

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

FRIDAY, OCTOBER 4, 2024

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COMMITTEE MEMBERS

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Allen Azizian, PhD (via Zoom)

Maria Dinis, PhD, MSW (via Zoom)

Catherine Hess, PhD

Jonni Johnson, PhD

Laura Lund, MA

Carrie Kurtural, JD

Philip Palacio, EdD, MS (via Zoom)

Juan Ruiz, MD, Dr.PH, MPH (via Zoom)

John Schaeuble, PhD, MS

Maria Ventura

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator, CDII Deputy
Director

Sussan Atifeh, Staff Services Analyst

Karima Muhammad

Nicholas Zadrozna (via Zoom)

CDII

Jared Goldman, General Counsel

Maggie Schuster, Legal Counsell

John Ohanian, Chief Data Officer

APPEARANCES (CONT.)

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Medicine

PUBLIC

Becky Armstrong, UC Berkeley

Evan White, JD/MPP California Policy Lab

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1 P R O C E E D I N G S

2 CHAIR DICKEY: This is the October 4th, 2024,
3 meeting for the Protection of Human Subjects. I am Larry
4 Dickey, the Vice Chair. I'll be chairing this meeting.

5 And why don't we go around and introduce
6 everybody.

7 COMMITTEE MEMBER VENTURA: Dr. Maria Ventura.

8 COMMITTEE MEMBER HESS: Dr. Catherine Hess.

9 COMMITTEE MEMBER KURTURAL: Carrie Kurtural.

10 COMMITTEE MEMBER JOHNSON: Dr. Jonni Johnson.

11 MS. ATIFEH: Sussan Atifeh.

12 MR. GOLDMAN: Jared Goldman.

13 MS. SCHUSTER: Maggie Schuster.

14 DR. RYKACZEWSKA: Peter, introduce yourself?

15 COURT REPORTER: Court Reporter Peter Petty.

16 MS. MUHAMMAD: Karima Muhammad.

17 COMMITTEE MEMBER SCHAEUBLE: Dr. John Schaeuble.

18 DR. RYKACZEWSKA: Agnieszka Rykaczewska.

19 CHAIR DICKEY: Great. And are there members of
20 the public that would like to introduce themselves? Okay.

21 DR. RYKACZEWSKA: I'm not seeing any hands.

22 CHAIR DICKEY: Before we --

23 DR. RYKACZEWSKA: And you have got folks online or
24 members online?

25 CHAIR DICKEY: Yes, I was including those online.

1 Can you introduce yourselves?

2 COMMITTEE MEMBER DINIS: Maria Dinis.

3 COMMITTEE MEMBER LUND: Laura Lund.

4 COMMITTEE MEMBER RUIZ: Juan Ruiz.

5 COMMITTEE MEMBER AZIZIAN: Allen Azizian.

6 MR. OHANIAN: John Ohanian.

7 MS. ARMSTRONG: Becky Amstrong.

8 COURT REPORTER: Who?

9 DR. RYKACZEWSKA: John Ohanian.

10 COURT REPORTER: Thank you.

11 MS. ARMSTRONG: Becky Armstrong, Director at UC
12 Berkeley for Human Subjects.

13 COURT REPORTER: Is that a member of the public?

14 MS. ARMSTRONG: Yes.

15 COURT REPORTER: Thank you.

16 CHAIR DICKEY: Is that everybody? All right.

17 I just want to remind everybody to, if you are on
18 remote, to keep your camera on if at all possible.

19 Dr. Bazzano is --

20 DR. RYKACZEWSKA: No on yet.

21 CHAIR DICKEY: Do we have a quorum without her?

22 DR. RYKACZEWSKA: Yes.

23 CHAIR DICKEY: Okay. Before we start, I would
24 like to congratulate Sussan and Karima for birthdays
25 recently.

1 MS. ATIFEH: Thank you so much.

2 MS. MUHAMMAD: Thank you.

3 COMMITTEE MEMBER SCHAEUBLE: Happy birthday.

4 MS. ATIFEH: Thank you so much.

5 COMMITTEE MEMBER SCHAEUBLE: And for Nick and
6 Agnieszka, basically for their one-year anniversary.

7 COMMITTEE MEMBER SCHAEUBLE: Happy anniversary.

8 CHAIR DICKEY: Surviving with us.

9 DR. RYKACZEWSKA: Thriving.

10 CHAIR DICKEY: Thriving with us. Okay.

11 Agnieszka, we were talking about a quorum. Do you
12 want to --

13 DR. RYKACZEWSKA: Yes.

14 CHAIR DICKEY: -- say something?

15 DR. RYKACZEWSKA: So the Bagley-Keene Open Meeting
16 Act includes conditions where a member can attend and
17 participate in a remote location and be counted towards the
18 majority required to hold a meeting.

19 Ahead of today's meeting, Ms. Lund shared with me
20 the administrator reasons for participating from a remote
21 location that satisfy these requirements in the Bagley-Keene
22 Open Meeting Act for attending remotely and being counted
23 towards our quorum today.

24 CHAIR DICKEY: Okay. And we've done the roll
25 call, I believe. Do we need to do a formal roll call for

1 the quorum purposes?

2 MS. ATIFEH: The quorum is established today.
3 They introduced.

4 DR. RYKACZEWSKA: Yeah, I think we're good.

5 CHAIR DICKEY: Okay. And any public comment
6 before we move to our first items? We're going to try to
7 make room for public comment on every item we discuss today,
8 regardless of whether it's a voting issue or not.

9 So hearing none, first issue is Subcommittee
10 Updates, and Ms. Lund will give that presentation.

11 COMMITTEE MEMBER LUND: Great. Thank you, Dr.
12 Dickey. So I'm going to give the update for the
13 Subcommittee that met, the purpose of which is to develop
14 recommendations for language for regulations to support the
15 use of projects under the IPA.

16 So before I give the Subcommittee update, I just
17 want to make sure that the Committee understands what that
18 Subcommittee is about, because I noticed in comments from
19 the public that there seems to be a lot of confusion, and I
20 want to make sure that the Committee is not confused.

21 So if you recall, for quite a while now, well over
22 a year, we have been, as a Committee, having discussions
23 about projects that we review under the IPA, particularly
24 projects that we have some concerns about in regard to
25 linkages, large data sets, extremely sensitive information,

1 and the use of people's data from state databases, and just
2 general concerns around that.

3 The IPA language has criteria for doing those
4 reviews. IPA projects come to us as projects over which we
5 don't have IRB purview. So just as a reminder for
6 everybody, we act as the IRB if there's a state agency
7 conducting the research, if a state agency is funding the
8 research, if a state agency is participating in the research
9 by providing staff or other resources, or if state agency
10 data being released is going to be used to contact human
11 subjects, or if we are actually asked to be the IRB in some
12 cases. So IPA projects are projects that we are required by
13 statute to review that don't fall within our IRB purview.

14 So this Committee has wanted to establish some
15 standardized criteria for reviewing those projects that
16 would clarify the very general criteria that are offered in
17 the IPA, and so that is the purpose of this Subcommittee.
18 So we met on, I think, September 4th, but I don't have that
19 date right in front of me, s we met on September 4th. And
20 we started with the document that was prepared by Dr.
21 Schaeuble. And we do have a copy of that in the materials
22 for this morning.

23 I just want to say a huge thank you to Dr.
24 Schaeuble for providing us with that foundational document.
25 A lot of work went into it, a lot of revisions. The

1 Committee was very happy to start with that to form the
2 basis of our ongoing discussions, so we accepted that
3 document. And much of our subsequent discussions revolved
4 around that document itself and the issues that it raised.

5 So I don't need to go into the full scope of
6 everything that was discussed. I think our work was
7 summarized in the motions that came out of that meeting, and
8 so I'll talk about each one of those. And I wonder if
9 somebody could put those up on the screen for me?

10 DR. RYKACZEWSKA: Just one moment, Laura. We're
11 pulling it up right now. That should be up now.

12 COMMITTEE MEMBER LUND: Okay, great. Thank you.

13 So the first element of the motion is to strike
14 the last item in the second section. The reason for that is
15 that we want the language in the regulations to be very
16 clear that there are objective and not subjective criteria
17 that we'll be using in that last item. It seemed very
18 subjective and so it was removed.

19 The second item in the motion was that Dr.
20 Schaeuble will work with Jared Goldman to refine the
21 wordings of items one and two in the last section of the
22 document. Jared Goldman, you all may know him, is our
23 counsel for the Committee, and he was present at the
24 Subcommittee meeting and had some excellent suggestions
25 about how to refine this wording so that it would get at the

1 concerns that the Subcommittee is trying to address while at
2 the same time being consistent with the language of the IPA.
3 So we are going to bring that rewording to the next
4 Subcommittee meeting for the Subcommittee to review.

5 Ms. Kurtural will work with our counsel, Jared and
6 Maggie, to create an outline for the regulations package for
7 discussion at the next Subcommittee meeting.

8 So I don't know how many of you are familiar with
9 the regulations process. If you're not in the state
10 government, you may not be. This is a bit of a lengthy
11 process. There is a standard format for the regulations.
12 They have to go through a standard process. There is an
13 opportunity for public comment. So this is all a very
14 structured process, and we'll be working with our counsel on
15 that.

16 And thank you, Carrie, very much for offering to
17 take this first step in pulling together an outline for the
18 regulations package.

19 And then, our counsel, Jared Goldman, will review
20 the last two items of Section 3 to determine whether these
21 criteria are already included within the IPA. These
22 criteria are a concern to the Subcommittee, but if they are
23 already included in the IPA language, then we do not need to
24 include them in the regulations package.

25 So what I'd like to do next, I'd like to ask the

1 other Subcommittee members if they have anything to add, or
2 if I misstated anything and they want to correct it. I'd
3 like then for the Committee itself to be able to have the
4 opportunity to ask questions and offer comments, and then
5 I'll turn it over to Dr. Dickey for any members of the
6 public who would like to speak to this.

7 So other members of the Subcommittee?

8 COMMITTEE MEMBER SCHAEUBLE: Thank you, Laura. I
9 think your summary is very excellent of what the
10 Subcommittee's meeting did, so I have nothing further to
11 add.

12 COMMITTEE MEMBER LUND: Thank you.

13 COMMITTEE MEMBER KURTURAL: I don't have anything
14 much further to add, except this outline on the regs will be
15 a very, very rough draft at the next Subcommittee meeting.

16 COMMITTEE MEMBER DINIS: Excellent summary, Laura.
17 Nothing else to -- nothing further to add.

18 COMMITTEE MEMBER LUND: Great, thank you all.

19 So, Committee members, do you have comments or
20 questions?

21 Okay, hearing none, I'll turn it back to Dr.
22 Dickey.

23 CHAIR DICKEY: I would just like to point out that
24 we have received four letters from the public regarding this
25 effort, and they should be posted on our website.

1 But at this point, would anybody in the public
2 like to comment on this issue?

3 DR. RYKACZEWSKA: I am seeing no hands right now.
4 If you are on Zoom and would like to comment, please raise
5 your virtual hand.

6 And, Nick, are there any folks in person that
7 might have any comment?

8 MR. NICHOLAS: There are no one in public that
9 would like to comment.

10 DR. RYKACZEWSKA: Okay, no in-person comments.
11 And I'm just giving it one more minute -- well, a few more
12 seconds, not a full minute. I am not seeing any virtual
13 hands.

14 CHAIR DICKEY: Okay, this is likely to be the
15 shortest meeting in CBHS history. Having been here 27
16 years, I've never seen one that's going to be this short, I
17 think. Okay.

18 COMMITTEE MEMBER LUND: Dr. Dickey, I'm wondering,
19 since this is a formal Subcommittee and subject to Bagley-
20 Keene and all of that, if we could have a motion from the
21 Committee to accept the report of the Subcommittee?

22 CHAIR DICKEY: Okay. Who would like to make the
23 motion? I can't move it.

24 COMMITTEE MEMBER SCHAEUBLE: I will move that the
25 Committee accepts the report from the Subcommittee for the

1 meeting on September 13th.

2 COMMITTEE MEMBER LUND: And I second.

3 CHAIR DICKEY: Okay. Could we call the vote?

4 MS. ATIFEH: Sure.

5 Dr. Dickey?

6 CHAIR DICKEY: I'm not voting, I think, because
7 I'm Chair.

8 MS. ATIFEH: Dr. Azizian?

9 COMMITTEE MEMBER AZIZIAN: Yes. There is a
10 comment in the chat box. I don't know if that was noticed
11 or not. I think it's from the public.

12 CHAIR DICKEY: Oh, can we see that?

13 DR. RYKACZEWSKA: Yes, we have a comment from
14 Becky Armstrong. "Can we see what the original motion is to
15 know what the Subcommittee comments refer to?"

16 DR. RYKACZEWSKA: And just to clarify, Becky, do
17 you mean from the September 13th meeting that was displayed
18 on screen?

19 MS. ARMSTRONG: Yes, sorry, I'm --

20 DR. RYKACZEWSKA: Yes, absolutely. That is posted
21 to our website, so I'm happy to share screen again, just to
22 have it on here, and it is also posted in the website along
23 with the document that was discussed at the Subcommittee.

24 CHAIR DICKEY: I think what she's referring to is
25 the document that was being changed by these motions.

1 DR. RYKACZEWSKA: That is also posted.

2 MS. ARMSTRONG: I mean, I don't -- to be able to
3 know, you know, strike out the item in the second section, I
4 don't know what that section is. I mean, if it's posted on
5 your website, I haven't been able to find it, I mean the
6 original motion as it came through.

7 DR. RYKACZEWSKA: It is posted to the September
8 13th Subcommittee meeting page, the link, and I will put
9 that in the chat in just a moment.

10 MS. ARMSTRONG: Okay. Thank you.

11 DR. RYKACZEWSKA: Absolutely.

12 CHAIR DICKEY: And I would say that after
13 reviewing that, if you have any questions or comments, you
14 know, later on in the meeting, we're still open to public
15 comment later on.

16 MS. ARMSTRONG: Okay, thank you.

17 Well, the next item is a follow-up on the issue of
18 letters.

19 COMMITTEE MEMBER DINIS: Wait, we have to do the
20 vote.

21 CHAIR DICKEY: Oh, I'm sorry, we didn't vote.

22 MS. ATIFEH: Okay, it starts with Dr. Azizian?

23 COMMITTEE MEMBER AZIZIAN: Yes.

24 MS. ATIFEH: Dr. Bazzano?

25 Dr. Dinis?

1 COMMITTEE MEMBER DINIS: Approve.

2 MS. ATIFEH: Dr. Hess?

3 COMMITTEE MEMBER HESS: Approve.

4 MS. ATIFEH: Dr. Johnson?

5 COMMITTEE MEMBER JOHNSON: Approve.

6 MS. ATIFEH: Ms. Kurtural?

7 COMMITTEE MEMBER KURTURAL: Approve.

8 MS. ATIFEH: Dr. Palacio?

9 COMMITTEE MEMBER PALACIO: Approve.

10 MS. ATIFEH: Dr. Ruiz?

11 COMMITTEE MEMBER RUIZ: Approve.

12 MS. ATIFEH: Dr. Ventura?

13 COMMITTEE MEMBER VENTURA: Approve.

14 MS. ATIFEH: The motion passed.

15 CHAIR DICKEY: Before I was so rudely

16 interrupted -- just kidding -- the next issue is the follow-

17 up on the letters of support.

18 If you remember, in the July meeting, we talked

19 about the issue that business use case proposals have been

20 submitted as letters of support for project applications to

21 us. And at that meeting, it was decided that -- to require

22 all research projects have letters of support from all

23 departments who are the original owners of the data being

24 requested, and that a BUCP does not satisfy the requirement.

25 After that, we received comment from Department of

1 Health Care Access and Information that this motion may
2 conflict with their statutes. And Jared Goldman and some of
3 us have had discussions with them about that, and I'll turn
4 it over to Jared to talk about that.

5 MR. GOLDMAN: Thank you. Maggie Schuster has
6 actually been our lead on this issue.

7 CHAIR DICKEY: Okay.

8 MR. GOLDMAN: And I will turn it over to Maggie.

9 MS. SCHUSTER: Thank you.

10 Yeah, so as Dr. Dickey was saying, after the we
11 passed the motion, after the Committee passed the motion in
12 July that required letters of support from departments who
13 are the original owners of the data being requested, we got
14 some outreach from Philly Ocean (phonetic) over at HCAI, and
15 they raised for Jared and I that they may have some statutes
16 that prevent HCAI from being able to provide this letter of
17 support in some situations, so we had a discussion with HCAI
18 to see what their concerns were.

19 Essentially, HCAI has a statutory obligation to
20 share certain data with other departments within the agency,
21 so this is namely hospital discharge data, emergency care
22 data, ambulatory surgery data. And there's a statute in the
23 Health and Safety Code that requires HCAI to share this data
24 with DHCS, CDPH, Covered California. And under the same
25 statute, there's language that states that the department

1 that receives the data from HCAI is the department that
2 should be complying with the Committee, CPHS's, review
3 requirements.

4 And so HCAI's concern is essentially that they are
5 required to share this data statutorily with these
6 departments, and so they don't feel that it makes sense,
7 aligns with their statutory requirements, to provide a
8 letter of support saying we support this research project
9 when they don't have an option as to whether or not they can
10 share the data.

11 So what HCAI has proposed, and Jared and I think
12 that this route makes sense, is the department that receives
13 the data from HCAI, so the department that then goes on to
14 share the data with the outside researchers, should be the
15 department that provides a letter of support, not HCAI.

16 So we would propose for your consideration a
17 modification of the motion that was passed in July that
18 would carve out an exemption for a department that is
19 statutorily required or required by law to disclose data
20 from the letter of support requirement.

21 Does that make sense? Are there any questions?

22 COMMITTEE MEMBER LUND: So I have a question.
23 Could we then -- because I am really concerned about this
24 issue of releasing data in compliance with statute, because
25 I know that that hasn't always been the case in the past,

1 and it just, it provides us as a Committee with assurance
2 that that's happening.

3 So I'm wondering if another agency is releasing
4 data on behalf of HCAI, and I understand everything that
5 you've said about once they release it to CDPH and so forth,
6 which they're required to do by law, it's sort of out of
7 their hands, what CDPH then does with it, sharing it with
8 third-party researchers and so forth, could we then ask in
9 the letters of support from agencies that are releasing HCAI
10 data that they call out that they will release both their
11 own data and the HCAI data in compliance with all state
12 laws?

13 MS. SCHUSTER: I think that would make sense.
14 Yeah, I think the concern is really the original data owner
15 in the situation would be HCAI, and they're the ones that
16 are hesitant to provide the letter of support just because
17 they have to share the data. But the department that is
18 making the decision of whether or not to share the data with
19 outside researchers, so CDPH, for instance, that's receiving
20 the HCAI data, I don't see an issue with them stating in
21 their letter that they are releasing their data and also
22 releasing data that they have received from HCAI, if
23 that's -- if that would help with the concern.

24 COMMITTEE MEMBER LUND: Yeah, I would be comfortable
25 with that.

1 CHAIR DICKEY: What if they put in the letter that
2 they're releasing data that they received by statute from
3 HCAI? Because we're not -- we may have trouble keeping
4 track of which departments have statutes that require this,
5 and I'm just suggesting that they state it's by statute.

6 MS. SCHUSTER: Yeah, I think that could be
7 helpful.

8 COMMITTEE MEMBER AZIZIAN: Yeah, I think, if I may
9 ask a question on this pertaining to situations that I just
10 walked you through an example? For Department of State
11 Hospitals, there are forensic evaluations and you
12 periodically get requests for someone who wants to evaluate
13 that and extract data from that forensic evaluation that has
14 been conducted in the Department of State Hospitals. Now
15 that forensic evaluation could have summaries from CDCR,
16 could have a summary from regional center, could have
17 summary from county probation and the list goes on.

18 Would this in any way impact them, that when
19 they're releasing the forensic evaluation that we have to
20 tell them, well, these are the data that technically the
21 owner could be regional center, CDCR, DOJ, and now you have
22 to obtain separate authorization from all those agencies to
23 use that particular section of the evaluation?

24 MS. SCHUSTER: Yeah, I mean, I think that raises a
25 different issue than the issue of being statutorily

1 obligated, unless I'm misunderstanding and there is a
2 statutory obligation for those departments to share those
3 pieces of data.

4 But that seems like it would raise a separate
5 issue that we may want to look into, because if there is a
6 data set that's been made up of data from other many other
7 departments and we're requiring the original owner to give a
8 letter of support, then that doesn't sound like we would
9 have to go to each of those departments to provide that
10 letter of support, which could be burdensome. So that might
11 be another issue to look into. But I do think that is
12 probably separate from this specific statutory obligation
13 issue.

14 CHAIR DICKEY: So would that fall under our
15 original motion though that --

16 MS. SCHUSTER: I mean, yeah. Do you have the text
17 of the original motion? Maybe we could pull it up to look
18 at?

19 DR. RYKACZEWSKA: Yeah, I can pull it up. It's a
20 good thing our folders are well organized. Okay, July
21 motion.

22 All right, and for those participating online, we
23 will display these, and after this meeting we will post them
24 as well. Here we go. Motion one.

25 MS. SCHUSTER: All right, so the motion is written

1 broadly enough that it does sound like this scenario that
2 Dr. Azizan has raised would likely fall under it. If we're
3 requiring letters of support from all departments who are
4 the original owners of the data being requested, if there is
5 data sources that were that provided data to another
6 department and that department is now providing data to
7 outside researchers, it does appear that we would want to
8 reach back to the origination of where the data started
9 from.

10 MR. GOLDMAN: If I could jump in? It seems to me
11 like the requirement of having a letter of support from an
12 original owner of data is going to be problematic because
13 that could mean that we have to reach back for multiple
14 generations or create, you know, a pedigree or a lineage for
15 every piece of data that is ultimately disclosed. And it
16 seems like that wasn't the intent of the motion but really
17 to reach back just to the agency that is disclosing it to
18 the outside entity and not multiple generations of
19 disclosure which ultimately landed in the disclosing
20 department.

21 I don't want to try to read the mind of the
22 Committee when they passed the motion, but it seems like
23 that would be -- the alternative would be really hard to do.

24 COMMITTEE MEMBER LUND: Who was that?

25 MR. GOLDMAN: Jared.

1 CHAIR DICKEY: That was Jared speaking.

2 COMMITTEE MEMBER LUND: Ah. Thank you.

3 CHAIR DICKEY: So you're saying the issue of
4 original owners should be better defined how far back it
5 goes or how far out it goes?

6 MR. GOLDMAN: I mean, maybe we could say all
7 research projects require letters of support from the
8 disclosing department rather than the original owner.

9 CHAIR DICKEY: I think that's what we've been
10 doing in the past.

11 COMMITTEE MEMBER LUND: So I just want to make
12 sure that -- and I'm not saying I'm opposed to that -- I
13 just want to make sure that there's language in that letter
14 that the disclosing department knows that they are on the
15 hook for sharing the data not only knowing their own
16 statutes but in compliance with the statutes that govern all
17 of the data that they're sharing.

18 So if CDPH is sharing HCAI data, that's fine with
19 me, and it's fine with me to have a letter that says CDPH is
20 sharing their own data and HCI data, but I want to make sure
21 that they understand that they need to know the HCAI
22 disclosure statutes when they share that data. And the same
23 would be true with any other agency that's sharing somebody
24 else's data.

25 In my experience agencies are not super familiar

1 with statutes that govern data disclosure of other agencies.
2 And so I just want to make sure that we don't get into a
3 situation, which we have had in the past, where people are
4 disclosing data not in compliance with state law and go, oh,
5 I didn't know; right? So I want to make sure that we build
6 in some accountability here.

7 COMMITTEE MEMBER KURTURAL: Chiming in a little
8 bit on this is I think that there's also going to be a data
9 use agreement, beyond getting the letter of support, which
10 is going to address the concerns kind of laid out. And the
11 question is, is does it go too far? And, you know, is it
12 our responsibility to really -- our jurisdiction, our
13 authority to really think about the department's liability?

14 I mean, I'll give you an example. My department
15 might get EDD data, which is like wage data. I know I've
16 signed an agreement with EDD that has some pretty strict
17 reigns on what I'm allowed to do with employee wage data.
18 You know, it goes through the legal division whenever we
19 issue a letter of support and get out a DUA. And me
20 protecting the department as the attorney would say, no,
21 sorry, this does not get included in a data set for a
22 research project, because I know I'm not allowed to release
23 that bucket of data in our possession. And I think that
24 that's really a liability concern of the department.

25 That's my two cents.

1 COMMITTEE MEMBER LUND: So I'm not so much
2 concerned about department liability.

3 COMMITTEE MEMBER KURTURAL: Okay.

4 COMMITTEE MEMBER LUND: I'm concerned with adverse
5 events and inappropriate data sharing. And we are charged,
6 under the law, with ensuring that we only approve projects
7 that are in compliance with the law. We can't approve a
8 project that's not in compliance with the law. And if the
9 releasing agency releases data not in compliance with the
10 law, we shouldn't be approving that. And that letter
11 assures us that that agency that's releasing the data,
12 giving that data away, has done due diligence in ensuring
13 that they are doing it in full compliance with the law.

14 So if it is too complicated, then they shouldn't
15 be releasing it, in my opinion, to protect human subjects.

16 COMMITTEE MEMBER KURTURAL: Are you saying that we
17 just don't trust the department in their letter of support?

18 COMMITTEE MEMBER LUND: So I'm saying I would like
19 them to assure us in their letter of support what their
20 internal workings are in the department to get to the point
21 where they can provide us with that assurance. That's up to
22 them. I'm not going to micromanage how departments do their
23 job. What I want to see as a reviewer is a letter that
24 says, we are going to release these data in compliance with
25 all state laws.

1 CHAIR DICKEY: Well, unless I'm mistaken, I think
2 we required that wording in the letters in the past. We
3 even included the requirement that it say in compliance with
4 all state laws, not just their own, but all state laws.

5 COMMITTEE MEMBER LUND: Yeah, I think it was vague
6 and that was what made the problem come up in the first
7 place. I don't know. It's just I, having been through a
8 couple of adverse events now where data were inappropriately
9 disclosed, I just would like this assurance.

10 CHAIR DICKEY: Dr. Schaeuble?

11 COMMITTEE MEMBER SCHAEUBLE: So I think I'm
12 hearing two things here as far as possible adjustments to
13 the motion that was passed earlier. One is to change the
14 language to say that the letter of support needs to come
15 from the department that is releasing data to the
16 researcher, which may include not only data from that
17 department but possibly from other departments that have
18 provided data to the releasing department.

19 And the second thing that Laura seems to be asking
20 about is a clear statement that the data will be released --
21 the releasing department that is releasing the data in
22 compliance with any laws that apply to that department, and
23 also any requirements of the original departments that
24 supplied data.

25 So am I correct, that we really have these two

1 things that we're discussing here for consideration?

2 COMMITTEE MEMBER LUND: Yeah, I think so. And to
3 simplify, I would be happy with a statement that just says
4 something like that they're -- it doesn't have to be
5 complicated, it just has to be an assurance that they will
6 release all the data in compliance with any state laws that
7 apply, so that way if it's their own data and the other
8 department's data and all of the laws are covered. So I'm
9 not asking for something complicated, but I think --

10 COMMITTEE MEMBER SCHAEUBLE: Okay.

11 COMMITTEE MEMBER LUND: -- you've summarized the
12 two issues.

13 So I'm asking Agnieszka if she can pull up the
14 existing template letter that we have on our website to see
15 if that satisfies it or, if it doesn't, how it should be
16 changed.

17 DR. RYKACZEWSKA: This is a test of --

18 CHAIR DICKEY: This is a test of your --

19 DR. RYKACZEWSKA: -- do I know where everything is
20 on our website. Okay, there we go.

21 CHAIR DICKEY: All right, a template for --

22 DR. RYKACZEWSKA: Yes.

23 COMMITTEE MEMBER DINIS: You want to display that?

24 DR. RYKACZEWSKA: Let me just zoom in here. There
25 it is. There you go. Hopefully that's visible.

1 CHAIR DICKEY: Oh.

2 DR. RYKACZEWSKA: This is also available on our
3 forms section of our website.

4 CHAIR DICKEY: So when I take a look at this, at
5 the bottom it says, "Any release of personal information to
6 the principal investigator for the project will be in
7 compliance with all applicable state statutes."

8 COMMITTEE MEMBER KURTURAL: Yeah, we could
9 probably say state and federal law and regulations to expand
10 that, but --

11 CHAIR DICKEY: Well, should we change it to all
12 state and federal statutes?

13 COMMITTEE MEMBER KURTURAL: And regulations.

14 CHAIR DICKEY: Statutes and regulations.

15 MR. GOLDMAN: Or you could just say state and
16 federal law and that would cover it.

17 COMMITTEE MEMBER KURTURAL: Yeah.

18 MR. GOLDMAN: Just --

19 COMMITTEE MEMBER KURTURAL: There we go.

20 CHAIR DICKEY: So all applicable state and federal
21 laws?

22 COMMITTEE MEMBER LUND: Yeah, I'm okay with that.

23 CHAIR DICKEY: So I think there would probably be
24 two motions here, if -- from what I've heard so far. One
25 would be to withdraw the motion we passed in the July

1 meeting and then to change the wording in our, the required
2 wording in our template letter. But I can't make motions.

3 COMMITTEE MEMBER LUND: Well, I'll do it. I move,
4 motion number one, I move that we withdraw the motion that
5 was made at the July meeting in regard to the letters of
6 support.

7 COMMITTEE MEMBER SCHAEUBLE: Do we want to
8 withdraw that or change it along the lines that Jared was
9 talking about?

10 COMMITTEE MEMBER LUND: So I think the second
11 motion was going to be that we change the letter of support
12 to the wording that was just discussed here --

13 COMMITTEE MEMBER SCHAEUBLE: Well --

14 COMMITTEE MEMBER LUND: -- or am I wrong? That
15 was --

16 COMMITTEE MEMBER SCHAEUBLE: Well, I'm asking
17 because what we just discussed here was the last sentence in
18 the letter of support which deals with the second issue that
19 you raised but not the earlier thing that we were talking
20 about.

21 MR. GOLDMAN: I think if we were to change the
22 motion to require a letter of support by the disclosing
23 department, that would simply be consistent with our
24 existing policy.

25 CHAIR DICKEY: Right.

1 MR. GOLDMAN: So there would be no need for a new
2 motion. We could just withdraw the last one.

3 CHAIR DICKEY: It would be the pre-existing policy
4 that's already in place.

5 DR. RYKACZEWSKA: Would it address the BUCP piece
6 that was part of that July motion?

7 CHAIR DICKEY: Yeah, it wouldn't necessarily. We
8 can keep that portion of it that says the BUCP does not
9 satisfy the requirement.

10 COMMITTEE MEMBER LUND: So how about if the motion
11 is that we modify the motion that was made at the July
12 meeting to state, instead of requiring a letter of support
13 from the originating owner, the agency originally owning the
14 data, that we require the letter of support from the agency
15 releasing the data using the templates with the language
16 that we have discussed here today. Does that cover it?

17 CHAIR DICKEY: And that a BUCP would not satisfy
18 the requirement.

19 COMMITTEE MEMBER LUND: Yeah, so all I'm doing is
20 modifying the motion, so I didn't take out the BUCP part.

21 CHAIR DICKEY: Oh, okay. All right.

22 COMMITTEE MEMBER LUND: I just changed the letter
23 of support piece.

24 CHAIR DICKEY: Got it.

25 DR. RYKACZEWSKA: I'm about to put it up in just a

1 second. Let me see if I got this right. I think I'm
2 missing a piece.

3 CHAIR DICKEY: Can we just let it --

4 COMMITTEE MEMBER LUND: Releasing Department.
5 Okay, so at the end of the Releasing Department, "The
6 Releasing Department, each letter should include a statement
7 that release will be in compliance with all state and
8 federal laws."

9 DR. RYKACZEWSKA: Did I get it right this time?

10 COMMITTEE MEMBER LUND: Yeah, that looks good to
11 me. What about everybody else?

12 CHAIR DICKEY: I would just take something that
13 says the requirement that if a BUCP does not satisfy, this
14 requirement remains or is not rescinded.

15 COMMITTEE MEMBER LUND: Okay.

16 DR. RYKACZEWSKA: Amend it?

17 CHAIR DICKEY: That's rescinded. Is not
18 rescinded. Okay.

19 DR. RYKACZEWSKA: That's not how you spell that.

20 CHAIR DICKEY: I think it's S- --

21 COMMITTEE MEMBER LUND: S-C-I.

22 CHAIR DICKEY: Okay.

23 DR. RYKACZEWSKA: There we go.

24 CHAIR DICKEY: All right.

25 COMMITTEE MEMBER SCHAEUBLE: Then an S on

1 includes.

2 DR. RYKACZEWSKA: Includes? Thank you.

3 CHAIR DICKY: Second?

4 COMMITTEE MEMBER VENTURA: I second.

5 CHAIR DICKY: Could you please call the roll?

6 MS. ATIFEH: Sure.

7 COMMITTEE MEMBER SCHAEUBLE: Who seconded. I'm
8 sorry.

9 MS. ATIFEH: (Indiscernible) Ventura? Okay.
10 Dr. Azizian?

11 COMMITTEE MEMBER AZIZIAN: Sorry, I'll abstain.

12 MS. ATIFEH: Dr. Bazzano?
13 Dr. Dinis?

14 COMMITTEE MEMBER DINIS: Approve.

15 MS. ATIFEH: Dr. Hess?

16 COMMITTEE MEMBER HESS: Approve.

17 MS. ATIFEH: Dr. Johnson?

18 COMMITTEE MEMBER JOHNSON: Approve.

19 MS. ATIFEH: Ms. Kurtural?

20 COMMITTEE MEMBER KURTURAL: Approve.

21 MS. ATIFEH: Dr. Palacio?

22 COMMITTEE MEMBER PALACIO: Approve.

23 MS. ATIFEH: Dr. Ruiz?

24 COMMITTEE MEMBER RUIZ: Approve.

25 MS. ATIFEH: Dr. Schaeuble?

1 COMMITTEE MEMBER SCHAEUBLE: Approve.

2 MS. ATIFEH: The motion passed.

3 CHAIR DICKY: Yeah, public comments on this?
4 Maybe we should have asked for that before we passed it, but
5 are there any public comments?

6 MS. ARMSTRONG: I'm not -- I would just say, I
7 think when you had the motion up, the word indicate maybe
8 should be indicates. I'm not a grammar queen on this, but
9 it wouldn't change the substance of what you just did, but I
10 just --

11 CHAIR DICKY: We got includes.

12 MS. ARMSTRONG: Oh, I thought it just said
13 include.

14 CHAIR DICKY: Yeah, we caught that before you --

15 DR. RYKACZEWSKA: But thank you for the sharp eye.

16 MS. ARMSTRONG: I work in compliance, you know?

17 DR. RYKACZEWSKA: Any other hands?

18 MR. NICHOLAS: No comments in public.

19 DR. RYKACZEWSKA: Thank you, Nick. And I am not
20 seeing any further hands online.

21 CHAIR DICKY: All right. And thank you to Jared
22 and Maggie for their work on this. I appreciate it.

23 This item is approval of the July 12th, 2024
24 meeting minutes. So are there any edits from Committee
25 members? Or would the public like to make any comments

1 about those meeting minutes, if they've had a chance to look
2 at them?

3 Do I hear a motion to adopt the July 12th meeting
4 minutes?

5 COMMITTEE MEMBER SCHAEUBLE: I'll move approval of
6 the July minutes.

7 COMMITTEE MEMBER DINIS: Second.

8 CHAIR DICKEY: Okay. No? Okay.

9 Could you call the roll?

10 MS. ATIFEH: Sure.

11 CHAIR DICKEY: Thank you.

12 MS. ATIFEH: Dr. Azizian?

13 UNIDENTIFIED FEMALE: Is that your phone?

14 COMMITTEE MEMBER AZIZIAN: Approve.

15 MS. ATIFEH: Dr. Bazzano?

16 Dr. Hess?

17 COMMITTEE MEMBER HESS: Approve.

18 MS. ATIFEH: Dr. Johnson?

19 COMMITTEE MEMBER JOHNSON: Approve.

20 MS. ATIFEH: Ms. Kurtural?

21 COMMITTEE MEMBER KURTURAL: Approve.

22 MS. ATIFEH: Ms. Lund?

23 COMMITTEE MEMBER LUND: Approve.

24 MS. ATIFEH: Dr. Palacio?

25 COMMITTEE MEMBER PALACIO: Approve.

1 MS. ATIFEH: Dr. Ruiz?

2 COMMITTEE MEMBER RUIZ: Approve.

3 MS. ATIFEH: Dr. Ventura?

4 COMMITTEE MEMBER VENTURA: Approve.

5 MS. ATIFEH: The motion passed.

6 CHAIR DICKEY: Okay. Okay, next item on the
7 agenda is adverse events, project deviations, and probably
8 for the first time in a long time there haven't been any.

9 So that moves us on to our one and only project to
10 discuss at this meeting. And is the researcher on with us?
11 Is Dr. John on?

12 DR. JOHN: Yes, I'm here.

13 CHAIR DICKEY: Oh, okay. Great. And I'm going to
14 turn this over to Dr. Hess, who is the primary reviewer.

15 COMMITTEE MEMBER HESS: Thank you.

16 Hi, Dr. John. Are there any other members of your
17 team here? Let me just see.

18 DR. JOHN: No, I'm the only person.

19 COMMITTEE MEMBER HESS: Okay. In that case, do
20 you want to give the Board a very brief overview of your
21 project?

22 DR. JOHN: Yes, I'll be happy to. So my name is
23 Esther John. I'm a professor at Stanford University, and I
24 have several protocols with CTHS, so you might actually know
25 me.

1 Now this one is a new study where we're going to
2 look at health-related quality of life and various sources
3 of stress. And we look at these topics in long-term breast
4 cancer survivors who are enrolled in the Northern California
5 Breast Cancer Family Registry.

6 This Family Registry was established in 1995 and
7 includes about 4,000 women with breast cancer. They were
8 diagnosed in 1996 and 2009 and were identified through the
9 California Cancer Registry. Over the years, these Family
10 Registry participants have completed follow-up
11 questionnaires on various topics, so we stay in close
12 contact with the participants. And they have also been
13 followed for outcomes through periodic linkage with the
14 California Cancer Registry. And for that linkage we have a
15 separate CTHS protocol.

16 At this time, so many years after they were
17 enrolled, we still have about 1,250 long-term breast cancer
18 survivors who were diagnosed more than 15 years ago and
19 they're still active participants in the Family Registry.
20 They are now 42 years or older. Seventy percent are from
21 racially and ethnically minoritized populations. And about
22 over half of the Asian and Hispanic participants are foreign
23 born. So these are very unique characteristics of our
24 report.

25 In this new study, we will collect three types of

1 data. We will collect, first, questionnaire data on quality
2 of life and multiple sources of stress. We'll ask about
3 cancer-specific stressors such as symptoms and side effects
4 related to treatment, fear of second cancer, financial
5 hardship, health care-related stress. And we will also ask
6 about social stressors such as general stress,
7 discrimination of culture-related stress, neighborhood
8 cohesion, social support. And in our package for CPHS we
9 included the questionnaire so you see what the details are.

10 The second type of data we collect is we will
11 geocode the participant's current residential address and
12 then we'll link the geocode to neighborhood stressors. We
13 will look at variables such as racial residential
14 segregation, neighborhood deprivation, social environment
15 variables.

16 And then the last type of data we will collect is
17 for a subgroup of participants. We will collect a blood
18 sample and we will measure inflammatory biomarkers.

19 And we will use these data to study the
20 relationships between quality of life, individual stressors,
21 neighborhood stressors and inflammatory biomarkers. We
22 hypothesize that the quality of life and the burden of
23 stressors varies across racial and ethnic groups and that a
24 higher burden of stressors is associated with lower quality
25 of life.

1 We expect to collect questionnaire and
2 neighborhood data for about 500 participants. And because
3 of a limited budget, we'll only be able to collect blood
4 samples and do the laboratory analysis for 132 participants.

5 As I mentioned before, our study is unique in that
6 we're studying the quality of life in long-term breast
7 cancer survivors. Most prior studies have only included
8 short-term survivors of less than five years.

9 And the other unique feature is the very high
10 racial and ethnic diversity. Many studies of quality of
11 life have been conducted in non-Hispanic White women or
12 small groups of other populations. So we are -- we think
13 this will really be a contribution to better understanding
14 the quality of life in long-term breast cancer survivors
15 from multiple populations.

16 And then the last point I want to mention is last
17 week this protocol was also approved by the Stanford IRB.
18 And we understand from Dr. Hess that we'll need to update
19 the CPHS protocol, adding additional clarifications. And it
20 sounds like we also need to work on the consent form, and we
21 have actually worked on it already in the last two days.

22 And once we get these additional documents that
23 are being changed we need to get them approved by Stanford
24 IRB. Once that is approved then, hopefully, we can start
25 the study in early November.

1 And that is my summary, and I'll be happy to
2 answer questions.

3 COMMITTEE MEMBER HESS: Great. Thank you very
4 much. As you mentioned, I sent you a number of points of
5 clarification and requested edits. And I'm satisfied that
6 you are -- have -- will make or have made the changes that I
7 requested.

8 I understand the difficulties in lowering the
9 reading level of the consent form. And I do appreciate that
10 you provided context that we had a similar issue for the
11 Northern California Breast Cancer Family Registry that we
12 reviewed earlier in the summer and that we did approve your
13 consent form at that time with the language required by
14 Stanford.

15 So, you know, anything you can do to lower the
16 reading level, I think, of the non-Stanford required
17 language would be appreciated, but I understand that there
18 are some limitations there.

19 So I will open it up to the rest of the Board for
20 questions and comments.

21 COMMITTEE MEMBER VENTURA: I just, Dr. John, I had
22 a clarifying administrative question. All of the research
23 will be done at Stanford, is that correct?

24 DR. JOHN: Yes, that's correct. Yes.

25 COMMITTEE MEMBER VENTURA: Okay.

1 DR. JOHN: The Family Registry consists of six
2 centers internationally. But this particular study will
3 only be done on one site at the Stanford site.

4 COMMITTEE MEMBER VENTURA: Okay. Just under the
5 risk description section of your protocol, you state that no
6 identifying information will be shared with any
7 collaborators. And I just never -- I didn't read any
8 information about potential collaborators. So I just wanted
9 to make sure that all of the data is only accessible by
10 Stanford researchers?

11 DR. JOHN: Right. That's correct, but there is a
12 requirement now for all NIH-funded studies that the data
13 that are being generated in any NIH-funded project have to
14 be, the identified data, have to be deposited in a data
15 repository, in an NIH data repository. And that is now
16 actually a condition of the award we got, and it's a
17 condition of all the awards that are being made, so we don't
18 have any choice in that. Either, you know, we do that or we
19 will not be able to do the work, the research.

20 So we will have to deposit the data to a
21 repository. And anyone who wishes, any scientist who
22 wishes, they can access those data. And, you know, analyze
23 it themselves. I don't call them collaborators, really,
24 because they don't have to contact me to get access to the
25 data. They just can go to the repository and access the

1 data.

2 In the Family Registry, we've had a lot of
3 collaborations over the years. And even if we -- you know,
4 through collaborations with other scientists, we never share
5 PHI data, never. They stay only at Stanford. Those are
6 private, confidential data, and we treat them like that. So
7 the only thing we share are the identified, you know,
8 variables that we derive from the questionnaires and other
9 sources.

10 Does that answer your question?

11 COMMITTEE MEMBER VENTURA: It does. It raises
12 some other concerns, but anyway, okay, yes. Yeah, for these
13 purposes, it does.

14 COMMITTEE MEMBER HESS: Any additional questions?
15 Is there anything, like a point of clarification you'd like
16 them to make, or not, in the protocol?

17 COMMITTEE MEMBER VENTURA: Do researchers have to
18 submit the list of variables that are required in the
19 repositories? I mean, your sample is N of 500, and then
20 blood samples are, you know, N of 132. It's getting smaller
21 and smaller. Just what is required to be deposited into the
22 repository? The questionnaire data? The blood sample data?

23 DR. JOHN: Yeah. Yes, the questionnaire data,
24 the, you know, the biomarker data, the neighborhood data.
25 All the data that we collect as part of, you know, this

1 funding, we have to deposit.

2 COMMITTEE MEMBER HESS: But no demographic data or
3 other identifiers?

4 DR. JOHN: Well, we have to deposit, like race,
5 ethnicity. We have to --

6 COMMITTEE MEMBER HESS: Yeah.

7 DR. JOHN: -- deposit like, you know, age of the
8 participants, like we can do that in age groups. I mean,
9 those are demographic variables; right?

10 COMMITTEE MEMBER HESS: Yeah.

11 DR. JOHN: So we have to do that.

12 But what I meant was we're not sending PHI data,
13 like name or address or social security number. I mean,
14 those we don't even have and don't collect. But birth
15 dates, things like that, we never share. Those data never
16 leave Stanford University. They never have for the last 30
17 years.

18 COMMITTEE MEMBER HESS: Okay. Yeah. No, I think
19 that age is okay under Safe Harbor.

20 CHAIR DICKEY: It's under the HIPAA Safe Harbor.

21 COMMITTEE MEMBER HESS: Yeah, yeah. I think
22 you're okay with age. And then ethnicity, you know, it's
23 nothing strictly restricted on ethnicity under Safe Harbor.
24 So I'm not seeing an issue on the privacy front.

25 CHAIR DICKEY: Okay.

1 COMMITTEE MEMBER HESS: Dr. Schaeuble, did you
2 have a question?

3 CHAIR DICKEY: Any other questions?

4 COMMITTEE MEMBER SCHAEUBLE: I'm wondering if what
5 Maria was starting to ask about was the extent to which the
6 information in the repository would ever make it possible
7 for individuals to be reidentified. I know we've had
8 concerns in the past in looking at research studies that
9 removing the HIPAA identifiers is an obligation, of course,
10 but sometimes there's enough information from the totality
11 of the variables being accumulated that individuals could
12 possibly be identified by other means.

13 So, Maria, is that sort of what you were --

14 COMMITTEE MEMBER VENTURA: Getting at.

15 COMMITTEE MEMBER SCHAEUBLE: -- getting at --

16 COMMITTEE MEMBER VENTURA: Yeah.

17 COMMITTEE MEMBER SCHAEUBLE: -- in asking what
18 variables were going into the repository?

19 So maybe you could respond to that? And if
20 there's any lack of -- lack -- excuse me. If there's any
21 lack of clarity about which variables are indeed transmitted
22 into the federal repository, that, I'm sure, should be part
23 of the protocol.

24 DR. JOHN: Yes. Is that Dr. Schaeuble speaking?

25 COMMITTEE MEMBER SCHAEUBLE: Yes, it is. Sorry, I

1 didn't identify myself.

2 DR. JOHN: I recognize your voice.

3 One thing, I mean, if the Committee would like to
4 see that, what I can do is, as part of the proposal to NIH
5 that we had to develop, it was a requirement, we had to
6 develop a data management and data sharing plan, and that's
7 like a binding document, I can, you know, I can submit that
8 to the CPHS if you would like to see that document.

9 I don't think in that document we spell out
10 variable by variable that we will transmit. The expectation
11 is that, you know, all the data we collect -- and maybe I
12 should say not all the data we collect, maybe I should say
13 the data that we use in the analyses and in the
14 publications, those are the data that we will transmit. And
15 so it's not even going to be raw data. I think it's going
16 to be like transformed, like derived variables that we
17 create for the analysis. Those are the variables we would
18 be transmitting.

19 So I can be a little bit more clear on that in the
20 protocol, and I can submit the data management plan if that
21 is desired.

22 COMMITTEE MEMBER HESS: Okay. I think that would
23 be great.

24 DR. JOHN: And I know, Dr. Schaeuble, we talked a
25 lot about this issue, whether, you know, participants could

1 eventually be identified because we collect so many data.

2 You and I had a lot of discussions about that --

3 COMMITTEE MEMBER SCHAEUBLE: Right.

4 DR. JOHN: -- in the previous protocol. And, you
5 know, I don't think there's a big likelihood of that
6 happening. Can I say it will absolutely never happen? I
7 don't think anybody can say that.

8 COMMITTEE MEMBER SCHAEUBLE: I think that --

9 DR. JOHN: And it is for that reason that we don't
10 include, you know, any personal identifiers or any dates,
11 you know, date of diagnosis, date of birth, date of
12 whatever. We don't include any of those things. And
13 hopefully that will, you know, mitigate that risk.

14 COMMITTEE MEMBER SCHAEUBLE: I appreciate your
15 answer. And I think the Committee's general concern is, as
16 we review all of these projects, simply trying to assess as
17 best we can, is there a -- is the project one where the risk
18 of re-identification is more than the close to negligible
19 that one would otherwise expect or not? And, you know, it's
20 just part of our review process that we have to try to think
21 about such things.

22 DR. JOHN: Yeah, I understand, and I appreciate
23 it.

24 COMMITTEE MEMBER HESS: I was going to say, I
25 think it's always worth including your agreement, like with

1 NIH for the data repository in the protocol, just so it's
2 documented that we've seen it and we know that you're
3 sharing this into a federal repository.

4 You know, we don't, I think -- because you don't
5 even know what the analytic data set that you will be -- and
6 end up depositing there will look like because you haven't
7 collected the data yet. But I think just some general
8 language around, this is the type of information that will
9 be transmitted to the NIH, it will be, you know, a statement
10 that it will be fully de-identified, it will not contain
11 PHI, I think something like that would be a good addition to
12 the protocol.

13 COMMITTEE MEMBER SCHAEUBLE: And probably --

14 DR. JOHN: Yes.

15 COMMITTEE MEMBER SCHAEUBLE: -- and probably good
16 to also add that much of the data will be transformed in
17 some way for purposes of your analysis so that it's not
18 original data pieces that are likely to end up in the
19 federal repository so much as analytic variables that you're
20 using.

21 DR. JOHN: Yes, and this is particularly true for
22 the type of questionnaire we'll be using where, Dr.
23 Schaeuble, your psychologist, you might actually be familiar
24 with some of these scales, like Cohen's General Stress
25 Scale.

1 COMMITTEE MEMBER SCHAEUBLE: Yes.

2 DR. JOHN: You know, it has, I don't know, 12
3 questions. And then, you know, out of these answers, you
4 create a score, so that would be the variable. The analytic
5 variable would be a score and that's what we would be using
6 in the analysis.

7 And this applies to a lot of the other concepts,
8 also, that we ask questions and then we will derive a score.
9 And then participants will be categorized either, you know,
10 low stress, intermediate stress, high stress. So those are
11 the kinds of transformations that we do.

12 And I can definitely explain that more in the CPHS
13 protocol. I think we already talked about that we have to
14 transmit the data, but I can explain in more detail just
15 what it is we're going to be transmitting based on the
16 suggestions that have been made today.

17 COMMITTEE MEMBER KURTURAL: Dr. John, one
18 question. You mentioned no address information. Are you
19 providing this information via zip code or is it just going
20 to be from the whole state data, like geographic?

21 DR. JOHN: I'm sorry, I cannot -- for some reason,
22 I cannot hear you very well.

23 COMMITTEE MEMBER KURTURAL: Are you providing any
24 sort of --

25 DR. JOHN: Can you speak louder?

1 COMMITTEE MEMBER KURTURAL: -- geographic
2 information to NIH? Can you hear me?

3 DR. JOHN: You're asking about geographic
4 information?

5 COMMITTEE MEMBER KURTURAL: Yes. Is any type of
6 geographic information going to be submitted?

7 DR. JOHN: Yeah, no, we will not submit like
8 address. We will not submit geocodes.

9 COMMITTEE MEMBER KURTURAL: Okay.

10 DR. JOHN: But from -- by geocoding, we will
11 characterize the neighborhood. So we will have variables,
12 let's say, about neighborhood composition, you know, where
13 the women live.

14 COMMITTEE MEMBER KURTURAL: Okay.

15 DR. JOHN: What is the racial ethnic composition
16 of the population where the women now live? And that will
17 be, again, a transformed variable. That will be a variable,
18 like they live in a neighborhood where, you know, half of
19 the participants are from multiple racial ethnic groups,
20 half are non-Hispanic White.

21 COMMITTEE MEMBER KURTURAL: Okay.

22 DR. JOHN: Or they live in a neighborhood that's
23 predominantly non-Hispanic White. Or they live in a
24 neighborhood that's predominantly racially and ethnically
25 minoritized population. So it's --

1 COMMITTEE MEMBER KURTURAL: Right.

2 DR. JOHN: So, again, it will be a variable, you
3 know, that will have like three or four categories. But
4 that information, one will never be able to link that back
5 to an actual address where the women live. So no --

6 COMMITTEE MEMBER KURTURAL: Okay.

7 DR. JOHN: -- no geographic information will be
8 transmitted in the federal data depository.

9 COMMITTEE MEMBER KURTURAL: Thank you.

10 CHAIR DICKEY: Can I ask if there's any public
11 comments on this before we make a motion and vote?

12 DR. RYKACZEWSKA: Giving folks a moment online to
13 raise your virtual hand.

14 And while I'm doing that, Nick, is there any
15 public comment in the room?

16 MR. NICHOLAS: No public comment in the room.

17 DR. RYKACZEWSKA: Thank you. And I am not seeing
18 any virtual hands. Giving it five, four, three, two, one.
19 No virtual hands.

20 CHAIR DICKEY: Okay, Dr. Hess, do you want to make
21 a motion?

22 COMMITTEE MEMBER HESS: I would like to make a
23 motion for deferred approval, one-year minimal risk, pending
24 the researchers make the changes that I emailed to them on
25 September 29th.

1 CHAIR DICKEY: Is that sufficient of a motion?

2 COMMITTEE MEMBER HESS: Is that okay?

3 CHAIR DICKEY: I was just asking if --

4 COMMITTEE MEMBER HESS: Okay.

5 CHAIR DICKEY: -- we need to have more specificity
6 for that or --

7 DR. RYKACZEWSKA: I don't believe so. Could you
8 give the date one more time?

9 CHAIR DICKEY: September 29th.

10 COMMITTEE MEMBER HESS: September 29th.

11 DR. JOHN: I thought the date was clear. I
12 checked that.

13 COMMITTEE MEMBER HESS: And these are also, for
14 Dr. John, these are all comments in IRB management that
15 you'll see after the meeting as well.

16 And so it's the requested changes I made on
17 September 29th, and that the researchers provide more detail
18 about the data that will be transmitted to the NIH per their
19 agreement with the NIH.

20 DR. RYKACZEWSKA: Transmitted to the NIH
21 repository?

22 COMMITTEE MEMBER HESS: Yes, the NIH data
23 repository.

24 Are there any other -- am I missing anything? Are
25 there any other comments that I don't have?

1 Okay, that's my motion.

2 CHAIR DICKY: And that's for review by a

3 Subcommittee?

4 COMMITTEE MEMBER HESS: Of me.

5 CHAIR DICKY: Of you?

6 COMMITTEE MEMBER HESS: Yeah.

7 CHAIR DICKY: Okay. Did I hear a second?

8 COMMITTEE MEMBER VENTURA: I'll second.

9 CHAIR DICKY: Could you please call the vote?

10 MS. ATIFEH: Sure.

11 Dr. Azizian?

12 COMMITTEE MEMBER AZIZIAN: Approve.

13 MS. ATIFEH: Dr. Bazzano?

14 Dr. Dinis?

15 COMMITTEE MEMBER DINIS: Approve.

16 MS. ATIFEH: Dr. Johnson?

17 COMMITTEE MEMBER JOHNSON: Approve.

18 MS. ATIFEH: Ms. Lund?

19 COMMITTEE MEMBER LUND: Approve.

20 MS. ATIFEH: Dr. Palacio?

21 COMMITTEE MEMBER PALACIO: Approve.

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

23 COMMITTEE MEMBER RUIZ: Approve.

24 MS. ATIFEH: Thank you.

25 Dr. Schaeuble?

1 COMMITTEE MEMBER SCHAEUBLE: Approve.

2 MS. ATIFEH: And Dr. Ventura?

3 COMMITTEE MEMBER VENTURA: Approve.

4 MS. ATIFEH: Okay. Motion passed.

5 CHAIR DICKEY: So before we move on, I just want
6 to bring up something. If, you know, these requirements for
7 submitting to repositories is becoming common, and I think
8 it is, should we have something in IRB Manager that asks
9 them to give us -- designate the information they're going
10 to be submitting to repositories?

11 COMMITTEE MEMBER VENTURA: Yeah.

12 CHAIR DICKEY: That is a totally separate issue.

13 COMMITTEE MEMBER HESS: And then we can just
14 specify right there in the IRB Manager what information we'd
15 like to see.

16 CHAIR DICKEY: Right.

17 COMMITTEE MEMBER HESS: You know, it would be a
18 good idea.

19 COMMITTEE MEMBER VENTURA: Like upload your, just
20 like you upload all other attachments, just the data
21 management, data sharing agreement --

22 COMMITTEE MEMBER HESS: Yeah.

23 COMMITTEE MEMBER VENTURA: -- with the agency?
24 Typically NIH, like government, public funds have that. I
25 don't know if public -- or private have that.

1 COMMITTEE MEMBER SCHAEUBLE: And along with that,
2 an explanation of what particular data will be shared,
3 enough of a description that we can have a sense, as we had
4 in this project, that much of the information would actually
5 be transformed --

6 COMMITTEE MEMBER VENTURA: Transformed, yeah.

7 COMMITTEE MEMBER SCHAEUBLE: -- in some way before
8 it was submitted to a repository, as opposed to being raw
9 data.

10 CHAIR DICKEY: Yeah.

11 COMMITTEE MEMBER SCHAEUBLE: Things like that
12 would be helpful in the description within IRB Manager.

13 CHAIR DICKEY: All right, so I don't think we need
14 a motion on this. I think that's a procedural sort of
15 thing. But maybe, Agnieszka and Sussan, you could report
16 back to the Committee as to, after you talk to IRB Manager,
17 whether we can do that.

18 DR. RYKACZEWSKA: Absolutely.

19 CHAIR DICKEY: Okay. I think, Dr. Johnson, you
20 wanted to give us some report on a particular project.

21 COMMITTEE MEMBER JOHNSON: Yeah, there was
22 originally on the agenda a second study that the Board was
23 going to review. That was 2024-149. It has a different
24 name than what's on the agenda. It's for a social
25 determinants of health survey among African-American

1 prostate cancer survivors.

2 Just for transparency, for the Board's awareness,
3 in my preliminary review, I noted several concerns.

4 CHAIR DICKEY: Before you move on, I just want to
5 ask, are the researchers actually present for this?

6 COMMITTEE MEMBER JOHNSON: They had previously
7 said they were.

8 CHAIR DICKEY: I know it said they were not, but I
9 just wanted to make sure.

10 COMMITTEE MEMBER JOHNSON: Sure.

11 CHAIR DICKEY: Okay, I'm sorry to interrupt you.

12 COMMITTEE MEMBER HESS: No, no worries.

13 Just the short, long list was secondary database
14 concerns, linkages, recruitment consent, minimum data
15 necessary, missing materials, greater than minimal risk, and
16 inconsistencies with the application of materials submitted.
17 So given that the study was going to have substantial
18 revisions, I requested that the study be bumped to be
19 reviewed in December, so that is why it is missing from
20 today's discussion.

21 CHAIR DICKEY: Any questions about that?
22 Concerns?

23 COMMITTEE MEMBER VENTURA: So the researchers are
24 going to significantly revise --

25 COMMITTEE MEMBER JOHNSON: Yeah, and they did

1 submit.

2 COMMITTEE MEMBER VENTURA: -- and resubmit for
3 December?

4 COMMITTEE MEMBER JOHNSON: Yeah, they submitted
5 another on Wednesday, but it's still going to require major
6 revisions. So I've already contacted them to work with them
7 to get it into a better shape for the Committee to make an
8 informed decision.

9 CHAIR DICKEY: Okay, let's see. There are Items I
10 through O on the --

11 DR. RYKACZEWSKA: Dr. Dickey?

12 CHAIR DICKEY: Oops, I'm sorry.

13 DR. RYKACZEWSKA: No full board --

14 CHAIR DICKEY: Oh.

15 DR. RYKACZEWSKA: -- can (indiscernible) or
16 amendments today.

17 CHAIR DICKEY: Okay.

18 DR. RYKACZEWSKA: (Indiscernible.)

19 CHAIR DICKEY: All right.

20 DR. RYKACZEWSKA: And any public comments before
21 we close out for --

22 CHAIR DICKEY: Yeah, but I think I have to first,
23 also, ask if there's any questions about I through O.

24 Okay, there being none, I'll open it up to any
25 further public comments that anybody might want to make.

1 DR. RYKACZEWSKA: I do see a hand from Dr. White.

2 MR. WHITE: Oh, hi there. I was not present
3 earlier when the Subcommittee read out, so I didn't have the
4 opportunity to make a public comment at that point, but I
5 wanted to reiterate that I think that the regulations under
6 consideration by the Subcommittee are catalyzed, are not
7 supposed to do it for this body, and would seriously
8 jeopardize a lot of very important policy development
9 research in the state of California in that (indiscernible)
10 Committee when they get the opportunity to do so to
11 (indiscernible).

12 I also wanted to draw the Committee's attention to
13 the several strongly worded letters that were posted on the
14 website. I encourage them to review those and consider
15 them.

16 COMMITTEE MEMBER KURTURAL: Dr. White, we received
17 all of the comments and, you know, we will be considering
18 them. We do not have a draft outline or regulations yet.
19 Regulations are to clarify existing law, which will be the
20 IPA, not to impose any major, major new requirements to
21 clarify the existing law under the IPA. So we will take
22 that into consideration when we're drafting our outline and
23 moving along. Thank you.

24 CHAIR DICKEY: Any other comments from the
25 Committee or from the public on any issue?

1 DR. RYKACZEWSKA: Please raise your virtual hand
2 if you're virtually.

3 And, Nick, do we have any public comments in the
4 room?

5 MR. NICHOLAS: No public comment in-person.

6 DR. RYKACZEWSKA: Thank you, Nick.

7 Any further virtual hands? Seeing none.

8 CHAIR DICKEY: All right, well, that being said, I
9 think this probably was the shortest meeting in Committee
10 history, and I think we will adjourn at this point. And the
11 next meeting of the Subcommittee is going to be November
12 1st; is that right?

13 DR. RYKACZEWSKA: No.

14 CHAIR DICKEY: Oh.

15 DR. RYKACZEWSKA: The Committee is November 1st.

16 CHAIR DICKEY: Okay, November 1st.

17 DR. RYKACZEWSKA: The Subcommittee, I believe, is
18 November 8th --

19 CHAIR DICKEY: Okay.

20 DR. RYKACZEWSKA: -- which is the following
21 Friday.

22 CHAIR DICKEY: All right. Okay, with that, we are
23 adjourned.

24 (The meeting adjourned at 9:49 a.m.)

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