

MEETING
STATE OF CALIFORNIA
HEALTH AND HUMAN SERVICES AGENCY
CENTER FOR DATA INSIGHTS AND INNOVATION
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FRIDAY, FEBRUARY 6, 2026

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 (Via Zoom)

Maria Dinis, PhD, MSW (Via Zoom)

Catherine Hess, PhD

Jonni Johnson, PhD

David Lang, PhD

John Schaeuble, PhD, MS

Lemeneh Tefera, MD, MSc

Maria I. Ventura, PhD

Millard Murphy, JD (Alternate) (Via Zoom)

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

OTSI

Adam Dondro, Director

Mark Owens, Chief Counsel

David Haynes, Attorney

APPEARANCES (CONT.)

Consultants Present

Cheryl Byers, Advarra Consulting

Joshua Fedewa, Advarra Consulting

PRINCIPAL INVESTIGATORS AND ASSOCIATE INVESTIGATORS

Melissa Labriola, RAND (Via Zoom)

Stephanie Brooks Holiday, RAND (Via Zoom)

Bridgette Lery, Urban Institute (Via Zoom)

Kerry Padgett, CDPH (Via Zoom)

PUBLIC

None Present

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P R O C E E D I N G S

VICE CHAIR DICKEY: I'm Larry Dickey. I'm the Vice Chair and Acting Chair. This is the February 6, 2026, meeting of the Committee for the Protection of Human Subjects.

And please call the roll.

MS. ATIFEH: Sure. Okay, let me start with Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present. Good morning.

MS. ATIFEH: Good morning.

Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Present.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Present.

MS. ATIFEH: Thank you.

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: Okay, a quorum is established.

VICE CHAIR DICKEY: Okay. To start out -- well, welcome to everybody. And, actually, welcome back Mr. Murphy.

MR. MURPHY: Thank you very much.

VICE CHAIR DICKEY: It's been a while but --

So, we -- so, just some updates. We've been meeting -- we, I mean staff and the chairs have been meeting -- or, yes, the chairs have been meeting with the Advarra team, who are here today.

Would you care to introduce yourselves?

DR. FEDEWA: So, I'm Dr. Fedewa. I'm a Managing Director for Advarra Consulting.

MS. BYERS: I'm Cheryl Byers, Senior Vice Presenting for Consulting at Advarra.

VICE CHAIR DICKEY: They are happy to be on the West Coast, being from the East Coast and the Midwest.

So, we've had some productive discussions about our policies and procedures and they're helping us become up to date in terms of sort of national standards.

And it probably will be, probably not until next meeting that we're able to actually discuss any of what they are recommending to us. But stay tuned, you guys should be

getting something before the meeting, before the next meeting. At least that's the plan. Right. Okay.

Just a reminder that the deadline for the CITI training is coming up, which is March 31st. Most of you have actually completed it. There may be some that haven't.

For those who haven't completed it by March 31st, we will have some discussions about that. But it is a serious issue for us. So.

And anything else that I should discuss before I hand it over to you, Agnieszka?

COMMITTEE MEMBER DINIS: Could I ask a question about -- I think I've finished mine, but I don't know that I got a verification. Is there a way that the staff can let us know if we've finished all of the modules?

DR. RYKACZEWSKA: Absolutely.

VICE CHAIR DICKEY: Yes. They have a way of monitoring this.

COMMITTEE MEMBER DINIS: Okay.

DR. RYKACZEWSKA: Yeah. So, actually, I think what we can do is for all the members we can send you an email to confirm whether our records show that you have completed the required training or not.

COMMITTEE MEMBER DINIS: Thank you.

DR. RYKACZEWSKA: All right, I believe that's now Item B.

VICE CHAIR DICKEY: Yup.

DR. RYKACZEWSKA: All right, so this is the nomination of the new CPHS Chair. Just as a reminder, the CPHS policies and procedures state that the CPHS Chair is nominated by the CDII Director, voted upon by the Committee, and then submitted for appointment by the Secretary of Cal-HHS.

We're getting a little bit of feedback. So, if someone could mute, please.

VICE CHAIR DICKEY: Yeah, everybody online needs to mute.

DR. RYKACZEWSKA: Thank you.

So, today I have the pleasure of introducing Adam Dondro, the Cal-HHS Chief Information Officer and the Director of the Office of Technology and Solutions Integration, to formally make our nomination.

MR. DONDRO: Thank you, Agnieszka. Happy to be here to do this. And so, just to clarify, and I think these notes are in the documents as well, but as the CDII director position is vacant and we've administratively moved that within Cal-HHS' Office of Technology and Solutions Integration, so in that role I'm here until we get that role filled to be able to take on those responsibilities.

As you all know, in the December meeting Dr. Hess stepped down as Chair and extremely pleased to have her back

at Cal-HHS as the Chief of Epidemiology and Evaluation Unit, in the Substance and Addiction Prevention branch within CDPH, making her again eligible to be Chair.

Before I move through this, I also want to thank Dr. Dickey for stepping in as Acting Chair and keeping us moving forward. Very much appreciate that.

So, after consideration of the eligible candidates, I would like to formally nominate Dr. Hess for the CPHS Chair position again. We've included her bio and CV in the meeting materials.

And just to share a few things that pop out from there. Dr. Hess received her doctorate from Bournemouth University in Environmental Anthropology. She has extensive epidemiological background including early work investigating how residential segregation impacted exposure to toxic metal pollution in urban apartheid South Africa.

She was a post-doc fellow at both John Hopkins and UC Berkeley, leading critical research in tobacco, e-cigarette and alcohol use.

In her current role she leads epidemiological research focused on substance use, including tobacco, cannabis, alcohol and opioids.

And obviously, with all of that, brings deep expertise and research ethics and has served as a member of the Committee for the Protection of Human Subjects since

2021. And was appointed Chair in January 2025 and has demonstrated exceptional leadership over the past year, fostering collaborations, strengthening processes, and ensuring the Committee's work upholds the highest ethical and compliance standards.

Dr. Hess has expressed her interest to step back into this role and CDPH has endorsed her nomination.

And I, with that, will turn it back over for comments or a vote.

DR. RYKACZEWSKA: Do we need to have a motion?

VICE CHAIR DICKY: Yeah, I guess this is a voting issue, right. So, but I can't make a motion for you, so can another member make a motion?

COMMITTEE MEMBER TEFERA: I move to move the nomination for Chair forward.

VICE CHAIR DICKY: Second?

COMMITTEE MEMBER VENTURA: Second.

THE REPORTER: Who seconded?

MS. ATIFEH: Okay.

VICE CHAIR DICKY: Please call the roll.

MS. ATIFEH: Sure. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve, yes.

MS. ATIFEH: And Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Approve.

MS. ATIFEH: Thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: The motion passed.

DR. RYKACZEWSKA: Thank you, Sussan.

Congratulations.

MR. DONDRO: Congratulations and thank you.

COMMITTEE MEMBER HESS: No, thank you.

MR. DONDRO: And with that, I'll take that back to
the Secretary for the formal --

DR. RYKACZEWSKA: So, we should anticipate a
swearing in ceremony, we hope, should the Secretary agree in
the April meeting.

COMMITTEE MEMBER HESS: Okay.

VICE CHAIR DICKEY: You're now the once and future
--

(Laughter)

VICE CHAIR DICKEY: Okay. So, we move on to
approval of meeting minutes for the December 5, 2025
meeting.

DR. RYKACZEWSKA: Oh, we need to check for public comments.

VICE CHAIR DICKEY: Oh, that's true, yeah.

DR. RYKACZEWSKA: Are there any public comments for Agenda Item B, since we did have a motion and a vote there?

If members of the public could please make -- if you would like to make a comment, please raise your virtual hand if you are on Zoom. And acknowledging there are no members of the public in the room.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: Okay. All right, moving on to the meeting minutes for December 5, 2025. Are there any comments from the Committee or comments from the public about those minutes, before we vote on them? Okay.

DR. RYKACZEWSKA: Again, if you're a member of the public online, please raise your virtual hand. And again, acknowledging no members of the public in the room.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: No virtual hands.

VICE CHAIR DICKEY: Somebody please make a motion on that one, please?

COMMITTEE MEMBER HESS: I'll move to approve the meeting minutes from December 5th.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER SCHAEUBLE: I'll second.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Abstain.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Murphy?

VICE CHAIR DICKEY: I mean, Dr. Murphy's going to have to abstain because he wasn't at the meeting.

MS. ATIFEH: Yes, okay. But he is muted.

DR. RYKACZEWSKA: Oh, you are muted, Dr. Murphy.

VICE CHAIR DICKEY: I think I can see he's saying he's abstaining. No, I can't. (Laughter)

DR. RYKACZEWSKA: Dr. Murphy, can you unmute and let us know if you are abstaining?

MR. MURPHY: I abstain.

DR. RYKACZEWSKA: Thank you so much.

MS. ATIFEH: Thank you.

DR. RYKACZEWSKA: Now, we have it for the record.

Thank you.

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. At this point we move on to discussion of projects. The first project to discuss is the CARE Court Program Independent Evaluation. And Dr. Ventura is the reviewer.

COMMITTEE MEMBER VENTURA: Good morning. Is Dr. Labriola on the call? Or any member of the research team on the call, yet?

DR. RYKACZEWSKA: I am not seeing them. That's unusual.

MS. ATIFEH: Nick is calling them.

DR. RYKACZEWSKA: Hmm?

MS. ATIFEH: Nick is calling them.

DR. RYKACZEWSKA: Oh, Nick is calling. Wonderful. Let's give them a couple minutes to join then.

VICE CHAIR DICKEY: Should we move on to the other one in the meantime?

DR. RYKACZEWSKA: They're not there, yet, either.

COMMITTEE MEMBER HESS: We could do the continuing review.

DR. RYKACZEWSKA: I suppose we could.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Since that one doesn't have the research team joining.

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: Yeah, so just a context on this.

COMMITTEE MEMBER HESS: Do you want me to give context?

VICE CHAIR DICKEY: We have a continuing review project. The projects that are more than minimum risk actually need to come back to the full Committee for continuing review. And so, Dr. Hess, would you like to address this issue with the board?

COMMITTEE MEMBER HESS: Yeah. So, in an effort to kind of improve processes all, as Dr. Dickey said, all projects that are greater than minimal risk are, kind of moving forward, going to be brought to the board for continuing review, rather than just have single reviewer.

So, this project is a CDPH project investigating silicosis in workers making artificial stone. So, it's -- again, it's CDPH.

I have reviewed it. They are still in the recruiting phase of their project and they are doing x-ray imaging and blood draws on manufactured stone workers throughout the state. They've had no adverse or unanticipated events. They -- that actually summarizes it.

They are moving forward. They have not published anything, I believe.

DR. RYKACZEWSKA: Are they (indiscernible) --

COMMITTEE MEMBER HESS: Yes. So, they have asked for a year's extension on their IRB approval from us because they are experiencing some slow recruiting and enrollment of participants. They expect to complete enrollment within the next year, however, and then move to data analysis and reporting.

My recommendation is that we approve the continuing review and that we approve their request for an additional year of approval.

VICE CHAIR DICKEY: So, it's the imaging that makes it more than minimum risk, correct?

COMMITTEE MEMBER HESS: Yeah, I believe that was what our original --

VICE CHAIR DICKEY: Yeah. The blood draws, themselves, do not create an additional risks.

COMMITTEE MEMBER HESS: Yes.

VICE CHAIR DICKEY: I think they're doing chest CTs.

COMMITTEE MEMBER HESS: Yes. Chest x-rays. I don't think they were doing CTs, if I recall correctly.

VICE CHAIR DICKEY: Oh.

COMMITTEE MEMBER HESS: So, I would like us to

make a motion that we approve the continuing review of this greater than minimum risk project for six months, and that we approve their request to extend their end date from August 31, 2026 to August 31, 2027.

VICE CHAIR DICKY: Any -- before --

DR. RYKACZEWSKA: The comments.

VICE CHAIR DICKY: Yeah, comments from the public.

DR. RYKACZEWSKA: Well, any discussion or --

VICE CHAIR DICKY: Yeah, or discussion from the board. So, this all had to do with silicosis and --

COMMITTEE MEMBER TEFERA: Just a historical question. When was this project first approved?

COMMITTEE MEMBER HESS: 2023.

COMMITTEE MEMBER TEFERA: So, this is like it's third visit to the Committee?

COMMITTEE MEMBER HESS: No, they're on a six-month continuing review, so I've seen this project several times.

COMMITTEE MEMBER TEFERA: Okay.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER TEFERA: So, they're even more frequent, okay.

COMMITTEE MEMBER HESS: Uh-hum.

VICE CHAIR DICKY: We haven't brought it to the Committee.

COMMITTEE MEMBER HESS: We haven't brought it to the Committee.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Well, any -- so, any public comments on this item? If you're a member of the public on -- virtually on the Zoom, if you could please raise your virtual hand. Acknowledging no members of the public in the room.

And I see no virtual hands.

No, we can have --

COMMITTEE MEMBER HESS: Do you need me to remake the motion or --

VICE CHAIR DICKEY: No. Who -- did anybody second it?

COMMITTEE MEMBER TEFERA: I second.

VICE CHAIR DICKEY: He seconds it.

MS. ATIFEH: Oh, I thought Dr. Johnson seconded.

COMMITTEE MEMBER JOHNSON: That's fine.

(Laughter)

MS. ATIFEH: Dr. Tefera, you second?

COMMITTEE MEMBER TEFERA: Sure, yeah.

MS. ATIFEH: Okay. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Murphy?

DR. RYKACZEWSKA: Dr. Murphy, are you -- you are muted.

MR. MURPHY: Approve.

DR. RYKACZEWSKA: Thank you, Dr. Murphy.

MS. ATIFEH: Thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, motion passed.

VICE CHAIR DICKEY: A fun fact, there's a lot of companies in Sacramento that make these tabletops that are located on Silica Avenue, if you're -- just a little ways from here. Appropriately named.

Okay, moving on to the next project, which is -- got it now, they're present?

DR. RYKACZEWSKA: Dr. Labriola, are you online? Yes, I see her.

DR. LABRIOLA: Good morning.

DR. RYKACZEWSKA: Good morning.

VICE CHAIR DICKEY: Okay. So, we are moving on to the CARE Court Program Independent Evaluation. Dr. Ventura, take it away.

COMMITTEE MEMBER VENTURA: Good morning, Dr. Labriola. Are you joined by any team members this morning.

DR. LABRIOLA: Yes.

COMMITTEE MEMBER VENTURA: And could --

DR. LABRIOLA: Dr. Stephanie Brooks Holiday is on the phone, as well.

COMMITTEE MEMBER VENTURA: Wonderful. Can you go ahead and introduce yourself and whoever -- Stephanie's on the call. And then, if you can just give a brief overview of the project for the Committee members, and then we'll jump into it from there.

DR. LABRIOLA: Sure. So, Melissa Labriola, Senior Researcher at RAND.

Stephanie, would you like to introduce?

MS. HOLIDAY: Sure. Hi. Hello. I'm Stephanie Holiday, I'm also a Senior Researcher at RAND.

DR. LABRIOLA: And as for your brief, just I'll start with a brief summary of the project, the background and objectives.

The CARE, which stands for Community Assistance Recovery and Empowerment Act in California, establishes a civil court process that allows family members, first

responders, and others to petition the court to connect individuals with untreated schizophrenia spectrum or related psychotic disorders to a court-ordered CARE plan that includes treatment and supportive services.

An evaluation of the CARE Act is required in concordance with California Welfare and Institutions Code Section 5986, and RAND was hired to conduct an independent evaluation for the implementation process and outcome.

The evaluation needs to understand the implementation of the CARE Act at both individual and system levels, and effectiveness of CARE at achieving its intended participant outcomes.

Our application outlines our six main research questions. We have four process evaluation questions and two related outcome evaluation questions.

After a description of the human subjects, our evaluation will utilize a mixed methods approach, analyzing both quantitative and qualitative. And I will briefly describe these biometric flushing (phonetic) efforts.

The first is, duh, data. Our team will work with DHCS to acquire the data needed. So, this is going to include data also collected by Health Management Associates, which is the technical assistance provider, and as well as supplement with data that we receive from DHCS through RVAA.

The DHCS is the only state department releasing

any state data. And we will have access not only to HMA's data dictionary, but as well will also have HCAI, Medi-Cal claims data, DHS and CalOPS (phonetic).

The second which -- the second data collection method is the survey. We will conduct a survey with CARE respondents and petitioners. And this survey will try to reach all CARE respondents. And we will work with DHCS, the public defender's office, and other county level behavioral health leadership on proven strategy.

We're going to receive contact information from DHCS and HMA, through their county level reporting that they already do. And this information will be used to conduct outreach and recruitment for our survey. And this survey will allow us to better understand the CARE process and outcomes from the client's perspective.

It will be conducted at two points in time. And all interviewees will be over the age of 18. And their sex and ethnicity will vary based on who is enrolled.

The third data collection effort is qualitative interviews. And we're going to interview a range of staff implementing CARE, as well as DHCS and other relevant state level agencies.

We're selecting 12 counties across California for these interviews. And we're hoping to interview 15 to 20 people per county. And also, 15, 10 to 15 state level

partners.

We're going to work with DHCS and HMA to identify the appropriate behavioral health needs depending on the primary point of time.

These county and state level staff would be interviewed up to two times.

The fourth, I'm trying to go quickly, sorry, are the respondents qualitative interview. So, we're going to recruit participants across stages of their CARE process, as well as different points of their trajectory within the program.

So, we're really hoping to coordinate with community level implementation partners to identify participants who are willing to participate in an interview. Again, they'll be over the age of 18, and their sex and ethnicity will vary depending on who will be enrolled.

We hope to speak to 20 individuals in each of the 12 partnering counties, which will total approximately 240. They will receive a \$50 gift card for participating and they're only going to be interviewed once.

And lastly, there's going to be the petitioner qualitative interviews. Again, in the selected counties. And that's to learn about the process of submitting a petition. They include behavioral health providers, first responders, law enforcement, and/or family members.

Everybody will be over the age 18, sex and ethnicity will vary. We hope to speak to 20 --

COMMITTEE MEMBER VENTURA: Okay.

DR. LABRIOLA: Oh, did I go over?

COMMITTEE MEMBER VENTURA: No, no.

DR. LABRIOLA: Oh, I'm sorry, I thought that's -- okay, I'm almost done.

Over the age of 18. And they also will receive a \$50 gift card.

Lastly, just because I wanted to talk about potential risk, there is a small risk that some of the questions we ask will be upsetting. Because we're going to be asking about their services and their experience within the process.

This will be laid out perfectly in the -- this is in the consent form. They can skip any questions they don't feel comfortable with and still be part of the evaluation. They can stop the interview or survey at any time with no consequence to their services.

We will provide RAND's IRB phone number to all respondents, and provide paper copies as well.

There's a potential risk of breach of confidentiality, but we really believe this is a minimal risk and unlikely to occur. The data will not include personal identifiers and everything is stored on RAND's

secure, password protected devices.

And the quantitative data is download in our cold room, which on all RAND premises. And then, de-identified data will be stored in any RAND-approved secure device.

So, I'm hoping that kind of covered an overview.

COMMITTEE MEMBER VENTURA: Thank you so much, that was helpful. As you can -- as you know, this is a lot. There's a lot of pieces to this.

DR. LABRIOLA: Yes.

COMMITTEE MEMBER VENTURA: So, if we can walk through the different sections, because I do thank you for addressing some of my comments this week, but there were still some things that I wanted to discuss with the Committee and with you.

So, just starting with like study procedures, I thank you for ensuring that the reading level for the consenting scripts and everything were low enough. Just note that this is a vulnerable population, they're impaired decision making, they're mental illness, and so I wanted to make sure that it was understandable.

And also, thank you for adding those questions to check for understanding before you proceed with enrolling people in your study. So, that was resolved for me.

One of the things that I still needed clarification on, so you have respondents or clients, you

have the petitioners, you also have staff, state staff who are participating in interviews. It wasn't clear if staff will be consented before -- I understand they're not going to be compensated, but will they be consented before they participate in the interview?

MS. HOLIDAY: Yes, there's a consent process for staff members who participate, as well.

COMMITTEE MEMBER VENTURA: Okay. And then, the other piece that's still -- there was a mention of social media recruitment. I know you were going to be contacting people via phone and email. Are you still potentially reaching out to people via social media? I didn't see any procedure for that.

MS. HOLIDAY: For the -- it's not mentioned in my (indiscernible) -- to the client survey. It is not part of our outreach strategy. We are planning to do that survey at multiple points in time for the same individual. So, our survey research group is one of those passages (phonetic) to obtain as many different forms of contact information for folks so that they can, after they do the initial survey work for them. So, that includes phone numbers. It can include email addresses, physical addresses, contact information for providers or family members who might be -- know how to reach them and get their contact information.

And sometimes we will also ask for any social media handle, if that's the preferred form of contact. But that would be something that clients would be opting in to share, if we were to do this.

COMMITTEE MEMBER VENTURA: Okay. Were there any comments with regards to social study procedures from the Committee? Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Yes. For people who might become upset by something that is -- comes up in the survey questions or is discussed in the interviews, the normal situation, I think, is that people would have an opportunity to reach out to a resource for help with that, that does not involve having to contact the researchers who are conducting the project.

And I'm wondering if you couldn't provide some appropriate list of resources that people could self-refer to, rather than their only option being to reach out to RAND.

MS. HOLIDAY: Sure, that is something that we could add. For other studies we've done, where we've provided a resource sheet with contact information, for example for 988.

Also, all of the folks that we survey are going to be hooked up with behavioral health at the county level. So, I think referring people back to their providers will be

the other option that we would suggest they take advantage of.

COMMITTEE MEMBER SCHAEUBLE: People do receive a copy of the consent information. I saw that it was a verbal consent. But they do receive a copy, is that right?

MS. HOLIDAY: I'm just looking to confirm.

DR. LABRIOLA: We have written that paper copies can be made available.

COMMITTEE MEMBER SCHAEUBLE: I was asking because the logical place it seemed to do something like this would be in, I think it was the third paragraph, in at least one of the consent forms I looked at that touched on this issue. And could provide a link at that point to some document that had resources for people if they wished to take advantage of that. And that's why I was asking if they were, in fact, receiving a copy of the consent, so that they would have that information if they needed it.

MS. HOLIDAY: Yes. They can if they request it. But I think our concern is that many of these folks are not necessarily going to have stable addresses, or access to technology to be able to -- to be able to get access to that, as well.

So, I think the more that we can provide this information in a simple way, as part of a verbal consent process too, I think that that will be very important.

COMMITTEE MEMBER SCHAEUBLE: Well, in any case, if you could clarify for us, in whatever revisions you do, how you would handle that so that people would have the information. That's basically what I was asking for.

MS. HOLIDAY: Absolutely.

VICE CHAIR DICKEY: With regard to that, if -- having a copy of the consent is something that's available to them, it probably should be revealed on the consent form. You know, you can request a copy of this and it will be provided to you.

I noticed at the end it says you -- if you have questions or concerns about participation, contact RAND's IRB. And I think typically the language is if you have questions about your participation, about your rights as a research subject contact the IRB.

But then, usually, in terms of questions about the study itself, contact information is provided for the researchers. Is that provided elsewhere or is it not on this?

COMMITTEE MEMBER VENTURA: I think that could -- that should be differentiated.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER VENTURA: And clarified on the consent document.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: So, questions about the research project you go to the PI. Questions about just the rights --

VICE CHAIR DICKEY: Your rights as a research subject.

COMMITTEE MEMBER VENTURA: Yes. Can go to IRB.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER VENTURA: And then, additional resources also -- I think that's a good place to provide for them --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: -- all the contact information in just kind of a section that's clearly available to them.

VICE CHAIR DICKEY: Right. So, they're referring here to the RAND IRB. Traditionally, we've just said there needs to be one IRB at least. Even though we're reviewing it, we haven't insisted we be on that. Just because it's kind of confusing to people.

COMMITTEE MEMBER VENTURA: Uh-hum.

VICE CHAIR DICKEY: But that's good to be asking the question, should we cite all the IRBs, and traditionally we don't. I think legally they have to have one.

MS. HOLIDAY: Okay, we can be sure to add a contact information there.

COMMITTEE MEMBER VENTURA: Okay, thank you.

Any other comments from the Committee on the study procedures section?

Okay. Actually, any other major concerns from the Committee? I believe the researchers addressed -- let me just look through my notes.

COMMITTEE MEMBER TEFERA: I had a general question while you're doing that.

COMMITTEE MEMBER VENTURA: Yeah, yeah, thank you.

COMMITTEE MEMBER TEFERA: Hi, good morning. I was curious, do you have a projection of the percentage of the subjects that you'll be able to recontact at the nine-month interval? You're dealing with a very transitory population and I'm just wondering your thought process about, you know, how to stay in touch and, yeah.

DR. LABRIOLA: Well, you know, honestly we're just now receiving our -- they're just collecting the information for even that first contact, and so we don't even know -- we're anticipating a pretty low level for the first contact. So, yes, we are anticipating an, obviously, lower level for any sort of follow up.

So, that is really why our goal is just to reach as many as -- you know, there's no sampling or anything like that. We're just really going to try to ask -- reach out to everyone that we can, with the expectation that these

contact rates will be low.

MS. HOLIDAY: That said, our survey research group is very practiced at longitudinally following populations like this over time. They've been able to achieve follow-up response rates as high as 80 to 90 percent, with really similar populations because they are so careful to track as many different kinds of contact information as they can when they make that first contact with folks.

So, basically, 85 would be (indiscernible) -- a doable project given the population and given how many different counties we're going to be working with. It is also the reason why we have a higher incentive amount attached to the follow-up survey to, hopefully, you know, incentivize folks to keep their contact information current with us. We often let people know that, hey, if your phone number changes, you can reach back out to us to update us in the in between, to make sure we can contact you for that second survey.

So, that's some of how we'll try to increase our response rate, too.

COMMITTEE MEMBER TEFERA: Thank you.

COMMITTEE MEMBER VENTURA: Another -- so, regarding the data that you'll be receiving as part of the BAA, so you mentioned the use of all the linked data, HCAI, DSH. DOJ, is that part of that business.

Yeah, thank you, yeah, BAA. Is that part of it or will that have to be a separate data request, like maybe a future amendment or something requesting the DOJ data? I'm just wondering if that --

DR. LABRIOLA: Well, right now --

COMMITTEE MEMBER VENTURA: Yeah.

DR. LABRIOLA: Oh, DHS is working with the DOJ to obtain data, but that's still in --

COMMITTEE MEMBER VENTURA: Okay.

DR. LABRIOLA: -- prelim talks.

VICE CHAIR DICKEY: Well --

COMMITTEE MEMBER SCHAEUBLE: Where would this data be?

DR. RYKACZEWSKA: That would need to be an amendment.

COMMITTEE MEMBER SCHAEUBLE: What kind of data would that be that you say you could --

DR. LABRIOLA: Oh, and -- and so, that would help with our measurement of an outcome. So, I mean, sort of, you know, rearrest, or any reengagement in the justice system.

VICE CHAIR DICKEY: So --

COMMITTEE MEMBER LUND: But I, we have -- oh, I'm sorry.

VICE CHAIR DICKEY: No. So, DHCS is getting the

data from the Department of Justice, and then they'll pass it to you, right?

COMMITTEE MEMBER LUND: Right. It's going to, hopefully.

VICE CHAIR DICKEY: Yeah. So, we went through this previously, you know, where it's really DHCS that needs to assert that this release is according to all state laws.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: We don't do it separately for each department.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: We went through that with our legal counsel previously.

COMMITTEE MEMBER VENTURA: All right. And because they have a BAA with DHCS, then they will, once DHCS irons that out, they'll have access to everything that the HCAI --

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER VENTURA: -- DOJ, DHS data, all that.

VICE CHAIR DICKEY: Within the bounds of the BAA.

COMMITTEE MEMBER VENTURA: Right, okay. Okay, I just wanted to clarify that.

COMMITTEE MEMBER HESS: So, they don't need an amendment for additional --

VICE CHAIR DICKEY: I don't think so.

COMMITTEE MEMBER HESS: Okay.

VICE CHAIR DICKEY: If it's part of this, they don't need it separately.

COMMITTEE MEMBER VENTURA: Okay.

DR. RYKACZEWSKA: Yes, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm wondering if I'm the only person who has difficulty here seeing the big picture of the total amount of information that potentially could exist about individual people represented in the data.

I'm seeing petitioners from several sources. And we're now talking about justice data, where there's no identification of particular pieces of information that might come from that source.

Is it possible to provide, and would you be willing to provide, some listing of all of the variables potentially for an individual respondent, and what the sources are for those variables, so that we could have a better flow of the total situation here?

VICE CHAIR DICKEY: I agree with you, Dr. Schaeuble. When I said they don't need a separate -- basically, you know, a separate letter from each department, but I think we still need to know the variables, all the variables that are being collected.

DR. LABRIOLA: Well, sure, of course. Yeah, we can put that together. So, basically, a list of all the

information we would have for each -- for the data and what source that would be coming from.

Do you -- we need that for the data. Would you also like that for the qualitative interviews and survey, or is this -- or are you asking this more for the data that's coming in, also?

COMMITTEE MEMBER SCHAEUBLE: I think I'm concerned primarily about the clients, whether it's interviews or surveys, or data about clients. More -- not so much for the state or county staff, that situation. But particularly for the people who are in the system --

COMMITTEE MEMBER VENTURA: Yes.

COMMITTEE MEMBER SCHAEUBLE: -- where the most sensitive information resides. And you've got an awful lot of sensitive information here, let's face it.

COMMITTEE MEMBER VENTURA: Uh-hum.

DR. LABRIOLA: Sure.

COMMITTEE MEMBER VENTURA: Yeah, they've provided quite a few data dictionaries --

COMMITTEE MEMBER SCHAEUBLE: Uh-hum.

COMMITTEE MEMBER VENTURA: -- and Excel spreadsheets --

COMMITTEE MEMBER SCHAEUBLE: I looked at them.

COMMITTEE MEMBER VENTURA: Yes. With -- they did clarify some of the things where it indicated that maybe, or

unsure if RAND was going to use that data. I asked them to just take those out. Like, I need to know which variables exactly they're requesting from -- I forget which Excel spreadsheet that was.

DR. LABRIOLA: (Indiscernible).

COMMITTEE MEMBER VENTURA: Thank you. And there was a DCR -- DRC data dictionary that was added. So, I agree, I think having an overview, identifying exactly what variables from each client and the source will be helpful. Thank you.

Okay. Was there anything else from the Committee regarding this?

COMMITTEE MEMBER SCHAEUBLE: I did have a couple of other places that I wanted to get into, yes.

COMMITTEE MEMBER VENTURA: Yes. Go ahead.

COMMITTEE MEMBER SCHAEUBLE: In the section of the application that discusses small cell sizes I think this is the first instance we've seen, so far, of people trying to apply the scoring that's in the data guidelines document. And also, the first instance, I'm aware of, of researchers saying that it might not be necessary to suppress cell sizes smaller than 11.

And I'm wondering what kinds of variables you believe may lead to that circumstance?

In the past I believe there -- it's been very

automatic that any cell sizes smaller than 11 would be not reported in that way. So, can you go into that a little bit for us?

DR. LABRIOLA: So, I'm looking at -- so, this is -- so, you're speaking of where it says, "after speaking with the director's office multiple times, we know that not all data requires suppression."

COMMITTEE MEMBER SCHAEUBLE: Yes. Am I misreading what you're saying there? Are you --

DR. LABRIOLA: I don't --

MS. HOLIDAY: I think that this line may be from a discussion that we had with the office that was because numbers are small across counties for some of these processes that were we were to suppress all cell sizes smaller than 11, I think they were concerned that that means that there's possibly relevant information about the population that wouldn't be known because it couldn't be shared back in (indiscernible) for them.

So, I know it was them who encouraged us to think about making sure that we're applying these criteria in only specified cases in which it's really required.

I don't think that we have a use case in mind for this situation, necessarily, where it may percent itself that we would have a cell size less than 11 and so be presenting it.

But I think that was the (indiscernible) --

COMMITTEE MEMBER SCHAEUBLE: I guess I'm not quite sure how to follow up on my train of thought here, but I guess I'm concerned that I would somehow want to see some feedback of -- if this actually happens, some feedback to us about situations where you would choose to do this differently than what we've seen in the past. Because I find this a little disconcerting that -- Agnieszka, please weigh in.

DR. RYKACZEWSKA: Well, I wonder if I may give a suggestion. Because at this point it sounds like we don't know whether this will be -- turn out to be an actual reality.

COMMITTEE MEMBER SCHAEUBLE: Right, we don't.

DR. RYKACZEWSKA: And I almost wonder if we remove it for now, and say anything under 11 would be suppressed. But if the research teams comes and finds out that there are findings that are policy relevant, that do require reporting of numbers less than 11, that may be an amendment at that time, and they would come back to the board to discuss the specifics of that case.

Because I think right now it's very conceptual.

COMMITTEE MEMBER SCHAEUBLE: It's very amorphous.

DR. RYKACZEWSKA: Yes.

VICE CHAIR DICKEY: Would that be acceptable to

the researchers?

MS. HOLIDAY: I think that -- I just want to clarify a little further because we wouldn't be making these decisions based on our own discretion, but we would be following the detailed DHCS scoring guide that's outlined in that document that we linked. And so, it's not that we would be saying, oh, we think that this is something that qualifies. But there's some pretty clear criteria where certain types of pieces of information get scored a higher score, so that very sensitive things do get suppressed and less sensitive things do not.

So, I just -- I guess I just would to share a little bit more about the concerns with that guidance from DHCS.

VICE CHAIR DICKEY: Dr. Hess would like to say something about this.

COMMITTEE MEMBER HESS: I mean I think that the DDG guidelines do allow for reporting cell sizes smaller than 11. There's a very detailed scoring criteria based on denominators. And I feel like as long as they're following those guidelines in the DHCS DDG guidelines that I would be fine with them, potentially, reporting a cell size less than 11.

Right. So, the point of those guidelines is that we don't have to have this blanket one-size-fits-all,

anything -- any cell size less than 11 can't be reported. It's based on the population, a whole number of demographics and factors that go into determining what the appropriate denominator is.

VICE CHAIR DICKEY: So, it sounds like we maybe need to know more about those guidelines.

COMMITTEE MEMBER HESS: I mean, they're -- they haven't really changed much from the previous guidelines. So, I mean, my view is that if they're following CHHS, California HHS guidelines on data suppression that's appropriate.

DR. RYKACZEWSKA: It is very rare. So, I do have a follow-up question. But it is very rare, but there are instances based on DHCS' department-specific guidelines of the CalHHS general guidelines that account for certain ways that HIPAA requires de-identification to be done and documented, and the statistical analysis that has to go into it.

So, there are rare instances where there would be a number, because of the way that the scoring is required to be done, that is less than 11. But because of the size of the denominator, let's put it that way, it's a way simplification of the scoring. But because of the size of the denominator there's not a risk of re-identification in those cases.

And I think one of my questions was going to be who is doing the scoring? Is it DHCS or is it the research team? For the de-identification.

MS. HOLIDAY: I believe it would be the research team.

DR. RYKACZEWSKA: Okay.

MS. HOLIDAY: That would be applying this formula. Because we will have -- in doing the analysis of the data.

DR. RYKACZEWSKA: Okay.

COMMITTEE MEMBER VENTURA: But even if the research team is doing the scoring, I mean, ultimately, the reporting, it falls within DHCS. So, they have to follow --

VICE CHAIR DICKEY: They have to review it and approve it.

COMMITTEE MEMBER VENTURA: Yes, they have to review it and if it's not appropriate to report a small cell, then they will have to suppress.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER VENTURA: Even if the director's office wants to know county level, there will have to still be some masking there.

So, I'm okay with what was included. I don't know, Dr. Schaeuble, do you still have any suggestions to address your concerns.

COMMITTEE MEMBER SCHAEUBLE: Well, I guess, as I

said at the beginning, I'm uneasy because I can't recall any instance of researchers telling us that they were, in fact, going to be reporting some data with cell sizes smaller than 11, or might do so.

It's the first instance I can recall, in my time on the Committee, of that coming up.

DR. RYKACZEWSKA: That has --

COMMITTEE MEMBER SCHAEUBLE: And that makes me uneasy in the sense that I can't visualize the impact of the scoring process, if we haven't seen the outcome of it in past instances, to know whether there are any implications from our vantage point in what we see as reviewers for research projects.

So, that's the source of my uneasiness.

VICE CHAIR DICKEY: But I think we have accepted their statements that they would follow the guidelines. They might not have explicitly said it, that there may be instances.

But it sounds -- maybe it may just not be as sophisticated as these researchers in terms of understanding the guidelines.

COMMITTEE MEMBER SCHAEUBLE: Well, this is the first reference I've even seen to people referring to the scoring model.

VICE CHAIR DICKEY: Well, that's new, isn't it?

DR. RYKACZEWSKA: No. The scoring model -- the scoring model has stayed consistent. It has become a little bit more standardized across departments. But the scoring model is the same, especially for DHCS.

What is different -- the primary thing that is different in this DDG is that we added additional vulnerable categories that have scoring. So, things that previously might have not been seen as high risk, now that we're taking into account these vulnerable populations those scores might be higher than they would have been in the past.

So, that is the primary thing that has expanded in terms of the new version of the DDG. But the scoring methodology, especially for DHCS, we kind of largely standardized the approach that DHCS has been using across agency.

COMMITTEE MEMBER SCHAEUBLE: So, you know, it seems like others are satisfied here and I won't pursue it further. As I said, it's the first time I've seen anybody reference using scoring, instead of simply saying they were going to suppress less than 11. So, I had to ask.

DR. RYKACZEWSKA: And I appreciate the question.

COMMITTEE MEMBER DINIS: I have a comment. I mean, to me, I would feel uncomfortable that it came back as an amendment if they found those instances where they needed to report out less than 11. Otherwise, our criteria, then,

to me doesn't mean anything because if researchers can pick the times that they can do this, it doesn't seem like it's right to me. To protect the privacy of others.

DR. RYKACZEWSKA: To clarify, Dr. Dinis, just -- and I'm not saying -- I'm not advocating against the amendment approach because I suggested it, so.

But just to clarify, it isn't the research team that gets to choose when to do this. It is decided by the risk scoring based off of the data de-identification guidelines.

So, only if they saw that the risk score within the data de-identification guideline that a allowed score, the reporting based off of that, just to pull it out of the -- only then would they be able to do it. They wouldn't be able to do it for any, just any variable.

VICE CHAIR DICKEY: This would probably be a relatively rare experience, I'm assuming, right.

DR. RYKACZEWSKA: Correct.

VICE CHAIR DICKEY: So, basically, what you're saying is you'd like to have some way to confirm that they applied that scoring correctly. Is that --

COMMITTEE MEMBER SCHAEUBLE: No, I'm really saying that I would --

VICE CHAIR DICKEY: -- your objectives with scoring?

COMMITTEE MEMBER SCHAEUBLE: -- I would like to know the circumstances and the particular variables that turned out to be --

VICE CHAIR DICKEY: So, you'd like to look at it, yourself?

COMMITTEE MEMBER SCHAEUBLE: -- reportable under this exception to what we have normally seen otherwise in the past. I don't have a good sense of what situation or what kinds of variables might potentially be reported under this scoring procedure, where we've otherwise seen researchers ordinarily saying --

DR. LABRIOLA: But the guidelines will indicate which variables can be reported 11 or under.

COMMITTEE MEMBER SCHAEUBLE: I understand that, but --

DR. LABRIOLA: So, are you asking like in what situation can that be suppressed?

COMMITTEE MEMBER SCHAEUBLE: No, all I'm really asking is, in the way of feedback to the Committee, so that we would understand when it has turned out that a variable can be reported according to the scoring model with cell sizes less than 11. What happened in that regard in the project. Because I have no sense of how this might turn out.

VICE CHAIR DICKEY: So, you'd put that for as

education of the Committee.

COMMITTEE MEMBER SCHAEUBLE: Right.

VICE CHAIR DICKEY: So, I don't see particular harm in that. That for our education, if this were to happen, that they come back and inform us of this. And then, would it be sufficient for the primary reviewer to look or would you like the full Committee?

COMMITTEE MEMBER SCHAEUBLE: They would be -- depending on what the primary reviewer sees, I would say sufficient for the primary reviewer to see it --

COMMITTEE MEMBER VENTURA: Then I could bring it to the Committee.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: -- and he or she could bring it to the Committee if it looked like relevant information for the whole Committee to see.

VICE CHAIR DICKEY: Are you okay about that?

COMMITTEE MEMBER VENTURA: That's satisfactory, yes. That's fine, Dr. Schaeuble. I think if there is something less than 11 that comes in the -- in the instance it happens, and I feel that it's important --

COMMITTEE MEMBER SCHAEUBLE: It's not going to show up until you probably see a continuing review or something like that.

COMMITTEE MEMBER VENTURA: That's right. Yeah.

And then, if it is concerning, I could bring it to the board -- back to the Committee.

COMMITTEE MEMBER SCHAEUBLE: Uh-hum.

COMMITTEE MEMBER VENTURA: Okay. I'm okay with it.

MS. HOLIDAY: Can I ask a clarifying question about what that process would look like, just because we have to think about what this would mean for timelines of the project, and like the additional levels of review we already have from DHCS, and what does that look like in practice?

VICE CHAIR DICKEY: Well, wouldn't it be before any publication that they would come back and inform us of -- inform the primary reviewer of any instances?

COMMITTEE MEMBER SCHAEUBLE: That would be a logical --

VICE CHAIR DICKEY: So, before publication. You just need to inform the primary reviewer if there are any instances of less than 11 and provide the justification for that.

DR. RYKACZEWSKA: And as an addition to that, because all of our documents are public record, I would request that you only list the variables or the -- yeah, the variables that we find numbers under 11, but not list the actual numbers because then that would be publishing it,

publicly.

MS. HOLIDAY: Yeah.

VICE CHAIR DICKY: Yeah.

COMMITTEE MEMBER SCHAEUBLE: Uh-hum.

MS. HOLIDAY: And what is -- what is the timeframe for review does that take up --

VICE CHAIR DICKY: Well, that would just be an expedited review. I guess you'd probably submit it as an amendment, which can be reviewed as expedited review by the primary reviewer.

COMMITTEE MEMBER VENTURA: As soon as it's received.

DR. RYKACZEWSKA: Yes, unless the primary reviewer then determines that the full Committee needs to --

VICE CHAIR DICKY: Yes.

DR. RYKACZEWSKA: At which point it would be the next --

VICE CHAIR DICKY: The next meeting, which is every two months.

MS. HOLIDAY: Oh, every two months, that is concerning.

VICE CHAIR DICKY: Well, we don't know that it's coming back to the full Committee.

DR. LABRIOLA: I know.

MS. HOLIDAY: It could just come back --

DR. LABRIOLA: I know, but in our -- we would have to -- I think we have to plan for the, right --

MS. HOLIDAY: Right.

COMMITTEE MEMBER TEFERA: I have a question here.

DR. LABRIOLA: And could we, as part of the justification, if DHCS wants us to report it and it's okay by their guidelines, is that part of the justification -- you know, and it's something that's important to them regarding it's an important finding, it's policy related, is that part of the justification that we can --

VICE CHAIR DICKEY: I would think so. Don't you think, Dr. Ventura?

COMMITTEE MEMBER VENTURA: Yeah. I am leaning towards like if -- I mean DHCS is -- ultimately, they have to follow, you know, CalHHS DDG guidelines. And if they determine that reporting under 11 -- I don't know.

COMMITTEE MEMBER TEFERA: I just have a process question. This conversation right now, assuming we will eventually approve this project, is this conversation about an amendment or is this conversation about not an amendment, but just requesting internal information that then the next -- the next time the project is reviewed?

VICE CHAIR DICKEY: No, it's they would need to put something into their current protocol, an amendment

saying that they're going to do this.

DR. RYKACZEWSKA: So, essentially it is determining what is it -- should the board approving, what is it that they are approving right now? What is the scope and what is outside of what we are approving right now?

VICE CHAIR DICKEY: Right. So, the --

COMMITTEE MEMBER TEFERA: I mean, I guess my concern there is that the conversation is essentially an extended counterfactual. Like, we're just, you know, thinking about what could happen. And I think that's difficult for anyone to respond to, and kind of prepare, and organize.

So, absent a strong reason to think that this unlikely event is going to happen, I'm not sure that should be raised to the level of amending the project. It's a reasonable question, but we have answers to the questions that are reassuring. And this is being administered by a department in Health and Human Services that has a clear protocol. That, itself, is, you know, very, very reassuring. And that department is intimately involved in the project. That also speaks to a level of oversight.

So, I'm not sure requiring an amendment makes sense for an event that may never happen, and certainly has not happened yet.

COMMITTEE MEMBER HESS: I would just --

COMMITTEE MEMBER DINIS: Well, I'm sorry, if it doesn't happen, then they don't have anything to report. But if it does, look, I think, as a Committee member I would like to know what the circumstances were that they have to go to a suppression of under 11.

COMMITTEE MEMBER HESS: I guess I would ask is a possible outcome of an amendment would be that we would be overwriting DHCS' de-identification guidelines? I mean, not -- that would be the entire point of bringing it back to the board, though.

VICE CHAIR DICKEY: Well, we do have that right.

COMMITTEE MEMBER HESS: We do, but the guidelines are developed for a reason and --

VICE CHAIR DICKEY: I understand.

COMMITTEE MEMBER HESS: -- they are very rigorous in terms of protecting individuals from reidentification. So, it would --

COMMITTEE MEMBER SCHAEUBLE: Again, my reason for raising this was for information to the Committee. I didn't -- I didn't raise it with the idea that we were going to approve or disapprove something that is within the guidelines of the agencies themselves.

But I guess --

VICE CHAIR DICKEY: Well, then it would just be a -- if it's not a requirement, then it would just be a

recommendation which is actually not binding, unless it's in the -- unless it's pushed as a requirement. So.

COMMITTEE MEMBER TEFERA: I'm sorry. I don't understand, when you say recommendation you mean to the researchers or --

VICE CHAIR DICKEY: To the researchers.

COMMITTEE MEMBER TEFERA: Sure. And that seems reasonable, as well, to make a -- if we make a recommendation to the researchers, it seems highly likely that they would respond to that.

VICE CHAIR DICKEY: Yeah. I mean, we've had motions in the past where we say we recommend, but we don't require. That's sort of in between.

COMMITTEE MEMBER HESS: I feel like if it's for information purposes, then that's a thing that could be picked up in a continuing review. They could report. If it's not something that we would vote on and it was just for the information of the Committee, it would be better for them to report that in continuing review, rather than bringing it to us for an amendment where we would be considering whether or not we would even approve that.

I'm a little uncomfortable with the thought of us overriding standard de-identification procedures without very good cause.

VICE CHAIR DICKEY: When I said that they would

come back to us as an amendment, it's just that we don't have a mechanism, other than an amendment, to get feedback on projects. We do on continuing review. But that assumes that they're not going to publish before they do their continuing review. It's really the publication where the cell size is an issue.

COMMITTEE MEMBER TEFERA: I mean, from what's described by this project, this will not be published anytime soon. As far as recruiting patients, I don't think that's a risk, itself, where you have active turnaround.

VICE CHAIR DICKEY: No, it's not -- no, it may be years but --

Dr. Ventura?

I mean, I think it's -- you probably need to figure out a motion to make that we can vote on, on this issue. We don't need to get to the motion, yet, but --

COMMITTEE MEMBER HESS: Dr. Ventura won't be making the motion, she's abstaining.

VICE CHAIR DICKEY: Oh, that's right. And I can't make the motion, so -- is it okay if --

COMMITTEE MEMBER HESS: I can make a motion if Dr. Ventura walks me through it.

VICE CHAIR DICKEY: Okay. All right.

COMMITTEE MEMBER VENTURA: Well, we --

COMMITTEE MEMBER HESS: Well, I want to make sure

that we've like finished the discussion first, though.

COMMITTEE MEMBER VENTURA: Yes.

COMMITTEE MEMBER HESS: Like what are we actually going to require.

VICE CHAIR DICKEY: Well, it sounds like we have two different, maybe three different versions. One is they don't need to do anything additional, we just go by the guidelines.

And an in-between is we recommend that they let us know about these instances.

And the third would be that they need to come back and tell us about this and we make --

COMMITTEE MEMBER HESS: Prior to any publication.

VICE CHAIR DICKEY: Prior to any publication.

COMMITTEE MEMBER TEFERA: But to clarify, those first two options, the first option just being approval without condition.

VICE CHAIR DICKEY: On this issue.

COMMITTEE MEMBER HESS: On this issue.

COMMITTEE MEMBER TEFERA: On this issue.

VICE CHAIR DICKEY: There are other issues that --

COMMITTEE MEMBER TEFERA: Oh, right, on this issue. I would still think the researchers would contact the Committee if there was an event worthy of notification.

VICE CHAIR DICKEY: But just on this issue. We're

saying do we make this an issue where they need to contact us if it goes -- you know, if this occurs. Or, are we recommending that they contact us. Or, they don't need to do anything, other than what they're saying they're going to do, now.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I don't know whether it helps or hurts, but I'll make a personal recommendation that we pursue this as recommending to the researchers that they identify to the Committee, if it occurs, situations that under the scoring guidelines had led to reporting cell sizes smaller than 11 in --

VICE CHAIR DICKEY: In a publication?

COMMITTEE MEMBER SCHAEUBLE: Prior to publication, so that we're aware of it.

VICE CHAIR DICKEY: Right, okay.

COMMITTEE MEMBER SCHAEUBLE: But that it be simply reported to us as information to --

VICE CHAIR DICKEY: So, you're recommending the middle path on that.

COMMITTEE MEMBER TEFERA: And just to clarify, the middle path does not add extra burden for the researchers as far as coming to --

VICE CHAIR DICKEY: We're making it a recommendation, it's not a requirement.

COMMITTEE MEMBER TEFERA: Okay, great.

VICE CHAIR DICKY: Move on to other issues. The -- it's been brought to our attention and, actually, our consultants actually can participate in our discussions because they're paid consultants to us. But we've got a message.

In terms of the consent we need to have it explicit they're requesting a waiver of --

COMMITTEE MEMBER VENTURA: Documented.

VICE CHAIR DICKY: -- documented --

COMMITTEE MEMBER VENTURA: Yes.

VICE CHAIR DICKY: -- informed consent, but also an alteration of the consent requirements. This doesn't have all of the requirements in it. Certain things are left out.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKY: Am I putting that correctly?

MR. FEDEWA: Yes.

VICE CHAIR DICKY: And so, that would have to be part of the motion that it's a waiver of documented consent and a waiver of the --

MR. FEDEWA: An alteration of the consent.

VICE CHAIR DICKY: An alteration of the consent. Right.

Anybody have questions about that?

COMMITTEE MEMBER SCHAEUBLE: Not about that, but I did have one other area.

VICE CHAIR DICKEY: Okay. We'll get to that, okay.

Also, there's the issue of the -- and we do have our prison consultant with us, prisoner consultant, Mr. Murphy.

Are any of these respondents going to be prisoners? Is that contemplated?

MS. HOLIDAY: Some of the people who are referred to care are done so through CDCR or through Department of State Hospitals because they've been found incompetent to stand trial. So, yes, there are some. And there are also some possibility that people who are under care in the community may be arrested and could end up incarcerated.

No one involved in the primary data collection, the surveys, or the interviews will be incarcerated at the time that we are conducting the surveys or interviews, but the administrative data may reflect their incarceration.

VICE CHAIR DICKEY: So, is there any potential that the data collected could have any effect on their incarceration, or return it to incarceration?

MS. HOLIDAY: No. It won't affect their legal status.

VICE CHAIR DICKEY: Do we need reassurance about

that in the consent? Can I ask you guys?

MR. FEDEWA: I don't think it necessarily needs to be in the informed consent. But the prisoner regulations still apply because the data's being collected that includes their potential prisoner status.

VICE CHAIR DICKEY: Uh-hum.

MS. BYERS: Yes. So, you would need to go through the subpart to clarify which category is it this research project goes into.

VICE CHAIR DICKEY: So, they haven't submitted the prisoner checklist.

MS. HOLIDAY: No.

VICE CHAIR DICKEY: Can we -- is there any way we can display that checklist?

DR. RYKACZEWSKA: Give me just one minute.

VICE CHAIR DICKEY: So, that maybe we can run through it.

DR. RYKACZEWSKA: I think they would still have to --

VICE CHAIR DICKEY: They would have to submit it.

DR. RYKACZEWSKA: -- submit it, but it's worth discussing. Let me just pull it up right now and I can put the -- well, let's just pull it up. Okay, let me share screen. Okay.

VICE CHAIR DICKEY: So, can you -- can the

researchers see this checklist?

DR. LABRIOLA: Yes.

MS. HOLIDAY: Yeah.

VICE CHAIR DICKEY: So, the first question is does it involve any funding from Department of Health and Human Services.

MS. HOLIDAY: No.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Could the research team take the questions one by one?

MS. HOLIDAY: Yes. For the first item, yes, (indiscernible) --

VICE CHAIR DICKEY: So, basically, the way it functions, though, is you need to come with one yes, I believe.

DR. LABRIOLA: Yeah.

VICE CHAIR DICKEY: So, you're saying --

DR. RYKACZEWSKA: I think we should still go through all of them for --

VICE CHAIR DICKEY: No, I'm --

DR. RYKACZEWSKA: -- documentation purposes.

VICE CHAIR DICKEY: Okay. Well, can you go through the next one.

MS. HOLIDAY: Sure. So, these (indiscernible) -- as incarcerated persons. Yes, would apply there.

Are the conditions particularly affecting prisoners of the class? No.

Study practices that we intend to use have a probability of improving health and well-being of the subjections? No.

Epidemiology of research (indiscernible) prisoners are not a particular focus? No.

VICE CHAIR DICKEY: Okay. So, yes on the first two.

The next one?

MS. HOLIDAY: Let's see, possible (indiscernible) -- yes.

DR. LABRIOLA: Why yes?

MS. HOLIDAY: Because the possible advantage are not of such a magnitude that it would eliminate -- it would impair the subject's ability to waive the risks of research.

VICE CHAIR DICKEY: Okay. The next one?

MS. HOLIDAY: Yes.

VICE CHAIR DICKEY: So, it's commensurate with the risks that would be accepted by non-prisoners.

And then, the last one?

MS. HOLIDAY: Yes.

VICE CHAIR DICKEY: Okay. And I think there's some more, right?

DR. RYKACZEWSKA: There is a page two, yep.

VICE CHAIR DICKEY: Yeah.

MS. HOLIDAY: Five is not applicable.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Because there are no control subjects.

VICE CHAIR DICKEY: Yeah.

MS. HOLIDAY: Six is also not applicable because they are sharing the administrative data, so it would not be directly to them with information about the study.

DR. RYKACZEWSKA: And we've confirmed that the consent forms are appropriately --

COMMITTEE MEMBER VENTURA: For the interview.

DR. RYKACZEWSKA: For the -- oh, I see. Okay.

COMMITTEE MEMBER VENTURA: We're talking about the data.

DR. RYKACZEWSKA: Yep, okay.

MS. HOLIDAY: Adequate insurance provided that parole boards do not take into account -- the parole boards will not have access to any information and involvement in the study. So, yes.

Clearly informed in advance that it will have no effect on parole. Again, this is not applicable because we won't be communicating with them directly about the use of their data.

And have adequate provisions been made? I think

this, again, is not applicable in this instance.

DR. RYKACZEWSKA: And I believe that is it.

VICE CHAIR DICKEY: Do you guys have any questions about having seen us go through that checklist with them?

MR. FEDEWA: No.

VICE CHAIR DICKEY: Okay. So, they would -- as part of their application they need to upload that checklist.

Mr. Murphy? Being a former prison lawyer, do you have any questions or concerns?

DR. RYKACZEWSKA: Mr. Murphy, if you could please unmute because we don't think we're hearing you.

We still do not hear you, Mr. Murphy.

MR. MURPHY: There?

DR. RYKACZEWSKA: Oh, almost.

VICE CHAIR DICKEY: Now, we got it.

DR. RYKACZEWSKA: Oh, oh, it's -- there it is.

MR. MURPHY: All right, thank you. That was me trying to unmute. I don't know why we are applying the information on the form only to the administrative data. I'm wondering why it's not also applied to the interviewing activities that are taking place. And maybe it's because prisoners will not be interviewed.

VICE CHAIR DICKEY: Right.

MR. MURPHY: If they're in the study, I'm

wondering how they are participating in the study, other than through having their administrative data used.

VICE CHAIR DICKEY: Maybe the researchers can address that?

MS. HOLIDAY: Yeah, absolutely. So, for the interviews and for the surveys there is a chance that people who have been incarcerated, and are now receiving care in the community will be involved in the study. And we do know that some people are entering the CARE program because they're getting released from CDCR and the referral is being made to CARE so that they can get connected with County Behavioral Health Services.

So, those folks will have an equal opportunity to be involved in the study as a survey participant. But they will no longer be incarcerated at the time that (indiscernible) -- in the study.

So, folks who are actively be incarcerated, it would only be through the administrative data.

VICE CHAIR DICKEY: So, the answers you gave to that checklist would apply both to the interview data and other data, right?

MS. HOLIDAY: I think some of the responses -- the initial questions would be the same. Some of the responses that were not applicable for the admin data, I think the answer would be different. Like the informed consent line

would be, yes, people are being informed of their rights as research participants.

DR. RYKACZEWSKA: Let me pull it up again.

MS. HOLIDAY: Okay. Yeah, I do have mine, thank you. Let's see --

DR. RYKACZEWSKA: I think it was --

MS. HOLIDAY: I guess number eight is maybe the one that could necessitate an update to the consent form, because there is a possibility that someone could be on parole after being released from CDCR. So, we could add a line to the consent form, saying, if you are on parole, participating will have no effect.

I think that's the one that would be answered differently.

VICE CHAIR DICKEY: Right. I think you say it would not affect benefits. But for prisoners or former prisoners it would really need to also say would not affect your parole, or anything to do with it.

MS. HOLIDAY: Yes. We can make that.

VICE CHAIR DICKEY: Mr. Murphy?

MR. MURPHY: So, with that addition to the -- can you hear me?

VICE CHAIR DICKEY: Yes.

MS. HOLIDAY: Yes.

MR. MURPHY: Okay. With that addition to the

consent form, I think that the form would be applicable and would be handled in a way that where the project could go forward.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Thank you, Mr. Murphy.

MR. MURPHY: You are welcome.

VICE CHAIR DICKEY: And I think for the purposes of approval of the motion, we're learning from our consultants, Advarra, we would need to designate the exact wording that would be included in the consent form.

COMMITTEE MEMBER VENTURA: Okay.

VICE CHAIR DICKEY: And that's what we would be voting on. We wouldn't just be voting on you'll include a clause. They're telling us we need to be more specific in our motion.

COMMITTEE MEMBER VENTURA: Do we need the wording now --

VICE CHAIR DICKEY: Yeah, we will need it now.

COMMITTEE MEMBER VENTURA: -- or can we provide it to the --

MR. FEDEWA: I actually think that what you've described, you have a very good sense of the clause that's going to be added.

VICE CHAIR DICKEY: Uh-huh.

COMMITTEE MEMBER VENTURA: Right.

MR. FEDEWA: I think that's --

VICE CHAIR DICKEY: Okay, so --

MR. FEDEWA: -- that's appropriate.

VICE CHAIR DICKEY: All right.

COMMITTEE MEMBER VENTURA: All right. I don't know -- and can we provide it to them later on?

VICE CHAIR DICKEY: It sounds like they've said it's fine. Yesterday, they put the fear of God into us.

(Laughter)

VICE CHAIR DICKEY: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Yes. I was looking also at the portion of the application under linkages, and it caused me to think about several things there. It describes, of course, all the datasets that are being linked.

Would you please clarify for me, is there any linkage of the interview responses or survey responses to the data sources that are coming from DHCS?

MS. HOLIDAY: The interview data will not be linked.

Melissa, do you recall if the survey data will be linked?

DR. LABRIOLA: No.

COMMITTEE MEMBER SCHAEUBLE: So, the survey and the interviews are totally separate entities by themselves.

Prior to --

MS. HOLIDAY: Yes. And also, (indiscernible) each other, yes.

COMMITTEE MEMBER SCHAEUBLE: Okay, good.

Can you also help me understand a little more clearly the description of what the lead quantitative person does when the data are received from DHCS? You spoke of the data being transferred into a cold room. And what, exactly, does the person who receives that data do at that point?

MS. HOLIDAY: So, once the data are received in the cold room, our analyst is removing all of the sensitive identifiers from the data. And the cold room is fully isolated from the rest of RAND server, that's what makes it a cold room.

And that is -- and she's creating an analytic dataset that just includes the study ID, and it doesn't include the identifiers. So that, then, any dataset that's used for analysis that is stored on our general RAND server for the project is de-identified.

COMMITTEE MEMBER SCHAEUBLE: So, at that point we're talking about a de-identified dataset that RAND analysts are going to be working with.

Is that person also extracting contact information for people to be recruited for the interviews and surveys?

MS. HOLIDAY: Yes. And then, that contact

information will be maintained by our survey research group. They use it for outreach there. Their server is also fully separate from the general RAND server. And then, they provide us with datasets from the survey. It also will not include any identifiers (indiscernible) -- as well.

COMMITTEE MEMBER SCHAEUBLE: So, if I'm understanding right, then the only reason you said that identifiable data needs to be maintained in the cold room for the duration of the project is to have continuing recruiting for interviews and surveys?

MS. HOLIDAY: That, and also we receive, potentially, multiple data deliveries of some of those administrative sets. So, that allows us to link, over time, using the same study ID, if we get multiple data deliveries.

COMMITTEE MEMBER SCHAEUBLE: Okay. And I think that covers most of my thoughts. And we did clarify earlier that if you're going to put together a composite list of variables for us, that would include the sources you've already talked about and the potential ones from the Department of Justice.

MS. HOLIDAY: Yes.

COMMITTEE MEMBER SCHAEUBLE: Okay, good. Okay, that takes care of my questions.

VICE CHAIR DICKEY: Okay. So, the issue of HIPAA has arisen. You have a HIPAA waiver from a different IRB,

is that correct?

DR. RYKACZEWSKA: From RAND.

VICE CHAIR DICKEY: From RAND?

DR. RYKACZEWSKA: That was indicated.

VICE CHAIR DICKEY: HIPAA waiver of authorization.

DR. LABRIOLA: Yes, I'm just double checking.

VICE CHAIR DICKEY: Well, it actually doesn't matter a whole lot because DHCS is requesting us, our body, to look at the issue of waivers of authorization, regardless of whether another IRB has done it.

So, you provided the rationale for the waiver. I'm looking at it right now. And it's largely based on the fact that the study could not be conducted without the waiver because how would you try to get authorization from all these different individuals.

But yes, Agnieszka?

DR. RYKACZEWSKA: Sorry. And a clarification. So, my understanding is that the waiver of authorization is for the administrative data. And then, there's a separate of alteration because the interview -- you won't -- the interviews are verbal consent. Not signature, right?

VICE CHAIR DICKEY: Well, but we already addressed that. That's the consent form. There's a waiver of -- we're approving an alteration of the consent requirements, as well as not documenting consent, it's being verbal.

But the waiver of HIPAA authorization is a different issue, which is where individual patients, or whatever are not being asked to sign a form that says I authorize you to access my data. And there are various requirements for providing such a waiver.

The main one that I'm seeing here is the issue that the research could not be conducted, practically, because you'd have to contact all these individuals, individually, which would make the research -- to use their database be impossible.

Is that correct?

DR. LABRIOLA: That is correct.

VICE CHAIR DICKEY: But in the past when we've voted on projects, we have not separately addressed the issue of a HIPAA waiver of authorization and put it into the motion.

MR. FEDEWA: Yeah. And, Dr. Dickey, I just do want to clarify. Because they're getting health information through the survey, surveys and focus groups, you do need to both do the waiver of documentation consent, as well as an alteration of HIPAA authorization. So, you're not receiving, you're altering the physical signature requirement for a HIPAA authorization.

VICE CHAIR DICKEY: So, are you getting protected health information through -- no, you only need a HIPAA

waiver when you're getting the data from a covered entity.

DR. RYKACZEWSKA: Yeah.

VICE CHAIR DICKY: And getting data through an interview is not a covered entity. So, this really only applies to the data.

COMMITTEE MEMBER VENTURA: Because they have -- because they're consenting to the interview process.

VICE CHAIR DICKY: Yes. Right.

COMMITTEE MEMBER VENTURA: And it's the HIPAA, I believe, only applies to the data that --

VICE CHAIR DICKY: You get from a covered entity.

COMMITTEE MEMBER VENTURA: Right. From DHCS in this case, or DOJ, all the --

VICE CHAIR DICKY: Right. But we do need to put that in the motion that, you know, if we are approving a waiver of authorization under HIPAA. And, actually, the letter that goes to the researchers, then it's supposed to designate the variables are being -- for which the waiver is being granted.

COMMITTEE MEMBER VENTURA: Okay, so specifying that it's only for the administrative data.

VICE CHAIR DICKY: And which variables in the administrative data.

COMMITTEE MEMBER VENTURA: Oh.

VICE CHAIR DICKY: And they've listed them here.

And in the past Sussan, I believe, has been looking at these applications and actually generating a list of variables.

MS. ATIFEH: Yes.

DR. RYKACZEWSKA: That's included in the approval letter.

VICE CHAIR DICKY: That's included in the approval letter.

But I think that you would need, the motion has to say the variables as listed in the application.

COMMITTEE MEMBER HESS: Well --

VICE CHAIR DICKY: Right?

COMMITTEE MEMBER HESS: -- have they listed them appropriate?

VICE CHAIR DICKY: That's a good question.

COMMITTEE MEMBER HESS: Because they've got in the covered entity section, Sussan left a note for them in December, will health information be obtained from a covered entity. The answer should be yes.

VICE CHAIR DICKY: That was answered wrong. But if you go down further --

COMMITTEE MEMBER HESS: Okay, yeah, I see where they're describing it but -- where they're asking for a waiver of alteration of HIPAA authorization, but then they need to go back --

VICE CHAIR DICKY: They need to change that

answer, right.

COMMITTEE MEMBER HESS: Yeah. And then they --
this is where they would provide --

COMMITTEE MEMBER VENTURA: The specific variables.

COMMITTEE MEMBER HESS: -- the specific variables.

Dr. Labriola and Dr. Holiday, are you seeing where
in the application that the list -- the variables need to be
specified?

COMMITTEE MEMBER VENTURA: It's in the section
called covered entity, under the HIPAA determinations.

MS. HOLIDAY: Yes.

COMMITTEE MEMBER VENTURA: Yeah.

MS. HOLIDAY: I do see it.

COMMITTEE MEMBER VENTURA: Okay, so that's where
the list and list it out, the specific variables that we are
requesting for that.

VICE CHAIR DICKEY: And I think they are largely
there because the variables include names, social security
number, birthdate, Medi-Cal index, et cetera.

COMMITTEE MEMBER HESS: But then --

COMMITTEE MEMBER VENTURA: But the data that
they're -- but the data that they're going to -- as part of
the administrative is more than that, I believe.

VICE CHAIR DICKEY: Yeah, okay. You know, I
haven't read any of the details.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER VENTURA: So, I think they're going to have to include a comprehensive list.

COMMITTEE MEMBER HESS: And it's my understanding that if they go back and they click, yes, in this covered entity section that gives them like another form, another set of questions to answer.

MS. ATIFEH: Yes.

COMMITTEE MEMBER HESS: Okay. So, that would then be -- so, they need to do that, HIPAA determination section.

VICE CHAIR DICKEY: Is that something that could be doing an expedited review by --

COMMITTEE MEMBER VENTURA: By me, yes.

COMMITTEE MEMBER HESS: I mean, do we think this is minimal risk.

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

COMMITTEE MEMBER HESS: Okay.

COMMITTEE MEMBER VENTURA: All right, do we need to open it up further?

VICE CHAIR DICKEY: Yeah, public.

DR. RYKACZEWSKA: Any further comments from the board? Anything that we've missed. Okay.

Any other comments from the board or from the board online?

I am not seeing any virtual hands from our board members online. I am not seeing any hands from our board members in the room.

Are there any public comments? Acknowledging no members of the public in the room. If you are on Zoom, please raise your virtual hand. I am not seeing any virtual hands.

We are ready for a motion.

COMMITTEE MEMBER HESS: I will make a motion. I move to recommend approval, deferred approval for this project, for one year, provided the following conditions are met.

DR. RYKACZEWSKA: Is it minimal risk?

COMMITTEE MEMBER HESS: It is minimal risk. I apologize for that, it's right there.

So, the first condition -- I will slow down.

DR. RYKACZEWSKA: Thank you. Okay.

COMMITTEE MEMBER HESS: Is that all Spanish translated study materials will need to be reviewed and approved prior to beginning the study. And I -- are we asking for those to be submitted as an amendment or as part of this approval, conditional approval.

DR. RYKACZEWSKA: I think it can depend -- I don't think we have to specify.

COMMITTEE MEMBER HESS: Okay.

DR. RYKACZEWSKA: It depends on when they're ready. If they're ready now, I think they could do it now.

COMMITTEE MEMBER HESS: Okay. Second condition is that they need to provide documentation of waiver of written informed consent.

VICE CHAIR DICKEY: And alteration of --

COMMITTEE MEMBER HESS: Yes. Since consent is obtained verbally, and alteration of consent form.

The third condition is the researchers must submit the prisoner checklist. And must state in the consent form that the information collected will not impact their incarceration or parole.

VICE CHAIR DICKEY: How about continuing to say that information collected will not be shared such that it could affect their parole.

COMMITTEE MEMBER HESS: I like that.

The fourth condition is to change the language on the consent form to direct questions about the study to the PI. And to direct questions about rights as research participants to the RAND IRB. And add resources in instances of participant distress -- resources for participants in case they experience some distress, in that section of the consent form.

The fifth condition is the HIPAA waiver authorization. So, they should amend the HIPAA

determination section of their protocol in IRBManager.

DR. RYKACZEWSKA: HIPAA waiver determining --

VICE CHAIR DICKEY: HIPAA waiver of --

COMMITTEE MEMBER HESS: HIPAA determination, yes.

VICE CHAIR DICKEY: HIPAA waiver of --

COMMITTEE MEMBER HESS: Well, they need to first change it in IRBManager and that's the HIPAA determination section, and then that should generate the appropriate checklist and things for us to issue the waiver.

VICE CHAIR DICKEY: It's HIPAA waiver of authorization, though.

COMMITTEE MEMBER HESS: Yeah, sorry.

Okay. So, amend HIPAA waiver authorization in IRBManager.

And now, we get to the cell size issue, reporting issue. And were we going with the three different options or did we settle in option two.

VICE CHAIR DICKEY: The recommendation, as opposed to the requirement.

COMMITTEE MEMBER HESS: Okay. So, the sixth condition would be a recommendation that the researchers provide documentation to CPHS in any instance in which they are reporting cell sizes less than 11. And that they would simply provide variables and justification for doing so.

VICE CHAIR DICKEY: And justification, okay.

MR. ZADROZNA: And then, for number three, I think you have to add the "and incarceration" at the end.

COMMITTEE MEMBER HESS: Or incarceration?

MR. ZADROZNA: Yeah.

COMMITTEE MEMBER LANG: Six, we will not have any language regarding the data de-identification guidelines?

COMMITTEE MEMBER HESS: I don't think we need that.

VICE CHAIR DICKEY: Well, it's part of the --

COMMITTEE MEMBER HESS: They have it, yeah.

COMMITTEE MEMBER SCHAEUBLE: I think on six, though, we were asking prior to any publication of information that they --

VICE CHAIR DICKEY: Yeah, so, rather than reporting, it would be publication.

COMMITTEE MEMBER HESS: Yes.

DR. RYKACZEWSKA: Prior to any publication.

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: The one additional thing that I had was that on the consent form they should include language that participants can request a copy of it.

COMMITTEE MEMBER HESS: Oh, yeah. We can add that to number four.

VICE CHAIR DICKEY: Four.

MS. ATIFEH: Dr. Hess, do you think we need to --
the request for the list of variables that they --

VICE CHAIR DICKEY: For the HIPAA.

MS. ATIFEH: Yes.

COMMITTEE MEMBER HESS: That's this one. Because
if they amend it in IRBManager --

VICE CHAIR DICKEY: It will be part of that.

MS. ATIFEH: Okay, so you don't want to list it
specifically, request them to provide the list for the
variables.

VICE CHAIR DICKEY: Well, you can just put that in
there, saying including that, a list of covered variables.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Okay. To be reviewed by?

COMMITTEE MEMBER HESS: To be reviewed by a
subcommittee consisting of Dr. Ventura.

Do you -- would you like a second right here?

COMMITTEE MEMBER VENTURA: I might. I think
because I -- well, does that make it then --

COMMITTEE MEMBER HESS: No. I think we can have a
second reviewer, if you would like. We just need a
volunteer.

COMMITTEE MEMBER VENTURA: Okay. Right. Would
anyone like to --

DR. RYKACZEWSKA: Do you want a second here?

COMMITTEE MEMBER VENTURA: Yes.

DR. RYKACZEWSKA: Okay.

COMMITTEE MEMBER AZIZIAN: Folks, may I interrupt in here, and not to prolong the conversation on this. But I have some numbers -- I just wondered if it's necessary for us to even include that. I mean, if you're making a recommendation, well, if they decide they're going to do that, it's up to them. If not, then not have it there at all.

COMMITTEE MEMBER VENTURA: I think we want to document it, though.

COMMITTEE MEMBER AZIZIAN: I think what purpose does it serve to include that on both on that -- if you make a recommendation and you reach a consensus, then it would be up to their discretion.

VICE CHAIR DICKEY: Well, it's just verifying that the Committee as a whole is making that recommendation, as opposed to individuals.

COMMITTEE MEMBER HESS: I think it's more about documentation, than anything else.

COMMITTEE MEMBER DINIS: And that we vote if we're going to make a recommendation, instead of regarding it?

COMMITTEE MEMBER HESS: I mean, we can pull that out and have a separate motion on number six.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER DINIS: I would prefer that, yes.

COMMITTEE MEMBER TEFERA: I don't think, from the conversation, there's a plurality that supports that. That seems unnecessary to do that.

VICE CHAIR DICKEY: Well, then, pull it out and we'll vote on it.

COMMITTEE MEMBER HESS: Yeah. I mean, we can vote, if there's not a plurality. I mean, what do you think?

VICE CHAIR DICKEY: Since it's sort of the area where there may be some disagreement, let's pull it out and have a separate motion.

COMMITTEE MEMBER HESS: Yeah. And then, at least, people can have their views documented.

COMMITTEE MEMBER TEFERA: But just to be clear, you made a motion here with the six points. It seems the next step would be to vote on this. And then, if this vote passes that would answer the question of --

VICE CHAIR DICKEY: Well, but it could be that some people may want to vote against just because of that one thing, but they vote for the other five. It's sort of like approving the shutdown of the budget for the federal government. We take DHCS out of it.

COMMITTEE MEMBER TEFERA: But that's okay. I mean, someone could vote against the whole thing because --

VICE CHAIR DICKEY: I know.

COMMITTEE MEMBER TEFERA: -- they're dissatisfied with that.

VICE CHAIR DICKEY: It's just for efficiency's sake, it's probably better just to take it out and vote explicitly on that.

COMMITTEE MEMBER TEFERA: I guess, I think it's the opposite. I think it's more efficient to vote on this and if the plurality --

VICE CHAIR DICKEY: That's assuming it's going to pass.

COMMITTEE MEMBER TEFERA: Right. If it doesn't, then you go to the next step of trying to find a path to --

VICE CHAIR DICKEY: Well, Dr. Hess is making the motion, so we'll leave that up to her.

COMMITTEE MEMBER HESS: I mean, I'm fine with pulling it out, as inefficient as it may be. I don't think it would change the outcome, so I'm fine with doing that, if other board members would prefer that.

I really don't think it's going to affect --

VICE CHAIR DICKEY: Okay, but are you pulling it out or not?

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: Okay. Is there a second to that motion, with that pulled out?

DR. RYKACZEWSKA: Wait, before -- before, Dr. Ventura asked for a second reviewer.

COMMITTEE MEMBER HESS: Okay.

VICE CHAIR DICKEY: Well, yeah, we haven't even gotten -- we haven't passed it, yet.

DR. RYKACZEWSKA: No, no, for the subcommittee.

COMMITTEE MEMBER HESS: So, first -- we're on the first motion. Is there anyone who would like to be a reviewer?

COMMITTEE MEMBER JOHNSON: I will.

COMMITTEE MEMBER HESS: Thank you. Okay.

DR. RYKACZEWSKA: Okay, we have a motion.

COMMITTEE MEMBER HESS: Okay, we have a motion.

VICE CHAIR DICKEY: Do we have a second?

COMMITTEE MEMBER LANG: Second.

DR. RYKACZEWSKA: Thank you, Dr. Lang.

We already had public comment, right?

COMMITTEE MEMBER HESS: We did.

DR. RYKACZEWSKA: Yes. We did do public comment, all right.

MS. ATIFEH: Okay. Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Approve.

MS. ATIFEH: Thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Abstain.

MS. ATIFEH: Okay. Yeah, the motion passed.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER HESS: Now --

VICE CHAIR DICKEY: Now, would you like a motion
to --

COMMITTEE MEMBER HESS: I will make a second
motion -- so, we've just pulled this out for a second
motion.

VICE CHAIR DICKEY: Uh-hum.

COMMITTEE MEMBER HESS: Okay.

DR. RYKACZEWSKA: I'm not making your motion for
you, I'm just suggesting some language.

COMMITTEE MEMBER HESS: Okay, so I move to make a
recommendation that the researchers provide documentation to
CPHS in any instance in which they are reporting cell sizes

less than 11, and that they would simply provide variables and justification for doing so prior to any publication.

VICE CHAIR DICKEY: Is there a second?

COMMITTEE MEMBER SCHAEUBLE: I'll second.

VICE CHAIR DICKEY: Okay. And discussion?
Public?

DR. RYKACZEWSKA: Any members of the public, could you please raise your virtual hand. Acknowledging no members of the public in the room.

And I --

COMMITTEE MEMBER DINIS: Well, I mean I --

DR. RYKACZEWSKA: Go ahead.

COMMITTEE MEMBER DINIS: I didn't get a chance to say. I mean, I prefer there was the requirement. I don't think a recommendation makes much difference because then it's up to them. Either we have an enforcement of that rule or we don't. And it applies to everybody. So, it's like we're making special cases. I'm worried about those special cases.

DR. RYKACZEWSKA: I think we --

VICE CHAIR DICKEY: Other comment?

DR. RYKACZEWSKA: Other comments?

Thank you, Dr. Dinis, for the comments.

VICE CHAIR DICKEY: Any comment from the public?

DR. RYKACZEWSKA: If you could please raise your

virtual hand? Acknowledging no members of the public in the room. And I am not seeing any virtual hands.

Oh, I see a hand from Dr. Schaeuble.

COMMITTEE MEMBER SCHAEUBLE: I understand Dr. Dinis' concern. I guess my hope is that researchers would be helpful to us, given our attempts to be helpful to them, and would be willing to follow through with a recommendation, even if it's not stated as a required. So, that's my thought, at least.

DR. RYKACZEWSKA: Thank you.

VICE CHAIR DICKEY: So, we have a second.

DR. RYKACZEWSKA: Yes.

MS. ATIFEH: Dr. Schaeuble seconded.

DR. RYKACZEWSKA: Dr. Schaeuble seconded. Thank you, Dr. Schaeuble.

VICE CHAIR DICKEY: Okay. So, I guess we need to call the roll.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: I vote not.

MS. ATIFEH: No. Okay.

Dr. Dinis?

COMMITTEE MEMBER DINIS: I also -- yeah. No.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER HESS: I think they have to -- I think they have -- we have to give a reason for a no vote,

is that correct?

DR. RYKACZEWSKA: That's correct.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER DINIS: Well, mine is because I want it to be a requirement.

VICE CHAIR DICKEY: She's said it already, though.

COMMITTEE MEMBER DINIS: Yes.

COMMITTEE MEMBER AZIZIAN: Well, my reasoning is that there's already a system for that and I don't find it necessary. I wouldn't know what to do with that information coming in.

DR. RYKACZEWSKA: Thank you, Dr. Azizian.

COMMITTEE MEMBER JOHNSON: I vote no for reasons of recommendation versus requirement.

MS. ATIFEH: No. Dr. Johnson, no?

COMMITTEE MEMBER JOHNSON: No.

MS. ATIFEH: Okay.

Dr. Lang?

COMMITTEE MEMBER LANG: I vote no, as well.

MS. ATIFEH: Okay.

VICE CHAIR DICKEY: Reason?

COMMITTEE MEMBER LANG: I think that we have the data de-identification guidelines and we should -- we should stick to those for that rationale. They have a very fair rationale of (indiscernible) -- rule of -- score of 12. And

I feel that is sufficient.

VICE CHAIR DICKY: Okay.

MS. ATIFEH: Okay.

Dr. Murphy?

MR. MURPHY: I vote yes. And my reason for voting yes is that I think we're looking at preventing a harm that we're not able to right now identify under the guidelines that we have. That we're looking for harm that we feel, but don't know how to articulate. So --

DR. RYKACZEWSKA: Thank you, Mr. Murphy. Oh, sorry, go ahead.

MR. MURPHY: I would like to have the information. That might show us that there's an actual harm. That's my reason.

MS. ATIFEH: Okay.

DR. RYKACZEWSKA: Thank you, Mr. Murphy.

MS. ATIFEH: Thank you.

Dr. Tefera?

COMMITTEE MEMBER TEFERA: No. The reasoning is that the Department of Health Care Services already has a robust process for reviewing the same concern. I don't think they need to be duplicated.

VICE CHAIR DICKY: Okay.

MS. ATIFEH: Okay.

Dr. Ventura?

COMMITTEE MEMBER VENTURA: Abstain.

MS. ATIFEH: Okay, the motion failed.

VICE CHAIR DICKEY: Okay. Does anyone else want to make a different motion?

COMMITTEE MEMBER DINIS: It doesn't look like either a recommendation or a requirement passes. I think that the notion of the cell sizes 11, Dr. Murphy is -- you know, there's always the concern that people will be reidentified. That's always the risk. That's why there's a requirement that for some kind of cell size, people from a small area, you know, a few persons that quality in that, then known to be in that study.

But it doesn't look like with this Committee, right now, recommendation, nor requirement, will pass.

COMMITTEE MEMBER DINIS: So, do you want to make a -- you don't want to make a motion, Dr. Dinis?

COMMITTEE MEMBER DINIS: I would make the same motion, let's say a requirement. Then, I venture to say it's going to fail.

VICE CHAIR DICKEY: Well, but you never know until you make it.

COMMITTEE MEMBER DINIS: Okay, fine. Make a recommendation that the researchers provide documentation --

DR. RYKACZEWSKA: Recommendation of requirement.

VICE CHAIR DICKEY: That it be a requirement, not

a --

COMMITTEE MEMBER DINIS: Not a recommendation, a requirement.

VICE CHAIR DICKEY: -- not a recommendation.

COMMITTEE MEMBER DINIS: Yeah, just change the word to requirement.

DR. RYKACZEWSKA: And we are on motion six.

Any comments from members of the public? I am not seeing any virtual hands and acknowledging no members of the public in the room.

MS. ATIFEH: Who seconds?

DR. RYKACZEWSKA: Does anybody second the motion?

COMMITTEE MEMBER JOHNSON: I'll second.

DR. RYKACZEWSKA: Dr. Johnson seconds.

MS. ATIFEH: Okay.

VICE CHAIR DICKEY: Call the roll.

MS. ATIFEH: Okay. Dr. Hess?

COMMITTEE MEMBER HESS: No.

MS. ATIFEH: No.

COMMITTEE MEMBER HESS: For because I think that the DDG guidelines are adequate in this case.

MS. ATIFEH: Okay.

Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: No. There are guidelines in place, already.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: No. The same reasoning that there are existing guidelines in place.

MS. ATIFEH: Okay.

Dr. Murphy?

MR. MURPHY: I vote yes.

MS. ATIFEH: Okay.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Yes, for the same reasons that Dr. Murphy identified earlier.

MS. ATIFEH: Okay.

Dr. Tefera?

COMMITTEE MEMBER TEFERA: No. Guidelines already are in place.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Abstain.

MS. ATIFEH: Abstain.

The motion failed.

VICE CHAIR DICKEY: Oh, yeah. Okay, so that -- does anybody else want to make a motion?

DR. RYKACZEWSKA: And I believe if there is no motion relating to this item, that would mean this would not be a recommendation or a requirement for the researchers.

VICE CHAIR DICKEY: Exactly.

COMMITTEE MEMBER HESS: Correct.

VICE CHAIR DICKEY: It would be as it is in the protocol.

DR. RYKACZEWSKA: Okay.

COMMITTEE MEMBER HESS: Can we just double back with the researchers, just to make sure they don't have any outstanding questions, because that was a bit of a --

DR. RYKACZEWSKA: That was a whirlwind.

COMMITTEE MEMBER HESS: -- merry-go-round.

DR. RYKACZEWSKA: Any questions from the research team?

MS. HOLIDAY: None from me.

COMMITTEE MEMBER HESS: Okay.

MS. HOLIDAY: Thank you.

VICE CHAIR DICKEY: Okay, so as I understand it, there's no more motions anybody wants to make.

DR. RYKACZEWSKA: Related to this study.

VICE CHAIR DICKEY: Yeah. Okay, so we have completed our review and you'll be getting a letter specifically, I think probably within a week or two.

But you know what the recommendations will be, so you can start working on them.

And Dr. Ventura and Dr. Johnson will review what you submit. Okay.

MS. HOLIDAY: Sounds good. Thank you so much.

VICE CHAIR DICKEY: Good luck with your research.

MS. HOLIDAY: We appreciate it.

DR. LABRIOLA: Thank you. Have a good day.

VICE CHAIR DICKEY: Let's take a -- if it's okay with everybody to take a 10-minute break.

COMMITTEE MEMBER TEFERA: What else do we have on the agenda?

VICE CHAIR DICKEY: We have one more full project and then we have that adverse event issue.

DR. RYKACZEWSKA: Amendment.

VICE CHAIR DICKEY: Well, it's called an amendment, but it's related to the adverse event.

DR. RYKACZEWSKA: We are going to take a 10-minute break and we will return at 10:35. See you then.

(Off the record at 10:25 a.m.)

(On the record at 10:35 a.m.)

DR. RYKACZEWSKA: Are we all ready? We'll have to redo the roll.

VICE CHAIR DICKEY: Just a minute, we're ordering lunch.

(Laughter)

DR. RYKACZEWSKA: Are we ready?

VICE CHAIR DICKEY: Okay. All right. We're reconvening and the next project to discuss is evaluating --

DR. RYKACZEWSKA: Oh, can we reestablish a quorum, please. Since we took a break.

MS. ATIFEH: Oh, okay.

DR. RYKACZEWSKA: All right.

VICE CHAIR DICKEY: Why don't you just do this.

(Laughter)

MS. ATIFEH: Okay. I start with -- you know, should I name Dr. Dickey?

DR. RYKACZEWSKA: Yeah. The whole roll call, please.

MS. ATIFEH: Okay.

Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present.

MS. ATIFEH: Dr. Dinis?

DR. RYKACZEWSKA: Dr. Dinis, are you online?

MS. ATIFEH: I think she left.

DR. RYKACZEWSKA: Let me just check. I am not seeing Dr. Dinis online.

COMMITTEE MEMBER SCHAEUBLE: She probably had to go to class.

MS. ATIFEH: Yes. Okay.

Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Present.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Present.

MS. ATIFEH: And Dr. Murphy?

DR. RYKACZEWSKA: Dr. Murphy, you are muted.

MS. ATIFEH: Yes, I see him.

DR. RYKACZEWSKA: So, we do see you.

MS. ATIFEH: Okay.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: And Dr. Tefera?

COMMITTEE MEMBER TEFERA: Present.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, a quorum is established.

DR. RYKACZEWSKA: Thank you, Sussan. Back to you,
Dr. Dickey.

VICE CHAIR DICKEY: Before I was so rudely
interrupted --

DR. RYKACZEWSKA: I'm so sorry.

VICE CHAIR DICKEY: Evaluating Children's --
California Children's Crisis Continuum Pilot Project. And
Dr. Lang is the reviewer.

COMMITTEE MEMBER LANG: Thank you.

Are Dr. Benatar and Dr. Lery online? Fantastic.

DR. LERY: I'm here today, Dr. Lery. I'm joined

by my colleague, Laura Packard Tucker, here. But Dr. Lery will be attending.

COMMITTEE MEMBER LANG: Fantastic, thank you so much. I'd like to invite you to give a brief overview of your proposal in the protocol.

DR. LERY: Great. Yes, so this is an evaluation of the Children's Crisis Continuum Pilot Program, which was legislated in AB-2786 to improve the continuum of care for foster youth who have specialized healthcare needs, essentially, are particularly high acuity.

And included in the legislation was a mandated evaluation. What we are here before the board about today is the site visit work, which will be interviews with stakeholders in the eight pilot counties that were funded, as well as focus groups with individuals 18 to 21, who would have been eligible, if they had been -- if the pilot had been in place prior to them aging out of care, or prior to them turning 18, unless they may still officially be in care. And family members of youth who would similarly have qualified.

So, this is a baseline -- this is the baseline period that we are studying right now. So, none of these individuals will have been actually involved in the pilot program.

And this is also an -- sort of officially, an

amendment. We did get expedited approval to do a survey with staff from the pilot counties to understand what they are specifically implementing in their counties, in response to the funding that they've received.

COMMITTEE MEMBER LANG: All right. So, forgive me if I missed it, but I -- you are also doing staff -- you are also doing staff interviews.

DR. LERY: Correct.

COMMITTEE MEMBER LANG: Could you give a brief overview of that, as well?

DR. LERY: Oh, sure. Sorry, if I -- I thought I heard that. But, yes, in each of the pilots we will also be interviewing staff. So, those would be individuals who are either in charge of implementing the pilot program with direct service staff, who are helping to implement the continuum for each of -- for youth who are enrolled in the pilot. As well as community-based organizations who are being brought into the continuum of care to improve the outcomes for the youth who are -- who are eligible and enrolled.

COMMITTEE MEMBER LANG: Thank you. Apologies, this is my first time doing this so --

VICE CHAIR DICKEY: Sure.

COMMITTEE MEMBER LANG: I've reviewed the protocols. I believe they are mostly adequate. I've been

corresponding with Dr. Benatar and Dr. Lery, and suggested some very modest modifications of the consent forms and survey protocols.

Specifically, I've asked that they make modifications and addendums to abbreviate acronyms and initials, since that might be unfamiliar to the participants. Particularly, those that might involve sensitive subjects, such as substance use disorders.

Additionally, I've asked them to put additional clarifying language into the staff interview protocol and consent forms to clarify that there are no employment ramifications for their participation or nonparticipation in the study.

But other than that, I have no material comments.

DR. RYKACZEWSKA: Comments from the Committee?

COMMITTEE MEMBER VENTURA: Yes. I do have some questions. I was wanting clarification on the role of USC, and also Think Of Us, the Think Of Us group.

DR. LERY: Yes.

COMMITTEE MEMBER VENTURA: So, there was a researcher from USC included in your research personnel, but there was no description of how that individual or team of people will be accessing the data, what's their role?

And then, similarly, the Think Of Us group were not listed on your research personnel, but I think they have

a significant role in recruitment.

And then, you described that if there was any distress from the interviews that they would be the ones to -- you would direct them to Think Of Us. And so, they have access to participant identifiers and, potentially, dealing with interacting with participants.

So, what was the decision in not including them as research personnel?

DR. LERY: So, thank you. First, in terms of the folks at CCWIP, the California Children's (indiscernible), Child Indicators Welfare -- I actually can never remember what the acronym is, at UC Berkeley.

But that includes an individual who is actually a professor at USC. So, they are subcontractors to us on this evaluation and they are involved with us as part of the research team.

So, they will also be conducting -- they will be participating in the interviews and the focus groups with us, though we will -- any -- they will only have access to de-identified notes, ultimately. And all recordings will be saved on the Urban Institute server, so they won't have any -- they won't be directly interacting with those materials.

Think Of Us was contacted by CDSS to support recruitment or the focus groups. There, we specified that there are a few different ways in which recruitment may

happen. And we are supposed to be -- we are collaborating with Think Of Us on developing the materials to support recruitment. They will either be recruiting through a consent-to-contact process, where county staff and/or community-based organizations present the flyers or materials to potential participants. And then, those folks contact Think Of Us directly to indicate that they are interested in learning more and potentially participating in focus groups.

The second way that might happen is that the county staff, themselves, might actually do the recruitment and then provide first name, last initial, and then contact information only to Think Of Us to do follow-up reminder calls.

I don't expect that -- oh, yeah, so, the consent-to-contact, there's a possibility that folks will -- consent-to-contact allows the information to go to Think Of Us to contact them, to follow up to determine eligibility.

The flyers, et cetera, allow participants to contact Think Of Us directly. And then, there is the possibility that county staff or community-based organizations would do the recruitment, themselves. In which case, Think Of Us would not necessarily have any access to any individual information.

They are not going to be leading any focus groups.

They are not going to be taking any notes. They are not going to be participating in the focus groups. They are just hired by CDSS to support the recruitment process.

Does that help clarify?

COMMITTEE MEMBER VENTURA: What about the piece about any distress. I mean, like they would be participants who are distressed by the survey if -- or by the interviews, excuse me.

They're directed to Think Of Us, so they will have, they could potentially have interactions with participants. Is that -- am I understanding that correctly?

DR. LERY: I probably need to re-review that, but my recollection, and I will certainly re-review that and make sure it is clear in any revisions, would be that we would provide information to participants for whom they might contact.

Think Of Us, actually, does not feel like the right resource, to me. So, I would -- somebody in the county. And if that was put in there, then I think that's probably a mistake and something that we can certainly address.

COMMITTEE MEMBER VENTURA: Okay. It's under your risk description. And you describe that if someone experiences emotional distress during the focus group, that they will immediately connect them with TOU.

DR. LERY: Okay.

COMMITTEE MEMBER VENTURA: So, if you're saying that it's now someone in the county, instead, then that needs to be clarified in your protocol.

DR. LERY: Yeah. Yes, we did -- we will update that. Think Of Us is a great resource because they are an organization of individuals with lived experience in the foster care system. But I think that for our specific local resources, I mean, they don't -- they're not the -- they don't make the most sense in that scenario.

So, we can -- we will update that.

COMMITTEE MEMBER VENTURA: So, it's also in your medical service risks section, you mentioned TOU again.

I also had a question about -- so, the recordings of your focus group, you ask for permission to record. But if a participant declines, are they allowed to still participate in the focus group? And it wasn't clear if it's audio or video recordings of the focus groups. So, can they maybe participate, but just not be video recorded, or how are you going to handle that transcribing?

DR. LERY: So, we will only be doing audio recording.

COMMITTEE MEMBER VENTURA: Okay.

DR. LERY: No video. When they agree -- when they indicate that they're interested in participating, we will

let them know that there -- we plan to record, digitally record by audio, the audio of the group for note taking purposes, only. And if they're not comfortable with that, then we would recommend that they not participate.

It is very challenging, without an audio recording, to get their notes accurately transcribed.

And we will, again, at the beginning of the focus group let folks if they are not comfortable being record that they can leave. They don't need to participate. And they will still get their incentive.

But I don't think that we can -- I don't think that it is a good idea to proceed without a recording of a group because I think risks to accuracy of the notes are too great.

COMMITTEE MEMBER VENTURA: Okay.

COMMITTEE MEMBER LANG: There's one other issue that I also wanted to recommend. Is that reviewing your consent form, you currently are doing initials. That's an alteration of consent.

My current understanding is that we sort of have two options. One is we could -- we could have a waiver of consent or we require the full names. Is that accurate?

Logistically, do you have a preference in terms of how you would like to resolve that?

DR. LERY: So, the waiver of consent would be

something that we request and is reviewed by the board, is that --

VICE CHAIR DICKEY: That would be a waiver of documented consent.

COMMITTEE MEMBER LANG: A waiver of documentation, yes.

VICE CHAIR DICKEY: Not waiver of consent.

DR. LERY: Oh, waiver of documentation.

COMMITTEE MEMBER LANG: Pardon my language.

DR. LERY: A waiver of documentation. Yes, that would be my preference because I've rather not collect full names of participants, for their privacy.

VICE CHAIR DICKEY: So, the section in the Common Rule that applies to that is where the only thing linking the participant to the information would be their name

COMMITTEE MEMBER LANG: Right.

VICE CHAIR DICKEY: Good.

DR. RYKACZEWSKA: I'm just going to ask a question, if that's okay. Has Urban Institute's IRB already approved the study?

DR. LERY: Yes.

DR. RYKACZEWSKA: Okay, thank you.

VICE CHAIR DICKEY: I just wanted to confirm that even though you talk about foster youth, none of the participants are less than 18, correct?

DR. LERY: None of the participants in this round are less than 18. We will come back to the board, subsequently, to request permission for the second round. CDSS has requested that we do include youth less than 18 in our second rough of focus groups. But we are not implementing anybody less than 18 in this round of focus groups.

VICE CHAIR DICKEY: Then, you'll have to deal with assent and parental consent.

COMMITTEE MEMBER LANG: Right.

DR. LERY: Correct.

DR. RYKACZEWSKA: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Two small things. Dr. Lang had in his notes in the protocol about undefined acronyms in the recruitment materials. I did see at least one undefined acronym also in the protocol on the consent for the youth and family focus groups. So, that should be taken care of all of those places.

The other thing I wanted to mention is the recruitment materials said that people would be offered a meal. Most places it said a meal. I think I saw a small meal in one place. There wasn't anything about that in the protocol or the consent form.

And it's not clear to me exactly what your intention is, but if you're doing it, maybe it should be

said something like you will be given a gift card at the end of the session, and we invite you to stay for a meal or something of that sort.

It seems to be -- at least it should be consistent throughout the materials, whatever you're really doing there. Maybe at the --

DR. LERY: Okay, we will check the materials for consistency, yes. So, we plan to feed everybody during each of the focus groups and provide a \$75 incentive.

COMMITTEE MEMBER SCHAEUBLE: Okay, good.

COMMITTEE MEMBER TEFERA: I have a question for other staff or other board members. Is there a precedent or guidance about how best to describe vendor support in a research project? Which is, essentially, the topic here that was discussed. But criteria where a vendor, in this case helping organize focus groups, would have to be listed as part of the research team versus not?

Are there known criteria or is that kind of an ad hoc decision? Just for my learning.

DR. RYKACZEWSKA: You raised a question that was in my mind, too. I don't believe we have a strict policy on this.

VICE CHAIR DICKEY: I mean, there are certain criteria for who is considered being engaged in research. And I don't think providing logistic support is considered

to be involved and engaged in research.

COMMITTEE MEMBER TEFERA: I agree. And I think, just to be clear for the researchers, this is unrelated to your project. This is for our processes.

VICE CHAIR DICKEY: Yeah. But if you're involved -- if they're involved in getting an informed consent, anything like that, then they would be considered to be engaged in research and they would have to be part of the research team.

COMMITTEE MEMBER TEFERA: But we don't have an existing framework for consideration of this?

VICE CHAIR DICKEY: No, not separate, other than what's in the Common Rule about engagement.

COMMITTEE MEMBER TEFERA: Okay, great. Thank you.

COMMITTEE MEMBER HESS: Would that include national vendors, like Dynata, and social service, or like big research vendors, Gallup, these things? Would we consider those part of a research team if they're doing recruiting and -- they would generally be doing consent at the time of recruiting.

VICE CHAIR DICKEY: Well, if they're doing consent. But I think, actually, recruitment, and this why we have our consultants here, I think actually recruitment is not considered to be engagement. But am I wrong about that?

MR. FEDEWA: You're right. I think it all depends on what's happening within those recruitment activities. If they're informing participants about the possibility of the study, and then passing off the informed consent activities to the researchers then, yeah, I would say they're not engaged.

If people are informing in and starting those first conversations about the informed consent, giving it to them, then usually that crosses the line.

VICE CHAIR DICKEY: Crosses the line, yeah.

MR. FEDEWA: Yeah.

COMMITTEE MEMBER TEFERA: I mean, that's helpful for me. And maybe we can just flag that for a future action for our consultants, maybe like a half-page, to share with the board for our information.

VICE CHAIR DICKEY: Yeah, and part of the policies and procedures we really haven't worked on is engagement.

COMMITTEE MEMBER HESS: Can I -- can I ask follow up. Not to derail this, but since we're discussing it. What constitutes actually a team for consent.

So, if a recruiting firm is, say, just putting out a survey with informed consent on an online survey incorporated, but they haven't done anything to develop the survey, they're basically just this vehicle by which to obtain this consent, are they engaged in research?

And I'm just, again, thinking of national, like large-scale research companies, like Gallup, who put out an online survey on their platform, where they obtained consent at the beginning of the survey, but they're not actually developing consent, they're not engaged -- yeah.

COMMITTEE MEMBER VENTURA: Can I add to that, though? Because the piece for me is like checking for understanding. And like with, you know, Gallup, are they the ones who are responsible? Like they provide the consent information, if someone checks, yes, and, you know --

COMMITTEE MEMBER HESS: Then they're -- they would have the contact information that would go back to the research team, though, if they didn't understand something.

They wouldn't contact Gallup and say, I don't understand this consent form.

MR. FEDEWA: I'd say to your question, Dr. Hess, I would say in that case, Gallup or other companies like that, and Amazon Emptor, are a service provider.

COMMITTEE MEMBER HESS: Uh-huh, yes.

MR. FEDEWA: They're providing a service. They're not necessarily performing the research activity.

COMMITTEE MEMBER HESS: Okay.

MR. FEDEWA: Yeah.

VICE CHAIR DICKEY: So, they're not participating in creating in the informed consent document or designing

the research.

MR. FEDEWA: Correct.

VICE CHAIR DICKEY: They are basically just aiding to carry it out.

MR. FEDEWA: Right.

VICE CHAIR DICKEY: Right.

MR. FEDEWA: It would be similar in like lab draw situations. If you're sending somebody to like a Quest Diagnostics or, you know --

VICE CHAIR DICKEY: Right.

MR. FEDEWA: -- something similar to that, they're providing a service, even though they're obtaining research samples.

COMMITTEE MEMBER TEFERA: Thanks.

VICE CHAIR DICKEY: Good discussion. Any other questions, comments from the board members?

Okay, public?

DR. RYKACZEWSKA: Any comments or questions from the members of the public? Acknowledging no members of the public in the room. Any virtual hands?

And I am not seeing any virtual hands.

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

COMMITTEE MEMBER LANG: Yes, I motion to approve deferred, one-year, minimal risk, conditional on the

following board changes.

That we -- that there is a waiver -- that the consent protocol is modified --

DR. RYKACZEWSKA: Yes, I will pull it up.

VICE CHAIR DICKEY: Yeah. And be as specific as you can in terms of those.

DR. RYKACZEWSKA: And you are very fast.

COMMITTEE MEMBER LANG: Okay, yes.

DR. RYKACZEWSKA: Okay. I heard approve -- move for a deferred approval, one year, minimal risk.

COMMITTEE MEMBER LANG: And so, the four key things that I want to highlight are that the protocol is modified to include a waiver of documentation.

VICE CHAIR DICKEY: Oh, you mean, documented informed consent?

COMMITTEE MEMBER LANG: Yes, of consent document.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Yeah.

COMMITTEE MEMBER LANG: Acronyms and initialisms are spelled out in the consent form and associated survey protocols.

DR. RYKACZEWSKA: Acronyms and?

COMMITTEE MEMBER LANG: Initialisms.

DR. RYKACZEWSKA: Are spelled out in the informed consent and --

COMMITTEE MEMBER LANG: And survey protocols.

The referral of the support services and referrals that point to us, I believe the researchers agreed they'd point to the appropriate county services.

And that language is added to the SAC (phonetic) consent form to indicate that there are no ramifications for --

VICE CHAIR DICKEY: Not participating.

COMMITTEE MEMBER LANG: -- for not participating, on their employment.

VICE CHAIR DICKEY: Does there need to be an alteration of informed consent? Do they have all of the required elements, do you think?

COMMITTEE MEMBER LANG: I believe -- I believe all of the elements of consent are there. I need to double check, I did not see that required a signature or initials, like the other survey form.

DR. RYKACZEWSKA: That would be the documentation that --

VICE CHAIR DICKEY: That's a documentation issue.

COMMITTEE MEMBER LANG: Oh, yeah.

VICE CHAIR DICKEY: But all the elements that need to be included.

COMMITTEE MEMBER LANG: I believe so.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Okay, and to be reviewed by a subcommittee of --

COMMITTEE MEMBER LANG: Yes.

VICE CHAIR DICKEY: -- of yourself.

DR. RYKACZEWSKA: Are we missing any part of our motion?

COMMITTEE MEMBER SCHAEUBLE: We did talk about also clarifying compensation included gift card and being invited to a -- stay for a meal.

DR. RYKACZEWSKA: Would you like to add that?

COMMITTEE MEMBER LANG: Yes. Clarifying what their amount of compensation -- it includes just a gift card or a meal, as well.

COMMITTEE MEMBER VENTURA: Is that making it consistent throughout all the --

COMMITTEE MEMBER LANG: Yes, so making it consistent throughout the recruitment material.

VICE CHAIR DICKEY: Any comments?

COMMITTEE MEMBER SCHAEUBLE: Well, it's actually recruitment and consent materials because that was the discrepancy. It appeared in some kinds of materials and not in the others.

VICE CHAIR DICKEY: Any comments from the Committee or consultants?

Public?

DR. RYKACZEWSKA: We already asked the public.
Anything else? We already had public comment.

VICE CHAIR DICKEY: Not about the motions?

DR. RYKACZEWSKA: The order is the Committee
discussion, public comment, then a motion, then a vote.

VICE CHAIR DICKEY: All right, so they can't
comment anymore.

Second?

COMMITTEE MEMBER TEFERA: Second.

MS. ATIFEH: Who? Dr. Ventura?

COMMITTEE MEMBER VENTURA: Dr. Tefera.

COMMITTEE MEMBER TEFERA: Either.

MS. ATIFEH: Tefera?

COMMITTEE MEMBER VENTURA: It doesn't matter,
yeah.

VICE CHAIR DICKEY: We have a third.

MS. ATIFEH: Dr. Tefera.

COMMITTEE MEMBER VENTURA: Dr. Tefera is fine.

MS. ATIFEH: Okay.

Dr. Hess?

COMMITTEE MEMBER HESS: Approve.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Dinis is not here.

Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Approve.

MS. ATIFEH: Thank you.

Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: And Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: Okay, the motion passed.

DR. RYKACZEWSKA: And, Sussan, just for the record, can we make sure to note that Dr. Dinis was absent, but she was here earlier?

MS. ATIFEH: Yes, yes, I have it.

DR. RYKACZEWSKA: Yeah.

MS. ATIFEH: Yes, definitely.

DR. RYKACZEWSKA: Okay, thank you.

VICE CHAIR DICKEY: Okay. You will receive a letter from the Committee and specifying this, but you can start working on these things before. And Dr. Lang will be your reviewer.

The next and the last item --

DR. RYKACZEWSKA: Can I say --

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Sorry. Just real quick --

VICE CHAIR DICKEY: Here she goes again?

DR. RYKACZEWSKA: I know, I'm all over the place today. I'm sorry. I just want to say congratulations to Dr. Lang on your first full board process.

COMMITTEE MEMBER LANG: Thank you.

(Laughter)

DR. RYKACZEWSKA: Thank you, again, to the research team.

COMMITTEE MEMBER LANG: Thank you.

DR. LERY: Thank you.

VICE CHAIR DICKEY: Okay. The last item is basically revisiting the unanticipated problem/adverse event through a report on the project that is titled Using Infant Feces and Serum for Polymerase Chain Reaction and Assay with Large Immunosorbent Surface Area Assay. I won't go over the rest of it.

And Dr. Padgett, is Dr. Padgett here?

DR. RYKACZEWSKA: I thought I saw her.

DR. PADGETT: I'm here.

VICE CHAIR DICKEY: Oh.

DR. PADGETT: Good morning.

VICE CHAIR DICKEY: Okay, great.

The Committee made a number of recommendations after we heard this at the last meeting, and the researchers have submitted some potential amendments to this.

And we thought it would be good to bring it back

to the full board so that you can see the amendments. And also, we have an issue of, and here our consultants can help us out, in terms of how we deal with unanticipated problems versus adverse events.

And we need to put certain things in our motion regarding certain issues.

So, maybe we can just start out with our consultants giving us a framework for what we need to put in a motion and what we need to consider. Is that okay?

And then, as part of this, also, is the issue of reporting unanticipated problems to OHRP, or FDA.

So, ready, you want to take it away?

MR. FEDEWA: Sure, I can. Agnieszka, do you want me to just go through the slides really quickly?

DR. RYKACZEWSKA: I think that would be great.

MR. FEDEWA: Because that would help inform sort of the details for the motion. So, and I think in everybody's packets, and it's also available online, we just put together four very quick slides.

The first thing really just clearly sets out some definitions for what an adverse event is and what a serious adverse event is. Adverse events being any untoward medical occurrence or event. And serious adverse events being an adverse event that results in death, is life threatening, requires hospitalization, causes significant disability, a

general ailment (phonetic), anomaly, birth defect, or is medically important. I'm realizing that there is a typo right there.

But the federal regulations, when they describe the IRB responsibilities, the IRBs are required to have policies that require researchers to report not necessarily adverse events to the IRB, but unanticipated problems, as well as serious and/or continuing noncompliance.

So, the next slide, if you just flip your papers over, just includes the three criteria that the federal regulations outline as far as what an unanticipated problem, or a UAP, include.

So, an unanticipated problem must be unexpected. And that includes in nature, severity, frequency and the participant characteristics. So, this can include both there was a description of this adverse event potentially happening in the protocol, but it's happening more than we expected. We thought it would be a 10 percent occurrence rate and we're really seeing it closer to 15 to 20 percent.

Or, it just was not mentioned at all. We did not anticipate that this could potentially happen. It has to be related to the research where there's a reasonable possibility of this thing being caused by the research procedures. And it needs to suggest a greater risk of harm for the subjects or others. Because it's not necessarily

just unanticipated problems are not just focused on subjects of the research, but it can include the research team. It can include the participants' families. It can include anybody who might have been affected by this event.

And those harms can be physical, psychological, economic or social. And those harms should be greater than what we have previously known and/or expected.

So, just in terms of this particular event, when it was being discussed in December, we had just identified that the board needed to make a determination specifically about whether what happened on this study meets the criteria of an unanticipated problem, and very clearly document that with in the motion.

And if it does meet those criteria of an unanticipated problem, then this would require reporting to the federal government.

VICE CHAIR DICKEY: Well, if it increased risk.

MR. FEDEWA: Right. Well, if it meets the criteria of an unanticipated problem.

VICE CHAIR DICKEY: And increases risk.

MS. BYERS: Right, that's one of the criteria.

VICE CHAIR DICKEY: Yeah. Yeah. So, then it wouldn't be a problem. It could be unanticipated, but it wouldn't be a problem.

DR. RYKACZEWSKA: If it didn't increase risk.

VICE CHAIR DICKEY: If it didn't increase risk.

MR. FEDEWA: Right, yeah. And I just want to take a very quick -- the board just needs to go through and have that discussion, but the last slide that you'll see, we have some examples of unanticipated problems. Obviously, this is not an inclusive list, but it's just some helpful descriptions of things that might not necessarily be an adverse event.

And then, the last slide that's just in this packet, the other thing that the board should consider anytime that you're seeing an unanticipated problem, if it wasn't clearly just an adverse event, or a serious adverse event. Like somebody received a drug and had a medical outcome.

But in this case, there was a procedure that didn't necessarily go right. In that case, the board needs to consider is this noncompliance? And if it is noncompliance, is that noncompliance serious and/or continuing.

The one thing that I'll note is that these are proposed definitions. There is no federal definition of what serious and/or continuing noncompliance are. But these definitions conform with what SMARTIRB, which is a group that produces a lot of guidance around reliance, this is -- conforms with the definitions that they have put out, and

that many IRBs around the country adopt, as far as what serious and continuing noncompliance includes.

So, with that, happy to take any questions and/or turn it back over to Dr. Dickey for the board to have a discussion about the amendment.

VICE CHAIR DICKEY: There's a lot there. The question is do we go outside of this project or do we talk about this project now, and put off the rest of the -- I think you're saying that we need to, one, determine whether this project is an unanticipated problem that -- in that it created increased risk.

In which case, that would say we would need to do a report to the FDA in this case, I guess. Wouldn't it be the FDA?

DR. RYKACZEWSKA: It would be OHRP.

MR. FEDEWA: OHRP.

VICE CHAIR DICKEY: OHRP.

MR. FEDEWA: Yeah. And I will just note that sounds very serious, but this is a very common thing that institutions and IRBs around the country do this quite frequently. Things happen on research studies that we can't necessarily predict or expect.

And so, it's actually more concerning to the federal government if they're not receiving these reports from IRBs. They expect that things are potentially going to

go wrong. And as long as the PI and the IRB are taking appropriate steps to try to make sure that that thing doesn't happen, and that subjects were protected, then they acknowledge the report and move on.

VICE CHAIR DICKY: And then, part of that report is what happened and what are the proposed interventions to mitigate it.

MR. FEDEWA: Correct.

VICE CHAIR DICKY: So --

COMMITTEE MEMBER TEFERA: But to be clear, the first steps of all this is whatever happened being something serious or of concern.

VICE CHAIR DICKY: Well, it has to be considered an increased risk.

DR. RYKACZEWSKA: So, it has to be these things right here, yeah.

MS. BYERS: Right. So, the question is what about the event that occurred, the reportable event that the investigators submitted to the Committee to contemplate, whether or not it meets the criteria of an unanticipated problem.

And so, it has to meet all three criteria to become an unanticipated problem.

VICE CHAIR DICKY: And I think we can agree, probably, that this was unanticipated. And what resulted

was an extra blood draw for a child.

COMMITTEE MEMBER TEFERA: Well, I'm not sure an extra blood draw in a hospital would be described as unanticipated.

VICE CHAIR DICKEY: Well, it's not -- as part of this project it was unanticipated.

But the question is does it increase the risk greater than what they would be normally subjected to. I would say -- you could say would it be greater than anticipated -- they would be subjected to in this project or greater than they would be subjected to in the hospital.

It's really a discussion.

COMMITTEE MEMBER VENTURA: Because in the project it was intended that there were no blood draws -- extra blood draws for research purposes. Only extra material.

And so, in that -- in the case -- or in the instance that we reviewed last meeting, it was intentional -- you know, it was for this research project they drew blood.

COMMITTEE MEMBER TEFERA: Sure. No, I understand. A phlebotomist saw an order, took blood specifically instead of getting -- to get serum for this research project.

And I guess what I'm noting is that, especially in children, if a child is hospitalized for any condition, the experience of children in pediatric hospitals involves lots

of phlebotomy, for whatever reason ordered by the doctor for their clinical care.

This is also true for adults, but especially for kids. Kids with serious conditions, they can be -- you know, the volume of phlebotomy is not small.

So in -- which is why I say that a child or a patient, adult, receiving an extra test could happen for lots of reasons. Hospitals have protocols about lab results.

Well, without consenting or asking a physician, they'll request repeat testing, repeat phlebotomy without any clinician involved.

So, considering the number of events where adults and kids are poked for some reason or (indiscernible) -- my question is how different is this event?

COMMITTEE MEMBER HESS: But I think that would get to the risk portion. So, it wasn't expected --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER HESS: -- in that it wasn't part of the protocol. It was related to the research in that the extra blood was drawn because of the research project.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER HESS: But as you're pointing out, is it really an increase in risk for that child given --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER HESS: -- what their experience was normally going to be in a hospital setting. That would be that third part of it, that greater risk.

And what I'm hearing you say is that actually, no, it probably isn't an increase.

VICE CHAIR DICKEY: And I'll point out that I think OHRP guidelines are that blood draws do not make something more than minimal risk.

But that doesn't necessarily say that there's not a slight additional risk.

COMMITTEE MEMBER SCHAEUBLE: Well, is the question here, though, what the experiences of the child would be in the hospital or what the experiences of the child would be in the research study?

COMMITTEE MEMBER HESS: Aren't all --

COMMITTEE MEMBER SCHAEUBLE: Because those are two different situations.

COMMITTEE MEMBER HESS: Weren't all of the children in the hospital.

VICE CHAIR DICKEY: They're in the hospital, yeah. But he's saying that what --

COMMITTEE MEMBER SCHAEUBLE: But their participation in the study isn't specifically related to what's happening to them in the hospital. The study is

taking samples that exist in the absence of whether the child's currently in the hospital or not.

VICE CHAIR DICKEY: I guess we could ask the researchers whether there are other instances in the study where blood is drawn. Is there?

DR. PADGETT: Can you clarify that because --

VICE CHAIR DICKEY: Are there other instances in the study where blood is drawn? Not just in this case, but in other cases?

DR. PADGETT: This is the -- the study really is for the question of noninvasive samples, so that we are not requesting any blood draws. And that's --

VICE CHAIR DICKEY: Okay, that's not a normal part of the study.

DR. PADGETT: -- so, I would reiterate.

VICE CHAIR DICKEY: Yeah. All right.

So, it really is, you know, the Committee needs to decide. That's one of the things they need to decide is this a risk, really a risk for which we would then classify this as an unanticipated problem.

In which case, it would trigger us to report it to OHRP.

But like I said, reporting to OHRP is not necessarily a bad thing. You know, it's a procedural issue.

MS. BYERS: Can I ask the investigator, do you

know how much blood was drawn?

DR. PADGETT: Yes, 1.5 mil of blood was drawn.

MS. BYERS: And if I remember correctly, this was a three-month-old, is that correct?

DR. PADGETT: Yes, uh-hum.

MS. BYERS: Okay.

VICE CHAIR DICKEY: So, there's that issue. Maybe we can put that off so we discuss other aspects of it. Because I think it's relevant to what they're proposing to do in terms of the changes.

COMMITTEE MEMBER HESS: I think that we should do the -- we should first do the determination and then discuss the amendment.

All right, you're not Chair, yet.

(Laughter)

VICE CHAIR DICKEY: I'd like to go ahead and discuss -- I think kind of reacquaint everybody with the project, if we go and discuss the other things, their proposed solutions. And then, we'll put it all in one.

So, could you review for us the changes that you have -- the amendment you've made to deal with our concerns from last meeting?

DR. PADGETT: Yeah. And I just wanted to highlight that Connie Chung is also joining us, and she's from our Infant Botulism Treatment Prevention Program which,

you know, she's very familiar with like communications and help to edit some of our responses.

But I'll just go through. I know that the amendments that were requested, I thought I would just highlight what we have changed, because I know there are a lot of different documents.

The first, we revised a script for the hospital staff. We wanted to emphasize the different words that could be used. So, residual and leftover serum were included.

We revised a fact cover letter. We included the following, we are only able to accept residual serum. Please do not perform any new blood draws on this patient for our research study. And note, residual and new were underlined.

On our fax, we clarified and we discussed at our last meeting, the subject line wording. We added "residual only" to the subject line. And requests for leftover serum from patient, only, in parenthesis (residual only).

So, we were trying to put that in as many places as we could.

We also extended, for addressing the extended communication, the instructions that were sent to the hospital care staff. We added, the addition to clearly state, we are only able to accept residual serum and no

blood draws should be performed on this patient for this request. And we also clearly request, please make a note of this in the patient's electronic medical record. And I know we discussed that at the last meeting, at length.

Also, regarding the hospital system request, our feedback with Dr. Dickey, this week, we inserted a question to really ensure the staff confirm our request.

So, we inserted, in order to ensure that no inadvertent blood draws are performed, we request that a notation is inserted in the EMR that no blood draws are performed in response to this CDPH IVTTP request, and do acknowledge this request.

So, we would, you know, really that would be kind of a back and forth, so it would make sure that they really did understand our request.

And then, for the parents, we amended for the parent notification, we also added verbal consent for the sample use. That was also something that Dr. Dickey recommended. So, we have that inserted as well.

And also, on our verbal request we had, do we have your verbal consent to use your child's serum in our program request.

We also added, for a verbal consent for serum, that the addition to the parent's consent to note that no new blood draws are needed. And that states the risks

involved, it has happened in the past, but it is very rare.

So, Connie, did I -- I don't know if you want to add anything else, you know, in terms of you had kind of the real experiences in these communications with the --

VICE CHAIR DICKEY: So, I just -- before you go on, that last thing you said about this has happened in the past, can you say that again? What --

DR. PADGETT: You mean, the variable we added in there?

VICE CHAIR DICKEY: That's in the -- that's in the consent form, now. Is that right?

DR. PADGETT: Yes.

VICE CHAIR DICKEY: Can you read what it says?

DR. PADGETT: The verbal consent form for the serum use, we added, you know, that no new blood draws are needed. And that states the risks that are involved, it's happened in the past, but very rare.

So, you know, we did acknowledge this has happened, you know, in the past --

VICE CHAIR DICKEY: Okay.

DR. PADGETT: -- and we are, you know, trying to find ways to ensure that this does not ever happen again.

VICE CHAIR DICKEY: So, that would make, if it happened in the future, not unanticipated because you've acknowledge in the consent that it might happen. Which was

going to be my suggestion is that since some of this you can't control, it's beyond your control, you can only ask people to do it, it's going to happen. And you just have to acknowledge it in the consent form, which you've done.

Any questions about their solutions to this or their proposed way to deal with it?

So, then, that gets us back to is this unanticipated problem in terms of the risk. I guess we maybe are going to need to vote on that.

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: It seems like we do need to clarify the situation that we are referencing in trying to make that decision. Because if you talk about the everyday life of a child, or you talk about the circumstances of the child as it pertains to this research study, we're not talking about blood draws being part of those situations.

If we were talking about what a child experiences when being hospitalized, then, yes, it would be typical there.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER SCHAEUBLE: But I think we need to specify what framework we're using here if we're trying to assess whether these criteria apply. And I haven't heard

that so far.

VICE CHAIR DICKEY: Yeah. Other comments?

So, I think there probably should be two separate motions. One should be do we accept their proposed solutions, as they've delineated.

And then, the second motion should be whether this meets the criteria of an unanticipated problem that needs to be reported.

MS. BYERS: Excuse me --

VICE CHAIR DICKEY: Go ahead.

MR. FEDEWA: Dr. Dickey, I would just also suggest in this case, because it was a deviation from the protocol, that the board discuss whether this is noncompliance.

VICE CHAIR DICKEY: Well, I --

MR. FEDEWA: And then, ultimately, the board just need to make a determination. Does this meet that definition or not.

VICE CHAIR DICKEY: Okay, it's worth discussing here. You're going to make this more complicated.

The question is what is compliance? Noncompliance with the Common Rule or noncompliance with what's in the protocol is noncompliance.

The question is, if somebody does something that you can't control, such as a hospital staff, and does something that's not in the protocol, is that noncompliance

on the part of the researcher.

My opinion is it's not. But that is something to discuss.

MR. FEDEWA: Yeah.

COMMITTEE MEMBER VENTURA: So, is that a third motion? Does that need to be a third motion?

VICE CHAIR DICKEY: That could be -- well, it's a third issue. But do you have any opinions about that?

COMMITTEE MEMBER HESS: I don't think that the research team met the criteria for noncompliance. They did not fail to follow their own protocols. They did not fail to follow what the protocol they had submitted to us previously.

They took steps to tighten up their protocol after a previous incident. The hospital still did the blood draw. I don't feel like that's noncompliance on behalf of the research team. And so, I agree with you on that.

COMMITTEE MEMBER SCHAEUBLE: And I would agree, as well.

VICE CHAIR DICKEY: But I guess it would be worth having a third motion to document that.

Anybody else have opinions about that?

MR. MURPHY: Dr. Dickey? Noncompliance comes in another way, also, in that usually research done under a protocol has a whole lot of cases. And cases that are --

that happen when something -- with a protocol deviation,
that individual case is not going to be part of the ultimate
(indiscernible) --

VICE CHAIR DICKEY: Well, it depends on what the
-- what the protocol says as to whether -- and we've had
cases like that where we've had to decide can you -- can
they keep the data in the study.

In this case, part of our motion, that we adopted,
was they can use the specimen if they get consent from the
parents. And part of what they provided was a consent
script for the parents, to use this -- to use this specimen
that had been mistakenly drawn. So, I think we've dealt
with that.

MR. MURPHY: Okay.

VICE CHAIR DICKEY: Okay. I can't make a motion,
so do you want to make a motion?

COMMITTEE MEMBER HESS: Okay.

MS. BYERS: Before you make a motion --

VICE CHAIR DICKEY: Uh-hum.

MS. BYERS: -- can we look at -- so, Dr. Dickey,
you're absolutely correct the OHRP does give some framework
around blood draws, and what's appropriate and what's not
appropriate.

Agnieszka, I don't know if you can show that.

So, this is what qualifies for a study to meet the

criteria if it's drawing a blood sample for expedited review. So, considering minimal risk.

And I think in this case, when you're looking at risk, and making the determination of whether or not this specific issue of the additional blood draw taking place on this infant, is causing, or could potentially have caused an increased risk to this one particular child. Or, if it happens again, multiple children.

But if you look at B, these are just some things that the regulations that you have to take into consideration. So, you have to consider the age of the child, the weight of the child, the health of the child, and then the amount of blood drawn cannot exceed the lesser of 50 mils or 3 mils per kilogram in an eight-week period. And it cannot occur more frequently than two times per week.

VICE CHAIR DICKEY: Well, this wouldn't quality. I mean, this is 1.5 milligrams -- or, 1.5 mls. And I assume the kid probably weighs a couple of kilograms, so --

COMMITTEE MEMBER LANG: Let's do the motions.

COMMITTEE MEMBER HESS: Okay.

VICE CHAIR DICKEY: But thank you, that's worth knowing, that there's a --

MS. BYERS: Yeah, just for everyone's information.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER HESS: So, the first motion is

whether or not this event meets the criteria --

VICE CHAIR DICKEY: Why don't we do the first motion being their solutions, we accept their solutions, their amendment.

COMMITTEE MEMBER HESS: The amendment, okay.

So, I move that we accept the additional -- sorry, my brain is fried. The additional steps in the protocol --

VICE CHAIR DICKEY: The amendment.

COMMITTEE MEMBER HESS: In the amendment to address this event.

VICE CHAIR DICKEY: Is there a second.

COMMITTEE MEMBER VENTURA: You mean like to prevent it, like their --

COMMITTEE MEMBER HESS: And prevent the likelihood of future events.

MS. ATIFEH: It's a complete approval, right?

COMMITTEE MEMBER HESS: Yeah.

MS. ATIFEH: Complete approval.

COMMITTEE MEMBER HESS: Do we want to vote and then go to the second motion or do you want me to just go through all the --

VICE CHAIR DICKEY: Well, let's just do one motion at a time.

DR. RYKACZEWSKA: So, public comment. If there's any members of the public online that would like to raise

their virtual hand to make a public comment? Acknowledging no members of the public in the room.

And I am not seeing any public comment.

COMMITTEE MEMBER HESS: We need a second.

COMMITTEE MEMBER VENTURA: Second.

VICE CHAIR DICKEY: Call the roll, please.

MS. ATIFEH: Okay.

Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

One quick question. Can we modify the motion to clarify if its adverse events?

VICE CHAIR DICKEY: Well, no, it's not actually an adverse event.

COMMITTEE MEMBER LANG: Oh, it's not.

VICE CHAIR DICKEY: We're not making --

COMMITTEE MEMBER HESS: We're not making a judgment, yet.

COMMITTEE MEMBER LANG: Okay.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Approve.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Okay, and just for the record Dr. Dinis is absent when, you know, this -- for the discussion of this amendment.

And the motion passed.

COMMITTEE MEMBER HESS: Okay. So, the next motion is move -- do I have to make a recommendation one way or the other?

VICE CHAIR DICKEY: Yeah. Does this constitute noncompliance?

COMMITTEE MEMBER HESS: I make a motion that this does not meet the criteria for noncompliance.

VICE CHAIR DICKEY: Second? Or for discussion.

DR. RYKACZEWSKA: Public comment.

VICE CHAIR DICKEY: Public comment?

DR. RYKACZEWSKA: If there are any members of the public who would like to make a comment online? Acknowledging there are no members of the public in the room.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: Second?

COMMITTEE MEMBER VENTURA: Second.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: I approve.

MS. ATIFEH: Okay.

Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Abstain.

MS. ATIFEH: Abstain.

VICE CHAIR DICKEY: Okay.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Approve.

MS. ATIFEH: Dr. Tefera?

COMMITTEE MEMBER TEFERA: Approve.

MS. ATIFEH: Okay, the motion passed.

And again, just for the record Dr. Dinis is
absent.

COMMITTEE MEMBER HESS: Okay. So, the third and
final motion, I guess I would move that this also does not
meet the criteria for an unanticipated event, unanticipated
problem. But do we want to -- do we need to discuss that.

VICE CHAIR DICKEY: Well, we can't discuss about
your motion, but --

COMMITTEE MEMBER HESS: Okay.

DR. RYKACZEWSKA: Do we need to state a reason to

which criteria is not met?

COMMITTEE MEMBER HESS: I don't believe it meets the criteria for placing a subject at increased risk.

VICE CHAIR DICKEY: Discussion?

COMMITTEE MEMBER LANG: Do we want to cite any language with regards to the blood draw? What was that guidance you showed us?

COMMITTEE MEMBER VENTURA: Oh, you're talking about the blood draw guidance.

COMMITTEE MEMBER LANG: Yeah.

COMMITTEE MEMBER HESS: Yeah, we don't have to.

VICE CHAIR DICKEY: We don't have to cite it. It will be in our minutes.

COMMITTEE MEMBER LANG: Uh-huh.

COMMITTEE MEMBER HESS: Does anyone disagree?

VICE CHAIR DICKEY: Well, we'll find out.

Public comment.

DR. RYKACZEWSKA: If there are any members of the public who would like to make a comment, please raise your virtual hand. Acknowledging that there are no members of the public in the room.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: Is there a second?

COMMITTEE MEMBER TEFERA: Second.

MS. ATIFEH: Okay, Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Approve.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Approve.

MS. ATIFEH: Dr. Lang?

COMMITTEE MEMBER LANG: Approve.

MS. ATIFEH: Dr. Murphy?

MR. MURPHY: Abstain.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I will abstain.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Approve.

MS. ATIFEH: So, we need to -- can I ask Dr.

Dickey to break the tie?

VICE CHAIR DICKEY: All because of the
abstentions?

MS. ATIFEH: Yes, we have six, we need one more.

DR. RYKACZEWSKA: So, we have a tie.

MS. ATIFEH: We have a tie.

DR. RYKACZEWSKA: Just for the record.

VICE CHAIR DICKEY: You're going to put me in this
potion.

DR. RYKACZEWSKA: At which point, just for --
again for the record, per our policies and procedures, if
there is a tie in the vote, the chair must vote to break the
tie.

VICE CHAIR DICKEY: Okay. I approve.

MS. ATIFEH: Approve. Okay, the motion passed.

DR. RYKACZEWSKA: I am seeing some questions from our consultants.

MS. BYERS: So, this tie was between the in favor of the motion and the abstentions?

MS. ATIFEH: The tie was between the approval --

DR. RYKACZEWSKA: How many approvals, how many abstentions --

VICE CHAIR DICKEY: We have to have a majority voting, yes.

DR. RYKACZEWSKA: Right.

VICE CHAIR DICKEY: Do we have a majority voting yes?

MS. ATIFEH: The majority of yes?

VICE CHAIR DICKEY: Yes.

MS. ATIFEH: We had six before you. When you said yes, we reached to seven, which is the minimal.

VICE CHAIR DICKEY: Okay. There. So, that's the criteria.

MS. ATIFEH: Yeah.

VICE CHAIR DICKEY: We have to -- even if they abstain, they have to have a majority of our quorum to approve something.

MS. ATIFEH: We need seven.

DR. RYKACZEWSKA: Seven yes.

COMMITTEE MEMBER TEFERA: So, the abstentions essentially count as a no for the voting purposes?

VICE CHAIR DICKEY: Essentially, in this case.

MS. ATIFEH: And, so this motion was passed. And again, for the record, Dr. Dinis was absent in this motion.

VICE CHAIR DICKEY: But we did make the seven.

MS. ATIFEH: Yes.

VICE CHAIR DICKEY: Okay. I would like to report to OHRP but --

DR. RYKACZEWSKA: You would like to report?

VICE CHAIR DICKEY: Well, you know, we need -- we need practice doing this but --

DR. RYKACZEWSKA: You'll have it.

(Laughter)

DR. RYKACZEWSKA: It's fine.

So, do we need to tell the researchers what --

VICE CHAIR DICKEY: Yeah, so are the researchers still with us?

DR. RYKACZEWSKA: Yeah.

VICE CHAIR DICKEY: Yeah. So, you heard that and we approved your amendment and we're not reporting you to anybody at this point. But, obviously, if anything -- you know, we want to know if this recurs. I know, now, if it recurs it won't be unexpected. But I think for our

information it would be good to know.

COMMITTEE MEMBER HESS: It's still reportable.

VICE CHAIR DICKEY: It's still reportable. And it's -- I'd like to say that, you know, problems that are not necessarily unexpected, or protocol deviations, et cetera, still need to be reported to us, whether they are of the severity that we need to report them, then, to higher up is an issue.

DR. RYKACZEWSKA: Thank you so much to the research team.

DR. PADGETT: Thank you.

VICE CHAIR DICKEY: Okay, so I guess we have --

DR. RYKACZEWSKA: That concludes --

VICE CHAIR DICKEY: Yeah, we have Items O through P --

DR. RYKACZEWSKA: H through O, actually.

VICE CHAIR DICKEY: H through O, okay, which includes projects that -- you know, you can see the list, exemptions that have been approved, et cetera.

Any comments on any of those?

DR. RYKACZEWSKA: Any comments from the public?

VICE CHAIR DICKEY: Any comments from the public?

DR. RYKACZEWSKA: If there are any comments from the public on Items H through O, if you could please raise your virtual hand? Acknowledging no members of the public

in the room.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: I'm not seeing any virtual hands.

VICE CHAIR DICKEY: Any comments from the public on items that weren't on the agenda?

DR. RYKACZEWSKA: If there are any comments from the members of the public on items not on the agenda, please raise your virtual hand. Acknowledging no members of the public in the room.

And I am not seeing any virtual hands.

VICE CHAIR DICKEY: I want to say that we had a discussion, at least here, about possibly talking about the de-identification criteria, and maybe trying to educate the Committee more on the specifics of that, even if we don't hear anything back from those researchers.

So, maybe let us know in the meantime whether you agree with that or you think it would be a good idea.

So, anyway, with that I think that we are ready to adjourn.

Our next meeting is going to be February --

DR. RYKACZEWSKA: No, April.

VICE CHAIR DICKEY: Friday, April 3rd.

DR. RYKACZEWSKA: Meeting adjourned at 11:46.

MS. ATIFEH: 11:46.

(Thereupon, the meeting was adjourned at
11:46 a.m.)

--oOo--

REPORTER'S CERTIFICATE

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 20th day of February, 2026.



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IN WITNESS WHEREOF, I have hereunto set my hand this 20th day of February, 2026.



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