to align with the CalHHS data de-identification statistical masking.

DR. RYKACZEWSKA: Data statistical masking or --

COMMITTEE MEMBER LUND: To align with the data de-identification guideline.

DR. RYKACZEWSKA: Okay, just align with the data de-identification guidelines.

VICE CHAIR DICKEY: Well, actually, the wards of

the state --

COMMITTEE MEMBER LUND: It is wards of the state.

VICE CHAIR DICKEY: -- or other agency.

COMMITTEE MEMBER KURTURAL: I wonder, do they use wards of the state or dependencies?

VICE CHAIR DICKEY: I don't know.

COMMITTEE MEMBER LUND: Are you looking at OHRP?

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Should we follow up to confirm the language from CPHS?

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Just to give us more time to confirm the exact language we're looking for.

VICE CHAIR DICKEY: Yeah, whether it's wards of the state or wards of the court.

MS. MISCH: Yeah, I'd love that. Being a former ward of the state, as a foster child, I'd love to get some recommendations on how we would word that for a sixth grade reading level, too. If we did have a young person, and would they necessarily know what that meant.

VICE CHAIR DICKEY: Yeah.

MS. MISCH: And then, I know that this is also a concern when it ends up when -- I think we just want to make sure we delineate foster care, and sometimes you also have a caregiver that's -- they're in foster care, but it's a

caregiver that's a family member, and making sure that we --

COMMITTEE MEMBER KURTURAL: Oh, yeah.

MS. MISCH: -- are thinking about all of those. And that we translate that, I think, to the best of our ability so that it's clear in the assent form.

CHAIR HESS: Is there a distinction, really, between a foster -- a child who's in foster care, and a child who's in foster care, but the foster caregiver is family?

COMMITTEE MEMBER KURTURAL: It's all a whole separate area of law.

CHAIR HESS: Okay.

COMMITTEE MEMBER KURTURAL: That, admittedly I've never practiced in. But I have plenty of friends that have practiced in this area. And, yet it is a legal determination that you are a ward of the court.

But I also remember dependency being used. And so, how about this, we can follow up on that and then I'm happy -- I'm willing to serve on a subcommittee for this.

COMMITTEE MEMBER VENTURA: Thank you, yes.

COMMITTEE MEMBER KURTURAL: If you want me to kind of figure out and help you guys navigate this one on that.

DR. SCHLEIDER: That would be great, because I worry that even foster youth fall in their category, if they're 14 may not recognize that term.

COMMITTEE MEMBER KURTURAL: Oh, yeah. Yeah, yeah, me, too.

DR. SCHLEIDER: So, I wouldn't trust their responses to be accurate.

COMMITTEE MEMBER KURTURAL: Oh, yeah. Yeah.

DR. SCHLEIDER: So, it would be great if we could have an add on that we could write.

CHAIR HESS: Does an assent form need to contain the actual term, though, and then can have a subsequent explanation. So, are you currently a ward of the court or state? By that, we mean--

COMMITTEE MEMBER KURTURAL: That might be -- you know, we'll look at the Common Rule. Let me go ahead and talk with someone who's experienced in this area, and in a subcommittee, and then we can figure out what will work for this one.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER KURTURAL: Because, you know, I am concerned of a child not knowing what that means.

VICE CHAIR DICKEY: Yeah. And I'm not absolutely sure that they can't be included in the research, or they absolutely have to have an advocate. But it's gray enough, it looks like it's something we should look into.

COMMITTEE MEMBER KURTURAL: Yeah, I just think we have to follow up on that. Thank you for raising it, Dr.

Dickey, because it -- I wasn't even thinking of that.

DR. SCHLEIDER: I also appreciate you raising that. It's never -- we've done so many studies with parental consent readers, and nobody's ever asked that question before.

CHAIR HESS: Yeah.

DR. SCHLEIDER: So, I really am grateful that you brought it up, because I know I have to look into it further.

COMMITTEE MEMBER VENTURA: Okay. That concludes my motion.

COMMITTEE MEMBER LUND: Okay. And did you move to have a subcommittee with the two of you?

COMMITTEE MEMBER VENTURA: Oh, yes, with a review of a subcommittee by myself and Ms. Kurtural.

DR. SCHLEIDER: Thank you all so much.

CHAIR HESS: So, a second. Do we have a second?

VICE CHAIR DICKEY: Second.

CHAIR HESS: Okay.

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 researchers, thank you to Dr. Ventura. You'll be receiving probably quite a bit of communication from CPHS members prior to receiving a letter. So, thank you.

MS. MISCH: Thank you so much for this. And I also just wanted to do a shout out for Angelique (phonetic), who's been amazing working with Northwestern, and to Soluna in the whole process. We've both said that the customer care that we've received and just the navigating through this process has been probably one our most amazing bureaucratic experiences. So, hats off to Angelique in particular, but then to all of you. Really appreciate this.

CHAIR HESS: Thank you. Okay, I guess we move on to public --

DR. RYKACZEWSKA: Items H through P.

CHAIR HESS: Okay, are they --

COMMITTEE MEMBER VENTURA: Sorry, Dr. Hess.

CHAIR HESS: Yes.

COMMITTEE MEMBER VENTURA: Was there supposed to be room for public comment on that protocol?

VICE CHAIR DICKEY: Oh, yes.

CHAIR HESS: Yeah, can we take public comment after a motion, probably?

DR. RYKACZEWSKA: I think so.

CHAIR HESS: Thank you, actually, Dr. Ventura.

So, is there any public comment from any members of the public who are present on the project just discussed?

DR. RYKACZEWSKA: If you could please raise your virtual hand, if you're on Zoom? And I do not believe we have an in-person attendees. I am not seeing any public comment.

MR. ZADROZNA: Yeah, there's no comments in person.

DR. RYKACZEWSKA: Thank you.

CHAIR HESS: Okay, thank you.

Okay, is there public comment on Items H through P?

COMMITTEE MEMBER LUND: Actually, I have a comment that I think falls somewhere in H through P.

CHAIR HESS: Okay.

COMMITTEE MEMBER LUND: And I just wanted to bring it to the board and ask, perhaps, if we could make time on the agenda at future meetings to have a board discussion. And this is specifically about IPA reviews, but it may occasionally come up for us for Common Rule reviews. And I

know that we're not talking about the regulations package here.

What I am concerned about is that our IPA reviews very often involve datasets that have PII attached to information that may be criminalized by the current administration or in some states.

For example, medical record information that might involve reproductive health care, and specific kinds of procedures that people have received.

Immigration status and status as a nonbinary or transgender individual.

This is in many of our state datasets. And we are sometimes asked to approve these datasets to go to out-of-state researchers, in states that are now passing laws that criminalize some of these behaviors, that can be discovered in these datasets.

And I'm just really, really concerned about this. Really concerned.

VICE CHAIR DICKEY: Wasn't there something, a directive we got --

DR. RYKACZEWSKA: For abortion there is a law that passed and is in effect, in terms -- instructing IRBs to consider when abortion-related data is released to out-of-state, to take that into consideration.

VICE CHAIR DICKEY: That's a California law.

DR. RYKACZEWSKA: That is a California law, yes.

VICE CHAIR DICKEY: So, there is that for abortion.

COMMITTEE MEMBER LUND: So, but I am now -- I am just looking at what's happening nationally. I'm really worried about these other kinds of data and how they might be weaponized against specific individuals.

Especially in light of the fact that the current administration does not seem to have any regard for data privacy and that with the changes that are happening so rapidly, I don't think that we can anticipate funding to university. Federal funding is being weaponized to try to get universities to do things.

And if the federal government were to threaten to withhold funding from universities if they don't turn over data, I don't know what might happen.

I mean, I'm just expressing that as a citizen and a person who's very concerned about these data.

So, I would like if the board, if anyone else shares my concerns, to have a discussion about what we might do with these kinds of reviews. Should we be requiring certificates of confidentiality for these kinds of datasets, when they're going to go out of state?

Should we be asking for assurances from the universities, in which the data will be housed, that they

will not be releasing record level data, you know, if we allow them to hold it.

So, anyway.

COMMITTEE MEMBER VENTURA: With certificates of confidentiality, as you said --

COMMITTEE MEMBER LUND: Uh-hum.

COMMITTEE MEMBER VENTURA: -- can that still, I mean legally, like if it were subpoenaed, or whatever the terminology is --

COMMITTEE MEMBER LUND: So, the current rule -- the current rule around NIH certificates of confidentiality is that it -- the date are protected from being compelled through court order or other law enforcement means.

However, the data still fall under any legislative requirements, like child abuse reporting, or elder abuse reporting, and so on and so forth.

So, the researcher is a -- if the state law requires the researcher is a mandated reporter of child abuse, but a court cannot subpoena the records in a child abuse case. If that helps.

COMMITTEE MEMBER VENTURA: Okay.

DR. RYKACZEWSKA: I just want to note, for the purposes of ensuring that we are adhering to the Bagley-Keene Open Meeting Act, this item is not on the current agenda, so we cannot as a board discuss it right now. But

acknowledging the request to add it to a future agenda.

COMMITTEE MEMBER LUND: Yes, that's the whole purpose. I understand that we're not having the discussion today, or making decisions, or action items today. But my request was that if the board agrees, I would really like to have this discussion at a future meeting.

VICE CHAIR DICKEY: I think it would also be good to involve legal counsel.

COMMITTEE MEMBER LUND: Yes, absolutely.

VICE CHAIR DICKEY: Because there may be other laws that are relevant.

COMMITTEE MEMBER VENTURA: I would like -- like similar to how they prepare kind of like information sheets for the Committee members, if we can ask Jared, or whomever, to also have some information ready for us as far as how to deal -- like understanding, you know, certificates of confidentiality, if we require that, and all that entails.

DR. RYKACZEWSKA: Absolutely, that request is also received.

CHAIR HESS: Are there any other public comments?

MR. ZADROZNA: There's no public comments in person.

DR. RYKACZEWSKA: And I am not seeing any public comments on the virtual attendees.

CHAIR HESS: Okay. Any public comments on items

that were not on today's agenda?

DR. RYKACZEWSKA: If you would like to raise your virtual hand, please do so now.

I am not seeing any virtual hands. Nick, any other public comments on the room?

MR. ZADROZNA: No public comments in person.

CHAIR HESS: Okay. We just want to acknowledge that we received 14 public comments, which should be available to the public. And they've all been (indiscernible) and available to the public at this point.

So, with that, our next meeting will be on April 25th, 2025.

And I guess we can go ahead and adjourn at 11:13.

(Thereupon, the meeting was adjourned at 11:13 a.m.)

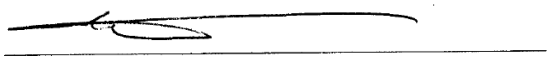
--oOo--

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 21st day of March 2025.



PETER PETTY CER**D-493

TRANSCRIBER'S CERTIFICATE

I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber. And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.
IN WITNESS WHEREOF, I have hereunto set my hand this 21st day of March, 2025.

Barbara Little Certified Transcriber AAERT No. CET**D-520