MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, DECEMBER 5, 2025

8:30 A.M.

OFFICE OF TECHNOLOGY AND SOLUTIONS INTEGRATION (OTSI)

2870 GATEWAY OAKS DRIVE, SUITE 200

SACRAMENTO, CALIFORNIA 95833

AND

ZOOM ONLINE MEETING PLATFORM

Reported by:
Peter Petty

APPEARANCES

COMMITTEE MEMBERS

Larry Dickey, MD, MPH, Vice Chair

Allen Azizian, PhD

Maria Dinis, PhD, MSW

Catherine Hess, PhD

David Lang, PhD

Laura Lund, MA

Philip Palacio, EdD, MS

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

Lemeneh Tefera, MD, MSc

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Nicholas Zadrozna

Karima Muhammad

ALSO PRESENT

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Consultants Present

Cheryl Byers, Advarra Consulting

ALSO PRESENT

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Dr. Joshua Fenton, UC Davis

Ms. Marykate Miller, UC Davis

Dr. Kerry Padgett, CDPH

Dr. Jessica Khouri, CDPH

Ms. Connie Chung, CDPH

Dr. Bridgette Lery, Urban Institute

Dr. Michael Hoyt, UC Irvine

Dr. Marcie Haydon, UC Irvine

Dr. Shannon Whaley, Public Health Foundation Enterprises (PHFE)

Dr. Sami Kitmitto, American Institutes for Research

PUBLIC

None Present

I n d e x

P R O C E E D I N G S

VICE CHAIR DICKEY: Okay. This is the December 5th, 2025 meeting of the Committee for the Protection of Human Subjects.

I'm Dr. Larry Dickey, I'm the Vice Chair.

And please call the roll.

MS. ATIFEH: Sure. I start with Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present.

MS. ATIFEH: Dr. Dinis?

DR. RYKACZEWSKA: Oh, she just joined.

MS. ATIFEH: Okay.

DR. RYKACZEWSKA: Dr. Dinis?

COMMITTEE MEMBER DINIS: Here.

MS. ATIFEH: Okay, good. Thank you.

DR. RYKACZEWSKA: Perfect timing.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Present.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Present.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: The quorum is established.

VICE CHAIR DICKEY: Great. I think on the agenda it says this was transitions. So, one transition is that we are in our new place. Our new office of technology --

DR. RYKACZEWSKA: Office of Technology and Solutions Integration.

VICE CHAIR DICKEY: Solutions Integration, there we go. Okay.

Also transitions, I went to Dr. Lowe's funeral, which was a nice occasion. Our former administrator was there. And as well as I think, Maria, your sister was there.

COMMITTEE MEMBER DINIS: Yeah. She went in my place. I couldn't make it, so I forced her to go.

VICE CHAIR DICKEY: Yeah. Anyway, it was -- you know, and it was at the National Cemetery. And we asked her daughter, you know, what did she do in the Navy. And her daughter actually said she tried to find out, but they wouldn't tell her.

So, I told her I'm imagining that she was a fighter pilot.

(Laughter)

VICE CHAIR DICKEY: She said, well, might have been.

COMMITTEE MEMBER DINIS: I thought she was in the Air Force.

VICE CHAIR DICKEY: You're right, it was the Air Force.

COMMITTEE MEMBER DINIS: Okay.

VICE CHAIR DICKEY: Yeah. Do you know what she did in the Air Force?

COMMITTEE MEMBER DINIS: She once told me it had to do with computers and communications, but I can't remember the exact details.

VICE CHAIR DICKEY: Okay, so she was a spy.

(Laughter)

COMMITTEE MEMBER DINIS: She was a spy. Sure.

VICE CHAIR DICKEY: Anyway.

And then, the next issue is that I'm acting as Chair today because congratulations to Katie for taking a new position. Which is a promotion, but it's in a commission that is outside of the agency. So, technically, she can't serve as Chair.

So, there are things to be established. And I think by next meeting we should have those things resolved. I don't know if you guys remember, Alexander Haig, when Reagan was shot, he was Secretary of State. And he said, oh, don't worry, I'm in charge here. Well, that's how I feel.

Anyway, I will turn it over to Agnieszka, now.

DR. RYKACZEWSKA: Thank you. So, I have a couple of updates to share today. The first one I'd like to start with is the Data De-Identification Guidelines.

So, this is just uplift of recent change at CalHHS. We recently approved a new version 2.0 of the CalHHS Data De-Identification Guidelines template. And we included that as part of the materials for today's board meeting.

Now, as background, the Data De-Identification Guidelines, or DDG, as we have shortened it. They describe a method and a process by which CalHHS (indiscernible) confidential data before the public --

So, this approach is really critical for balancing protecting Californian's privacy, and also offering transparency and (indiscernible) --

So, the first DDG was passed in 2015 and CalHHS -- the departments were then required to use the DDG template, version 1.0, to adopt the present specific version of the DDG. So, the overall DDG is a broad agency-level policy, but the rubber hits the road, so to speak, in the department-specific DDGs, where they become really specific to the data of that department and the processes within that department.

And so, nearly a decade since we adopted that policy, we felt that an update was critical to make sure that we continued relevant, as well as changed and evolved technologies have evolved, as have data packages.

So, for the last three years the CalHHS DDG peer review team, which I am privileged to be a part of, has conducted research, reviewed the (indiscernible) -- to help in inform what is now the DDG Template version 2.0.

So, updates include, we've created consistent risk scoring based on population sizes, and updated our population tables to reflect the 2020 year census data.

We've also add new risk scoring procedures for additional demographics variables, including sexual orientation and gender identity, immigration status, insurance coverage, expected (indiscernible) and public assistance, and deemed sensitive programs and others.

So, it was really a large expansion on guidance for risk scoring for those populations.

We also added a mock-through tables to better guide (indiscernible) -- how to use this this table with some specific guidance.

We also included special scenarios, such as data with increased specificity, high risk populations, and considerations related to artificial intelligence.

And then, we finally, also addressed gaps that were identified in Version 1.0. Such as we didn't previously provide guidance around survey data, and now we do.

So, CalHHS departments have until December 2026 to adopt a departmental DDG that is consistent with the Version 2.0 template. So, I know at least one department has already done so and several more are in the process this month.

And just wanted to share that because I know we often provide that as a resource to our researchers for their consideration when they are working with de-identified data (indiscernible) --

And so, any questions on that one? Yes, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Just a comment. There's a very nice star on page 9 of the document about what constitutes personal information.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER SCHAEUBLE: I would really urge that that be extracted and link that in the CPHS application, considered the way that researchers seem to not always understand the whole breadth of information that really is personal.

DR. RYKACZEWSKA: Absolutely, we can do that.

VICE CHAIR DICKEY: And it says that they -- departments have until December 2026 to adopt their own versions.

DR. RYKACZEWSKA: Uh-hum.

VICE CHAIR DICKEY: But what do we do in the meantime?

DR. RYKACZEWSKA: We can provide the template. The risk scores, themselves, do not change from department to department. It is more about specific, like, the (indiscernible) -- apply to their particular data or not, that changes some of the content, as well as they have to specify their own departmental procedures that essentially verify that the data has been de-identified. And so, that that's what goes into departmental DDGs.

But the broad guidance, in terms of the risk scoring, and the approaches for de-identification stays consistent.

VICE CHAIR DICKEY: And then, the departments will enforce their own specific versions of it?

DR. RYKACZEWSKA: That's correct. And they often require (indiscernible) --

Any other questions? I'll admit this is a (indiscernible) -- it's been a long time coming. And I think after the update we'll see a very (indiscernible) --

COMMITTEE MEMBER SCHAEUBLE: It shows the effort they put into it.

DR. RYKACZEWSKA: I will pass that on to our team, they'll be glad to hear it.

COMMITTEE MEMBER LUND: On a similar, you know, and you've been working on this as well, whatever happened to the common application form. Is that part of this effort?

DR. RYKACZEWSKA: It is not part of this effort. However, it is still slowly getting chipped away at. We have had lower resources than we've had in the past. So, actually, I'm going to call out Nick Zadrozna has been leading that effort for us.

We've been meeting with our agency information security officers, who review all of the security questions and come up with recommendations for an update, whether they should sit in an application, or whether they should be part of the application. What should the researchers be responding to versus what should our information security officers, who have the expertise, to actually speak to it.

So, we're rethinking all of that. It is still going, it is just very slowly being chipped away at.

COMMITTEE MEMBER LUND: And is this something that our (indiscernible) --

DR. RYKACZEWSKA: I do believe we shared that, but I'll double check it.

And, Cheryl, you're online. Have we shared our common application material?

MS. BYERS: I don’t think you have.

DR. RYKACZEWSKA: Okay.

MS. BYERS: And I just made a note to myself to ask for a copy.

DR. RYKACZEWSKA: Perfect. We will share that, then.

MS. BYERS: Thank you.

MR. ZADROZNA: Yeah.

COMMITTEE MEMBER SCHAEUBLE: I’m recalling that several years ago one of our researchers attached a very nice checklist summary to the data security letter, indicating how each of the requirements had been met, and if there were any exceptions to that.

And just recently, another researcher did something very similar.

Those are the only two occasions I can recall seeing something like that.

But somewhere along the way I think it would be worth considering if we could have a template where researchers would do that as part of their data security assurance, rather than all the questions that are on the application form, itself.

DR. RYKACZEWSKA: It’s funny you bring that up because just a few weeks Sussan re-sent that specific checklist to me. Dr.

Schaeuble uplifted this before, we should be considering this as we're going through these security questions. So, perfect timing.

COMMITTEE MEMBER SCHAEUBLE: Good.

DR. RYKACZEWSKA: Yeah, we're taking a look at that. And just this week we started conversations around, essentially, formatting. Right, how do we get, in this updated version, to make sure that we're getting the information that we need and that checklist is something we're definitely considering as part of this conversation.

COMMITTEE MEMBER SCHAEUBLE: Good.

VICE CHAIR DICKEY: I guess I'll ask again if (indiscernible) --

DR. RYKACZEWSKA: We'll (indiscernible) --

VICE CHAIR DICKEY: Oh, okay.

DR. RYKACZEWSKA: All right. Should I go to my second update, if there's no other comments or questions?

Okay. So, recently the Department of Health Care Services reached out to the chairs and the admin team to provide clarification for the requirements for HIPAA waivers.

Specifically, the DHCS clarified that we only accept HIPAA waivers that have been run by CPHS. And they will not accept HIPAA waivers granted by other institutions or other IRBs.

Simply because DHCS can't verify that they were (indiscernible) -- to meet certain criteria. And they currently do not have the capacity to (indiscernible) -- beyond these data.

So, this put forth a little bit of a conundrum for us because our CPHS polies and procedures currently state that CPHS will not consider a waiver, if such a waiver has already been granted by another IRB.

Now, we believe the intention behind this was just to avoid duplicates. If there's already a HIPAA waiver, why should we put forth more time?

But our legal team has examined the laws and rules for (indiscernible) -- HIPAA waivers and have advised us that there is no legal constraint that limits (indiscernible) -- a HIPAA waiver (indiscernible) -- granted.

Meaning that legally CPHS is allowed to grant a HIPAA waiver, even if another IRB has already granted one.

So, given this, I'd like to propose an update to our CPHS policies and procedures to allow CPHS to consider a HIPAA waiver when one has already been granted by another institution, if this has been requested by the data releasing department (indiscernible) --

COMMITTEE MEMBER LUND: Can I ask you a question?

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: So, currently our policies and procedures are, in my understanding, is revised and (indiscernible) -- because there's a lot of other changes in there, as well.

DR. RYKACZEWSKA: Yes, uh-hum.

COMMITTEE MEMBER LUND: So, would this -- and we agreed, almost a year ago, that we would stick with the old policies and procedures and not go piecemeal into the changes that are essential to the policies and procedures manual.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: So, my question is, would this be something that would go into effect immediately, because it sounds like we're in a position where if we have DHCS projects, and we're not granting a HIPAA waiver that puts researchers behind.

But, yet, there are many other important things that we are making an exception for and (indiscernible) -- so, where is the answer to that?

DR. RYKACZEWSKA: I open it up to the Committee. I do know that DHCS has been reaching out, a few times now, with concerns about releasing data because it was not a HIPAA waiver granted by CPHS.

COMMITTEE MEMBER TEFERA: I'm just not sure I understand the concern from DHCS. There is a HIPAA waiver from alternate --

DR. RYKACZEWSKA: IRB.

COMMITTEE MEMBER TEFERA: IRB.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER TEFERA: So, why are they --

VICE CHAIR DICKEY: There could be lots of different IRBs and they have to vet each IRB, and it's a lot of work for them. So, if they know it comes from us, they've already vetted us. That's the issue.

COMMITTEE MEMBER TEFERA: I can imagine (indiscernible) -- an institution, university based.

VICE CHAIR DICKEY: You would think it could be done quickly, but they don't believe it can.

DR. RYKACZEWSKA: Right. Is it something where they would have to unconditionally go through every single IRB and have -- gather information for the IRB criteria. Which I wonder if the researchers do request data from UCS (phonetic), so that could potentially make it longer for IRBs that we would have to vet.

COMMITTEE MEMBER TEFERA: No, those requests, those national requests for in-state requests, or do we know?

VICE CHAIR DICKEY: And it could be hundreds of projects for us because the DHCS is (indiscernible) -- database.

For us, it's -- you know, there is a place on the form, you know, in IRBManager, to request the HIPAA waiver, regardless of what department it's with. But we basically have been ignoring it, if another IRB has already issued a HIPAA waiver.

But the information is in IRBManager, already.

COMMITTEE MEMBER TEFERA: Yeah, I guess I’m -- what I’m trying to sort out is the -- if there’s a responsibility for this Committee to oversee the department. It seems like the department (indiscernible) -- that it’s asking or externalizing the steps involved with CPHS.

DR. RYKACZEWSKA: No. So, CPHS does review HIPAA waivers regardless, right. Right. So, if one hasn’t already been granted currently, if one hasn’t already been granted by the researchers’ IRB, then we would review and decide if we would grant one or not, based off of the information in the application.

COMMITTEE MEMBER LUND: So, our responsibility is to grant or not grant a HIPAA waiver. And our policies and procedures say that we don’t even engage with the HIPAA waiver question if another IRB has granted a HIPAA waiver.

And if I understand things correctly, DHS is saying that’s all well and good, but we’re only going to accept HIPAA waivers from CPHS, and not any other IRB that may have granted it.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: So, that’s -- that’s their policy decision, but it puts researchers, who are applying to us, in a bind. Because, currently, our policies and procedures will allow us to grant a HIPAA waiver if they’ve already got one from their

IRB.

VICE CHAIR DICKEY: They say they've tried to instruct researchers not to go to their own institutions for a HIPAA waiver, just to avoid this issue. But the message doesn't always get through.

COMMITTEE MEMBER HESS: Their institutions might require a HIPAA waiver from their IRB, as well.

VICE CHAIR DICKEY: Yeah. And It's apparently you can't have too many (indiscernible) --

(Laughter)

COMMITTEE MEMBER SCHAEUBLE: Well, let's make more, then.

COMMITTEE MEMBER LUND: And it's usually not too controversial. I mean, usually they're asking for a HIPAA waiver because they --

VICE CHAIR DICKEY: No. It's usually they -- if we would pass along the IPA, we would get (indiscernible) -- because the IPA is basically largely reflecting HIPAA.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: But it's kind of automatic for us, but we have this policies and procedures problem.

COMMITTEE MEMBER LUND: So, I'm just going to say we made this agreement last year and I'm totally in support of revising our policies and procedures (indiscernible) -- but we made this agreement as a Committee last year that we would not piecemeal and put new things that aren't in there.

And so, I guess I would object to implementing the piecemeal of (indiscernible) --

VICE CHAIR DICKEY: Well, I mean in reality the agency can change their policies and procedures without us, and they have done that. So, even if we object to it, DHCS will go to the agency and say, you know, we need to (indiscernible) --

COMMITTEE MEMBER VENTURA: I lean towards sticking to what we voted for and not implementing all these (indiscernible) -- for clarity for everyone that, you know, abiding by some parts of the policy and updating different parts. So, when is the amended timeline for the --

DR. RYKACZEWSKA: So, (indiscernible) -- our people have been working on reviewing our policies and procedures, and many of you have been interviewed, as well. And I believe in February we're anticipating to go through some initial (indiscernible) -- Cheryl, can you please correct me if I've got the timeline wrong?

MS. BYERS: No, that's correct. We are currently working on the policies and procedures and we'll have the initial draft to Agnieszka and Dr. Dickey, maybe, by the end of the year. And then we'll, in January and February, be going through those drafts and then making decision on finalizing.

VICE CHAIR DICKEY: But then it has to go to the agency.

DR. RYKACZEWSKA: Well, we would share with the board members.

VICE CHAIR DICKEY: And share with the board members (indiscernible) --

COMMITTEE MEMBER SCHAEUBLE: So, what is the input process for us on this, to look at what's being proposed and make our recommendations one way or the other?

DR. RYKACZEWSKA: We would be sharing those with the board members, not just the chair. The initial drafting, to answer some initial questions would go through the chair, but this will be shared with the board members before it goes through.

COMMITTEE MEMBER SCHAEUBLE: So, you're anticipating, then, that drafts would be widely circulated sometime before the February meeting, is that right?

DR. RYKACZEWSKA: That is what we are anticipating.

VICE CHAIR DICKEY: Is that a push.

DR. RYKACZEWSKA: That is what we are anticipating.

MS. BYERS: I would say either February or March.

VICE CHAIR DICKEY: There we go.

DR. RYKACZEWSKA: Thank you, Cheryl.

So, I am hearing a general support for not piecemeal updates to the policies and procedures right now, but we'll circle back (indiscernible) --

VICE CHAIR DICKEY: It sounds like we need to let them know they need to make sure they don't have HIPAA waivers for their IRBs, if possible.

DR. RYKACZEWSKA: Okay. Well, then, that completes my report.

I think the next one, the next item might be mine, too.

VICE CHAIR DICKEY: Sorry?

DR. RYKACZEWSKA: I think the next item is also mine.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: So, should I go?

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Okay. So, this is Item C, the nomination of a new chair. I am not Adam Dondro, I'm Agnieszka Rykaczewska.

Unfortunately, with the recency of Dr. Hess' move and (indiscernible) -- we were not able to call (indiscernible) -- to have the chair nominations today.

And so, as a result we're going to move the item to the February meeting.

But I did want to take this moment to just note why Adam Dondro was listed for this item. So, the CDII Director position is currently vacant. And so, if it continues to be vacant in

February, we will ask Adam Dondro to fill the responsibility as a position of the CDII Director (indiscernible) --

COMMITTEE MEMBER LUND: CDII or OTSI? I am confused by all of the --

DR. RYKACZEWSKA: It is a transition.

COMMITTEE MEMBER JOHNSON: A transition.

DR. RYKACZEWSKA: Yeah, it is a transition, so CDII now resides within --

COMMITTEE MEMBER JOHNSON: Okay. Thank you.

DR. RYKACZEWSKA: So, just did want to make that clarification. When we go over to the Chair nomination in February.

VICE CHAIR DICKEY: So, do we have to change the policies and procedures to designate him as the --

DR. RYKACZEWSKA: I do not know. I think, he steps in when the CDII Director is not available.

VICE CHAIR DICKEY: Yeah. So, I guess we move on to review and approval of the minutes for October 3rd meeting.

Actually, before we do that, I want to ask if there's any public comment on the things that we've talked about so far?

DR. RYKACZEWSKA: Acknowledging there is no members of the public in the room, is there any public comment online? If you could just raise your virtual hand. I am not seeing any virtual hands.

VICE CHAIR DICKEY: Okay. So, moving on to the October 3rd, 2025 board meeting minutes. Any comments from the Committee on those, before we vote?

Seeing none, any comments from the public before we vote?

Okay, please call the roll.

MS. ATIFEH: Making a motion.

VICE CHAIR DICKEY: Somebody needs to make a motion, I can't make the motion.

COMMITTEE MEMBER HESS: I move that we accept the meeting minutes from the October 3rd, 2025 meeting.

COMMITTEE MEMBER VENTURA: I second.

COMMITTEE MEMBER DINIS: Motion to approve.

DR. RYKACZEWSKA: It's been made.

COMMITTEE MEMBER DINIS: Oh, sorry.

MS. ATIFEH: Okay. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Okay, the motion passed.

THE REPORTER: Can I ask who seconded, I'm sorry.

MS. ATIFEH: Dr. Ventura.

THE REPORTER: Okay.

VICE CHAIR DICKEY: Okay, now we'll move on to adverse events. The first one is -- is Dr. Fenton or a representative on the phone here? Okay.

This is the Rigorous Evaluation of California Policies to Disseminate Emergency Department-based Services for Opioid Use Disorder.

Dr. Fenton, could you please describe the event for us, please?

DR. FENTON: Sure. I'm Dr. Fenton. I'm at the University of California at Davis. I'm here with our project coordinator, Marykate Miler.

And the agenda suggested we could summarize the methods. Is that correct, you want that first, before we get into the event?

VICE CHAIR DICKEY: If it will help us understand the event.

DR. FENTON: Yeah, I'll be very brief. Our study is particular a large program evaluation using California Medi-Cal claims data to assess the impact of a program called CA Bridge, which is a program that supports substance use services in California emergency rooms.

And we are using Medi-Cal claims data, using the CCW's Virtual Research Data Center. We've used that to identify California Medi-Cal claims and are looking at the impact of patient exposure to these -- to these (indiscernible) -- on the utilization of medications for opioid use disorder, as well as utilization of substance use services as outpatients.

And then, the other outcome is fatal overdoses. And so, to identify fata overdoses, we obtained review -- approval from this IRB to access California's death records. And we were allowed access to -- is that included partial social security numbers and a few other patient identifiers.

And the reason for -- that we requested this is so that we can identify patients who died of opioid overdose and then use -- link those records to the Medi-Cal claims that we have.

And there is a process, we're doing this through the CCW using a binder file.

So, our team follow these procedures and follow the approved procedures to identify the patients with the death records, and then to encrypt those data. And we sent the encrypted data to the CCW data vendor on a thumb drive, according to their instructions.

And we were alerted that the envelope that arrived to them was -- it was torn open and there was no thumb drive inside.

So, at that point we, you know, we realized we had a problem with data loss. There were patient-protected information that were lost on the thumb drive. And we reported this to this IRB, as well as our local IRB and compliance officers, and et cetera.

And so, that's what we're bringing to your attention today and that's the subject of today's discussion.

VICE CHAIR DICKEY: So, you proposed some solutions to prevent this from happening in the future, right.

DR. FENTON: Yeah. Well, I just want to add one other protection that we -- you know, was implemented at this time is, you know, the password for this protected file on the thumb drive was -- there was a password. It was password protected and we did not include that with the thumb drive. It was, you know, the procedures are to send that separately to the data processor. So, that's one important protection that was in place at the time.

To protect future disclosures, you know, we've been in touch with the CCW about this -- about this and, you know, they have told us that because we're working in this virtual research data center we are actually, you know, with -- when we do this in the future, we would be -- we could actually upload it into the virtual center without sending the thumb drive at all.

We were not aware of this because it was not on any of the printed instructions that we received from the data vendor. But it seems that that would be, you know, a highly secure method of getting the data out without, you know, having to deal with courier mail or anything.

So, that's basically what our plan is at this time. I know that's different than what we put -- we notified the Committee about. We had previously talked about more secure methods of courier mail, but we've since learned that we can actually upload the data directly, you know. We're not -- you know, once we have approval from this Committee to do that.

VICE CHAIR DICKEY: Sounds good to me.

DR. RYKACZEWSKA: I was wondering if you give additional information on the encryption method. I know you provided a little bit in the adverse event form --

DR. FENTON: Yes.

DR. RYKACZEWSKA: -- but if you could share it with the

Committee.

DR. FENTON: Of course. The encryption details, you know, the required encryption for the data vendor is that we use advanced encryption standard of 256-bit key. And we -- it's at the level, the encryption level 7-zip.

And this, apparently -- I don't know a lot more about encryption to be honest with you, but apparently this is a very high level encryption that we, you know, that was -- is the federal standard for privacy protections.

VICE CHAIR DICKEY: It was -- it's my understanding that the CDPH privacy officers looked at this, right?

MS. MILLER: Yes. Yes, they have.

VICE CHAIR DICKEY: And what was their determination?

MS. MILLER: They determined that it did not meet the recording -- or the reporting requirement. Let me find their exact verbiage. Yeah, that it did not qualify as a state breach.

"We have determined that that does not trigger notification to any individuals under any applicable laws and we'll be closing this matter."

COMMITTEE MEMBER LUND: So, I have a question. It sounds like you answered it partially. So, have the agencies whose data was involved been informed of this data loss? It sounds like you informed CDPH. Were any other state agencies informed or need to be informed?

MS. MILLER: Just CDPH and CPHS.

COMMITTEE MEMBER LUND: Okay, great. Thanks. And with regard to the changing the data transmission method, that sounds like a great idea to me. It will need, I think, an amendment, a formal amendment to the project to accomplish that. So, I think what we can do today as a Committee is to agree that it’s a good idea and let you know that you need an amendment to do that.

Those are my only two things.

VICE CHAIR DICKEY: Have you talked to the UC Davis? Is that right, IRB?

DR. FENTON: Yes, we have. We’ve informed the UC Davis IRB, the IT department, as well as the UC Davis compliance. And the compliance office investigated this and issued a report, and they’ve also closed the matter.

Our IRB is also -- they haven’t issued a final -- a final report, but they’re waiting -- they wanted to hear what -- they wanted to receive the compliance report and I sent that to them yesterday.

COMMITTEE MEMBER VENTURA: Are the researchers planning to do any data transfer in the near future or can we get the amendment submitted and --

DR. FENTON: Yeah, there is -- there’s no --

COMMITTEE MEMBER VENTURA: -- you’re not sending any in the meantime.

DR. FENTON: Yeah, there’s no urgency to proceed. We can wait for an amendment to be reviewed, that’s not a problem.

COMMITTEE MEMBER VENTURA: I would recommend that, an amendment for a secure data transfer to servers.

DR. FENTON: Okay.

VICE CHAIR DICKEY: Any other comments? I think, either from the Committee or the public.

MR. ZADROZNA: I have a question. Did the package that had the encrypted password, did that every successfully make it? You said you sent it in two packages.

DR. FENTON: Yes. They received -- they received an empty envelope from us.

MR. ZADROZNA: No, but then you sent another package with the encrypted password. You said you sent the thumb drive --

DR. FENTON: No. The encrypted password was never sent because we wait for the data vendor to receive the package, and then the procedures for them are they then request the password to be sent to them by encrypted email.

MR. ZADROZNA: Oh, okay.

DR. FENTON: So, yeah.

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

COMMITTEE MEMBER LUND: So, I move to accept the report of the adverse event and mitigation undertaken so far. I stipulate that the Committee recommend that the data transmission method be changed to the more secure electronic data submission and that an amendment be submitted to make that change.

And I think that that was the only -- was there anything else?

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER PALACIO: I second.

VICE CHAIR DICKEY: Call the roll.

MS. ATIFEH: Okay. Dr. Hess?

COMMITTEE MEMBER HESS: Approve. Sorry.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Okay. Thank you, Dr. Fenton.

DR. FENTON: Okay, thank you very much.

VICE CHAIR DICKEY: We're moving on to the next adverse event, which the effect of Using Infant Feces and Serum for Polymerase Chain Reaction and Assay with Large -- well, I'm not going to do the whole thing.

Dr. Padgett, are you on the line?

DR. PADGETT: I am. And my video doesn't seem to be working, but I'm here.

VICE CHAIR DICKEY: Okay, great. Could you briefly describe for us what happened and how you plan to address this?

DR. PADGETT: Yes. Beforehand do you want me to introduce myself and --

VICE CHAIR DICKEY: Sure.

DR. PADGETT: -- others on the line. Our group, you know, who can answer questions.

So, I'm Dr. Kerry Padgett and I am the Chief of the High Risk Pathogens Section, in the Microbial Diseases Laboratory Branch.

And I work closely with colleagues in the Infant Botulism Treatment Prevention Program. And with me are two of the leads of that program, Dr. Jessica Quarry.

Jessica, do you want to introduce yourself? And Connie Chung, and introduce yourself, too.

DR. KHOURI: Good morning, Committee. I think most of you know who I am. But I am Dr. Khouri, Senior Medical Officer at the Infant Bot program.

And Connie Chung, I'll turn it over to you.

MS. CHUNG: Hi. My name is Connie Chung. I'm an epidemiologist here at the Infant Botulism Treatment and Prevention Program. And our team deals with consenting for the specimens that we receive from families.

DR. PADGETT: So, this event is part of our project. So, we as -- the project in short, is that we receive residuals here at CDPH from infants with suspected infant botulism. We send reports in by the Infant Botulism Treatment and Prevention Program staff, and they're submitted by hospitals to the (indiscernible) pathogens that send to the laboratory to be tested in our Botulism Prevention Center here, at the California Department of Public Health.

The purpose of the project is to allow for development and validation of enhanced diagnostic (indiscernible) for infant botulism using residual feces and/or serum.

So, it has (indiscernible) -- as well as PCR-based (indiscernible).

The adverse event occurred on September 28th. A three-month old had one (indiscernible) -- to obtain serum for this research proposal. The request form was for residual serum, but blood was drawn purposely for this request.

On October 10th, the laboratory received the serum sample. Just of note, the patient was discharged October 9th.

So, the cause of the adverse event was human error and misunderstanding of a verbal request.

So, corrective actions that we took are to draft a script to be used by the Infant Botulism Treatment Prevention Program staff when asking for residual serum from hospital staff. And I'm happy to share what that script looks like. I can share my screen after (indiscernible) --

As well as a revised fact cover letter to highlight that no additional blood draws are to be performed at our request.

VICE CHAIR DICKEY: And then, there's also the question of what to do with the sample that you have?

DR. PADGETT: Right. We maintained it in our laboratory. We did not -- we did not accept it. So, this is pending, you know, review of whether or not this serum sample that was obtained, not as a residual but as a purposeful blood draw, if this is acceptable to be used as part of this protocol.

VICE CHAIR DICKEY: So, I guess there's the two questions. So, one is has a proposal as to how to prevent this in the future. Is that sufficient?

And the second one is what can they do with the sample? Can they use it or not?

COMMITTEE MEMBER LUND: So, I have a question. This sounds familiar and (indiscernible) -- is this the first time that this has happened on this project?

DR. KHOURI: No, it is not. This has happened on a couple of occasions before. We have updated language to make it explicitly clear that it’s only to be residual serum. And we’ve done additional -- as Dr. Padgett mentioned, we’ve done additional updates to the language to make it even more clear that it be residual, and that no intentional draw be done on the patients to provide us with residual serum.

COMMITTEE MEMBER LUND: And who receives that information? I mean, who’s responsible for holding this information and knowing that it needs to be -- I was just wondering because it sounds like there’s some sort of -- there’s a gap between who knows this is how it’s supposed to happen and the person who’s getting the order for it to happen. And so, I’m wondering if you have an idea about that.

DR. KHOURI: Sure. So, I think it would be helpful, Connie, can you walk the Committee through the process where we do the verbal consenting and request any information that we send for the request? I think it will be helpful for their context.

MS. CHUNG: Yeah, of course. So, we follow up with the families, the parents or guardians directly, first. And have a script that we use and we obtain verbal consent. And we make it clear that the request is for blood draws that have already been done, and that no new blood draw should be done per this request.

After the family gives verbal consent, we then follow up with the hospital laboratory and we ask if there's any residual serum leftover from blood draws on the specific date. And once they indicate that there is anything leftover, we ask our request letter that also specifically indicates that it's for residual serum, and then they include consent instructions.

COMMITTEE MEMBER LUND: And so, when you fax it over, I guess this is where I'm trying to find the devil's in the details. So, when you fax it over, who would receive that? I guess what I'm trying to find out on the receiving end is who is responsible for understanding, for knowing and understanding that this only a residual sample, and who would then have made the decision to actually do a blood draw, if a residual sample couldn't be found?

MS. CHUNG: We ask the person in the laboratory that we speak to where we can send the faxed instructions. And so, we ask -- either send it to them directly or we send it to their fax number where they are able to receive those (indiscernible) --

COMMITTEE MEMBER LUND: Does it go to the director of the laboratory, or the chief of hematology or, you know, I'm really trying to find out. Because it's not a consent happening. When you consented the parents, they gave consent with the understanding that nobody's going to stick their child. So, we have to deal with that (indiscernible) -- but I'm in the hopes of really making sure that you've addressed the problem and that it's not happen to another infant. I think that it sounds like there's some uncertainty on the receiving end in terms of who, specifically, is responsible for providing you with the sample and giving the command to draw blood from the baby that doesn't need to be drawn?

MS. CHUNG: So, we don't typically escalate it to a director, if that's not who we're able to reach when we make the initial call to the hospital laboratory. Oftentimes, it's laboratory personnel and not necessarily a director or a manager.

DR. KHOURI: So, I think the challenge is that we're actually making a request to the laboratory because they have the residual in the lab. And that's why we're asking for the residuals from the laboratory, directly.

We could add to the outreach, faxing the same letter to the hospital team that's on the (indiscernible) -- where the patient is hospitalized, for awareness. And that may help to avoid miscommunication between the laboratory and the unit.

As any of you who have worked in clinical inpatient settings before may be aware of there is a lot of turnover of staff, depending on shifts, and it's an academic hospital where this is the case for many of the infants who are hospitalized at tertiary care centers. There are rotations of attending residents and hospital-paid staff, and that lead to the changeover in the lab shifts. Which, of course, we don't have any control over. If the page is originally sent to a lab who's housing residuals serum, and then, you know, changing shifts, et cetera, it gets passed along. Even though we put it in writing and it's very clear in writing -- and I'm happy to share, either Dr. Padgett or I can share a screen if the Committee would like, so you can see what the outreach letter looks like, and the highlight and the bold font. And the explicit instruction not to draw any blood from the --

VICE CHAIR DICKEY: I think you -- I think you've provided that, haven't you, in your materials to us already?

DR. KHOURI: I believe we did submit that on our project, to confirm that the Committee had received a copy of both the fax cover that has the instructions, as well as the letter. If anyone wants to see it, we're happy to share a screen as well.

COMMITTEE MEMBER TEFERA: Just a clarifying question. Hi, good morning, this is Lemeneh Tefera. I work in lots of academic hospitals.

This seems like a, like you said, with staff and changes just a very productive or otherwise helpful for a lot of us that fall into the scenario that you described.

Can you give me a sense of just the total number of samples you've collected versus these incidents, just like the denominator of samples. Just to put this into perspective as far as how often or infrequent this occurs, please.

DR. KHOURI: Sure. Sure. Connie, do you have the updated data on the number of samples? Are you able to pull that? I don't want to quote from my memory. Connie, has that updated database.

DR. PADGETT: Yeah, just one minute. I need to pull that up.

VICE CHAIR DICKEY: Okay, while we're waiting on that, who would have ordered this additional blood draw. It would have had to have been the clinical team, wouldn't it?

DR. KHOURI: It would've been. It would have gone -- the message sent -- we didn't do the complete forensics on this, but I would imagine that what would have happened is that the message, after we requested residual serum, the lab may have identified that there wasn't residual available and communicated with the --

VICE CHAIR DICKEY: The clinical team. Because they had to have contacted them to get the blood draw.

DR. KHOURI: Exactly. And then, they -- you know, they became confused or the letter wasn't transmitted with that request, and the clinical team ordered a blood draw.

VICE CHAIR DICKEY: So --

DR. KHOURI: And then, again, that's speculative. We didn't do a whole, you know -- specifics back then. It's hard. It's hard when we follow up because, again, by that time the team has changed, too, so it's a little bit challenging to figure out who told what to whom.

VICE CHAIR DICKEY: I know. But I'm just saying that trying to improve the wording, where somewhere in there instructing both the lab and the clinical team do not order tests for this, you know, on both sides.

Because, you know, I can see the lab notifying some intern who's half asleep, please order this and, okay. That's how it happens.

DR. KHOURI: Yeah, that's why in our code sending, we could send a letter to the unit, too, and have it placed with the EMR. I'm not sure, you k now again, I don't know that that would be a full proof solution in that they would have to be looking or referencing that part of the EMR or record to know not to write the order at the time where the telephone happened, where the lab told somebody, and somebody told whoever was writing the orders.

VICE CHAIR DICKEY: Nothing's foolproof. Nothing's foolproof, but some things are better.

DR. KHOURI: Exactly. So, you know, if the Committee believes that would be a good solution, as well, in addition to the additional updates we've made to the language, we're certainly happy to include that step and make sure that the team at the site has a copy of the letter to place in the record there. Although, I'm also not certain whether the lab is already putting it in the EMR when we make the request.

MS. CHUNG: On the fax letter, we give our terms for it, on the subject line it says: Request for leftovers, for your information. We also refer to and highlight as we are only able to accept residuals herein. Please do not perform any additional blood draws on the patient.

One aspect we could do is on the subject line is just highlight, you know, residual serum, only, so it's printed in two different ways. So, as you see they just would get the subject, you know, just to really hone it in, you know, no additional blood draws. In case they don't read it (indiscernible)

VICE CHAIR DICKEY: Yeah, I mean that's helpful. But once you have something that the clinical team can see, like in the EMR.

COMMITTEE MEMBER TEFERA: I mean, I think the EMR option, coming from my experience of encountering many unwanted popups in ordering, it doesn't seem like it would be too hard to ask the -- whatever your EMR service is, or your technician team to either put a limit on the order, as far as who can make that order, or have a popup if that order is input with the advice that you have, so that the clinician would see it and know the procedure not to proceed.

Because I think, technically those aren't particularly hard. It might be easier than the faxing solutions in trying to reach, you know, transition team members.

VICE CHAIR DICKEY: Yeah, there's different EMRs, unfortunately.

COMMITTEE MEMBER TEFERA: They all have popups.

VICE CHAIR DICKEY: I know. I know, but it sounds like they can provide the technical solution to each hospital and have the --

COMMITTEE MEMBER TEFERA: Yeah.

VICE CHAIR DICKEY: Or, we could require them to do that.

COMMITTEE MEMBER LUND: Why -- just one change.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: Yeah, I'm not sure that that's feasible.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: But I think something that would go into the clinical record, saying do not draw blood for this specific one.

DR. KHOURI: We can make that a separate request. The clinical team, in faxing the letter we ask that they enter something into their system that no additional blood should be drawn for the CDPH Infant Botulism Treatment and Prevention Program.

However they're able to do that, I'm not sure. And, again, it would be hospital-dependent, and they're system-dependent. But we can certainly add that as a request when we send the letter.

COMMITTEE MEMBER LUND: I have one more question.

VICE CHAIR DICKEY: One more?

COMMITTEE MEMBER LUND: Yeah. So, were the parents notified of the adverse event?

VICE CHAIR DICKEY: In this particular sample she's asking were the parents notified or -- and that leaves the other issue of the sample, itself, would the parents need to be notified if you wanted to use the sample?

COMMITTEE MEMBER LUND: Yeah, so because the issue comes up. First, I think the parents should be notified that there was an adverse event associated with this taking (indiscernible) -- for research.

And then, I don't remember how we resolved this previously for this project, but I know that we have asked in situations that are similar for reconsent. For them to go back and reconsent to be able to use the sample because it was collected outside of what the parents agreed to consent for.

VICE CHAIR DICKEY: Yeah.

DR. KHOURI: So, I'll turn it over to Connie (indiscernible) --

MS. CHUNG: So, if we notify them, we really need to get them a new consent that allow us to limit us (indiscernible) -- really notify them of that, or ask for reconsent for use of the serum.

And then, to answer the earlier question, our program treats approximately 200 patients per year. And we request residual serum for most of these patients, plus (indiscernible) -- serum samples. And since 2021, we've received about a hundred.

VICE CHAIR DICKEY: I just want to point out to the Committee and I'm sure a lot of you have heard, but there's an infant botulism outbreak related to a particular type of formula. And I think you've gotten more of these cases this year than previously, right?

DR. KHOURI: Yes, we've had a record breaking year due to the outbreak. So, BabyBIG made distributions in a number of cases. So, and the outbreak started shortly after -- or the identification of the outbreak started shortly after this was identified and a request of the Committee to appear at the meeting.

So, I think, you know, our goal is to not do multiple follow ups with parents and to try to limit the amount of times that we're communicating with them, when they're at that site.

So, we wanted to wait with this Committee's recommendation so that we were very clear, and we would update what we would be requesting from the parents, and notifying them, and also making any re-requests for reconsent --

COMMITTEE MEMBER LUND: So, I just want to say, for the Committee, that there's an issue of informing the parents that's separate from the issue of reconsent.

In research, subjects who are the recipients of an adverse event have a right to know that an adverse event occurred to them. I mean, that's fundamental.

So, the parents absolutely need to be told that this adverse event happened and that their child had blood drawn that they didn't consent to. So, they need to know that, first.

And then, you can ask them to give their consent to use the specimen that occurred because of this accident. But you have to tell them.

VICE CHAIR DICKEY: Yeah, I think --

DR. KHOURI: Yes, of course. Yeah, we would -- we would have proceeding, regardless, to discuss with the parents. But I think part of that is the parents are logically going to ask what are you going to do with this serum that the hospital drew, and then we would be saying we need to wait for X number of weeks before we have a determination from the institutional review board, or from CPHS. So, absolutely, we will tell the parents.

And we do have a very -- we establish very good rapport with the families of patients who have infant botulism throughout the U.S., and wherever we treat a patient and deploy BabyBIG to. And so, we do very much value that relationship and close communication with them.

I think the hard part is we wouldn’t be able to answer their questions. And they wanted -- the baby would have done the blood draw done by the hospital staff, so we also don’t know what the hospital staff communicated to the family at the time, either. So, that’s --

COMMITTEE MEMBER TEFERA: I appreciate your --

DR. KHOURI: -- the unfortunate part, yeah.

COMMITTEE MEMBER TEFERA: Okay, I appreciate your rationale and I understand.

Just clarifying the numbers, so from 2021 a total of 100 samples and this was the second adverse event, is that right? Adverse event, is that right?

VICE CHAIR DICKEY: I think over the years. This has been going on for 20 years, right?

DR. KHOURI: Several years. I think the original protocol dates back about 12 to 13 years.

VICE CHAIR DICKEY: I don't know if it was in the last two years that we have this previous one, but we did have one.

COMMITTEE MEMBER TEFERA: Sorry, the numbers shared, though, I thought were from 2021, or please clarify.

DR. KHOURI: Correct. So, for the recent, yes. Exactly. So, those numbers of the denominator were from the past few years.

DR. PADGETT: Those are from the most recent numbers. Prior to 2021, we had 148 serum samples reviewed.

COMMITTEE MEMBER TEFERA: All right. So, the two adverse events out of roughly 125 draws.

COMMITTEE MEMBER VENTURA: Of the similar unnecessary draw.

VICE CHAIR DICKEY: We don't know when the other one was. It could have been 2021.

COMMITTEE MEMBER TEFERA: Whenever the other adverse event would be --

VICE CHAIR DICKEY: It could have been further back.

COMMITTEE MEMBER TEFERA: Okay, got it. So, it’s infrequent and rare, which is good.

DR. RYKACZEWSKA: Yeah, it would have been one of the previous --

VICE CHAIR DICKEY: Yeah.

Any other questions from the board? I’ll open it up to the public, any comments?

Go ahead.

COMMITTEE MEMBER VENTURA: Well, given that -- well, we need to notify the parents, I fully agree with that. And regarding the new consenting, this isn’t part of your study protocol to consent to use. So, would a formal, you know, consent form need to be --

VICE CHAIR DICKEY: Well, I don’t think we want to approve something where --

COMMITTEE MEMBER VENTURA: Right.

VICE CHAIR DICKEY: -- you have to notify the parents and then get consent.

COMMITTEE MEMBER VENTURA: Yeah. So, what would they’re --

VICE CHAIR DICKEY: We would want them to notify us, first, because that might just encourage -- no, I’m not saying they would do it, but it might encourage possible to draw blood as --

COMMITTEE MEMBER VENTURA: Will ask for permission after, yeah.

VICE CHAIR DICKEY: Yeah. But I guess the question is do we expect them in this case to notify the parents before they notify us or do they -- we want them to wait for our determination before they notify the parents.

COMMITTEE MEMBER PALACIO: I agree with the rationale to notify us, as we're doing now, before they notify the parents. And, obviously, they do need to notify the parents.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: I agree with that, yeah. And I -- and since nothing (indiscernible) -- I'm sure happened to the child, I think it's fine to go back and tell the parents we need to tell you that, you know, this happened in the hospital. I'm sure that's not the only time the child had blood drawn.

So, I agree with that.

DR. RYKACZEWSKA: And my suggestion was to formalize it in a protocol, so that we have (indiscernible) --

VICE CHAIR DICKEY: Well, I think that what would be in the protocol is that these -- these issues of how they're going to change the protection measure in the hospital. But, still, it would be if this happens, they have to notify us, which we know it's an adverse event. And then, we determine how the parents are notified, or whatever.

In this case, you know, what happens with these adverse events, they get reported to the chairs and then we make a determination if something has to be done right away. And if it was something that was particularly -- we could say to them you need to notify the parents right now.

In this case, the deed was done, we didn't think -- we thought it was best to wait to talk with the Committee.

But it's kind of clear to leave it up to Jared to determine whether we need to take immediate action right now or --

COMMITTEE MEMBER PALACIO: I agree with that.

COMMITTEE MEMBER LUND: And I think the whole point of making the changes that we've talked about today, in regards to changing wording, and adding something, and so forth, that we're hoping that this won't happen again. There is always a possibility that it might.

So, we don't think we need to change the protocol or change the content because of something that may or may happen again in the future.

I think taking the action for this particular event is sufficient.

VICE CHAIR DICKEY: So, it sounds like we need two motions. One about the prevention measures we're talking about and another about what do we do with this particular sample.

COMMITTEE MEMBER LUND: And I think Dr. Ventura still has the same question about what would be needed in regards to the reconsent.

COMMITTEE MEMBER VENTURA: Correct.

COMMITTEE MEMBER LUND: So, I think --

VICE CHAIR DICKEY: It's got to be an amendment, I suppose.

COMMITTEE MEMBER LUND: I don't know because we've handled these previously and it hasn't required an amendment. I think that we have allowed the researchers to directly ask the parents -- if we give permission for the blood to be used, to ask the parents if it can be used with the understanding that it was collected.

VICE CHAIR DICKEY: But usually, when they're consenting somebody, we'd like to have (indiscernible) --

COMMITTEE MEMBER LUND: Yeah, okay.

VICE CHAIR DICKEY: And that could be part of just an amendment, saying for this -- this is what we --

COMMITTEE MEMBER HESS: Well, could it be -- does it need (indiscernible) -- such as this one's adverse event --

COMMITTEE MEMBER LUND: Yeah, yeah.

VICE CHAIR DICKEY: I don't know, can we modify the adverse event report?

MS. ATIFEH: Yes, I can.

VICE CHAIR DICKEY: So, it becomes a part of the measures?

COMMITTEE MEMBER LUND: Because it's just for this one situation, it's not modifying the whole protocol, it's just modifying --

VICE CHAIR DICKEY: But they're going to need to submit an amendment for the prevention measures on what they're going to collect going forward.

COMMITTEE MEMBER LUND: Yes.

VICE CHAIR DICKEY: I mean for the exact language. I mean, we can tell them that we'd like an amendment that says these things. But then, it will be by expedited review when they bring it back.

Somebody want to make the motions?

COMMITTEE MEMBER HESS: Public comment?

VICE CHAIR DICKEY: I asked. Any public comment, further?

DR. RYKACZEWSKA: Acknowledging there's no members of the public in the room, does anyone of the virtual Zoom have any public comments, if you could please raise your virtual hand.

I am seeing no virtual hands.

COMMITTEE MEMBER LUND: I'll try.

VICE CHAIR DICKEY: Go for it.

COMMITTEE MEMBER LUND: All right, so I move that we accept the adverse event report and the mitigations that currently have been taken. And that the Committee approved -- recommends that the researchers submit an amendment to reflect the proposed new wording for the communications at the hospitals.

And also, that the researchers will work with the hospitals to somehow place this information in the EMR for the infant, so the clinical team can be aware.

VICE CHAIR DICKEY: No, that's a second, so we need to vote on that one.

COMMITTEE MEMBER LUND: Okay, so that's -- and I think that's the first one.

VICE CHAIR DICKEY: That's the first.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER HESS: I'll second.

DR. RYKACZEWSKA: Can you just double check that I've got this?

COMMITTEE MEMBER LUND: Okay, yes. Yes.

DR. RYKACZEWSKA: Great, thanks.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

COMMITTEE MEMBER LUND: Okay. The second motion for this adverse event. The Committee asks the researchers to notify the parents of the adverse event and permit the use of the blood drawn from the infant, if the parents provide consent for the use of the blood.

And do they need a consent form for this?

VICE CHAIR DICKEY: Could it just be verbal?

COMMITTEE MEMBER LUND: Yeah. Verbal consent.

VICE CHAIR DICKEY: And do we want to see the language?

COMMITTEE MEMBER LUND: Do you want to see the language?

COMMITTEE MEMBER TEFERA: No.

VICE CHAIR DICKEY: I'll be reviewing it. I mean, as part of the amendment I'll see that.

COMMITTEE MEMBER LUND: Okay, and submit the verbal consent language as part of the amendment.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER TEFERA: Just regarding the (indiscernible) item, you know, the researchers have stated that they were (indiscernible) -- the wording suggests that this is taken directly from (indiscernible) -- to confirm that the researchers are intent on identifying the (indiscernible) --

COMMITTEE MEMBER HESS: They concurred with the researchers --

VICE CHAIR DICKEY: As you intended?

COMMITTEE MEMBER TEFERA: Correct. I think that's more reflective of the (indiscernible) --

COMMITTEE MEMBER LUND: That we can concur with the researchers about it, but we're the (indiscernible) body.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: So, I think that -- you know, I think we really need to ask them to do what we've asked them to do, if they do it on their own or not. I don't know, it's not a help.

VICE CHAIR DICKEY: It’s not a -- but in general we usually give orders, you know.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER TEFERA: Just agree.

COMMITTEE MEMBER SCHAEUBLE: I agree with you.

COMMITTEE MEMBER LUND: You agree. All right.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER VENTURA: Second.

MS. ATIFEH: Dr. Ventura.

Okay, Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: Well, thank you, as always. And thank you for your great work on this important issue.

DR. KHOURI: Thank you very much.

VICE CHAIR DICKEY: And I think --

DR. KHOURI: And do we have a time frame by which you are requiring us to submit the amendment, just so that we're on the same timing.

VICE CHAIR DICKEY: Well, you'll get a letter from us within two weeks. And then, when you submit the amendment, if you let me know, personally, I'll review it immediately. But it's good to remind me.

COMMITTEE MEMBER LUND: So, I guess the time frame is as soon as reasonably possible.

VICE CHAIR DICKEY: Right, yeah.

DR. KHOURI: Perfect.

VICE CHAIR DICKEY: You know, you're not to take any action on this until we get an amendment.

DR. KHOURI: Thank you. Thank you very much for your confidence in our organization.

DR. PADGETT: Thank you.

VICE CHAIR DICKEY: Moving on to the next adverse event, the Evaluating California's Guaranteed Income Pilot Program. And

Dr. Palacio, you're the reviewer on this.

COMMITTEE MEMBER PALACIO: Yes.

Good morning, is Dr. Lery on the line?

DR. LERY: I am. Hello, good morning.

COMMITTEE MEMBER PALACIO: Good morning.

Please go ahead and introduce yourself and your team, and briefly describe the event.

DR. LERY: Sure. My name's Bridgette Lery. I'm the principal investigator for the Guaranteed Income Pilot Program Evaluation that the Urban Institute is leading.

And then, joined by our Project Director, Dr. Jaclyn Chambers.

The project essentially is delivering a guaranteed income on a monthly basis, for 18 months, to a couple of target populations. One is former foster youth, as they age out of the Foster Care System in California (indiscernible) --

COMMITTEE MEMBER PALACIO: Could you go ahead and tell me the exact -- tell the Committee the mitigation efforts?

DR. LERY: Sure. So, we work very closely with the state agencies, California Department of Social Services, that funds and supports the evaluation. The state was permitted to see the names of the individuals involved in other PII, involved with the study.

Urban did not have permission to see PII. We are permitted to see first names, however.

The address event is essentially that on October 17th I, and two other team members on the evaluation team at Urban received an email from our colleague at CHSS, regarding payment information for the Guaranteed Income for youth in the study. That was the topic of the email. And she had thought she had -- the woman who sent the email is aware of the protocols not to send PII to Urban. But she just -- she just forgot and accidentally included both first and last names in the email. Again, the email was not related to names, it just happened to be in the email.

And so, when I saw that I knew that we'd delete it. And went and reported it to our IRB internally, at Urban. And the tech team were instructions to sort of double delete everything. And the other two team members who received the email did not -- had not yet opened it, and so they also deleted the as yet unopened emails.

And so, then that satisfied our Urban IRB and the tech team. So, our next step was to report it to you.

COMMITTEE MEMBER PALACIO: So, in our conversation you confirmed that no additional PIIs were included in the Excel spreadsheets, other than the names, correct?

DR. LERY: Right.

COMMITTEE MEMBER PALACIO: Okay. Let me open it up to the Committee to see if there any further questions or comments.

COMMITTEE MEMBER LUND: So, what are you doing to make sure it doesn't happen again?

DR. LERY: Following the protocol that we had in place, which is that everyone involved with the evaluation, the state team knows that they are not to send PII. Again, this was an accident. She was aware that she wasn't supposed to do that and just forgot.

And so, we iterated that to her. All our partners at the state, the evaluation team and we know what to do if and when something like this happens, to avoid the information, you know, getting any further.

COMMITTEE MEMBER VENTURA: Do you have protocols around like lines, you know, this communication contains PII, for anyone which -- or of that sort? So, that before people open anything, they know what they're going to look at?

DR. LERY: Right. No, because we don't allow email to contain PII. That's part of the protocol would be that they -- if they were to send any PII in the future, if we have it, then it would go through SFTP. And the state does have -- the state's partners do have that information, so when we share data, even when there's not PII, we just go through the SFTP.

COMMITTEE MEMBER LANG: David Lang. What was the extent, how many individual's data were shared?

DR. LERY: Approximately 700.

COMMITTEE MEMBER DINIS: Can I say something? I was wondering, too, if there was a way, or a quick way that IT in your agency could essentially have some kind of reminder email, when people are pulling stuff, to sort of remind them is this, you know, PII information being sent, or something to that effect. So that people kind of like, oh, let me think about what am I sending in this email? Is there a way to do that?

DR. LERY: Do you mean sort of periodically?

COMMITTEE MEMBER DINIS: Yeah, some kind of a reminder email. Because sometimes it's just the kind of thing that people -- you know, you're just sending a lot of email and you're going to forget, and just to have some kind of reminder or thing to the staff.

DR. LERY: Sure. That's fair, we can do that.

COMMITTEE MEMBER DINIS: I don't know what others on the Committee thing, but I just was thinking about it. You know, we go through all kinds of training, right, but then we forget. And we do the trainings sometimes once a year, or every three years, and sometimes in between we just sort of approximately --

DR. LERY: Right. We can certainly do that. I don't know if -- I can also say, the youth, when they signed up for this program, the Guaranteed Income Program, they're agreeing, as a function of signing up for the program, they're agreeing that their data will be shared. That the state has a right to use their data for evaluation.

So, and they said, we don't want PII. We would rather, you know, minimize that information. So, but it's not that the youth didn't think that it's there, that's it's possible, right. We just -- we've taken extra precaution to avoid it because we don't need it. But it's -- we haven't violated their trust in that we are technically allowed to have it.

But we'll be happy to create an email that we maybe send quarterly. Because if too often, I think it would be annoying and ignored. But to be effective, maybe each quarter.

DR. RYKACZEWSKA: So, could a procedure be put in place to, before you open an email with data, or if you're moving to SFTP, even then before you transmit it over from SFTP to -- to verify with the data provider that there's no PII. So, it's like before they even open the -- let me just confirm no PII, right, and kind of --

COMMITTEE MEMBER PALACIO: Right.

DR. LERY: Yeah, uh-huh. I see.

COMMITTEE MEMBER LUND: Yeah, I guess I'm just -- I'm just puzzled. Because if the problem is she just forgot, then maybe she's not being blamed at all in this.

DR. RYKACZEWSKA: I would say both.

COMMITTEE MEMBER LUND: Right. Or, you know, there's not enough in place to make sure the person who essentially sent the information knows, oh, whoa, I don't do this, right.

So, I guess, I think we're all kind of struggling with that here. Because, you know, you have procedures in place but if the problem was not that she'd never heard it, but, oh, she just forgot, then that's not okay.

And I think we're all kind of trying to figure out a way to make sure that this doesn't happen again.

Because even though you have the permission from them generally, for participation in the program, you don't have permission as part of the (indiscernible) -- for PII. So, that's what we're strongly with.

DR. LERY: Okay, so I think we're very, very grateful (indiscernible) -- find her email. And I made it quarterly, does that feel right to everyone as a cadence that would work, that would make sense, which is one solution?

VICE CHAIR DICKEY: If it's more frequent than that, people ignore it.

COMMITTEE MEMBER LUND: Yeah, if it's too frequent people just go, that's that, yeah.

COMMITTEE MEMBER HESS: I mean, I think that's acceptable. And any other procedure that you want to implement, like if there's a project meeting, you know, maybe do some training for new staff who are onboarding. Those sorts of procedures (indiscernible) -- gently nudge and remind staff about this. Will that --

DR. LERY: Will do.

COMMITTEE MEMBER HESS: Nope, go ahead.

DR. LERY: Just saying will do. And then, the other -- other idea for just, you know, confirming that anything with data attached doesn't contain PII.

DR. RYKACZEWSKA: Is the -- are the data transfers on a cadence that you're receiving, where you would know --

DR. LERY: Yes.

DR. RYKACZEWSKA: Okay. Okay.

DR. LERY: You know, this is ad hoc.

DR. RYKACZEWSKA: Okay.

DR. LERY: And again, anything that would be a data transfer is not done through the (indiscernible) --

VICE CHAIR DICKEY: Any further comments from the Committee?

Any comments from the public?

DR. RYKACZEWSKA: Acknowledging no members of the public in the room. If there's anyone on the Zoom who would like to make a comment, please raise your virtual hand. I’m not seeing any.

VICE CHAIR DICKEY: Dr. Palacio, would you like to make a motion?

COMMITTEE MEMBER PALACIO: I move to accept the report and the mitigation efforts partly made. And recommend that reminder emails be sent quarterly to staff. And enhanced training measure to prevent reoccurrence of this event.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER SCHAEUBLE: I’ll second it.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: Thank you. And you’ll receive a letter from us in two weeks.

DR. LERY: Sounds good.

VICE CHAIR DICKEY: Okay.

DR. LERY: Thank you very much, everyone.

VICE CHAIR DICKEY: So, moving on to new projects now, we have -- we’re going to try to have like a ten-minute break at some point. I would recommend we do this new project then have a break, unless people want to have a break now.

COMMITTEE MEMBER PALACIO: I move that we have a break now.

COMMITTEE MEMBER HESS: Second.

(Laughter)

COMMITTEE MEMBER DINIS: I’ll be leaving now, thank you.

DR. RYKACZEWSKA: We are taking a ten-minute break. We will be back at 10:13.

(Off the record at 10:03 a.m.)

(On the record at 10:13 a.m.)

VICE CHAIR DICKEY: Do we need to go around again to call a quorum?

MS. ATIFEH: Yes. Let me start with Dr. Dickey.

VICE CHAIR DICKEY: I think I’m here.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: My apologies, what is --

DR. RYKACZEWSKA: Are you here?

MS. ATIFEH: Checking you're present.

COMMITTEE MEMBER AZIZIAN: Yeah, I'm present.

MS. ATIFEH: Dr. Dinis?

DR. RYKACZEWSKA: Dr. Dinis has left.

MS. ATIFEH: Oh, left. Okay.

VICE CHAIR DICKEY: We still have a quorum.

MS. ATIFEH: Yes.

Dr. Lang?

COMMITTEE MEMBER LANG: Present.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Here.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Present.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, a quorum is established.

VICE CHAIR DICKEY: Okay, so we move to the new projects. And the first one is Understanding Adverse Biopsychosocial Outcomes and unmet Needs Among Long-Term Young Adult Survivors of Testicular Cancer. And Dr. Schaeuble is the primary reviewer.

COMMITTEE MEMBER SCHAEUBLE: Dr. Hoyt, are you here with us?

DR. HOYT: Yes. Good morning.

COMMITTEE MEMBER SCHAEUBLE: Good morning. And do you have any others with you today or is it yourself?

DR. HOYT: Yes. Dr. Marcie Haydon is here, who is our Study Coordinator and probably the best to answer questions.

COMMITTEE MEMBER SCHAEUBLE: So, could you begin by providing a brief summary, for the Committee, of your research?

DR. HOYT: Sure. We have been conducting intervention studies with young adults with testicular cancer, that’s been funded by MCI.

This study is related in the sense that it was generated from a supplement to that parent grant. And the focus of this sub-study is to focus on longer-term survivors, who are still young adults, of testicular cancer.

And it’s pretty basic in the sense that we are going to recruit longer-term survivors of testicular cancer, who are still in the young adult age. And we’re going to do a one-time day collection of self-report questionnaires, with a focus on what being asked questions (indiscernible)
-- as they relate to survivorship, as well as relationships that sort of underscore our intervention. With the thought that in future studies we’re sort of assessing the appropriateness of the intervention approach for longer-term survivors.

VICE CHAIR DICKEY: Okay. So, I had exchanged some comments with you earlier. And thank you for responding in some depth to many of those comments. That was very helpful and I realize the time schedule was rather compressed for you to do that. But I do appreciate it.

I think there are probably three main areas that I would like to follow up on, that I still have some questions about.

The survey for your project is a lengthy one. It’s 24 pages long, with a great number of questions. Many of which may likely seem rather personal to the people responding to the survey.

In the description of your procedures you talk about maintaining a separate file that has the names of respondents and associated ID number from the survey.

And I’d like to suggest that you reconsider that aspect.

The reason that you gave for doing this, you said the use of numeric identifiers is necessary to track recruitment, ensure participants only take the survey one time, ensure the survey team does not contact participants who have already taken the survey for follow up. And conduct responder/nonresponders analyses at the close of the study.

I think an alternate approach here would be to make sure that you provide each name with one, and only one, unique access code to the survey, but not retain that ID number in connection with names. As long as you separately have a list of the names of people you have contacted, a list of names of the ones who have either declined to participate or were not reachable.

And because of the gift card that you're proposing to people, you would also have a list of names, at that point, of people who have completed the survey.

It seems to me that having the survey, itself, linked in any way to names doesn't contribute to your ability to do any of the goals that you've outlined.

And not adding the survey link does two very important things, in my mind. First of all, it's much more protective of the individuals, for the very extensive personal information you're asking about.

And secondly, I would think that the quality of the responses would likely be better because if you can tell people in your consent form that their responses will not be linked in any way to their names, I think they are likely to be more forthright in their answers to your questions.

And then --

DR. HOYT: Yeah, I --

COMMITTEE MEMBER SCHAEUBLE: Go ahead.

DR. HOYT: Marcie, do you want to -- I think I -- I think you’re right in many ways. Marcie, do you want to address this one?

DR. HAYDON: Yeah, I can speak to this. And thank you for bringing -- you know, bringing that up to us. Because I do think that that’s important for maintaining confidentiality and privacy.

And so, the way that we sort of conduct it is we’re a primary preventive entity through the California Cancer Registry. So, we would, you know, sort of give each individual a unique code. That code would be sent with their recruitment material. And then, when they would access the survey they would input that code the very first thing that they input.

In no way will the data be connected to the names at all. So, the sort of lift of the names and the code completely separate, very secure, you know, accessible only to me, study coordinator.

And then, the data would be completely separate.

But it would have that sort of code when they first enter into the REDCap survey. And again, that's the reasons that you mentioned just, you know, that we could make sure that they only take it once.

If we needed to, we could go and look, and then I could sort of see who we need to contact, who we don't need to contact.

Sometimes, in past studies, when people provide their name it doesn't quite match the registry. So, having that code to be sort of a second way of identifying people, that they would not be kept together. All data is completely separate, so there wouldn't be any names or anything with the data.

DR. HOYT: But we will still need the list that connects --

DR. HAYDON: Yeah.

DR. HOYT: -- the code to the participant that we invited. We would, on our end, have that link and so we'd destroy it, which we would after we're finished with collection. But the code is the invite.

COMMITTEE MEMBER SCHAEUBLE: I'm not seeing that it's an advantage for you to maintain such a list at all. Once people have received the access code for the survey, I don't see that that access code contributes to anything subsequent as far as your activities are concerned.

And I understand that you’re saying you would keep the data separate. That’s what people often do in research projects. But in this instance, I just don’t see the advantage of maintaining a list of names and code numbers for the survey. People are potentially identifiable as long as that list exists.

DR. HAYDON: I think there’s one thing that’s sort of comes up, especially with the way that the study, you know, runs. It’s that people will do a very short self-screening to make sure they have all of the criteria before they get access to the survey.

So, we wouldn’t have any information on who has sort of screened out of the study. So, if they, you know, were let’s just say not five or more years past diagnosis, or treatment, then we wouldn’t -- you know, we wouldn’t know who that is. We would just sort of know that, you know, X amount of people screened out, because we don’t collect names or information with that.

So, that could be sort of one instance where we wouldn’t necessarily want to make a follow-up phone call to those folks who have sort of screened out of the study. We would kind of want to know before we contacted.

So, I think it’s things like that. But I certainly understand your point about, you know, if it was anonymous survey that would be the highest level of protection that we could achieve.

DR. HOYT: I think (indiscernible) -- that Marcie wouldn't be -- (indiscernible) -- report back to the California Registry that someone has screened and was not eligible.

DR. HAYDON: Yes. Yes. Well, yeah, so we do, in our reporting data we do send that back. And the only time in the survey that we collect any sort of name or anything is if they kind of transfer out to a different survey to collect it for compensation.

So, only those who make it all the way through would be those that we would be getting information. And I think for the California Cancer Registry, we would also need to provide information about who was ineligible, but we don't collect names with the screener.

COMMITTEE MEMBER SCHAEUBLE: I think I'm not quite following you on what you are doing with the responses to the screener question that would cause you to report back to the Cancer Registry. I don't believe that is described in any way in the protocol. Can you explain?

DR. HOYT: My understanding is when we finish our study we're required by the Registry to indicate the outcomes of C-statistics, whether or not they screened ineligible, participated or not. I think that's their general operations.

COMMITTEE MEMBER SCHAEUBLE: So, if you have names of people who started the screener and they don't go on to the survey itself, those names would not show up along with people who have done the survey. So, if it's simply a case of reporting that people did not pass the screening questions and were not able to go on to the survey itself, it seems you would still know that from comparing the list of names contacted with the names of people who did the survey.

The difference is ones who didn't do the survey, they screened out.

COMMITTEE MEMBER VENTURA: You can't distinguish, though, who's ineligible versus who may be --

VICE CHAIR DICKEY: Yeah, maybe they can explain it to us.

COMMITTEE MEMBER HESS: I am not convinced there's a requirement for -- and, Laura, you're shaking your head -- from the Cancer Registry. So, I would want to confirm with the Cancer Registry that this is a requirement that they are placing on you.

COMMITTEE MEMBER VENTURA: To report back to them.

COMMITTEE MEMBER LUND: I've been working with Cancer Registry data for a decade --

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: -- and I've never seen this as a requirement, ever.

COMMITTEE MEMBER HESS: And I don’t -- probably not need it, but maybe is a need.

COMMITTEE MEMBER LUND: Is it in your data use agreement that you have with them? Where is this requirement located?

DR. HOYT: Why don’t we -- because if we don’t need to report it, then we don’t -- right, we can unlink them from the survey.

So, I’ll ask them to just clarify if that’s a requirement for the Registry and we can remove it, if it’s not.

COMMITTEE MEMBER HESS: That sounds good.

COMMITTEE MEMBER LUND: So, if my understanding from this is correct, if you go back and clarify and it turns out not to be a requirement, then Dr. Schaeuble (indiscernible) -- is concerned and talked about not retaining the names data. Correct?

COMMITTEE MEMBER SCHAEUBLE: Yeah --

COMMITTEE MEMBER LUND: And if it sounds like it’s a requirement, they would need to in order to fulfill their obligation to the Registry.

COMMITTEE MEMBER SCHAEUBLE: Yes.

VICE CHAIR DICKEY: All right. Are there other concerns?

COMMITTEE MEMBER SCHAEUBLE: Oh, yes. So, ideally then, you would make it totally anonymous and have a link of the survey that would go to an entirely separate survey for purposes of getting the contact information for the gift card.

And unless you can verify in some way that there is a Cancer Registry requirement that we seem not to be familiar, that’s the process that we’re proposing that you do. And I understand you’re saying you can’t.

Okay, secondary. There’s a discussion in your protocol in several places about medical record numbers, and in the recruitment aspect of this you talk about most of the participants coming from Cancer Registry, but some from screening of medical records at UC.

It wasn’t clear to me, at least, exactly how that screening takes place and it wasn’t clear to me why there would be any need to retain medical record numbers. It seems to me that those would simply point to the contact information for the individuals you’re trying to reach. And that once you have that contact information, the medical record numbers would be irrelevant.

So, can you describe the process that’s taking place there and the situation with regard to medical record numbers?

DR. HOYT: Yeah. Yeah, and you’re absolutely right. So, we get, through our honest broker, and validate through the UC --

COMMITTEE MEMBER SCHAEUBLE: And when you say -- when you use a name like that, I at least am not familiar with that term. So, honest broker doesn’t explain to me what that process is.

DR. HOYT: Yeah. So, (indiscernible) -- will submit to our UC IP, you know, a medical record entity, criteria for them clearing our medical records system. So, they do that. We don’t do that ourselves. We say, here’s our eligibility criteria and they send back a list of medical record numbers that we have criteria, and then it’s in our hands to get the contact information for those folks who may be (indiscernible) -- so, in that sense the medical record numbers are known to us at that point for us to get the contact information.

Once we get the contact information, we follow the same contact procedures that we would if they were known to us through the California Cancer Registry. And that’s where our involvement with the medical record ends, and the medical record numbers are destroyed on our end.

COMMITTEE MEMBER SCHAEUBLE: Okay. And it is your staff who search the medical records for the contact information once you have the list of numbers that have been provided to you.

DR. HOYT: That’s right.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I think some clarifications in the protocol would be needed surrounding those points.

Let me double check here, now, there was a third item. And the final thing I had was I looked at the resource sheet that you added for the materials you sent back most recently, as information that participants in the survey could use, if they wanted to.

And I was -- I was reflecting on the -- both the questions in the survey and the material in the resource sheet. And it occurred to me that someone answering your survey questions could, I think, easily conclude, well, I'm certainly not suicidal, but I'm not doing as well emotionally as I used to, or as well as other people my age seem to be doing.

And in that kind of situation, it wasn't clear to me that the resources on your sheet would provide help in that regard. There are a lot of resources, many, many, with information about cancer. Most of them testicular cancer, but others as well.

But as far as emotional support, or mental health support I didn't -- I wasn't able to detect much that seemed to be helpful in that regard.

And I'm wondering if you could revise the resource sheet in some way to be more helpful in that regard.

DR. HOYT: Yeah. Yeah, and we are certainly willing to enhance it to see if there's a little bit more of the things on emotional support. It's a sad reality. A lot of availability on emotional support, which is why we do the work.

And generally, these are long-term survivors, they're not in active treatments. And I suspect, from knowing the data that, you know, the vast majority, you know, should be familiar with their -- at least with sort of their diagnosis and cancer-related information.

But I think you're right, if resources are useful it would be more on if they're supportive. So, we can definitely try to enhance that aspect for the resource sheet.

COMMITTEE MEMBER SCHAEUBLE: Okay. So, those were the three areas that I wanted to discuss with you.

And I'll ask the Committee to weigh in with other thoughts or questions that they may have.

Laura?

COMMITTEE MEMBER LUND: I have a couple of things. And my apologies, because I believe that the version that I read is probably prior to your questions, so some of these things may have been resolved. So, you can just tell me if that's been resolved or not.

There's a request for a HIPAA waiver, but none of the data that you're requesting is subject to HIPAA. Self-report data are not subject to HIPAA and CCR is not subject to HIPAA. And those are the only two data sources that I saw.

VICE CHAIR DICKEY: Everybody wants a HIPAA waiver.

DR. HOYT: Yeah.

COMMITTEE MEMBER LUND: And so, I don’t think we should be granting HIPAA waivers when they’re not appropriate.

COMMITTEE MEMBER SCHAEUBLE: We were not asked for a HIPAA waiver. The UC IRB provided a limited HIPAA waiver only to screen medical records for recruitment.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER SCHAEUBLE: That was what was in their document.

COMMITTEE MEMBER LUND: Okay. So, I’m going to scratch it out. You’re not asking us for a HIPAA.

There was a request for an informed consent waiver. And I’m wondering why? I didn’t see anything that would make me believe that people couldn’t be appropriately consented before proceeding with the survey.

DR. HOYT: Marcie, you want to address that one?

DR. HAYDON: Yeah. So, with our UC IRB, if it’s just a survey and it’s only online, they waive consent. And then, we provide what they call the study information sheet.

So, in this case they, you know, asked us to proceed with kind of providing the study information sheet which has some of the information that you would find on the consent form. We just don’t need to get that formal signature.

So, that's kind of the protocol that we have here.

COMMITTEE MEMBER SCHAEUBLE: It's not a waiver of consent, Laura, it's a waiver of --

VICE CHAIR DICKEY: It's a waiver of written.

COMMITTEE MEMBER SCHAEUBLE: Waiver of signed consent.

COMMITTEE MEMBER LUND: So, I just want to make sure because people get these things mixed up. Yeah, there's a difference between a waiver of informed consent and waiving documented consent.

COMMITTEE MEMBER SCHAEUBLE: Right.

COMMITTEE MEMBER LUND: And I am -- I think it's perfectly find to be documented consent, as long as they go through the informed consent process. You don't have to have a signature on a written form to have informed consent. So, that would be -- so, I would just ask that there be an informed consent process.

Dr. Schaeuble can make sure that that's --

COMMITTEE MEMBER SCHAEUBLE: You may not have seen the most recent version.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER SCHAEUBLE: The information sheet was updated with a number of requests that I made. One of which was to explicitly give people a choice at the end of the consent form to say either yes, I’m willing to answer the survey or, no, I’m not willing to participate.

COMMITTEE MEMBER LUND: Great. That sounds -- that sounds absolutely sufficient. So, thank you. As I said, I may not have the changes that happened with your discussions.

VICE CHAIR DICKEY: But I think it’s good to point out. I think they often get the two confused.

COMMITTEE MEMBER LUND: I also didn’t see that the CCR brochure was going to be provided to folks, and that is actually a CCR requirement. So, if you could make sure that that’s in the packet of informational materials that participants receive.

And I think everything else was addressed. Okay. The consent was main thing, so thank you for clarifying that. I appreciate it.

DR. HOYT: Okay. Can I ask one question about the CCR brochure? Because I feel CCR has changed some things over the years. But is a link to their online brochure sufficient in this case, if they have an electronic version of that.

COMMITTEE MEMBER LUND: So, I think as long as they get the CCR brochure, in whatever format you are providing them other materials for the study, then that is sufficient. So, if everything is electronic, then I would think that having the CCR brochure will be fine.

You might want to, I don't speak for CCR, so you might want to clarify that with them, since it is their world.

DR. HOYT: Yeah. Yeah. They have allowed that in the past, but I wanted to make sure it was sufficient for you.

COMMITTEE MEMBER LUND: If it's okay with them, it's okay with me.

COMMITTEE MEMBER SCHAEUBLE: Is your primary contact by phone with reaching participants or by -- you don't have email addresses, do you?

DR. HAYDON: For CCR, we will have email addresses. For some of the people that we recruit through the UCI help, we'll have email addresses. But for CCR, we'll only be recruiting first with a physical letter. So, we can certainly include something in that mailing, whatever format, whether it's a link on the recruitment letter or an actual template.

And then, we follow with a phone call after the letter, if we haven't received a response within two weeks.

COMMITTEE MEMBER LUND: If you're sending them over a cover letter, I think you should send them the brochure.

COMMITTEE MEMBER SCHAEUBLE: So, if the initial contact is by letter, then include the brochure along with the letter.

COMMITTEE MEMBER LUND: Not just the link.

DR. HAYDON: Yeah, we can do that.

VICE CHAIR DICKEY: Any other comments, questions from the Committee?

How about from the public?

DR. RYKACZEWSKA: Acknowledging there’s no members of the public in the room, if there’s members of the public online who would like to make a comment, please raise your virtual hand. I am not seeing any virtual hands.

VICE CHAIR DICKEY: Dr. Schaeuble, do you want to move a motion?

COMMITTEE MEMBER SCHAEUBLE: Okay. So, I will move deferred approval, for one year, at minimal risk, with the following changes to be reviewed by a subcommittee of myself.

First, the survey will be made anonymous by not retaining a linkage between names and ID numbers for the survey, and having a separate survey for contact information for the gift card.

If there is a requirement to report to CCR individuals who did not pass the screening question, the protocol would come back to the reviewer for consideration.

Second, the protocol will explain that medical record numbers will not be retained once contact information has been extract for potential participants not coming from CCR.

Third, the resource sheet will be revised to provide some emotional support resources.

And fourth, the CCR brochure will be included in the initial mailing to potential participants from that source.

VICE CHAIR DICKEY: Is there a second?

COMMITTEE MEMBER VENTURA: I second.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Hess

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Motion passed.

VICE CHAIR DICKEY: Thank you very much. And you will receive a letter from us in two weeks regarding this.

COMMITTEE MEMBER SCHAEUBLE: And, Dr. Hoyt, I will mention to you that I had put an initial draft of comments on the points that we discussed with the Committee here today in the protocol, which you haven't been able to see, yet. But those will be visible to you this weekend about the things that we've talked about today.

So, you'll be able to look at that even before you receive the letter from the Committee. So, you'll have a chance to go ahead and work on some things before the formal letter even arrives.

DR. HOYT: Great. Thank you so much.

VICE CHAIR DICKEY: Okay, moving right along. I just want to -- I think we kind of have a hard stop at 12 o'clock. Some of the members have -- so, if we can possibly get these next three projects done.

So, the next project is Evaluation of the 2026 WIC Food Package Changes. And then, Dr. Ventura is the reviewer.

COMMITTEE MEMBER VENTURA: Dr. Whaley, are you on the call? Okay. Good morning, still.

Can you please introduce yourself and any team members that are with you this morning?

DR. WHALEY: Sure. Good morning, all. It's nice to see you all sitting together around the table again, after all of those COVID years.

And a special thanks to Ms. Atifeh. She has just been so lovely to work with and I really want to appreciate her in front of everyone.

I have Meg Demment here, also from CDPH -- I'm from CDPH WIC.

So, a new year and it's time for another WIC food package change. Many of you have been on this IRB Committee for a few years. Back in 2008 we did the first IRB for the 2008 WIC food package change. And now, in 2026 the WIC food packages will change to align with the federal guidance.

So, in 2009 we were the state that got out ahead and had a great study, thanks to all of you. And we want to do that again.

So, our study is to do two basic data collections. One before the food package changes next April and one about a year later. So, before and after the food package change.

So, our goals are really to understand how this change impacts redemption of WIC food and participation in the WIC Program. Both data elements we can capture from our existing administrative WIC data, so that reduces the burden on participants that they don't have to give us more information.

But we also want to understand how the food package impacts food intake, diet quality, food security, food purchasing and perceptions of the package. And for that we need a survey.

So, thank you, Dr. Ventura, I've really appreciated your back and forth in these last few weeks, and I loved how quickly you got responses back to us. Thank you for that.

So, in order to do that survey we will be pulling a random sample. Thanks to Meg and her team. All of that will come out of CDPH. A random sample of about 20,000. We'll some of them in January. Of course, pending approval of this proposal.

But the goal of 4,000 in our sample in February/March of 2026. And then, we'll follow that cohort a year later.

Dr. Ventura, does that suffice as an overview? Anything else?

COMMITTEE MEMBER VENTURA: That's sufficient for me. I had a few things. It's a large, a large team, and I realize that you weren't able to add them all in IRBManager, but we will see that in a future amendment, just for the Committee's awareness that they'll be adding more research team members.

My main concern was around language in the consent. Just thank you for making those revisions that I had suggested. Mainly, describing the linkage of their survey responses to some other sensitive WIC data, that people were aware that that would be linked to their data.

And then, I think this is related to a previous comment from the previous protocol, but they asked for a waiver of informed consent. But I think it's --

VICE CHAIR DICKEY: Documented consent.

COMMITTEE MEMBER VENTURA: -- actually a waiver for document -- yes, it’s actually a waiver for documented written consent because you do go through a consent script, which we worked on back and forth.

And so, there is a consenting process in giving the individuals information about the risk, the use of their data, give contact information if they have questions. So, I was satisfied with that, in your script.

So, I think we just need to modify your informed consent procedures as described, and that you’re asking for a waiver of documented informed consent, rather than -- you’re not asking for a waiver of informed consent.

DR. WHALEY: Correct.

COMMITTEE MEMBER VENTURA: So, that was just the last thing that I wanted to see amendment. And then, I open it up to Committee members for their comments on this protocol.

COMMITTEE MEMBER LUND: I had a couple things. And you may have changed these on your back and forth, so just stop me.

COMMITTEE MEMBER VENTURA: Yeah.

COMMITTEE MEMBER LUND: So, the invitations that they’re being invited to talk about include things like shopping, and so forth. It doesn’t specifically say they’re being invited to participate in research. And I think it’s an important part of the recruitment process that they be told that they're being invited to participate in research, because it (indiscernible) --

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LUND: The consent that I saw -- yes, I also have a comment that they be informed that their answers will be linked to potentially sensitive data. The current (indiscernible) follow up also needs to be somehow in the consent or noted somewhere that they --

COMMITTEE MEMBER VENTURA: They will be followed up a year later.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER VENTURA: That has been added.

COMMITTEE MEMBER LUND: Okay, great. And then, loss of confidentiality as a risk, especially since they're talking about (indiscernible) --

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LUND: I think I saw it in the protocol that CDPH will have access to the study data and not just the original data that they send. So, they need a data security letter from CDPH as part of the study.

COMMITTEE MEMBER VENTURA: Sorry, say that again?

COMMITTEE MEMBER LUND: So, I think I read in the protocol that WIC staff at CDPH will have access to the study data.

And if that’s correct, we need a data security letter from CDPH.

COMMITTEE MEMBER VENTURA: Dr. Whaley, can you confirm that that’s correct?

DR. WHALEY: Sure. We have our data security letter from PHFE on file in the application. With the new request, do you also need one from Meg’s team? We haven’t needed that on any of our prior work with CDPH, but that doesn’t mean -- I’m not trying to negate that that’s needed, now. But that would be a new request.

COMMITTEE MEMBER LUND: It depends -- it depends on whether CDPH will have access to the study data --

DR. RYKACZEWSKA: For storing WIC.

COMMITTEE MEMBER LUND: They will be separately storing and that kind of thing. Like, if they’re going to -- the information that they give to you, you know, you don’t need a data security letter. But the stuff that you’re collecting, you would need a data security letter.

So, if they’re going to have access to the data from your study, then they need a data security letter.

DR. WHALEY: Well, our intention that we anonymize the data before that they would get that data.

VICE CHAIR DICKEY: So, they --

DR. WHALEY: So, when you look at the variable list, they’re going to tell us all the stuff. We have our security letter in place. Before we put all the survey data and merge the survey data into it, we would strip it all before sending it back to CDPH.

COMMITTEE MEMBER LUND: So, completely anonymized, they would not be able to link any of the data to people who are in the program.

VICE CHAIR DICKEY: Right.

DR. WHALEY: Correct. Unless maybe you want to revisit that, in which case we can get a security --

COMMITTEE MEMBER LUND: That would work really well --

DR. WHALEY: I didn’t think you wanted the --

VICE CHAIR DICKEY: You mentioned a previous data security letter that you had from a previous project. This is a new project, so we can’t -- you probably need to upload that into this project.

DR. WHALEY: Right, we have it for this project.

VICE CHAIR DICKEY: Okay. All right.

COMMITTEE MEMBER LUND: Yeah, and then informed consent was my only thing. So, otherwise, I don’t have any others.

DR. WHALEY: Okay, thank you.

COMMITTEE MEMBER VENTURA: Any other Committee members comments?

VICE CHAIR DICKEY: Members of the public?

DR. RYKACZEWSKA: Acknowledging there are no members of the public in the room, if any of the members of the public online would like to raise their virtual hands and make a comment. I am not seeing any virtual hands.

VICE CHAIR DICKEY: Dr. Ventura, are you ready to make a motion?

COMMITTEE MEMBER VENTURA: Sure. So, I move for deferred approval, one year, minimal risk, with the following revisions. Or condition, I'm sorry, the wording on that is ticklish.

COMMITTEE MEMBER LUND: Stipulations.

COMMITTEE MEMBER VENTURA: Stipulations, thank you.

VICE CHAIR DICKEY: Requirements.

COMMITTEE MEMBER VENTURA: Thank you. In a future -- or, in a future amendment all CDPH research staff will be added. Until then, only those listed in the current submission will have access to the data.

We'd like to modify -- or, please clarify in the consent language that this is research, this is research.

COMMITTEE MEMBER LUND: Actually, it's in the recruitment, the message they get for recruitment.

COMMITTEE MEMBER VENTURA: Oh, okay. Recruitment, I'm sorry. In the recruitment --

DR. WHALEY: Could I -- could I add on to that? Because we actually matched that recruitment text off of a currently approved study. I can get you the study number. Maybe not as quickly as I'd like.

COMMITTEE MEMBER VENTURA: I think you referenced 67. This is its own study. I think we want to just add the research language in the recruitment material. We just want to prevent any --

DR. WHALEY: This is a departure from prior --

VICE CHAIR DICKEY: Is it a problem?

DR. WHALEY: I don't know the answer to that. You know, we have done a number of these studies and over the years have really learned what seems to be most effective, as well as there's the confidentiality and kind of choice that a WIC person can have in kind of proceeding.

So, I'm a researcher, I love the word research. But we've never had that in the outgoing text, so I -- I don't know what the impact would be, but this is a departure from what we've had in place for a current study that we're doing, as well as prior studies.

COMMITTEE MEMBER VENTURA: I would -- I would push back in that if someone were to receive a text regarding the WIC Program, and it's not explained that this is research, they might think that it is impacting a part of the program, it might impact their benefits.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: I know in the script it says that participation in this won't affect your WIC. But if someone were to get a text message or recruitment material and it's not explicit that it's research that they might think that they have to do this.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: So, I think that's just my concern is that they aren't given a chance to opt in or out.

VICE CHAIR DICKEY: Well, I mean when they read it they learn that they don't have to. But they might not open it if they thought it was research or something. I mean, is there another word that would get at it, that's not as --

COMMITTEE MEMBER LUND: Well, I think that you have HIPAA nailed on the head. If they're not going to open it because it's research, then that begins the informed consent process. But Title 45 is clear that informed consent starts at the time of recruitment, the first words they hear about the study.

And so, if they get a recruitment and it just says research, and they go, oh, I don't want that, all the more reason to put it in there because they're being informed from the get go what they're being asked to do.

VICE CHAIR DICKEY: Would the word evaluation be acceptable?

COMMITTEE MEMBER LUND: No, this is a research study, you know.

COMMITTEE MEMBER SCHAEUBLE: And this is standard in almost all situations we deal with. I can’t speak to what has happened in the past on prior projects that these researchers have been doing. But certainly, in other situations it’s just standard practice that the recruitment information states at the outset this is research we are asking you to participate in. So, I think it’s --

DR. WHALEY: So, I shared in the chat what we we’ve (indiscernible) in the prior. I -- if anyone want to help with a word search, that might be helpful for me.

DR. RYKACZEWSKA: I’m going to put it in the Word document just because I don’t know that --

DR. WHALEY: Yeah, I know. I can’t share my screen.

VICE CHAIR DICKEY: Yeah.

DR. WHALEY: This exactly matches our currently approved protocol on a different study. Of course, that’s about infant formula, so it’s not about WIC foods and shopping. So, I don’t want to -- I understand you’re on a time crunch, so if we can’t do this with the team that’s fine. I just would really love your input here on what the revision is so we don’t have to go back and forth in the coming weeks.

COMMITTEE MEMBER VENTURA: I think we’re not trying to (indiscernible) -- research survey, exactly, in the 30-minute research survey, and then click the survey link here. Or, you know --

DR. WHALEY: No, not --

COMMITTEE MEMBER VENTURA: Well, the first mention is sufficient in my opinion, but --

VICE CHAIR DICKEY: Yeah, I think we got it down.

COMMITTEE MEMBER VENTURA: Yeah.

DR. WHALEY: I think we’re going to be up against character limit to use it twice, but --

COMMITTEE MEMBER VENTURA: That’s fine. The first time, in the first line, I think that’s sufficient.

DR. WHALEY: Okay.

COMMITTEE MEMBER TEFERA: But just so I understand, so this Committee previously approved the prior language.

VICE CHAIR DICKEY: We reserve the right to be inconsistent.

COMMITTEE MEMBER TEFERA: I mean, there’s some humor there, but I think consistency is important.

VICE CHAIR DICKEY: I know.

COMMITTEE MEMBER TEFERA: And so, all of the sudden we're making a big thing out of one word.

VICE CHAIR DICKEY: I know.

COMMITTEE MEMBER TEFERA: That doesn't necessarily reflect well. So, I think we need to -- we need to discuss that as well for moving forward.

COMMITTEE MEMBER LUND: I would be the first to say that this Committee has made mistakes in the past. And just because we've done something that we would prefer to do differently now, doesn't mean we have to continue with anything.

COMMITTEE MEMBER VENTURA: How recent was this project?

DR. WHALEY: Very, within the last --

COMMITTEE MEMBER HESS: Yeah, I think I know the study. And it was the (indiscernible) --

DR. WHALEY: Correct.

VICE CHAIR DICKEY: Sometimes making changes --

DR. WHALEY: It went very -- it went very, very well and we have not had a single complaint.

VICE CHAIR DICKEY: Sometimes making changes, if you're trying to compare across time, you can't compare them if you change something. I don't think that's a factor in this case. Right.

COMMITTEE MEMBER SCHAEUBLE: It doesn't seem to. This is a separate study.

DR. WHALEY: I think the solution we've come up with, I can live with. I don't see any pushback on that. I will certainly be back with you if all of the sudden we learn something really fascinating, but I don't anticipate that we will. So, I'm comfortable with what you've written on the paper here, if everyone else is.

COMMITTEE MEMBER VENTURA: And then, the last point was to add just the risk of loss of confidentiality, to just inform participants. So, adding it to the consent script.

DR. WHALEY: Great. I'm looking at that now, and that should be easy. And thanks, Dr. Ventura, for (indiscernible) on that script.

COMMITTEE MEMBER VENTURA: And I believe that is -- those are all of the changes.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER SCHAEUBLE: Was there --

DR. WHALEY: Have you a word that you have used for the word confidentiality that is a lower read level, or do you always go with the word confidentiality. It's not a straight forward word, I don't think.

COMMITTEE MEMBER SCHAEUBLE: Your consent script, what was the other item about explaining the linkage to --

COMMITTEE MEMBER VENTURA: They added that, Dr.

Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: Oh, it’s already in there.

COMMITTEE MEMBER VENTURA: Yes, they added that and they added the follow up (indiscernible) language.

COMMITTEE MEMBER SCHAEUBLE: Okay. Both then.

COMMITTEE MEMBER VENTURA: Yes. That was in the last, yesterday, or Wednesday’s submission.

COMMITTEE MEMBER SCHAEUBLE: I didn’t see the last one, I guess.

VICE CHAIR DICKEY: I don’t think we addressed the question.

COMMITTEE MEMBER HESS: I don’t think -- I mean, I think that you would be within your rights to propose an alternative.

VICE CHAIR DICKEY: Privacy?

COMMITTEE MEMBER HESS: Yeah, loss of privacy.

COMMITTEE MEMBER LUND: So, could we say that could be wordsmithed?

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER LUND: And you can work it out and I would trust you.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: And then, if you were to work that out, to find a good word.

COMMITTEE MEMBER VENTURA: And I checked the language and the grade on everything else. Great, and then --

DR. WHALEY: You're welcome to do (indiscernible) --

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER SCHAEUBLE: I'll second.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: The motion passed.

VICE CHAIR DICKEY: Thank you, as always.

DR. WHALEY: Thank you. Enjoy the day.

VICE CHAIR DICKEY: You'll receive a letter from us in a couple weeks. Interesting discussion.

DR. WHALEY: Happy holidays, all.

COMMITTEE MEMBER SCHAEUBLE: You too.

VICE CHAIR DICKEY: The next project is Understanding Attitudes, Perceptions, and Behaviors toward Youth Cannabis Use. And Ms. Lund is the primary reviewer.

COMMITTEE MEMBER LUND: Yes. Moving through the --

COMMITTEE MEMBER HESS: I cannot, we will lose quorum. So, I am staying and --

VICE CHAIR DICKEY: She's not actually -- I'm no longer involved in the project since I have left CDPH.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER LUND: Great.

Okay, Dr. Azucar, are you with us?

DR. AZUCAR: Yep, present.

COMMITTEE MEMBER LUND: So, if you would please summarize your project -- first, introduce yourself and any members of your team that are here with you today. And then, summarize your project for the Committee.

DR. AZUCAR: Of course. Thank you, Ms. Lund.

So, my name is Dr. Danny Azucar. I'm a research scientist at Rescue Agency and I am the PI for the proposed project that we will present today.

On the call we also have Dr. Dawnyea Jackson, who is the responsible official for the study that I will discuss.

So, first I want to say thank you to the board for hearing about the procedures of the study. And, especially, thank you, Ms. Lund for your feedback and your suggestions to improve our protocol for our board review today.

What we're seeing is that California's legislation of adult cannabis use has increased youth exposure, has increased their access and (indiscernible) --

At the same time, we've noticed that perceived risk among youth continues to decline. With state data showing that about 12.8 percent of (indiscernible) -- report 30-day -- past 30-day cannabis use. And early or frequent use is associated with developmental, cognitive and behavioral harms.

So, because of this, the California Department of Public Health set the -- is partnering with us, the Rescue Agency, to develop a statewide cannabis use, prevention and cessation campaign for youth, young adults, and parents or caregivers of these youth and young adults.

So, to make sure that the campaign messages are developmentally appropriate, culturally relevant and effective, this study seeks to systematically understand the attitudes, perceptions and communication needs of those audiences.

So, the goals of this project is to, one, understand the knowledge, attitudes, beliefs and perceptions surrounding youth cannabis use.

Second is to understand the social norms, values and (indiscernible) -- to encourage or discourage use.

And third is to understand the messaging styles, tones and content that really resonate with different audiences and increase their willingness to either abort (phonetic) or delay cannabis use for youth.

In the protocol we outlined three phases of the research study. But for now, we are only seeking approval for phase one of the research which focuses specifically on formative qualitative research to inform messaging development for future campaign phases, which would be phase two and phase three.

For phase one, we aim to include up to 156 participants divided across three key groups.

And the first key group is teens ages 13 to 17, which will include up to 72 participants.

The second group is young adults ages 18 to 20, which will include up to 48 participants.

And the third group is parents or caregivers of -- ages 30 to 55, of children and teens ages 11 to 17. And this will include up to 36 participants.

So, we plan to recruit English-speaking teens and young adults, and both English- and Spanish-speaking parents and caregivers. And these participants will ideally represent diverse genders, ethnicities, and regions across California.

Teens and young adults will include both susceptible non-tryers, and experimenters. And what this means is that susceptible non-tryers are teens who have not used cannabis, but indicate that they are curious or would be willing to try cannabis in the future.

And experimenters are teens who report using cannabis in the past, from (indiscernible) --

And parents and caregivers included in the study will be those who do not frequently talk with their children about cannabis in order to better understand the barriers to communication needs for parents -- for the parent focus messaging.

The way that we will recruit participants for the study is -- first of all, this study will be conducted virtually. And participation includes three main steps.

So, we'll start with the screener survey to confirm eligibility and ensure demographic diversity and, really, a representation of different populations across California.

We then go to a brief (indiscernible) that collects non-identifying attitudes towards cannabis to kind of conceptualize the focus groups and get further insight into the theme that we'll gather from those discussions.

And finally, it is participation in a 90-minute virtual focus group that's going to be led by a trainer moderator with experience in facilitating sensitive discussions around cannabis use for teens, young adults, and their parents or caregivers.

These focus groups follow a structured set of activities, including a general discussion about cannabis perception, a statement-testing activity where participants will evaluate factual cannabis-related statements.

And for parents, a brief review of an existing educational resource, which is a website that provides parents with fact-based tapes about how they can initiate those conversations about cannabis with their teens or their young adults.

All the audiences will also provide reaction to preexisting ads to understand what styles, what tones of these ads are supported by the campaign communication.

And at the beginning of the focus group discussions, all participants are told that they need only answer the questions they feel comfortable answering, and may stop participating at any time without penalty.

To support our more accurate analysis, focus groups will also be audio recorded and privately live-streamed, so that external partners from CDPH and non-research Rescue Agency staff can observe without interacting with participants.

And I do want to highlight that the livestream is access limited, it’s password protected, and only available to staff who have signed the confidentiality agreement that are outlined in the protocol.

And those sections will be video recorded and participants can, therefore, choose to be on camera and show their faces, or turning off camera depending on their individual comfort level.

The focus groups will be audio recorded. Audio files will be transcribed promptly. All identifiers will be removed. And the de-identified transcripts will become the A file that we use in the analysis. And we will delete all audio files within one year of the data collection.

All the data that we use for this analysis, whether from survey or transcripts, will be stored using only unique participant IDs. And identifying information will be used for administrative purposes and kept in a separate secure location that will never be merged with (indiscernible) -- and de-identified datasets will be shared also with CDPH, but only after all identifiers have been removed.

And in the protocol you will see that we state that CDPH staff team members are external partners, which is also communicated in the consent form. So that participants know that if they do consent and participate in the study that data will be shared not just with us, the research team, but with members of CDPH who are viewed as partners and funders of the study.

Overall, this is a minimal risk behavioral study. And potential risks include emotional discomfort when discussing cannabis use, or personal experiences with cannabis use.

And to minimize these risks for participants, we iterate that all questions are optional and participants may skip any item without penalty.

We also highlight that teens cannot be contacted to complete the screener survey without obtaining parental permission first. And that both parental permission and youth assent are (indiscernible) -- to continue with the study.

We highlight that participants may be (indiscernible) during the focus groups discussions to protect their identity. We highlight that no video recording will happen during the focus groups. That audio is deleted after transcription.

And that observers cannot report or interact with participants.

And all staff who have access to audio or livestream content will a specific confidentiality, where they are able to. It’s very important.

And so, in the end, findings from this formative data will directly inform the development of a statewide prevention and education campaign. And this research will ensure that messages are scientifically accurate, that they are audience informed, that they're culturally appropriate, and effective at promoting or delaying the initiation, or reduce use of cannabis among youth.

And later phases, which is phase two and phase three, will include (indiscernible) and red blood testing. And those phases will be submitted as amendments once phase one data inform their development.

COMMITTEE MEMBER LUND: Great. Thank you very much. And I'd like to thank Dr. Azucar and his team. They've provided a document that's attached to the protocol in IRBManager. I had many questions and comments, and the addressed each of those point by point.

So, for anyone who is interested in all of their answers to my many questions, that document is in there.

So, that being said, I'm not going to go over all of my questions and concerns, given the time frame we're on here.

But I do have several outstanding issues that I wanted to bring up with the Committee for discussion, as part of the protocol.

So, the first one is the incentive issue. So, as Dr.

Azucar mentioned, he’s got two groups. He’s got parents who are the parents of teenagers. He’s got 18 to 20 year olds, and he’s got 13 to 17 year olds. And these are the focus group populations.

And he proposed a $125 incentive for each of these three groups. I don’t have a problem with this incentive for the parents. I think that for a nine-to-nine (phonetic) focus group interview, $125 seems like a reasonable incentive.

I do have very serious concerns about $125 incentive for 15 to 17 year olds. I think that falls well into the OHRP guidance around undue influence, especially for the younger end of that age group.

I looked at minimum wage in California. Minimum wage in California is $16.50 an hour. It’s $20 if they work food service. And they’re offering $125 to 13 year olds for (indiscernible) -- I just -- it’s hard for me to imagine that a 13 year old is seriously weighing the considerations of this research that’s providing a $125 incentive.

My recommendation was $34 to $40 for that group. Given what minimum wage is, that’s more than what they would make, you know, in that time. And it seems to be, to me, to not be an undue influence on their decision.

Because the issue is does it influence their decision to participate and make it possible that they haven’t taken all of this into consideration.

For 18 to 20 year olds, I still think $125 is too much. I would agree that paying them more than you pay the 13 to 17 year olds would be appropriate. But I still, given minimum wage and given the age group, that $125 is a lot. And I would see moving that to perhaps $75 or something in that range.

Dr. Azucar, in his revision I believe, has still requested and provided you with information on other studies that have used larger incentives for these age groups. You know, so as a way for you to kind of weigh whether or not we should grant this request.

But I really -- and this is one of the things that speaks to the heart of, you know, human subjects considerations as it might be of undue influence in whether or not to participate.

So, before we talk about anything else, I have a couple of things that I'd like to talk about and then we can go over some of the other things.

So, I'd like to open it up for comments to the group. And then, after the group has had a chance to comment, I'd like Dr. Azucar to have an opportunity to respond.

Yes?

VICE CHAIR DICKEY: So, would any of the groups be $125?

COMMITTEE MEMBER LUND: I don't have any objections to the $125 for the parent group. I think that that -- for people who are adults and have responsibilities in the world, and this may be -- have financial consequences for them. They may have to choose between activities that, you know, they would move forward and participate. I think $125 for a focus group is reasonable for them.

But for the 13 to 17 year olds and the 18 to 20 year olds, I do not.

VICE CHAIR DICKEY: Will there be anywhere the kids are -- the kids of the parents that are participating?

COMMITTEE MEMBER LUND: That’s an excellent question. Dr. Azucar, did you hear that question?

Will any of the 13 to 17 year olds or the 18 to 20 year olds be the children of parents who are also in one of your focus groups?

DR. JACKSON: No.

DR. AZUCAR: No, they won’t be children of parents who are in the focus groups. But for children that are between the ages of 17 -- 13 to 17, the parent will be the first line of contact for those teens and they will be informed of how much the incentive is before they’re able to grant permission for their child to complete the screener survey, and determine if the child is eligible for the study.

COMMITTEE MEMBER LUND: Yeah, so if you're worried about whether they're going to go home and compare notes, they will not be.

VICE CHAIR DICKEY: No, but there is a check in the system where the parents would have say, okay, it's okay to give my kid $125.

COMMITTEE MEMBER LUND: No, it's only -- well, they're told the size of the incentive, yes.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: And they can do that --

COMMITTEE MEMBER LUND: So, they can give permission, but the child is the one who actually has to make the decision about whether to assent or not. And that is the relationship that I'm concerned about.

The child, and I will remind everybody that under federal law they are children, and they are considered a vulnerable population. And we are called out, specifically under federal law, to ensure that we are protecting them, especially protecting them from any undue risk, and I consider this to be a risk.

VICE CHAIR DICKEY: So, what if the money went to the parents and not to the kids?

COMMITTEE MEMBER LUND: And the kids don't know about it?

VICE CHAIR DICKEY: No, the kids know about it.

COMMITTEE MEMBER LUND: I would still have a problem with that amount of money for these children to participate in an interview. I just --

COMMITTEE MEMBER TEFERA: I mean, I would respectfully disagree. In part because I think the adults, who are age 55 would also have the same incentive from money. There's no reason to think that just because they're in a higher age bracket doesn't mean they don't have --

VICE CHAIR DICKEY: Economic issues.

COMMITTEE MEMBER TEFERA: -- economic issues that would make the incentive compelling.

I think, you know, the kids, yeah, in that age group they may, they may not have economic distress. But if the concern is direct funding to the children, then having the money go to the parents would resolve that distress.

I also think it's a bit arbitrary to go from 17 to 18, 18 to 20, versus 13 to 17 and all of the sudden like the difference in economic impact, and also a noticeable difference in maturity and thoughtfulness, and one who is engaged.

Those in that age group know there's a lot of variance. So, I'm not sure that an arbitrary cutoff like that makes sense to justify a different in that group.

COMMITTEE MEMBER LUND: So, the OHRP guidance says, specifically, that you can consider -- and I don't know if you've had the opportunity to see the guidance on this. That you can consider and must consider specifically the needs of the particular group that's being offered the incentive. In this case, 13 to 17 year olds.

And individuals can vary inside groups. But as a group, right, I would say that this is -- and especially given, you know, for folks who've been on the board for a while, the kinds of incentives that we see people give, and for the kinds of work that they're being asked to do for a research project this is actually quite high.

So, I just -- you know, I have a problem with it.

DR. AZUCAR: So, if I may. So, our goal is to ensure compensation that is fair, that is industry-grounded, and proportionate to the time and effort required.

And contemporary research around incentives highlight that, for example teens, and adults, and parents are incentivized for the effort and the burden that they give, and not based on their age range.

And in this case teens, and adults, and parents will complete the same 90-minute virtual focus group involving equal time, cognitive effort, probably scheduling burden, and a discussion of this sensitive public health issue, which is underage cannabis use.

So, equal guidance advises that compensation should correspond to the burden, not the age. And to this study the burden is across all groups.

So, reducing the amount for teens would in a way under value their contributions, even though their perspectives are really essential to the project. Which is developing cannabis prevention as a campaign that is in formed by teen perspectives, and by the perspectives of the adults.

So, that's the reason why we recommend keeping it uniform across all three groups.

COMMITTEE MEMBER LUND: Anybody else from the board?

COMMITTEE MEMBER TEFERA: Dr. Azucar, would you have any issue with funding the parents of the teens?

DR. AZUCAR: I would not. I think that as long as the -- because when I think about the teen audience, I think about not just the teens, but their parents are allowing their teens to consent. So, if there's a way for us to split that incentive, maybe half for the parents, half for the teen, that would be fine for me.

I think it would be great to know that all participants are being -- that their perspectives are being valued and incentivized in the same way.

COMMITTEE MEMBER LUND: Other members have comments?

COMMITTEE MEMBER VENTURA: But splitting it between the teen participant and the parent, going back to your argument earlier, which is you're compensating teens on effort and, you know, cognitive, and their time commitment to it. I'm not sure splitting it will be fair.

What about -- and I'm sorry I didn't see your attached records to study that have provided similar amounts of compensation. But can you lower it across the board, where it's not so high as to possibly have that undue influence, but still be reasonable for everyone's participation?

DR. AZUCAR: Yeah. So, in previous studies that have been approved for CPHS research, before that had the same title had the same goal in mind, we had an incentive of $75 for teens, 13 to 17. And it was still $125 for those 18 to 25, and $125 for adults.

So, I would be comfortable lowering it to $75. And from my perspective, it's not just about providing the incentive, but ensuring that we're able to retain the participant incented to the study.

So, it's an issue about incentivizing folks for their time and effort, and also about teen -- I want to say the stewards of CDPH's funds, and making sure that we're not having to re-

recruit folks, and making sure that we keep participants engaged throughout the duration of the study.

So, I would be okay with lowering it to $75 for teens, if that’s what the board would recommend.

VICE CHAIR DICKEY: And keeping it $125 for the others?

DR. AZUCAR: Yes.

COMMITTEE MEMBER LUND: So, for 13 to 17 year olds and for 18 to 20 year olds it would be $75, and $125 for the parents?

DR. AZUCAR: No, I apologize. What my recommendation here is keep it at $125 for parents and caregivers, $125 for young adults, 18 to 20. And if the board recommends, then we would lower it to $75 for teens 13 to 17.

VICE CHAIR DICKEY: And you’ve done that before, that’s --

DR. AZUCAR: We’ve done that before, yeah.

VICE CHAIR DICKEY: All right.

DR. AZUCAR: It was protocol Number 21-128 that was approved back in 2021.

VICE CHAIR DICKEY: And did it work that way -- did it work okay with that one.

DR. AZUCAR: It worked fine, yeah. I don’t think there was any issues.

COMMITTEE MEMBER LUND: Okay, other thoughts from the board? I'm still uncomfortable, but I would really --

COMMITTEE MEMBER PALACIO: That sounds equitable to me.

COMMITTEE MEMBER LUND: Okay. All right, so then the next thing -- so, I want to talk about the screener. So, you're -- the eligibility screener. So, you're capturing a lot of information in the screener that doesn't appear to be related to eligibility.

So, you have described the criteria, the actual eligibility criteria for getting people into the focus groups, getting eligibility for the focus groups.

But then you ask for demographic information. And you've given this very broad we want to make sure that, you know, the groups match, you know, the populations that we're interested in.

But you have not described at all how you will accomplish that with this information that you're asking to collect, the demographic information.

So, if there are quota categories, we need to know that. Right. Because it's really -- even though you say there aren't any other inclusion/exclusion criteria, and you're not going to exclude people based on categories, in fact you are. Because it's an exclusion to say, oh, I have too many people of X characteristic in this group, so no more people from that characteristic can be in this group and I want these other characteristics.

So, you haven't described what those are. Like, do you have gender ratios? Do you have certain race groups that you're looking to be in those groups? I mean, what -- why are you asking these questions on the screener?

Because it really speaks to the informed consent issue. I mean, one of the things that you have asked to do is to retain information from the screener that was collected prior to informed consent, which is this demographic information.

So, there's a couple things in play here. So, my question, my first question is how exactly are you going to use that information? Why does it need to be in the screener and not in a later (indiscernible) survey? So, if you could address that question first.

DR. AZUCAR: Yes, of course. Thank you. The reason why we're collecting those demographic variables, really all the social variables involved in the screener is to make sure that we have profiles of people and not that are just representative of California demographics and populations. But that also reflect those populations that are more at risk or already using cannabis.

For example -- my apologies, I didn't add the sample demographic quotas into the protocol. I can do that, if that would help understand the rationale here.

But we see that Asian American populations in California are up to 15 percent. When you look at their cannabis use, they have much lower cannabis use than the other demographic profiles in California. Even though, for example, black and African American populations in California, by number, are less than Asian Americans, but those groups of African American and black populations are more likely to be (indiscernible) -- cannabis use.

So, in order to be able to find a profile of participants that match what we're trying to do, and match the target audience, that's why we have those demographic measures in place there.

COMMITTEE MEMBER LUND: So, those are actually, as you're describing it, inclusion and exclusion criteria and they need to be described in the protocol.

DR. AZUCAR: Okay.

COMMITTEE MEMBER LUND: So, if you -- and all of the questions that you're asking in the screener, if you are going to use them for screening you need to describe in the protocol how they're going to be used for screening. And that's not there at all.

So, for each of those demographics you are in fact using them to screen people into or out of the group.

DR. AZUCAR: Uh-hum. Yes. But it's not just a simple demographic. Like nobody will be excluded from the study if they respond to being a specific race or ethnicity. It will be more a combination of race/ethnicity, cannabis use, cannabis risk perception, and geographic location.

Because in addition to demographics in Cailfornia, we also want to be well represented in different geographic regions in California. Which would include rural, urban, suburban areas.

So, it’s more of a combination of geographic and demographic factors, and also psychosocial perspectives on what cannabis use is and what cannabis risk is. More so than a simple we won’t include this participant because of a specific race or ethnicity, or age, or geographic location.

COMMITTEE MEMBER LUND: Right. I understand what you’re saying. But you still need to describe those quotas in the protocol. And so, if it’s a combination of factors that’s fine. But it’s still inclusion and exclusion.

VICE CHAIR DICKEY: But I just want to add a perspective. This is focus groups.

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: We’ve never required really strict inclusion/exclusion criteria for focus groups.

COMMITTEE MEMBER LUND: Except they want to ask it in the screener. If they want to ask it in the --

VICE CHAIR DICKEY: Well, so they can get a mix of people. They may not know exactly, you know. Maybe they just want a balance of people. I’m assuming. They may not know what that balance is going to be until they see what they get.

I mean, I think it’s just focus groups. I think we’re going a little overboard on focus groups. Because they’re trying to get a balance. They’re not trying to -- it’s not a scientific study in terms of you have to do this, and (indiscernible) -- these would be hard to describe, I think.

COMMITTEE MEMBER LUND: Well, I would think if they’re asking race, then they have a plan for how they’re going to use that in incorporating people in their focus group.

So, likewise, if they’re asking sexual identity they have a plan --

VICE CHAIR DICKEY: But would it be sufficient if they say we want to get a representative sample of California? And so that the number of racial profile is basically if there’s 18 percent blacks in California, then there are 18 percent, they’re shooting for that in the focus group. They’re trying to get a balance of different characteristics.

COMMITTEE MEMBER LUND: Okay. If that’s what they’re doing, then they just need to tell us.

VICE CHAIR DICKEY: Is that true?

DR. AZUCAR: That’s correct, yes. And for example, Ms. Lund, to your question about why are we asking about sexual orientation or gender identity, what we're trying to do is match what our sample will be to what the LGBTQIA population, or nonbinary population of youth is in California.

So, we don't really have a way, yet, to understand if we want -- for example, we're not going to say we want five percent of the black or African American, or Latino participants who identify as LGBTQIA.

But what we want to do is make sure that our sample of participants represents the California population who is LGBTQIA, regardless of their race, or ethnicity, or geographic location.

COMMITTEE MEMBER LUND: Anybody else on this one?

Okay, so the other thing about the screener is the information is obtained prior to informed consent. And the researchers are requesting to keep the information as part of the study. And we haven't actually allowed that before.

So, I have concerns about that. There is a check-in survey that they do, where I think any information that they want to retain for the study. The check-in survey happens after the informed consent. So, that information they want to retain from the study, itself, could be asked in the check-in survey. And I would feel much more comfortable with that.

I don't have any objections to the questions, themselves. I just object to people providing their information based on what's told them at the time of screening, and then afterwards oh, by the way, here are all the risks, and benefits, and other things. So, those are my concerns.

Others?

VICE CHAIR DICKEY: So, would that require them reasking the questions?

COMMITTEE MEMBER LUND: Probably.

VICE CHAIR DICKEY: Would you be willing to do that?

DR. AZUCAR: So, we recommend not doing that. And based on, just responding to Ms. Lund’s comments, what we’ve found is that the screener data retention is possible for human subjects behavioral studies based on three main pillars.

The first is that participants are informed before they start the screener survey and during the screener survey that, if they choose to, their screener survey data could be retained as part of demographic profile data for the overall sample that will be reported in aggregate for the study sample as their recruited. And not for each individual participant.

The second is that they are able to consent or assent during the consent/assent form, or parent permission form that we are allowed to keep that screener data if they are found eligible for the study.

And the third, if that were approved, us retaining that screener data, that will be de-identified. That will be used for reporting and later phases.

And my recommendation here is to keep that data just so that we reduce the undue burden on participants, and limit the amount of questions that they have to answer during the screener survey.

COMMITTEE MEMBER TEFERA: And just to be clear, Dr. Azucar, so the participants are advised of the doctrines and clearly give permission for that from the beginning. So, they're aware.

DR. AZUCAR: Exactly. So, in the script of the screener survey we say that their responses may be kept if they agree, and if they are found eligible, to report the demographic and data of the sample in aggregate.

When they sign the parental permission form, the assent form, or the consent form we let them know, bring up -- if you look at the instrument, if they agree to participate then there's -- it gets -- there's another checkbox where we ask them, if you agree to participate are we able to report your screener data in aggregate form to report the overall sample characteristics.

So, we do have those checkmarks in place and participants will be informed that this is possible, if they agree to it.

COMMITTEE MEMBER TEFERA: Thank you.

COMMITTEE MEMBER LUND: Agnieszka?

DR. RYKACZEWSKA: Is the screener data kept for those who screen out of the study?

DR. AZUCAR: Absolutely not, no. Anybody's who is found ineligible, they're screener data will be deleted. And anybody who -- for example, if I'm a participant who is found ineligible that screener data will be deleted.

If I'm a participant is eligible and eventually drops out of the study at any point, that screener data will be removed as well.

So, we're only going to keep the screener data for participants who, one, agree that their data will be kept, consent to the study, and also finish all -- or complete all activities of the study until the end.

COMMITTEE MEMBER SCHAEUBLE: And you are saying that the screener data is not associated at an individual level with survey responses?

DR. AZUCAR: That's correct, yeah. And if I can expand on that. When we collect screener data, if a participant is found eligible, which we then can go on to the consent form, assent form, and then participate, that information that they provide will be assigned a unique participant ID. And that's the only way that we're going to be able to continue to trace their data.

So, let's say me, Daniel Azucar, does the screener survey, is found eligible, and I continue to the assent/consent form, check in survey, et cetera, all that information will be given to -- or, not given to, but tracked by this unique participant ID. And my name that I gave during the consent, assent form, parental permission form won't be associated to any of the data that will be used for analysis.

VICE CHAIR DICKEY: Ms. Lund?

COMMITTEE MEMBER LUND: So, those were all my specific questions. I'd like to open it up to the board for any other questions that you may have about the project.

COMMITTEE MEMBER SCHAEUBLE: Is there any retention of names and ID numbers?

DR. AZUCAR: So, there is going to be a retention of names from the parental consent, teen assent, and young adult and regular consent forms. So, that data will be stored separate from any survey data or focus group data that we have.

COMMITTEE MEMBER PALACIO: Did you say the study would be translated into Spanish?

DR. AZUCAR: Uh-hum, yeah. It will be translated to Spanish only for parents and caregivers. So, for phase one, we scheduled six focus groups for parents and caregivers. Two of those focus groups will be in Spanish.

And the reason for that is because a lot of the California population are Spanish speakers and that will give us insight into how we can better understand the differences that parents have in communicating with their teens about cannabis whether they are Spanish speakers, whether they are English speakers.

And because this (indiscernible) -- for parents will also be developed in Spanish, we really need to collect those insights to be able to inform, from participant perspectives, what the Spanish strategy and what the messaging will look like.

Because we find that that’s more effective than just translating English materials to Spanish. And having Spanish materials be really informed by audiences who are kind of living that truth, and really living their everyday lives speaking Spanish, and deciding whether or not to communicate with their teens based on their demographic profile, ethnicity and spoken language.

COMMITTEE MEMBER PALACIO: Are you anticipating that any of the remainder demographic speak other languages, other than Spanish?

DR. AZUCAR: We are. And in the screener survey we do ask if parents or the participant are mainly speakers, if they speak English and another language secondarily, or speak other languages and English in a secondary way.

But because of the demographics in California, and the many language that we have, we don't ask if they speak another specific language. We just want to know if they -- if English is their primary language, associated with another language, or if they speak another language and English as their secondary language.

COMMITTEE MEMBER LUND: Anyone else?

COMMITTEE MEMBER SCHAEUBLE: Laura, are you satisfied that your concerns have been appropriately addressed here?

COMMITTEE MEMBER LUND: No. Actually, I'm not. And I'm sort of struggling with that because I -- if I make the motion, it's an automatic vote to approve for me. And I'm leaning at this point towards I prefer to abstain based on the two issues that I think are still not -- I'm just not comfortable with them, in all honesty.

So, if it's -- if the group -- and I'm not hearing the same concerns or at least the level of concern from other members of the board, and that's fine.

But I would ask someone else to make the motion, if it's the will of the board to approve based on the discussion here today, you know, so that my vote can reflect my position.

VICE CHAIR DICKEY: Well, you wouldn't necessarily need to abstain, you could oppose to reflect your opinion.

COMMITTEE MEMBER LUND: Yeah, so that -- that would be something I would have to consider, which of those two options would be best for me. But I really -- I think the main thing is that I don't feel that -- I'm uncomfortable making the motion because that is my vote to approve and I don't feel that I can.

COMMITTEE MEMBER SCHAEUBLE: And the specific concerns are the size of --

COMMITTEE MEMBER LUND: The size of the incentive for the young people and retaining the screener data for the study prior to informed consent. Those are the two.

COMMITTEE MEMBER SCHAEUBLE: Uh-hum.

COMMITTEE MEMBER LUND: And I understand all of the issues and I appreciate everybody's, you know, thoughtful consideration and --

COMMITTEE MEMBER SCHAEUBLE: Well, I'm asking because I think those are fairly legitimate concerns and --

VICE CHAIR DICKEY: But they're concerns that we should vote on. And so, in order to vote on it, somebody's going to have to make a motion.

COMMITTEE MEMBER TEFERA: Are you able to do that, Dr. Dickey?

VICE CHAIR DICKEY: I'm not. Anybody else? It's up to you.

COMMITTEE MEMBER TEFERA: I’m happy to do it.

COMMITTEE MEMBER PALACIO: I will make a motion that the primary reviewer is okay. That the reviewer and the work that she has done.

COMMITTEE MEMBER LUND: But I also really feel strongly that I should not be the only person who --

VICE CHAIR DICKEY: Well, that’s why we have a Committee.

COMMITTEE MEMBER LUND: Great. And I am -- I am perfectly willing, if there are others on the board who believe that they would like to make a motion to approve this, I have no problem with that. As the primary reviewer, I’m happy to have that.

COMMITTEE MEMBER TEFERA: Sure, I’ll make a motion. Help me with any language.

VICE CHAIR DICKEY: Well, I guess what she’s -- if you -- what do you agree with? I mean, are you saying there should be a change on the $75?

COMMITTEE MEMBER TEFERA: Yes, conditionally approval with a change for $75 for 13 to 17 year olds. Those are the --

VICE CHAIR DICKEY: And the parents. The only change would be it’s $75 for the 13 to 17 year olds.

COMMITTEE MEMBER TEFERA: Yes, that’s the only change.

VICE CHAIR DICKEY: And would you make any other changes to the project?

COMMITTEE MEMBER TEFERA: I would not. I think it’s -- I think the rest is reasonable.

DR. RYKACZEWSKA: Can I just double check, one year, minimal risk?

VICE CHAIR DICKEY: Right. That’s always part of our motion.

COMMITTEE MEMBER TEFERA: Okay. It’s my first motion.

DR. RYKACZEWSKA: Incentive for 13 to 17 year olds --

VICE CHAIR DICKEY: To $75.

DR. RYKACZEWSKA: And 17 to --

VICE CHAIR DICKEY: No, no, just the 13 to 17.

DR. RYKACZEWSKA: No. Just the 13 to 17.

VICE CHAIR DICKEY: No.

DR. RYKACZEWSKA: Is this the right motion? Let me just check.

COMMITTEE MEMBER TEFERA: That looks right.

COMMITTEE MEMBER LUND: Now is the time to ask?

COMMITTEE MEMBER VENTURA: I mean, what if we just need a little more time, like this is -- we’re told that this has been used, this amount, for previous studies. Can we just have more time to look at what has been done in the past, if this is an acceptable amount? Like I'm --

COMMITTEE MEMBER LUND: Are you suggesting the motion is to table --

VICE CHAIR DICKEY: Are you making a separate motion to table?

COMMITTEE MEMBER VENTURA: Yes. Yes, I think that --

COMMITTEE MEMBER LUND: We can do that. If that is -- if the group would be happier with that, to table so that everybody has an opportunity to read Dr. Azucar's responses, and he's provided research, and you all can make an informed decision --

VICE CHAIR DICKEY: Well, there's a motion on the table. I think we have to see if it's seconded. Does anybody second it?

DR. AZUCAR: So, I know with the previous discussion of the presenter we said that this is a new project, it doesn't have to reflect the previous project. And somebody on the board said we have the right to be inconsistent. I understand that.

But a $75 incentive for teens, 13 to 17, was previously approved by this board. So, if you all are comfortable with us moving forward with that incentive, I would be comfortable to lowering it for those -- for that teen audience, as well.

COMMITTEE MEMBER AZIZIAN: May I ask a clarification? Ms. Lund, so what would be a reasonable incentive for that time for that age range? Is there a value that you want to associate with that?

COMMITTEE MEMBER LUND: Yeah, so I think, actually, the background on, you know, minimum wage was very helpful for me in providing context. Right. It’s 90 minutes. And minimum wage in California is, I don’t know, I don’t have it up on my screen anymore, $17, $17.50.

So, I think even at the top end, if you were to offer them $40, $45, $50 for a 90-minute interview, I think that that would not be undue influence.

My perspective, where I’m coming from this is that from the perspective of the participant, the participant doesn’t have all of this information, or the consent to participate doesn’t -- oh, you know, we’re going to balance this, this, this and this, and maybe we’ll do that, instead.

They’re going to go, oh, you’re going to give me how much to sit for 90 minutes and answer questions? Sure.

So, for me, for kids in that age group, I think that, you know, $45, $50 would be the maximum that I would feel comfortable with. And I certainly would want to see that $125 for the 18 to 20 year olds moved down, as well.

Again, this is -- they have to work a lot of hours for $125 and I think that that’s a factor in their consideration to participate in the research.

COMMITTEE MEMBER TEFERA: But again, 30 to 50 year olds have plenty significant economic concerns and they would have the exact same motivation based on the amount.

And I think that it’s not -- we need to be consistent about what is informing an individual’s decision. And it’s perfectly plausible that a 40 year old can have the same financial pressure or desire for $50, or $20, or $125 that a 14 year old could. And that’s a reality.

So, I understand your concern for the younger folks, but I think older folks could equally be having the same incentive to participate, which makes then the choice to only focus on the younger folks less -- less consistent, in my perspective.

COMMITTEE MEMBER LUND: So, it could be undue influence for them, too. And we have actually had projects in the past where these incentives were too large and we have the (indiscernible) --

And, you know, if you think that that’s too large, I would not be adverse to reducing for adults, as well.

So, I think there’s a motion on the table and we just need to decide if there’s a second or --

VICE CHAIR DICKEY: Do we have a second on the motion that’s on the table?

A second doesn’t mean that it’s going to pass, but it means we can vote on it.

If we don’t have a second, then we have to open it up for other motions.

COMMITTEE MEMBER VENTURA: I motion --

VICE CHAIR DICKEY: Not until we’ve resolved this one.

COMMITTEE MEMBER VENTURA: Oh.

VICE CHAIR DICKEY: And so, if --

DR. AZUCAR: I’m so sorry, excuse me. I will add, in the responses that I sent to Ms. Lund, we do cite studies, interviews that have looked into what the incentive amount is for participants, whether adults, or teens, young adults. This study looked into $100 incentives and used beignets (phonetic) to propose more high risk studies and more minimal risk studies for participants.

And across the board, regardless of what the incentive was, participants were more (indiscernible) -- to choose the minimal risk study, which highlights that the incentive, itself, doesn’t produce the undue influence that we’re discussing here. But the actually perceived risk of the study, from participants, whether it’s high risk or minimal risk, it really produces that influence of am I going to participate or not.

This looked at $100 incentives. So, we’re comfortable lowering it to $75. I truly believe that the incentive amount itself won’t produce that influence of whether a teen will participate or not. But the risk of participating in the study will.

VICE CHAIR DICKEY: So, the -- this is phrased as an incentive, not a reimbursement. So, to just base it on what the minimum wage is -- would be reimbursement.

An incentive is something higher than that.

The question is whether or not -- what is an undue incentive. So, that's where we make the judgment.

COMMITTEE MEMBER LUND: Well, and that's why -- I agree completely it's an incentive and not reimbursement. I only invoked minimum wage for the context of what does a dollar mean to these kids. Right. This is how many hours that they would have to work to make that money. And I think that that's a large amount of money. So.

VICE CHAIR DICKEY: All right. So, I'm going to call is there a second? And we'll give it like 20 seconds. And if there isn't, then I'll say that the motion has not -- has failed.

COMMITTEE MEMBER AZIZIAN: Okay. May I just, for clarity, you're just making a motion to vote on that, correct?

VICE CHAIR DICKEY: Exactly.

COMMITTEE MEMBER AZIZIAN: That's all, yes or no.

VICE CHAIR DICKEY: Yes.

COMMITTEE MEMBER AZIZIAN: I'll make -- I'll make the motion to vote on that.

VICE CHAIR DICKEY: Oh, okay, he needs a second.

COMMITTEE MEMBER AZIZIAN: I second.

VICE CHAIR DICKEY: All right, call the roll, please.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Lund votes?

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: I can vote, yes. Lund votes.

VICE CHAIR DICKEY: Lund votes.

COMMITTEE MEMBER LUND: I'll oppose.

MS. ATIFEH: Oppose, okay.

Dr. Palacio

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Oppose.

MS. ATIFEH: Oppose?

COMMITTEE MEMBER SCHAEUBLE: Yes.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Can I oppose if I want more time?

MS. ATIFEH: Okay, oppose.

Okay, the motion failed.

VICE CHAIR DICKEY: What's the count?

MS. ATIFEH: Okay. Four. We need seven.

COMMITTEE MEMBER LUND: Complete the roll call, please.

VICE CHAIR DICKEY: Complete the roll call.

MS. ATIFEH: So, I did. I went to --

VICE CHAIR DICKEY: No, you need to do the other members?

MS. ATIFEH: Oh, okay. I thought you decided to abstain.

(Chatter)

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

COMMITTEE MEMBER HESS: So, I abstain.

MS. ATIFEH: Abstain.

Yes.

VICE CHAIR DICKEY: Okay, so that motion failed.

Anybody else want to make a different motion?

COMMITTEE MEMBER LUND: So, I move to table the project to the February meeting to allow time for board members to review the meeting materials.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER PALACIO: I second.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Palacio seconded.

Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Opposed.

MS. ATIFEH: Opposed.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Let me count. So, we need Dr. Dickey to vote.

VICE CHAIR DICKEY: What is it now, it's a tie?

MS. ATIFEH: Yes. We have six. We need seven.

DR. RYKACZEWSKA: Can we give the exact count for the record?

MS. ATIFEH: Yes. We have Dr. Azizian, Dr. Lang, Ms. Lund, Dr. Palacio, Dr. Schaeuble --

DR. RYKACZEWSKA: No, no, the approvals and the opposes.

VICE CHAIR DICKEY: What's the count right now? Is it a tie right now?

MS. ATIFEH: Yes, it's six --

VICE CHAIR DICKEY: All right. All right, I will approve. Although I would, if I could have voted on the prior motion, I would have approved that one as well.

MS. ATIFEH: So, yeah, with you, your vote, this motion for tabling the project is passed.

DR. AZUCAR: Is everybody -- a call to lower the incentive, so that then you can approve the study, based on the board's recommendation here.

So, Ms. Lund previously stated that she would be comfortable for $40, and for teens and young adults.

If we move forward with that and we agree, is there a way that we can get this project approved today?

VICE CHAIR DICKEY: So, are we bargaining here?

COMMITTEE MEMBER SCHAEUBLE: That's what it sounds like.

DR. AZUCAR: I'm trying to come to an agreement with the board so that we can move forward with the research. I wouldn't call it a bargain, but just an understanding of mutual interest so that we can incentivize folks appropriately, and still move forward with the research.

COMMITTEE MEMBER LUND: So, how do we undo a motion?

VICE CHAIR DICKEY: Well, we can't undo a motion. We can have another motion and undo the previous one, yeah.

It's just the previous one would allow us more time to study and this would be a motion that, well, we don't need to study, we'll just talk your part, your offer.

Timing is an issue on this, huh?

DR. AZUCAR: Yeah. We are available to get started with this data collection in January. So, again, I'm willing to listen to what the board recommends. I'm aligned with reducing undue influence for all participants. So, whatever the board recommends here is what we will do. It's really that simple.

VICE CHAIR DICKEY: All right. So, what if we bargain, we pass something, and then you're finding out that there's a difficulty with it when you're actually implementing it? You can come back and request an amendment and we can consider it at that time. Right. If it's really an issue.

But what are you proposing right now?

DR. AZUCAR: What I'm proposing is that we reduce the teen incentive, the 13 to 17, to $40, which would be two hours of working at McDonald's.

We can do $75 to teens -- for 18 to 20 year olds, which would be in line with previous approved IRB protocols by this board. And we can keep the $125 incentive for parents and caregivers.

VICE CHAIR DICKEY: Okay. Just we just lost our quorum.

COMMITTEE MEMBER LUND: Is he gone?

DR. RYKACZEWSKA: He’s going to be back in about 15 minutes.

VICE CHAIR DICKEY: Yeah, and I have to make a phone call, too.

DR. RYKACZEWSKA: If it would be all right, we would like to break for about 15 minutes so that we can reestablish quorum.

VICE CHAIR DICKEY: We’re really sorry. And I have to caution the board if we take this break, we can’t talk about this during the break.

DR. RYKACZEWSKA: That’s correct.

VICE CHAIR DICKEY: Can you wait 15 minutes?

DR. RYKACZEWSKA: Dr. Azucar?

VICE CHAIR DICKEY: It sounds like you don’t have a choice. Okay, we’re going to take a break --

DR. AZUCAR: Is that for me?

VICE CHAIR DICKEY: -- 15 minutes, 15 minutes.

DR. AZUCAR: Yes, yes, yes, of course, I’ll be online.

VICE CHAIR DICKEY: Okay.

(Off the record at 12:01 p.m.)

(On the record at 12:20 p.m.)

VICE CHAIR DICKEY: Can you please call the quorum and see if we have a quorum?

MS. ATIFEH: Okay.

Dr. Dickey?

VICE CHAIR DICKEY: Here.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Present.

MS. ATIFEH: Okay.

Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Here.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Present.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, we have the quorum.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER LUND: Great. So, Dr. Azucar, thank you so much for your patience. I think before we have a motion I have one clarifying question to ask.

The screener data that you’re collecting, that you want to retain for the study, would it be fair to say that it’s anonymized? That it’s anonymized? Yes.

Would it be possible for you to add just a little brief statement to the statement that you make prior to collecting that information, that it will be anonymized and retained? Okay.

So, I’m just -- okay, so I’m good to make a motion.

VICE CHAIR DICKEY: Do we have -- based on his previous offer?

COMMITTEE MEMBER LUND: Based on your offer.

VICE CHAIR DICKEY: All right. Does the offer still stand?

COMMITTEE MEMBER LUND: Yes, does the offer still stand?

DR. AZUCAR: Forty dollars for 13 to 17, $75 for young adults 18 to 20, and $125 for parents and caregivers ages 30 to 55.

COMMITTEE MEMBER LUND: Okay, thank you.

All right. So, I move deferred approval, minimal risk, one year, with the following stipulations.

Stipulation one, we’re only approving phase one of the study at this time.

Stipulation two, that the incentives in the protocol will be revised so that 13 to 17 year olds will receive $40, 18 to 20 year olds will receive $75, and the parent group will continue to receive $125, and those need to be changed.

And a statement will be inserted prior to collecting the screener information that the data to be retained for the study will be anonymized.

VICE CHAIR DICKEY: Is there a second?

DR. RYKACZEWSKA: I'm catching up.

COMMITTEE MEMBER LUND: The screener language.

DR. RYKACZEWSKA: The 18 to 20 year olds will be $75. And we're not changing the adults so I will not add it.

COMMITTEE MEMBER LUND: Yeah, you don't need to put anything for the adults.

And then, the third one is inserting anonymized language prior to collecting screener data.

A subcommittee of one to review the changes.

VICE CHAIR DICKEY: And, actually, I want to -- if he finds it doesn't work, is it okay with the Committee that he comes back to a subcommittee, rather than having to come back to the full Committee?

COMMITTEE MEMBER LUND: Yes. So, I think that that's an excellent point. So, I would say that these dollar amounts can be revised. I can make that as part of the motion. These dollar amounts can be revised on expedited review, if there's evidence that the dollar amounts here are not working.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER LUND: Are you good with that?

DR. AZUCAR: Thank you.

VICE CHAIR DICKEY: I am good with it.

Is there a second?

COMMITTEE MEMBER HESS: Second.

VICE CHAIR DICKEY: Okay, please call the roll.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Abstain.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Okay, the motion passed.

DR. RYKACZEWSKA: And I just want to make sure, we can state for the record, that this motion replaces the previous motion. Is that correct?

VICE CHAIR DICKEY: Yes, that's true.

COMMITTEE MEMBER LUND: Yep.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Okay.

VICE CHAIR DICKEY: Maybe that should have been part of the motion but that's okay, we got it.

COMMITTEE MEMBER LUND: Well, we voted. We voted and the motion failed, so I think it's okay to have a --

VICE CHAIR DICKEY: Well, we passed one where we were tabling it.

DR. RYKACZEWSKA: The tabling motion.

COMMITTEE MEMBER LUND: Oh. Yeah.

VICE CHAIR DICKEY: I mean it's implied that we voted on it so, anyway.

COMMITTEE MEMBER LUND: I think we're good.

VICE CHAIR DICKEY: Okay. Well, thank God. No.

(Laughter)

COMMITTEE MEMBER LUND: Thank you, Dr. Azucar. You will get a letter laying this out. And as soon as you get that letter, you can make all of the changes and move forward.

DR. AZUCAR: Great. Well, thank you all so much. I appreciate your time and I appreciate you listening to the rationale that we have for the many future we have for this study.

VICE CHAIR DICKEY: Thank you.

The next project --

DR. AZUCAR: Thank you very much.

VICE CHAIR DICKEY: -- is a Child Care Policy Research Partnership with Dr. Kitmitto. I'm the primary reviewer. Although, I haven't had a whole lot of time to review it.

But is Dr. Kitmitto on?

DR. KITMITTO: Yes. Hello.

VICE CHAIR DICKEY: Hello. So, could you please summarize your project for us? I know it's rather complicated but summarize it for us.

DR. KITMITTO: Sure. I'll first introduce the team that we have on. I realize that we have a lot more people than maybe you're used to. But it is a big project and all of us are holding different pieces of information and we wanted to make sure we both were here for whatever questions you might have.

So, there's myself. I'm Sami Kitmitto. I'm the PI on the project.

And also with us on the -- in this meeting are Shannon Keuter, who's the Project Director, and Colleen Boggs who is the Deputy Project Director.

And then, our project has for tasks, research questions, which I'll go over. And each of them has a lead. So, the lead for our first task is Anian Zang. And the lead for task two and three is Leanne Elliott. And the lead for task four is Lisa White.

So, and now, I'm going to go ahead and summarize our project for you. So, the project is a partnership between us, the American Institutes for Research, and the California Department of Social Services. It's funded through a grant from the Federal Administration for Children and Families.

And our project aims to examine professional development as a strategy for improving access to quality childcare for young, dual-language learners in California.

The study examines the need for and access to dual-language learner related professional development.

And also, as part of our project we are developing an observational tool to measure dual-language learner specific instructional practices.

And as I said, our project has four parts or tasks, each with a corresponding research question. And two of these tasks require us to obtain restricted data from CDSS. And so, we are in the process of establishing a data sharing agreement with CDSS.

And one of the requirements for that agreement is that we obtain your review and approval of our plans for the use of those restricted data.

So, this project started a year ago. And I just want to disclose that the full project, meaning all four of our tasks, is currently, since we started, being overseen by our institution's IRB board. And we first received provisional approval in April of 2024. And we've been updating information with our own IRB board and have procedures and protocols reviewed by them as the study has progressed.

But we're here today to talk about the first two that require the restricted CDSS data. But we're happy to answer questions about any of the other four parts. It was our understanding from CDSS that they wanted those two parts that use their data to be reviewed before they entered into a data sharing agreement with us.

So, the first research -- I'm just going to go over the details of only those two research questions that we're asking you to review. But we're happy to talk about any aspect of the study, as you like.

So, the first research question is: What is the distribution of dual-language learners in California, in the California Health Subsidized Health Care System?

And our objective in studying this is to identify and describe the population of dual-language learners in the system, including their geographic location, setting type, subsidy programs used and languages spoken.

And so for this we are requesting de-identified administrative data collected by CDSS. They are currently collecting -- one dataset that we're currently asking from them is what they call their 801A data.

And then, they are also in the process of establishing a new system for collecting data, specifically about dual-language learners. And this was in response to State Law AB-393.

The full 801A data, about all subsidized -- about all children in the subsidized health care system is approximately about 300,000 students per month. And we will be asking them for a one-month snapshot.

There's no -- for this part of the study there's no direct interaction with subjects. And all data will be de-identified by CDSS prior to delivering to AIR. I think they -- the geographic identifier we'll be asking for is the zip code. So, that's sort of the, I think, most sensitive piece of information from those data.

The second research question is: To what extent is there access to dual-language learner focused professional development for providers across the state?

And the objective here is to understand how widespread the use of the dual-language learner focused professional development is, and where there may be gaps of usage.

So, for this, we're going to administer an online survey to the directors of childcare centers, and owners of family childcare homes, who receive subsidies through contracts with CDSS.

CDSS has no restriction on sharing contact information for the childcare centers, for the large family childcare homes. But they do have restrictions on sharing a comprehensive list of contact information for the small family childcare homes.

And that's the part that requires the data sharing agreement for our study is obtaining that contact information.

So, for this part of our study human subjects will be involved, at least as the center directors, or childcare home owners choose to respond to the survey. We're going to invite all CDSS contacted Title 5 childcare programs to participate in the study. And we anticipate that we'll be reaching out to approximately 2,600 programs to take the survey. And of those, 600 are small family childcare homes.

Participation in the survey is entirely voluntary. Respondents who complete the survey will receive a $25 gift card. No survey questions are mandatory. However, to be considered a complete survey for receiving a gift card, they have to provide identifying information, who they are, and the site or program for which they are responding.

So, we feel that the risks associated with this research are minimal. So, for the administrative data analysis, all data will be de-identified by CDSS before sharing with AIR. And the risk of re-identification is negligible.

For the survey of directors and owners of childcare homes and centers, the primary risk is potential disclosure -- well, the first risk is the potential disclosure of their personally identifiable information, meaning their contact information for the program directors and owners, and their names and site addresses.

However, we do note that this data is publicly available individually through the mychildcareplan.org website. It’s just not all in one place.

Another risk is that the survey responses will be disclosed. We feel that there’s minimal risk of harm because the survey does not include questions about sensitive topics. And responses will not be linked to individual staff members or children.

And then, although the requested administrative data and data collected, these surveys carry low risk of disclosure and harm. We will treat the data as we would any sensitive or restricted data. And we have strict data governance protocols that include secure storage, access controls, and systems that we use for other projects where we need to comply with federal and state standards on the use of restricted data.

And to minimize risk we will additionally, when we use to analysis, use de-identified versions of the survey data that are separate from the ones with the contact information of who responded.

And we will also report results only in aggregate and suppressed small cell sizes to prevent reidentification from any reporting.

So, that is my summary.

VICE CHAIR DICKEY: Thank you. That was very concise. I thought that was very clear.

For the benefit of the Committee, this is a case where agency data is being used to contact human subjects and, therefore, it makes it Common Rule. So, we need to look at the questionnaires and that process as we would normally.

If it didn’t involve that contact, it would have been an expedited review under the Information Practices Act.

I looked at the surveys, et cetera. I didn’t have any issue with them. Because it is a low risk population. I mean, it’s basically a program evaluation, kind of, asking questions about dual-language learners.

So, I didn’t have any -- personally, didn’t have any concerns about this. I didn’t have a whole lot of time to review it, so I may have missed something.

So, I'll open it up to the rest of the Committee for questions.

COMMITTEE MEMBER LUND: I just have one question for you. So, our purview here is because CDSS is releasing contact information. It would seem to me that the analysis was not the individual, it was an institutional level of analysis?

VICE CHAIR DICKEY: Well, they're going to be collecting information from individual dual-language learner providers.

COMMITTEE MEMBER LUND: Right, but if --

VICE CHAIR DICKEY: The analysis is going --

COMMITTEE MEMBER LUND: Right, but it's not about -- it's not an analysis of the providers themselves, but about their --

VICE CHAIR DICKEY: No. But we often have things where we collect from individuals and we aggregate it, and they come to a conclusion.

COMMITTEE MEMBER LUND: Right. Yeah. No, so that was just my question because I was -- if the unit of analysis isn't the individual, him or herself, but the institution, I was just unclear about --

DR. RYKACZEWSKA: But it's still PII.

COMMITTEE MEMBER HESS: The individual is the subject of the study.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER HESS: It’s not -- yeah, to me that the unit of analysis is the institution. An individual is representing an institution, but we’re not -- they’re not --

VICE CHAIR DICKEY: Right, but we’re interacting with individuals, human subjects.

COMMITTEE MEMBER LUND: Okay.

COMMITTEE MEMBER HESS: Okay.

VICE CHAIR DICKEY: Which is what makes it --

COMMITTEE MEMBER LUND: Okay. I just --

VICE CHAIR DICKEY: -- the Common Rule.

COMMITTEE MEMBER HESS: Okay.

COMMITTEE MEMBER LUND: I just wanted to know.

VICE CHAIR DICKEY: But it also makes it -- what you’re bringing up makes it low risk.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: Any questions from the Committee? Any questions from the public?

DR. RYKACZEWSKA: Acknowledging no members of the public in the room. Any members of the public that would like to raise their virtual hands?

I am not seeing any virtual hands.

VICE CHAIR DICKEY: I can’t make the motion. So, would you make the motion for me?

COMMITTEE MEMBER HESS: Yeah. So, you have no changes or --

Okay. So, I move that we approve this project as submitted, one year, minimal risk.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER TEFERA: Second.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Okay, Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Sorry. Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Approve.

MS. ATIFEH: Dr. Palacio?

COMMITTEE MEMBER PALACIO: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

VICE CHAIR DICKEY: So, this is one of those rare instances where we've actually approved something without a revision. I want you to savor this moment.

(Laughter)

VICE CHAIR DICKEY: All right. So, you will be getting a letter from us to this effect. And thank you so much for your, you know, concise presentation to us. And good luck.

DR. KITMITTO: Thank you all for your review.

VICE CHAIR DICKEY: Okay. Now, I guess we're through with the new projects.

Is there -- do we have Items I through O -- L through O, any comments on those? These are basically the projects that have been approved by expedited review.

Hearing no comment --

DR. RYKACZEWSKA: Any public comment?

VICE CHAIR DICKEY: Public comment?

DR. RYKACZEWSKA: Acknowledging no members of the public in the room. If you have a comment -- if you're a member of the public and have a comment in the room, please raise your virtual hands.

I'm not seeing any virtual hands.

VICE CHAIR DICKEY: Okay, moving on to Agenda Item P. Any public comments on items that were not on the agenda?

DR. RYKACZEWSKA: Acknowledging still no members of the public in the room. If you're a member of the public and would like to raise your virtual hand?

No virtual hands raised.

VICE CHAIR DICKEY: Okay. And so, the next meeting will be February 6, 2026. Happy New Year.

COMMITTEE MEMBER TEFERA: The website says February 5th.

VICE CHAIR DICKEY: I'm sorry.

DR. RYKACZEWSKA: It does. I just noticed that effort yesterday, so we will update that. It is Friday, the 6th. But just let me double check my calendar, Friday is the 6th.

MR. ZADROZNA: Friday, February 6th.

DR. RYKACZEWSKA: Yes. Thank you for raising that.

VICE CHAIR DICKEY: All right. Unless there's -- we are adjourned.

(Thereupon, the meeting was adjourned at
12:40 p.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 28th day of December, 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 28th day of December, 2025.

Barbara Little

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