

State of California—Health and Human Services Agency  
Committee for the Protection of Human Subjects



**GAVIN NEWSOM**  
*Governor*

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)  
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CalHHS)**

Friday, October 4, 2024  
8:30 a.m.

**Members**

**Darci Delgado, PsyD.**  
**(Interim Chair)**

**Larry Dickey, MD, MPH,**  
**Vice Chair**

Juan Ruiz, MD, DrPH, MPH  
Alicia Bazzano, MD, PhD  
Maria Dinis, PhD, MSW  
Catherine Hess, PhD  
Carrie Kurtural, JD  
Laura Lund, MA  
Philip Palacio, EdD, MS  
John Schaeuble, PhD, MS  
Allen Azizian, PhD  
Maria Ventura, PhD  
Jonni Johnson, PhD

**Remote Attendees**

Darci Delgado, PsyD.  
Allen Azizian, PhD  
Alicia Bazzano, MD, PhD  
Maria Dinis, PhD, MSW  
Laura Lund, MA  
Philip Palacio, EdD, MS  
Juan Ruiz, MD, DrPH, MPH

**Zoom:**

[CPHS October 4, 2024,](#)  
[Full Committee Meeting](#)

Meeting ID: 160 867 9248  
Passcode: 392301

**Location:**

1215 O Street,  
Allenby Building,  
11th Floor,  
Meeting Room 1181,  
Sacramento, CA 95814

**Phone:**

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York)

**Meeting ID:** 160 867 9248

**MINUTES**

**Alternate Member**

Millard Murphy, JD  
Lois Lowe, PhD

**CDII**

John Ohanian, Director  
Agnieszka Rykaczewska,  
Deputy Director

**CPHS Administrator**

Agnieszka Rykaczewska

**Committee Members Present in Person:**

Larry Dickey, MD, MPH  
John Schaeuble, PhD, MS  
Maria Ventura, PhD  
Jonni Johnson, PhD  
Carrie Kurtural, JD  
Catherine Hess, PhD

**Committee Members Present Remotely:**

Darci Delgado, PsyD.  
Allen Azizian, PhD  
Alicia Bazzano, MD, PhD  
Maria Dinis, PhD, MSW  
Laura Lund, MA  
Philip Palacio, EdD, MS  
Juan Ruiz, MD, DrPH, MP

**CPHS Staff Present in Person:**

Agnieszka Rykaczewska, PhD  
Sussan Atifeh  
Karima Muhammad  
Nicholas Zadrozna

**Center for Data Insights and Innovation Staff Present in Person:**

John Ohanian, Director  
Agnieszka Rykaczewska, Deputy Director

**California Health and Human Services Staff Present in Person:**

Jared Goldman, General Council  
Maggie Schuster, Attorney  
Francis Brown

**Also, Present (All via ZoomGov) Principal Investigators and Associate Investigators:**

James Yi  
Becky Armstrong  
Ester M. John  
Evan White

**A. Welcome**

**a) Chair Updates**

Dr. Dickey, CPHS Vice Chair, informed the committee he will Chair today's meeting since Dr. Delgado asked Dr. Dickey to Chair today's meeting since she will be attending remotely for today's meeting. Dr. Dickey congratulated Sussan Atifeh and Karima Muhammad for their birthdays this month, and Nicholas Zadrozna and Agnieszka Rykaczewska for their one-year anniversary working on the CPHS.

Agnieszka Rykaczewska, CPHS administrator, informed the committee that the Bagley-Keen, Open Meeting Act requires a majority of members attend in person to have quorum. However, the act includes some criteria where if the member is not able to attend in person, for reasons that meet that criteria and inform the administrator prior to the meeting, that member can attend remotely while being counted toward the quorum. Ahead of this meeting, Ms. Lund informed the

CPHS Administrator that they would attend remotely, and their criteria satisfied those requirements of the Bagley Keen, Open Meeting Act.

No public comments were made.

## **B. Subcommittee Updates**

### **a) Update from Subcommittee meeting on September 13, 2024**

Ms. Lund provides updates on the sub-committee that met on September 13, 2024, for the purposes to develop recommendations for language for regulations to support reviews of projects under the Information Practices Act (IPA).

Ms. Lund provides clarification to the committee before providing the update on the discussion at the subcommittee meeting. Ms. Lund notes that she is concerned of confusion from the public for the purposes of the proposed regulations and wants to make sure the committee has clarity on the purpose of the proposed regulations. The committee has had discussions for over the past year regarding reviewing projects under the IPA particularly with concerns over linkages, to large data sets with extremely sensitive information, and the use of people's data from state databases. Ms. Lund points out the IPA language has criteria for doing those reviews. CPHS acts as the IRB if there is a state agency conducting the research, if a state agency is funding the research, if a state agency is participating in the research by providing staff or other resources, and/or if the State agency data will be used to contact human subjects. CPHS can also be asked to be the IRB in certain cases. Ms. Lund explains IPA projects are required by statute to reviewed by CPHS that do not fall within CPHS IRB purview.

Ms. Lund explains the purpose of the subcommittee is to establish some standardize criteria for reviewing those projects that would clarify the general criteria that is offered under the IPA. The document that was discussed during the Subcommittee meeting was prepared by Dr. Schaeuble and a copy was posted online and provided to all the committee members. The subcommittee accepted the document Dr. Schaeuble provided, and majority of the discussion revolved around that document itself and the issues that it raised.

Ms. Lund suggests the work from the subcommittee meeting is summarized by the motion that was approved. Ms. Lund presented the motion that was approved and explains the four items that were approved. The first item approved in the motion is to strike the last item in the second section. The reasons to remove the last item in the second section is to establish language that is clear and objective, rather than subjective criteria. The second item in the motion approved, was Dr. Schaeuble will work with Jared Goldman to re-word items one and two in the last section of the document. The reason for have Dr. Schaeuble work alongside Jared Goldman, General Counsel of CalHHS, was Attorney Goldman has excellent suggestions for refining the wording to address the concerns of the subcommittee, while at the same time being consistent with the language of the IPA. The third item approved in the motion was to have Ms. Kurtural work with Jared Goldman and Maggie Schuster to create an outline for the regulations package for discussion at the next subcommittee meeting. The last item on the motion that was approved was to have Jared Goldman review the last two items of section three to determine whether these criteria is already included within the IPA. Ms. Lund notes these criteria are a concern to the subcommittee, but if they are already included in the IPA language, there is no need to include them in the regulations package.

Ms. Lund opened the discussion to the other subcommittee members to see if she missed anything from her overview. The other members of the subcommittee thanked Ms. Lund for her summary of the meeting and had no additional comments to add.

Ms. Lund opened the discussion for comments or questions to the committee members. Dr. Dickey points out CPHS has received four letters from the public and they are posted on the CPHS website.

Dr. Dickey opened the discussion for the public to comment on. Becky Armstrong asked in the chat box if she can see the original motion to know what the subcommittee comments refer to. Dr. Rykaczewska, CPHS Administrator, presented the document on the screen, and provided the link in the chat for where it is posted on the CPHS website, under the September 13<sup>th</sup> subcommittee meeting.

**Motion: Dr. Schaeuble moved, and Ms. Lund seconded the motion that the committee accepts the report from the Subcommittee for the meeting on September 13.**

**Approve: Dr. Schaeuble, Ms. Lund, Dr. Azizian, Dr. Dinis, Dr. Hess, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr. Ruiz, Dr. Ventura**

**Oppose: None**

**Abstain: None**

**Absent: None**

**(Dr. Bazzano vote was not caught on audio)**

Total= 10

In Favor- 10, Opposed- 0, Abstained- 0

### **C. Follow-up on Letters of Support**

#### **a) Overview of HCAI statutes**

Dr. Dickey provides a recap on the motion passed in the July Meeting, to require all research projects have letters of support from all departments who are the original owners of the data being requested and that a Business Use Case Proposals (BUCP) does not satisfy the requirement. After the motion was passed in July, CPHS has received comment from the Department of Healthcare Access and Information (HCAI) that this motion may conflicts with their statutes. Maggie Schuster, California Health and Human Services Attorney, provided an overview of the discussion that she had with the legal team at HCAI. Attorney Schuster brought up that HCAI has a statutory obligation to share certain data with other departments within the agency. Such as hospital discharge data, emergency care data, ambulatory surgery data has a statute that requires HCAI to share this data with DHCS, CDPH, and Covered California. Under the same statute there is language that states the department that receives the data from HCAI is the department that should be complying with CPHS review requirements. Attorney Schuster explained that HCAI was concerned that they are required to share this data with these departments due to the statute. The motion that CPHS passed did not make sense for HCAI to have to have to provide a Letter of Support when HCAI has no option due to the statute.

HCAI legal team has proposed that the department that receives the data from HCAI and shares it with researchers is the department that would provide the Letter of

Support. Attorney Schuster suggests modifying the motion that was passed in July based on the discussion she had with HCAI.

**b) Discussion of CPHS requirements related to Departmental Letters of Support \**

Ms. Lund asks if another agency is releasing data on behalf of HCAI can CPHS ask in the Letter of Support that they call out they will be releasing their departments data and HCAI's data in compliance with all state laws. Attorney Schuster does not see an issue with Ms. Lund's recommendation.

The motions passed in the July 2024 meeting were presented on the screen and are posted on the CPHS website for reference.

Attorney Goldman suggests changing the language to state all research projects required Letters of Support from the disclosing department rather than the original owns of the data being requested.

Ms. Lund requested having language in the Letter of Support that the disclosing department knows they are responsible for knowing both their own statutes and the statutes that govern all the data being are sharing. An example if CDPH is sharing HCAI data, CDPH would need to know both the CDPH and HCAI disclosure statutes when they share the data. Ms. Lund notes her concerns come from adverse events and inappropriate data sharing.

Dr. Schaeuble summarizes the two suggestions that were discussed. The first suggestion was to amend the language in the original motion to state the Letter of Support needs to come from the department releasing the data to the researcher. The second suggestion is having the departments add to the Letter of Support that the releasing department is in compliance with any state laws that apply to that department and the requirements of the department that supplied their data.

Dr. Rykaczewska presented on the screen CPHS approval letter to ensure the CPHS approval letters have the correct language. The committee agreed to change the language in the CPHS template letter from will be in "compliance with all applicable state statutes" to "compliance with all applicable state and federal laws".

**Motion: It was moved by Ms. Lund and seconded by Dr. Dickey that CPHS modify the motion made at the July meeting to state that instead of requiring the Letter of Support from the original owner of the data that we instead require a Letter of Support from the releasing Department, which includes a statement that the release will be compliant with all state and federal laws. The requirement that a BUCP does not satisfy this requirement is not rescinded.**

**Approve: Ms. Lund, Dr. Dickey, Dr. Ventura, Dr. Dinis, Dr. Hess, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr. Ruiz, Dr. Schaeuble.**

**Oppose: None**

**Abstain: Dr. Azizian**

**Absent: Dr. Delgado, Dr. Bazzano**

Total=11

In Favor-10, Opposed-0, Abstained-1

#### **D. Review and Approval of Meeting Minutes**

**Motion: It was moved by Dr. Schaeuble and seconded by Dr. Dinis to approve meeting minutes for July 12, 2024.**

**Approve: Dr. Schaeuble, Dr. Dinis, Dr. Azizian, Dr. Hess, Ms. Lund, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr. Ruiz, Dr. Ventura.**

**Oppose: None**

**Abstain: None**

**Absent: Dr. Delgado, Dr. Bazzano**

Total=10

In Favor-10, Opposed-0, Abstained-0

#### **E. Projects with Reported Adverse Events and/or Deviations**

None.

#### **F. New Projects – Full Committee Review Required)**

- |                 |   |
|-----------------|---|
| 1. Project #    | 2024-146 (Hess)   |
| Title:          | Stress, Inflammation, and Health-Related Quality of Life of Long-Term Breast Cancer Survivors |
| PI:             | Ester John, PhD   |
| Co-PI:          |   |
| Board Decision: | Approved Pending Conditions - Designee Review   |

##### **Discussion:**

This study focuses on health-related quality of life and various stress sources in long-term breast cancer survivors enrolled in the Northern California Breast Cancer Family Registry (BCFR). The registry was established in 1995 and includes about 4,000 women diagnosed between 1996 and 2009, identified through the California Cancer Registry. There are currently around 1,250 active participants, diagnosed over 15 years ago, most of whom are from racially and ethnically minoritized populations, with 70% being from these groups.

The study aims to collect three types of data:

1. Questionnaire data on quality of life and multiple stress sources, including cancer-specific stressors, social stressors, and healthcare-related stress.
2. Geocoding of current residential addresses to link with neighborhood stressors like racial segregation and neighborhood deprivation.
3. Blood samples for a subset of 132 participants to measure inflammatory biomarkers.

The study hypothesizes that a higher burden of stressors will be associated with lower quality of life, with variations across racial and ethnic groups. The study is unique due to the focus on long-term breast cancer survivors and its inclusion of racially diverse participants. The protocol

has been approved by the Stanford IRB, and clarifications are needed for the CPHS protocol, including updates to the consent form. These updates are in progress and will be resubmitted to Stanford IRB.

Dr. Hess, the reviewer, expressed satisfaction with the clarifications provided so far but highlighted the importance of lowering the reading level of the consent form. Dr. Hess acknowledged the need to simplify non-Stanford required language where possible, though limitations were understood.

Dr. Ventura asked if all research would be conducted at Stanford. Dr. John clarified that the study would be carried out solely at Stanford.

Dr. Ventura raised a question about data sharing and potential collaborators. Dr. John explained that due to National Institutes of Health (NIH) requirements, de-identified data must be deposited in an NIH repository. She clarified that personal identifiers (PHI) such as names, addresses, and social security numbers would not be shared. However, questionnaire, biomarker, and neighborhood data, including demographic variables like race and ethnicity, must be deposited.

Dr. Schaeuble raised concerns about the possibility of re-identification due to the accumulation of variables in the repository. Dr. John explained that only transformed and derived variables (e.g., stress scores from questionnaires) would be shared, and no raw data or personal identifiers would be included. She further clarified that no geographic information (such as addresses) would be transmitted, and the data would be de-identified to minimize re-identification risk. Dr. John explained that many of the questionnaire responses, such as those from stress scales, would be used to generate aggregate scores (e.g., Cohen's General Stress Scale). These scores are derived from participants' responses and represent different levels of stress (low, intermediate, or high). The analytic variables that are transmitted would be these derived scores rather than raw responses.

No public comments.

**Motion: It was moved by Dr. Hess and seconded by Ms. Kurtural to grant the project a deferred approval for one year, classifying it as minimal risk, pending the following specified minor revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Hess.**

- 1. Make the changes that Dr. Hess emailed on September 29th.**
- 2. Provide more detail about the data that will be transmitted to the NIH data repository per the agreement with NIH.**

**Approve: Dr. Hess, Ms. Kurtural, Dr. Azizian, Dr. Dinis, Dr. Johnson, Ms. Lund, Dr. Palacio, Dr. Ruiz, Dr. Schaeuble, Dr. Ventura.**

**Oppose: None**

**Abstain: None**

**Absent: Dr. Delgado, Dr. Bazzano.**

Total=10

In Favor-10, Opposed-0, Abstained-0

#### **G. Full Board Continuing Review**

None.

**H. Amendments – Full Committee Review Required**

None.

**I. Second Review Calendar**

None.

**J. New Projects – Expedited Review Requested**

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.

Total Project Count (13)

**K. Projects Requiring Continuing Review**

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.

Total Project Count (55)

**K1. Projects Requiring Continuing Review – Administrative Action Taken**

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.

Total Project Count (36)

**L. Amendments – Projects with Revisions Approved through Expedited Review**

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.

Total Project Count (21)

**M. Projects with Request for CPHS to Rely on Another IRB**

None.

**N. Exemption/Not Research Approvals**

Total Project Count (11)

**O. Final Reports**

Total Project Count (5)

**P. Public Comments**

Dr. Evan White voiced his concern that the regulations under consideration by the subcommittee are out of line and not appropriate for this body. Noting that the



regulations would seriously jeopardize a lot of very important policy relevant research in the state of California. Dr. White encourages the committee to review the public comments that were posted on the website.

**Q. Next Meeting**

The next CPHS meeting is scheduled to be held on Friday, November 1, 2024.

The next CPHS subcommittee meeting is scheduled to be held on Friday, November 8, 2024.

**R. Adjournment**

This meeting was adjourned at 9:45 AM on July 12, 2024.