State of California—Health and Human Services Agency

Committee for the Protection of Human Subjects

CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

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

Monday, February 27, 2023
10:00 a.m.
Zoom:
CPHS February 27, 2023, Meeting
Meeting ID: 161 145 7129
Passcode: 901315
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CDII
John Ohanian, Director

MINUTES

Committee Members Present:
Juan Ruiz, MD, DrPH, Chair
Larry Dickey, MD, MPH, Vice Chair
Laura Lund, MA
John Schaeuble, PhD
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
Shannon E. Whaley, PHFE WIC
Catherine Yepez, PHFE WIC
Susan Sabatier, CDPH WIC
Christopher Anderson, PHFE WIC
Alice Kang, UCB
Amy Yee, USC
Joseph Wiemels

A. Welcome

B. New Projects – Full Committee Review Required

1. Project # 2023-025 (Lund)
   Title: 2023 California WIC Survey: Families with Children
   PI: Shannon Whaley, PhD
   Co-PI: Lorrene Ritchie, PhD, RD
   Board Decision: Approved Pending Conditions - Designee Review

This study is the proposed 2023 WIC (Women, Infants, and Children) follow-up study that aims to improve WIC services. The preferred method by participants is to be contacted by text messaging. Researchers have proposed to send text messages to participants to ask them to complete a survey after three attempts by telephone If they are unable to reach participants. Nobody on WIC can receive text messages by researchers unless they've already opted in to receive text messages.
Researchers have already addressed most requested changes. The main concern is related to texting potential participants for recruiting them into the study which may incur a cost to receive text messages. Researchers need to ensure these people will not incur this cost unless they've agreed to it. The most important issue is “choice” and “the inherent rights” of the participants. Title 45, part 46 of the Federal regulations which governs common rule and research projects, requires researchers to ensure that potential research subjects do not incur any costs associated with the research prior to obtaining informed consent. Title 45, part 46 of the Federal regulations also requires the IRB to ensure that informed consent occurs. The potential participants in the study have not been provided with the opportunity to give informed consent prior to receiving text messages. They have opted in to receive WIC’s standard text messaging. CPHS is required to ensure that no potential participant incurs a cost or is subject to a risk that she/he has not consented to. PI of the project is concerned that if they do not text participants, they might be causing harm through limiting the potential feedbacks that can be received from their participants. Researchers believe that the opt-in script that they have for the WIC program for texting can be applied to this study because this study is an extension of the WIC program. It was clarified by Ms. Lund that there is not anything reasonably in the script that would lead a woman to believe that she's going to be contacted for a research study. The current Opt-in script can easily lead people to believe that this is about services, benefits, farmers work, programs, and other WIC related concepts because it doesn't even mention the word “research.” Researchers send a mail pre-approach letter to all participants before they call them, and they are willing to modify that pre-approach letter in any way that may help. There is a cost associated with reprinting the pre-approach letters. It was suggested that an Opt-in option for text messaging for recruitment for this study would be included in the letter as a possible solution.

Motion: It was moved by Ms. Lund and seconded by Dr. Schaeuble to deferred approval one-year minimal risk, with stipulation that the pre-approach letter contain information and providing an Opt-in option for text messaging for recruitment for this study.

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

Oppose: None.

Abstain: None.

Absent: Dr. Hess, Dr. Bazzano.

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

C. Amendments – Full Committee Review Required

1. Project # 2018-118 (Dickey)
   Title: Gene and Environment Risk Factors for Childhood Acute Leukemia Among Hispanics and Non-Hispanic Whites
   PI: Joseph Wiemels, PhD
   Co-PI: Catherine Metayer, MD, PhD, Xiaomei Ma, PhD
   Board Decision: Withdrawal of the Amendment

This study was submitted as a new data-only project and researchers were suggested to submit it as an amendment to an existing project. Researchers plan to use data that has been derived from a previous project approved by CPHS to combine that information with information from other research at different places, to get a larger database that allow to draw more conclusions and to enhance their ability to look at ethnic subgroups. This project is not asking for any new data and specimens from the State, but researchers have been required by the California Biobank Program (CBP) to seek CPHS approval for reusing the data that is derived from the blood spot which is owned by the CBP. It was recommended that USC IRB to be overseeing that larger project, and CPHS only approves the use of that data from the existing project that has been already approved. The individual level data will only be analyzed at the University of Southern California (USC) and a summary of associations will be combined with other international sites. There is no need to reconcile the name of the project with the name of the funding. Researchers had been advised several years ago not to amend an existing study if the projects are completely distinct. The reason that researchers explained about all the other data sets is because there is a section in the application that asks about linkage of California data sets to other data sets. No identifiable information that has been obtained from the state will be revealed to any other researchers during this consortium. Researchers will not receive any identifiable information from other entities mentioned in the application and they are establishing a database that has no identifiable information in it, and they will not share any parts of it. A question was asked from committee members to clarify if they approve a project where researchers request to use unidentified data derived from a project, to be combined with the other unidentified data from other places to reach more reliable conclusions, and it was clarified that it might depend on what those unidentified data are. For example, if this is biobank data, some biobank data contains information that was originally derived from the birth records, and some biobank data does not. And, even if the data are unidentifiable, but they were originally derived from birth certificates, and this must go through Vital Statistics Advisory Committee (VSAC) for approval for any reuse of those data sets. Also, if it's a HIPAA-covered entity, it might have to go through approval as well. This study has been submitted as an amendment for project 2018-118 that suggests too extensive changes to the project. The researchers at University of California, Berkeley (UCB) can re-identify the California Childhood Leukemia Study (CCLS) patients, but researchers at USC cannot identify them. Researchers plan to combine individual level data to produce summary statistics while those individuals are not identifiable and only summary level data goes to various other institutions around the world that are involved in the sharing of data. It is important to submit a very specific protocol about the USC And UCB projects, and CPHS reviewers will spell out that they will only review the use of the data from the two previously approved projects by CPHS, and they will not review in any way the sharing of aggregated data that will take place with the various other institutions that have been mentioned in submitted materials.

Motion: It was moved by Dr. Dickey and seconded by Dr. Schaeuble to request researchers to withdraw amendment and to modify the new project protocol that they have submitted to specify that they are only requesting approval for the use of the de-identified data from the two previously approved CPHS projects to be aggregated with the similar data from other sources which are also de-identified data.

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

Oppose: None.

Abstain: None.

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

D. Public Comments

None.

O. Next Meeting

The next CPHS meeting is scheduled for Friday, April 7, 2023.

P. Adjournment

This meeting was adjourned at 11: 29 a.m.