

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)**

Members

**Juan Ruiz, MD, DrPH, MPH,
Chair**

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

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

Alternate Member

Millard Murphy, JD

Administrator

Elaine Scordakis

Friday, February 3, 2023
8:30 a.m.

Zoom:

[CPHS February 3, 2023](#)

[Zoom Meeting](#)

Meeting ID: 160 559 3399

Passcode: 562847

Phone:

+1 669 254 5252 US
(San Jose)

+1 669 216 1590 US
(San Jose)

+1 551 285 1373 US

+1 646 828 7666 US
(New York)

Meeting ID: 160 559 3399

CDII

John Ohanian, Director

MINUTES

Committee Members Present:

Juan Ruiz, MD, DrPH, Chair

Larry Dickey, MD, MPH, Vice Chair

Catherine Hess, PhD

Laura Lund, MA

Philip Palacio, EdD, MS

Carrie M. Kurtural, JD

CPHS Staff Present:

Sussan Atifeh

Karima Muhammad

Center for Data Insights and Innovation

Sheryl McCarthy

Ruben Mejia

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

Paul Simon, LACDPH

Priya Batra, LACDPH

Todd Hughes, UCLA

Andrew Juhnke, UCLA

Mohamed Mostafa, UCLA

Rita Hamad, UCSF

Lia Fernald, UCB

Joanie Rothstein, UCSF

Wendi Gosliner, UC ANR

Lorrene Ritchie, UC ANR

Suzanna Matias Medrano, UCB,

Danielle Lee, UC ANR

Celeste Doerr, CDPH

A. Welcome

a. Chair Updates

- I. Lucila Martinez will be returning soon to join the CPHS until an administrator is hired.

- II. Frequently Asked Questions on CPHS Website.

Dr. Dickey mentioned, "Copies of the revised Frequently Asked Questions (FAQ) have been provided to all CPHS committee members for their review." Committee members can provide their comments in the document and send it to either Dr. Dickey or CPHS staff. Dr. Dickey recommended to post a copy of the revised FAQ document in the CPHS website before the next public meeting.

B. Administrator Updates

None.

C. CPHS Review Pathways Decision Tree

Jennifer Schwartz discussed the newly created "CPHS Review Pathways Decision Tree" that assists CPHS committee members in making decisions when reviewing projects' applications. This diagram has been designed by Center for Data Insights & Innovation (CDII) policy and compliance team.

The first choice in the diagram is whether state data or specimen is in use. If the answer to that question is no, then the next question will be "Are human subjects involved?" If the answer to this question is also "no" then CPHS has no purview over the project. If human subjects are involved, then the next question should be answered which is asking about the involvement of the CalHHS departments. If the answer to this question is "no" then "Common Rule Review" is optional, but if the answer is "yes", then the "Common Rule Review" is required.

If the answer to the first question regarding the usage of the state data and specimens is "yes" and researchers are going to use state data or specimen, then the next question is, "Does the project involve contact or interaction with human subjects?"

If the answer to this question is "no", then an "IPA Review" is required because the CPHS has a mandate to review research projects that are requesting state data regardless of whether the data is requested from the departments inside CalHHS or outside CalHHS.

However, if human subjects are involved, or information is going to be used to contact human subjects, while the "IPA Review" is still required, then the next question should be answered to clarify about the involvement of the CalHHS departments. If CalHHS departments are not involved, then the "Common Rule Review" is optional and if CalHHS departments are involved the "Common Rule Review" is required.

Committee members can provide written feedback to Jennifer Schwartz.

Ms. Lund mentioned, “Having specific examples from work to populate each box in the diagram makes it easier to understand, especially for the new committee members.”

Committee members were recommended by Jennifer Schwartz to decline an optional review in a case where researchers have already established an IRB to do that work for them, to prevent researchers from paying twice since CDII will start charging for this service soon.

Dr. Dickey mentioned that the classifications of the projects in IRBManager should be adjusted to follow the instructions explained in the “CPHS Review Pathways Decision Tree” diagram and this diagram should be posted in the CPHS website.

D. Review and Approval of Meeting Minutes

a. December 2nd, 2022

It was moved by Dr. Dickey and seconded by Ms. Lund to approve the December 2nd, 2022, Meeting minutes

Approve: Dr. Dickey, Ms. Lund, Dr. Palacio, Ms. Kurtural, Dr. Hess.

Oppose: None

Abstain: None

Absent: Dr. Dinis, Dr. Schaeuble, Dr. Bazzano

E. Projects with Reported Adverse Events and/or Deviations

1. Project # 12-08-0658 (Palacio)
Title: Personal Responsibility and Education Program (PREP) Evaluation
PI: Celeste Doerr, PhD
Co-PI: Mara Decker, DrPH
Board Decision: Approved

In this project, in one of the cohorts that received sexual health education in a school there was a student who received a survey whose parent had declined his or her participation. The cohort included thirty-three students. Researchers reached out to the local implementing agency in that school and discussed the protocol with them. Researchers have provided their documentation, including their required training, and reviewed with them their responsibilities for administering consent forms, and identified the issue, which was that they relied upon a teacher's report in this case that parental consent had been received for this student. Researchers have advised the agency staff that it is also their responsibility to ensure that proper consent has been obtained and not just relying on teachers' reports. Researchers have planned to update their training and to deliver a new version of the training within the local implementing agency where that issue occurred. The implementers are prepared to ensure that they will bring with them a list of students who may not complete the survey, and that they are going to use properly a passive consent process when they are working in the schools. Since researchers cannot identify the individual participants, there is no way to remove this survey data from the database and because it is just one survey obtained without parental consent, it is unlikely to change the outcome of the total results.

Motion: It was moved by Dr. Palacio and seconded by Dr. Dickey to accept this event as resolved and to approve the steps that the PI has taken to resolve the issue, and to ensure that it does not happen again.

Approve: Dr. Palacio, Dr. Dickey, Ms. Lund, Dr. Hess, Ms. Kurtural.

Oppose: None

Abstain: None

Absent: Dr. Dinis, Dr. Bazzano, Dr. Schaeuble.

Total=5

In Favor-5, Opposed-0, Abstained- 0

2. Project # 12-12-0949 (Dickey)
Title: Los Angeles Mommy and Baby (LAMB) Project
PI: Diana Liu, MPH
Co-PI:
Board Decision: Approved

The report is about unauthorized sharing of the Los Angeles Mommy and Baby (LAMB) project's data linked to vital records data from the California Department of Public Health (CDPH). Researchers reported 11 instances of unauthorized sharing between 2012 and 2019. Messages have been sent to all of the involved parties and responses received from seven of them that indicate all seven projects have been closed and the data has been destroyed. The state laws specifically prohibit sharing the vital records data with another researcher and also require that any use of information from the confidential portion of a birth certificate go through review by the Vital Statistics Advisory Committee (VSAC), and none of these projects went through VSAC review. The Data Use Agreement that was signed by the Los Angeles County Department of Public Health (LACDPH) specifically prohibited sharing the data. Researchers have informed CDPH about the adverse event and provided them with a list of the projects. The Principal Investigator (PI) of the LAMB project has changed over time and the management at LACDPH did not inform the most recent PI (or PIs) about the rules regarding not sharing the data. The state law doesn't allow sharing of even de-identified VSAC data and the only way that data can be shared is when the data is transformed so that it's no longer Vital Statistics data. LACDPH staff have taken all of the right actions since they became aware of the problem. The State law requires CDPH to have on file a list of all the data users that have utilized that data, their title, their organizational affiliation, the dates of their access, and the purpose of utilizing data. LACDPH will provide contact info for all eleven principal investigators to CDPH. CPHS will provide copies of those protocols that received unauthorized data to CDPH. It was clarified that not all of the eleven projects that received unauthorized data mentioned that the LAMB data had vital records data linked to it.

Dr. Dickey and Ms. Lund will work to develop the appropriate language for a notice to clarify this issue which is specific to VSAC for the public and for the members. The notice should inform researchers that CPHS approval is not sufficient for any requests regarding VSAC data and the requests should go back to VSAC even if the data is transformed or de-identified. This notice should be posted on the CPHS website and in the IRBManager.

It was moved by Ms. Lund and seconded by Dr. Dickey to accept the adverse event as reported with the following required actions:

- **LACDPH will provide CDPH with the contact information for the PIs of the eleven projects**
- **CPHS Will provide CDPH with the Protocols that were submitted for the eleven projects**
- **LACDPH will continue to try to follow up with the remaining four PIs to try to resolve the data issues in terms of destruction or returning of the data, and will, report back to CPHS in four months.**
- **Dr. Dickey and Ms. Lund as a subcommittee will develop language regarding the use of vital statistics data to post on the CPHS website and in IRBManager to be reviewed by our legal Counsel and CDPH.**

Approve: Ms. Lund, Dr. Dickey, Dr. Hess, Ms. Kurtural, Dr. Palacio.

Oppose: None

Abstain: None

Absent: Dr. Dinis, Dr. Schaeuble, Dr. Bazzano

Total=5

In Favor-5, Opposed-0, Abstained- 0

3. Project # 12-05-0176 (Dickey)
Title: California Health Interview Survey
PI: Ninez Ponce, PhD
Co-PI: Todd Hughes, BS
Board Decision: Approved

Through some discussions with the California Department of Public Health (CDPH), it has been determined by “California Health Interview Survey” (CHIS) project’s staff that the laptop configuration being used by CDPH did not meet the requirements as outlined in the CHIS funder data custodian agreement. The laptops are missing some important protections while accessing the confidential CHIS data files. CDPH shut down access to the CHIS data while alternative systems are explored. CHIS IT has provided multiple technical solutions to CDPH, which CDPH is now considering. CHIS has offered to provide configured laptops to CDPH. CHIS will work with CDPH to implement a compliant system and will ensure no confidential CHIS data file access by users at CDPH until that new system implementation has been completed and confirmed. CHIS plans to hold a webinar for all CHIS funders, to review what the requirements of the data custodian agreement truly mean. CHIS will ask each of the funders to provide more detailed documentation, including a checklist of confirming compliance on how all devices within their system will meet the requirements in the data custodian agreement. Data Custodian for CDPH is responsible for how the CHIS data is accessed. CPHS recommended demonstration of CDPH or other organizations of meeting CHIS data sharing requirements periodically. CHIS is considering repeating the webinar periodically as they go through the process of re-issuing the data custodian agreements for signature. It was mentioned by Marco Smolich from CDPH that CDPH has created a virtual environment for staff to conduct their work and these CHIS requirements may be unrealistic.

Motion: It was moved by Dr. Dickey and seconded by Ms. Lund to accept the adverse event report and ask researchers to continue to restrict use of data by CDPH until they can come back to committee with a security plan that will be approved.

Approve: Dr. Dickey, Ms. Lund, and Dr. Palacio, Dr. Hess, Ms. Kurtural, Dr. Ruiz.

Oppose: None

Abstain: None

Absent: Dr. Palacio, Dr. Dinis, Dr. Bazzano, Dr. Schaeuble

Total=5 In Favor-5, Opposed-0, Abstained- 0

F. New Projects – Full Committee Review Required

1. Project # 2023-005 (Hess)
Title: Child and Adult Care Food Program: Impacts of COVID-19 Changes to Meal and Snack Reimbursement Rates on Family Child Care Home Providers, Children and Families
PI: Lorrene Ritchie, PhD, RD
Co-PI: Susana Matias, PhD
Board Decision: Approved Pending Conditions - Designee Review

The Child and Adult Care Food Program (CACFP), also known as the Food Program, provides reimbursements for Family Child Care Homes (FCCH) to serve healthy foods. FCCHs received more money for participating in the Food Program during the COVID-19 pandemic. Researchers work with the FCCH and Food Program community to evaluate whether the higher reimbursement helped providers and families in California by sending out surveys and conducting interviews with FCCHs, sponsors, and families. Some minor changes were requested including not contacting participants via SMS, adjusting the one-hundred-dollar incentive, and some minor changes to consent forms all of which have been addressed by the researchers. The last outstanding item was regarding data security requirements. Initially, researchers planned on using a private server called “Box” for storage of the data that wasn't adequate. It was clarified that the data should be stored on a secure server in UC ANR, and It would be preferable to not have any data stored on a laptop, even a secure one and the project team should simply use Laptop to access that secure shared drive. Researchers will not use laptops as primary storage devices for the data, and they will wait until they have secured server storage from UC ANR.

Motion: It was moved by Dr. Hess and seconded by Dr. Dickey to grant the project a deferred approval for one year with minimal risk pending the following specified revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Hess.

- **Researchers are required to provide an updated Data Security Letter (DSL) from UC ANR that specifies the data will be stored on secure UC ANR hosted servers and the required changes should be uploaded in the application in IRBManager.**

Approve: Dr. Hess, Dr. Dickey, Ms. Kurtural, Ms. Lund, Dr. Palacio.

Oppose: None

Abstain: None

Absent: Dr. Dinis, Dr. Schaeuble, and Dr. Bazzano

Total=5 In Favor-5, Opposed-0, Abstained- 0

2. Project # 2022-229 (Lund)
Title: Targeting Access and Knowledge of Earned Income Tax Credit (EITC) Utilization and Policies (TAKE-UP)

PI: Rita Hamad, MD
Co-PI: Lia Fernald, PhD
Wendi Gosliner, DrPH, RD

Board Decision: Approved Pending Conditions - Designee Review

This project has evolved significantly since the committee first reviewed it. The project is based on communicating to increase awareness among women who utilize the Women, Infants & Children (WIC) program to educate them about the Federal Earned Income tax credit (EITC) program, which is a program that can offer up to several thousand dollars in tax credits to low-income women who meet some eligibility criteria. Researchers are proposing to conduct pilot research with participants to evaluate strategies that may improve the uptake of the EITC among WIC recipients.

Initially, the committee had serious concerns about one of the three activities which involved actually encouraging WIC participants to enroll in the EITC program. That particular activity was more than minimal risk and could have presented very real economic harm to some of the participants. The research team decided to remove that activity from the project, and instead move forward with interviews and surveys with the WIC Participants about their knowledge of EITC. Those aspects of the project are minimal risk since they are about knowledge and awareness. The research team has responded to all the requested changes and edits to the consent forms around the interviews, and surveys and now this project is truly minimal risk. Dr. Hess and Ms. Lund are pleased with the last round of changes and all the changes that were received in email should be incorporated into the protocol.

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

- **All of the changes outlined in the February 2nd email should be uploaded to IRBManager and incorporated into the protocol, including all of the additional and revised documents.**
- **This approval is only for the English documents and any additional Spanish documents would need to be submitted as an amendment.**

Approve: Dr. Hess, Dr. Dickey, Ms. Lund, Ms. Kurtural, and Dr. Palacio.

Oppose: None

Abstain: None

Absent: Dr. Dinis, Dr. Schaeuble, and Dr. Bazzano

Total=5

In Favor-5, Opposed-0, Abstained- 0

G. Amendments – Full Committee Review Required

None.

H. Second Review Calendar

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 (0)

I. 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 (14)

J. Projects Requiring Periodic Review Only (Including Greater than Minimal Risk)

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 (23)

J1. Projects Requiring Periodic Review Only (Including Greater than Minimal Risk) – 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 (100)

K. Projects with Major Revisions Requiring Periodic 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 (22)

L. Projects with Request for CPHS to Rely on Another IRB

M. Exemption/Determination Requests

Total Project Count (11)

N. Final Reports

Total Project Count (6)

O. Public Comments

None.

P. Next Meeting

The next meeting will take place on Friday, February 3, 2023.

Q. Adjournment

This meeting was adjourned at 10: 37 a.m.