

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, April 7, 2023
8:30 a.m.

CDII

John Ohanian, Director

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

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Millard Murphy, JD

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Administrator

Elaine Scordakis

MINUTES

Committee Members Present:

Juan Ruiz, MD, DrPH, Chair

Larry Dickey, MD, MPH, Vice Chair

Alicia Bazzano, MD, PhD

Maria Dinis, PhD, MSW

Laura Lund, MA

Philip Palacio, EdD, MS

Carrie M. Kurtural, JD

John Schaeuble, PhD, MS

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

Jesse Rothstein, UCB

Nick Gebbia, UCB

Bridgette Lery, Urban Institute

Sarah Benatar, Urban Institute

Katrina Brewsaugh, Urban Institute

CPHS Staff Present:

Sussan Atifeh

Karima Muhammad

Center for Data Insights and Innovation

Sheryl McCarthy

Ruben Mejia

A. Welcome

a. Chair Updates

Lucila Martinez will be joining the Committee for the Protection of Human Subjects (CPHS) as a retired annuitant as of Monday, April 10, 2023.

b. Updates for Newly Created Documents (“CPHS Basics”, “Not Research Application”, and “Exempt Application”)

A draft of the “CPHS Basics” guide created by Dr. Dickey was presented to the Committee. The purpose of this guide is to clarify for the researchers on how to approach the committee through some of the basic principles. Dr. Schaeuble provided some comments for this document which all were accepted. The revised document will be posted on website.

The “Exempt” and “Not Research” applications were proposed to the committee members as two separate forms. Members did not have any revisions to these forms and approved them to proceed to implement into IRBManager.

Dr. Dickey will work on preparing a special form for the entities that want to apply to determine if they are not under CPHS purview.

c. Los Angeles Mom and Baby (LAMB) Project Adverse Event Update

CPHS provided the California Department of Public Health (CDPH) with copies for nine of the eleven research studies that received data inappropriately. CPHS was not able to locate two protocols even in the hard copy archives. Los Angeles County Department of Public Health (LACDPH) has the contact information for the Principal Investigators (PIs) for those studies and has provided that to CDPH to follow up with them. CPHS also developed language regarding the important information for researchers using data originally sourced from birth or death certificates.

Los Angeles County Department of Public Health (LACDPH) has been attempting to reach out to the researchers who received the data. They have not been able to contact all of them. They will be coming back to CPHS at the June 2nd, 2023, full board meeting to provide a status update. They have provided all the requested information to CDPH regarding the adverse event and PIs information.

d. Implementing Language Regarding the Use of Vital Statistics Data

Ms. Lund and Dr. Dickey drafted information for researchers who want to use data that was originally sourced from either birth certificates or death certificates.

This document refers to three main points.

1. Researchers need to know that only the state registrar housed in the CDPH can legally provide vital records data. If researchers are getting data from other researchers, CPHS will require a letter of support from CDPH indicating that CDPH is aware, and this is okay with them.

2. Research studies requesting death or birth data must be reviewed and approved by the Vital Statistics Advisory Committee (VSAC) and researchers are being requested to attach their VSAC application to their research protocol to ensure that they have done that and to prevent the problem of getting data from other researchers instead of directly from CDPH. Having that VSAC application is evidence that CDPH is being made aware of the data strategies of the researcher.
3. Since this is not consistent with state law, CPHS will not approve studies proposed to develop registries or create linked data files that will be shared with other researchers, and they will be directed to CDPH to review their proposed plan.

Ms. Lund clarified that when researchers request birth and death data to share or to develop registries, VSAC science advisor works with them specifically to ensure that those data fields are transformed sufficiently and are different than the information that was originally on either the birth or death certificate. Regarding the vital records data, CDPH has a very narrow interpretation of sharing and reusing data, which indicates no individual data field, or combination of data fields can be shared beyond the originally approved protocol, including the PI and the research staff approved for that protocol.

This informational document has been revised by the Center for Data Insights and Innovation (CDII) legal team before being sent to the CPHS committee members and should be posted on the CPHS website and be added to IRBManager.

CDII legal team suggested that CPHS committee members to include this language in their boilerplate when approving vital records related data study. They also suggested that CDPH to include this information when they release data.

Also, California Cancer Registry (CCR) and Immunization Branch of the CDPH statutes are very specific about not sharing the data from one researcher to another. It should be clarified with CDPH if CPHS must have similar advisories for CCR data.

Ms. Lund recommended a meeting with CCR to clarify how tightly they're interpreting their data laws. Drs. Ruiz and Dickey agreed with this recommendation.

B. Administrator Updates

a. Posting Agenda and Meeting Materials Updates

CDII legal team provided new instructions to CPHS staff to simplify the process of posting agenda and meeting materials on the CPHS website for the CPHS full board meetings. Legal team clarified that agenda can only include a general description of the projects that will be discussed, and it does not have to include the very specific information of the projects like the exact number of the project, the name of the PI, title of the project, etc. CPHS staff were requested to separate the list of projects from agenda and post them as two separate documents, one as "agenda" and the other one as "meeting materials." Under the Bagley-Keene Open Meeting Act, we are required to post only the agenda ten business days before the meeting, not the meeting materials. The Meeting Materials can be posted at the same time of agenda and if necessary, it can be edited and reposted even relatively close to the day of the meeting so people can review the information related to projects during the meeting.

C. Review and Approval of Meeting Minutes

a. February 3, 2023

It was moved by Dr. Dickey and seconded by Ms. Lund to approve the February 3, 2023, Meeting minutes.

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

Oppose: None

Abstain: Dr. Schaeuble

Absent: Dr. Bazzano, Dr. Dinis, Dr. Hess

b. February 27, 2023

It was moved by Dr. Dickey and seconded by Ms. Lund to approve the February 27, 2023, Meeting minutes.

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

Oppose: None

Abstain: None

Absent: Dr. Bazzano, Dr. Dinis, Dr. Hess

D. Projects with Reported Adverse Events and/or Deviations

None.

E. New Projects – Full Committee Review Required

- | | |
|-----------------|---|
| 1. Project # | 2023-057 (Palacio) |
| Title: | Evaluating California’s Guaranteed Income Pilot Program |
| PI: | Bridgette Lery, PhD |
| Co-PI: | Sarah Benatar, PhD |
| Board Decision: | Approved Pending Conditions - Designee Review |

Discussion:

This project aims to evaluate the state’s first Guaranteed Income Pilot Program (GIPP) which was created under the SB 739. Under GIPP, 7 pilot sites were granted funding to provide up to eighteen months of cash payments to low-income youths transitioning out of extended foster care and pregnant people. The California Department of Social Services (CDSS) is contracted with the Urban Institute, and University of California, Berkeley (UCB) as a partner, to evaluate what it takes to implement this Guaranteed Income (GI) program as well as whether or not it has an impact on a variety of outcomes. In this study, researchers have requested approval for the baseline survey. Everyone who participates in the program is on a voluntary basis and researchers are not asking for Personal Identifiable Information as part of the application for the survey.

Researchers have prepared a draft of the translated materials and will request approval for the translated documents by submitting an amendment.

All participants will be an adult or an emancipated minor. All the pregnant people will be adults, or emancipated minors, and all the youth aging out of foster care will be twenty-one or older.

Researchers have provided a table to display the amount of GI by site. Each site is providing a slightly different disbursement amount depending on their geographic location. This table should be added to the project’s application.

AidKit is managed through CDSS. Urban Institute and AidKit are in the process of executing a data use agreement.

Researchers will ensure that there is consistency in the compensation information shared throughout the protocol. Incentive payments will be made via the AidKit platform. When enrolling in the program through AidKit, participants can elect to receive payments either via ACH direct deposit to a bank account or a pre-loaded refillable debit card.

Researchers should confirm in the application in the “INTERNET ACCESSIBILITY” section that they will not be collecting any PID, so nothing will be accessible to the Internet.

Researchers will ensure that the text of the consent form and the text of the “Consent Block” which is a section at the beginning of the survey will match.

Researchers will let the participants know that their carrier rates may apply to text messaging and not all text messaging services are free.

Researchers will clarify in the consent form under the “risks” section that the questions might be sensitive.

It was clarified by committee members that in general CPHS does not delegate reviews to other IRBs, except for Federal IRBs.

Motion: It was moved by Dr. Palacio and seconded by Dr. Dickey to grant the project a

deferred approval for one year with minimal risk pending the following specified minor revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Palacio.

1. Incorporate all the responses and revisions (provided to Dr. Palacio via email) into the application.
2. Confirm in the application that approval will be requested for the translated documents by submitting an amendment.
3. Clarify in the application that All participants will be an adult or an emancipated minor.
4. Add the table provided to display the amount of GI by site to the application.
5. Clarify in the application that AidKit is managed through CDSS and Urban Institute and AidKit are in the process of executing a data use agreement.
6. Ensure that there is consistency in the compensation information shared throughout the protocol.
7. Confirm in the application in the "INTERNET ACCESSIBILITY" section that you will not be collecting any PID, so nothing will be accessible to the Internet.
8. Ensure that the text of the consent form and the text of the "Consent Block" which is a section at the beginning of the survey will match.
9. Inform the participants and clarify in the consent form that their carrier rates may apply to text messaging and not all text messaging services are free.
10. Clarify in the consent form under the "risks" section that the questions might be sensitive.

Approve: Dr. Palacio, Dr. Dickey, Dr. Schaeuble, Dr. Bazzano, Ms. Lund, Ms. Kurtural.

Oppose: None

Abstain: None

Absent: Dr. Hess, Dr. Dinis

Total=6

In Favor-6, Opposed-0, Abstained-0

F. Amendments – Full Committee Review Required

1. Project #	2022-058 (Schaeuble)
Title:	Family Responses to College Financial Aid Incentives
PI:	Jesse Rothstein, PhD
Co-PI:	Ryan Fuller, EdD MA
Board Decision:	Tabled

Discussion:

The study is a collaboration with the California Student Aid Commission (CSAC) and this amendment requests to add the University of California Consumer Credit Panel (UC-CCP) dataset to the project which comes from consumer credit records with information about family debt in various categories to broaden the study. The Study aims to understand how well, families understand the financial aid system, to get themselves the most aid that they could be eligible for. Researchers mentioned, "The study is entirely using de-identified administrative data that's already collected, and that data is transferred to a center at Berkeley, the California Policy Lab (CPL), where all the analysis will be done."

Researchers will get datasets from CSAC and Credit Bureau that are hashed, and then link the credit data to the CSAC data to do the analysis. Researchers worked out a way of getting the aggregation to be done before the data comes into the study, so that they only use large-scale aggregates to reduce the amount of information that would be linked to the CSAC data.

Four entities are involved in this situation including the Student Aid Commission, the Credit Bureau, the California Policy Lab (CPL), and the researchers for that particular study.

With regard to the California Student Aid Commission (CSAC) data, for each individual research study, researchers reach out to CSAC for the data that is needed and would maintain that in the California Policy Lab (CPL) which is only the working data for that particular research study.

With regard to the credit data, there's a set of information that researchers have agreed and signed a contract with the Credit bureau to be provided those variables and that would be data that was maintained at UCLA. Researchers clarified that their Data hub has separate virtual machines for every data set and project with very robust security precautions. There's a virtual machine for storing the credit panel data and a different one that researchers will have access to. The virtual machines are walled off from each other and the researchers won't have access to the fuller credit panel data.

A research staff at the California Policy Lab (CPL), would compute the abstracted variables that would aggregate information about loans and credit cards and mortgages, etc., before it is linked to the CSAC data and pass them on to the researchers. The hashing is being done by the credit agency and by CSAC and CPL never sees the underlying names or social security numbers. The linking is done by CPL, however SALT which is a secret pass phrase is used to encrypt the data and to add to the security of the hashing.

Reviewers clarified the data used in this study is not totally de-identified and there are HIPAA identifiers that remain in the data.

Lack of consent from the individuals whose credit reports are being used is a big block. People who apply for a card or a loan, expect their data will be used for obtaining credit, but not for research projects and they never have given any opportunity to opt out of such a possibility that their credit history is being linked to the CSAC data. There is not any disclosure about the agency selling data for commercial and research purposes in the information notes provided by the credit Bureau. The only kind of opt out that was offered was for marketing purposes for offers of pre-approved credit. This is an ethical dilemma for the CPHS reviewers.

Researchers said, "The common rule specifies that studies with minimal risk are qualified for a waiver from consent and the addition of the credit panel data doesn't add to the risk, and even if

a breach could happen, data wouldn't be re-identifiable.”

People who are applying for aid with the CSAC have been told that their private information would not be divulged but in this project researchers plan to tie that database to another database.

There is a support letter from CSAC attached to the project's application stating that the data will be released in compliance with all laws.

Reviewers are concerned that the amendment is greater than minimal risk because of the addition of these large numbers of possibly identifying variables from this second database and given the changes that were made regarding the data, they still consider this to be greater than minimal risk.

The changes in the credit variables being requested are helpful but the fact that the credit data is being linked to student aid data that contains more than four hundred and fifty variables and the final working data file still has the risk of people being re-identified.

the Federal regulations do not allow to grant a waiver of informed consent for greater than minimal risk studies. One of the reasons that Information Practices Act (IPA) exists and one of the reasons that this committee exists is that very private data is coerced from individuals to provide them with government services. Ethically, when committee members grant a waiver of informed consent, they consider whether the class of people whose data are being used would benefit from the study. There is not an advantage for the people whose data are being used in this study and it is not appropriate for this committee to allow a research study that uses their data against them or others in their class. Combining databases might harm individuals and that is a legitimate concern.

Researchers mentioned, “The study is about improving policy. It's about helping us better educate families about how to use the financial aid system and improving the allocation to reach families who need it, which are part of a class of families who are studying here, and it is a very legitimate purpose.”

Researchers stated, “Based on Common Rule, even if this project is judged to be more than minimal risk, there's still a waiver of the consent for projects that are approved for the evaluation of public benefit programs, and this project can qualify under that rule.”

This project is using financial data and is not covered by HIPAA.

Dr. Dickey clarified that this project is covered under the Information Practices Act that emphasizes on the legitimate use for the data, minimum necessary data, and there must be guidelines and security measures in place to protect the data.

Dr. Schaeuble mentioned, “The dilemma for us as reviewers, has been whether we can believe that it is ethically justified to do this kind of linkage in this particular study, which is really a different question from whether it is legally possible to do it.”

The FAFSA has a disclosure notifying applicant that data could be linked for enforcement purposes but doesn't specifically point to the credit report.

the original study relies on the FAFSA data and researchers mentioned, “Adding UC-CCP to the original study does not increase the re-identification risk of the FAFSA data because there are no social security numbers and names on this, and this study is trying to improve public policy by approving a public benefit program which is a financial aid program and we're doing that at a very aggregated level.”

The main concern of the CPHS committee members is whether it is ethically justifiable in this particular circumstance to link credit data to the student aid data given the lack of information provided to the families when they apply for student aid, and when they deal with their credit reports.

Dr. Dinis mentioned, “This kind of research cannot be done basically, from the Federal perspective because these are Federal loans.”

https://www.nasfaa.org/uploads/documents/June_2019_Data_Sharing_White_Paper.pdf was provided during the meeting by Ms. Lund.

Ms. Kurtural mentioned, "We have to have information to show that this is a minimal risk, and we need information on what type of notice was provided at the time when a particular student would have applied for funding."

It was recommended by the committee members to ask the legal staff to review and provide input on the Federal law regarding the release of these particular datasets.

Dr. Schaeuble mentioned, "It's relevant to look at not only what is disclosed to families applying for student aid, but also what is disclosed to families with regard to their credit reports, because there are the two ways that people might be apprised of the possibility of their credit information being used for something other than the purposes they might otherwise expect."

This project is being reviewed under the Information Practices Act (IPA) and CPHS committee members are obligated under the Belmont Report to clarify whether the project is ethically justifiable.

Motion: It was moved by Dr. Schaeuble and seconded by Dr. Dinis to table discussion of the amendment until the next meeting, at which time the committee will consider evidence from the researchers about the applicable requirements under the Higher Education Act (HEA), the Family Educational Rights and Privacy Act (FERPA), California's Information Practices Act (IPA), and what disclosures were made to and what consent was provided by families when applying for student aid and applying for credit reports.

Approve: Dr. Schaeuble, Dr. Dinis, Dr. Dickey, Ms. Lund, Ms. Kurtural, Dr. Palacio, and Dr. Bazzano

Oppose: None

Abstain: None

Absent: Dr. Hess

Total=7

In Favor-7, Opposed-0, Abstained-0

G. 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)

H. 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 (28)

I. 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 (26)

I1. 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 (113)

J. 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 (29)

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

L. Exemption/Determination Requests

Total Project Count (17)

M. Final Reports

Total Project Count (1)

N. Public Comments

None.

O. Next Meeting

The next meeting will take place on Friday, June 2, 2023.

P. Adjournment

This meeting was adjourned at 11:40 am.