

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 6, 2023
8:30 a.m.

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

Zoom:

[CPHS October 6, 2023,
Full Committee Meeting](#)

Meeting ID: 161 258 4046

Passcode: 509127

Location:

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

Remote Attendees

Philip Palacio, EdD, MS

Maria Dinis, PhD, MSW

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Alternate Member

Millard Murphy, JD

Lois Lowe, PhD

Meeting ID: 161 258 4046

Administrator

Lucila Martinez

MINUTES

Committee Members Present In Person:

Juan Ruiz, MD, DrPH, Chair

Larry Dickey, MD, MPH, Vice Chair

Carrie M. Kurtural, JD

Catherine Hess, PhD

Laura Lund, MA

John Schaeuble, PhD, MS

Committee Members Present Remotely:

Maria Dinis, PhD, MSW

Alicia Bazzano, MD, PhD

Philip Palacio, EdD, MS

CPHS Staff Present:

Lucila Martinez
Sussan Atifeh
Nicholas Zadrozna
Karima Muhammad

Center for Data Insights and Innovation

Sheryl McCarthy
Ruben Mejia

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

Christine Borger, Westat
Bibi Gollapudi, Westat
Chelsea Hart-Connor, CDPH/WIC
Sussan Sabatier, CDPH/WIC
Miriam Komaromy, Boston Medical Center
Lia Pak, RAND Corporation
Shannon Coulter, SDCOE
Jonathan Isler, CDE
Yu (Elaine) Chen, CDE
Jennifer Tsui, USC
Lia Fernald, UCB,
Rita Hamad, Harvard University
Wendi Gosliner, UCANR
Nicole Fernández-Viña, UCB
Zoe Varner, UCB
Catherine Lopez, WIC
Deinya Phenix, Vera Institute of Justice
Rebecca DiBennardo, Vera Institute of Justice
Alma Torres-Nguyen, MPH, Kaweath Health
Abigail Ramirez, CDPH
William Jardell, CDPH
Elizabeth Rhoades, CDPH

A. Welcome

Chair Updates

a) The Oath of Committee for the New Members.

- i) The Committee for the Protection of Human Subjects (CPHS) swore in five new members including Dr. Maria I. Ventura, Dr. Allen Azizian, Dr. Jonni Johnson, Ms. Carrie Kurtural, and Dr. Catherine Hess. Nick Picinich the Deputy Director of Policy and Operations in the Center for Data Insights and Innovation (CDII) administered the Oath to serve on CPHS.

b) Update on CPHS Support Letter Template

- i) Dr. Schaeuble revised the current CPHS Support Letter to a new version. He described the changes and mentioned, “ The first paragraph has been changed because the agency that releases the data must very clearly confirm that they will be able to release the requested data. Also, the second paragraph has been altered to provide a space for entering the name of variables that the agencies are not willing or cannot release.”

Motion: It was moved by Dr. Schaeuble and seconded by Dr. Dickey to start using the revised version of the CPHS Support Letter as the version recommended to the researchers.

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

Oppose: None.

Abstain: None.

Absent: None.

c) Update on CPHS Policies and Procedures

- i) Jennifer Schwartz, Chief Counsel of the Center for Data Insights & Innovation (CDII), informed the committee members that the secretary of the California Health and Human Services Agency (CalHHS) has approved revisions to the CPHS’ Policies and Procedures handbook. The updates in the CPHS Policy and Procedures went into effect immediately after the CalHHS Secretary approved them.

Major Updates of the (CPHS) Policies and Procedures handbook.

- Revising the list of departments under CalHHS.

The new version of the CPHS Policies and Procedures handbook provides the updated list of the departments under the California Health and Human Services Agency that are required to use the CPHS as their IRB under the Federal Wide Assurance. In the updated list of these departments, the name of the Office of Statewide Health Planning and Development (OSHPD) has been changed to the “Department of Health Care Access and Information (HCAI)” and a new department named as “Office of Youth and Community Restoration (OYCR)” has been added.

- Clarifying about the standards of review for different types of projects.

The revised version of the CPHS Policies and Procedures handbook makes it very clear what the standards of review are for different types of projects, whether it's a priority IRB review, review from the Civil Code, or a combined review. In this updated version there is an explanation for the different types of review standards and is attempting to clarify what are the standards under different types of IRB review.

- ii) Dr. Dickey mentioned that the Information privacy act entails heavily on data security and the CPHS needs a security expert to advise on data only projects. He further stated that these security issues can be very complex.
- iii) Jennifer Schwartz clarified that the agency's chief information security officer's position is now vacant, and the agency is currently looking into getting a resource that the board can reach out to for questions about data security.

d) Update on Bagley-Keene Act Amendment

- i) Current rules that apply until December 31, 2023:

SB 143 (Section 6) restores Cal. Gov. Code section 11133 through December 31, 2023, and is repealed as of December 31, 2023.

- Section 11133 allows state bodies to hold public meetings through teleconferencing and make the meetings accessible to the public telephonically or otherwise electronically.
- It suspends the requirements to have members physically present as a condition of participation in (or to meet a quorum for) public meetings. A state body is not required to have a physical location available for members of the public to attend the meeting if the public can attend telephonically/electronically.
- It further suspends the requirements that each location a member is participating from be identified in the notice and agenda of the meeting, that each location be accessible to the public, that agendas shall be posted at all locations, and that at least one member of the state body be physically present at a location specified in the notice of meeting.
- If a state body holds a meeting through teleconferencing pursuant to Section 11133, it must do the following:
 - Implement a procedure for receiving and swiftly resolving requests for accommodation consistent with the ADA and advertise this procedure each time notice is given regarding how the public can join a meeting.
 - Give advanced notice of the meeting time and how the public can join and offer public comment and post the agenda in advance.

- ii) Rules that apply from January 1, 2024- January 1, 2026, and will be repealed after January 1, 2026:

SB 544 allows for any state advisory body to hold a meeting by teleconference if the meeting complies with the below requirements contained in the amended Gov. Code Section 11123.5:

- The state body must provide notice to the public at least 24 hours before the meeting that identifies any members who are participating remotely (although there is no requirement to disclose these members' locations). The notice must include information on how the public can observe the meeting remotely and must also identify a primary physical meeting location for the public to attend in person if they wish. The primary physical meeting location must also be disclosed in the agenda, which is to be posted at least 10 days before the meeting.
- At least one staff member of the state body must be present at the primary physical meeting location, and the agenda must be posted at the location.
- Members who are participating remotely must be visible on camera during the open portion of the meeting unless it is technologically impracticable to do so such as when a member experiences a lack of reliable broadband or internet connectivity that would be remedied by joining without video. If a member does not appear on camera due to challenges with internet connectivity, the member shall announce the reason for their nonappearance on camera. The members who participate remotely must be listed in the minutes of the meeting.
- If a member of the state body attends the meeting by teleconference from a remote location, the member shall disclose whether any other individuals 18 years of age or older are present in the room at the remote location with the member, and the general nature of the member's relationship to the individual(s).
- All votes taken during the teleconferenced meeting shall be by rollcall and the state body shall publicly report any action taken and the vote or abstention on that action of each member present for the action.

iii) Rules that become operative on January 1, 2026:

SB 544 allows for any state advisory body to hold an open meeting by teleconference if the meeting complies with the requirements below in the amended Gov Code section 11123.5:

- A member of the state body who participates in the meeting from a remote location shall be listed in the minutes of the meeting. The state body shall provide notice to the public at least 24 hours before the meeting identifying any members who will participate remotely. Notice shall be posted to the website or emailed to any person who has requested notice of meetings of the state body.
- The location of a member of a state body participating remotely is not required to be disclosed in the public notice or email and need not be accessible to the public. The notice of the meeting shall identify the primary physical meeting location.
- A quorum of members shall be in attendance at the primary physical location, and members of the state body participating remotely shall not count towards

establishing a quorum. All decisions during a meeting by teleconference shall be by rollcall vote.

- Upon discovering a means of remote access has failed during a meeting, the state body shall end or adjourn the meeting and provide notice of the meeting's end on its website and by email to any person who has requested notice of meetings.

B. Administrator Updates

- a) Lucilla Martinez, the CPHS Acting Administrator introduced Nick Zadrozna who joined the CPHS team as a new Staff Services Analyst.
- b) The Committee was informed that Dr. Ruiz is retiring from state service at the end of the month October 2023, and the Chair seat is vacant.

C. Review and Approval of Meeting Minutes

August 4, 2023, meeting minutes

Motion: It was moved by Ms. Lund and seconded by Ms. Kurtural to approve the August 4, 2023, Meeting minutes.

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

Oppose: None.

Abstain: None.

Absent: None

D. Projects with Reported Adverse Events and/or Deviations

1. Project # 12-08-0644 (Dickey)
Title: Women, Infants, and Children Infant and Toddler Feeding Practices Study–2 (WIC ITFPS-2): Feeding My Baby – A National Women, Infants, and Children Study
PI: Christine Borger, PhD
Co-PI: Lorrene Ritchie, PhD, RD
Shannon Whaley, PhD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This adverse event report was discussed in the CPHS' August 4th, 2023, full board meeting and was voted to be reconsidered and calendared for the CPHS' October 6th, 2023, full board meeting. Also, researchers were required to send unencrypted copy of the technical reports to CPHS and provide a notification letter to inform the affected subjects about the breach.

A subcommittee consisting of Dr. Dickey, Dr. Schaeuble, and Ms. Kurtural reviewed the adverse event report before the October 6th, 2023, full board meeting for compliance with IPA (Information Practices Act).

Researchers attached the requested documents to the adverse event application including the unencrypted copies of the reports completed by Westat and CrowdStrike.

The originally attached notification letter was very complex and the subcommittee requested a simpler notification letter that provides a simple description of the incident at an eighth grade or lower reading level, a statement of what specific information the hacker accessed for their particular child, an apology for this breach and a non-technical description of what has been done in response to this incident, an offer to delete the child's information and/or opt out from the study if the parents desire to do so, a notification of who the parents may contact at Westat for further information, and a notification that the parents can contact CPHS for information about the rights of their child as a research subject.

Researchers revised the notification letter. The revised notification letter covers most of the points requested by the subcommittee and is at a 7th grade reading level.

Researchers have not yet addressed the request for including an offer to the affected subjects to delete the child's information because they had explained in the original consent form that if parents decided to withdraw their child from study, the data would remain within the study. Committee members clarified "The families signed the original consent form under typical circumstances of the study and since this adverse event is about breaching their data, they should be provided with the options "to stay", "to leave the study and let their data remains", and "to leave the study and request their data being deleted from the study."

The option of "offering parents to delete the child's information and/or opt out from the study if they desire" should be added as an additional bullet point to the notification letter.

Researchers should provide clear contact information about the person who the affected subjects should contact.

Researchers should add an additional bullet point in the notification letter to provide clear contact information for connecting the affected subjects to Terry Aranda who is the Westat Study Liaison, and let the affected subjects know that they can contact Terry Aranda if they choose to remove the child's data from the study and/or remove the child from study.

The last two pages included in the notification letter regarding the steps that affected subjects

can take to protect their personal information, is a standard legal template that researchers are required to include in the notification letter.

Motion: It was moved by Dr. Dickey and seconded by Ms. Kurtural to accept the adverse event as resolved pending the following specified revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Dickey.

1. Revise the notification to give the parents the options of “their child remains in the study”, and or “having child’s data deleted from the study.

2. Make it explicit in the notification letter who the affected subjects need to notify if they want to leave the study.

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis.

Total=7

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

2. Project # 2022-085 (Dickey)
Title: Improving Access and Treatment for Co-occurring Opioid Use Disorders and Mental Illness
PI: Katherine Watkins, MD
Co-PI: Miriam Komaromy, MD
Board Decision: Approved

Discussion:

Researchers explained about the reported adverse event, and said, A member of the study team called a participant for a follow-up survey as part of the routine follow-up surveys with participants in the CLARO (Collaboration Leading to Addiction treatment and Recovery from Other stresses) study. The way that the patient answered questions about suicidality during the interview, triggered concerns that the patient was experiencing severe suicidality. The interviewer attempted to establish a transfer to a suicide hotline as specified in the protocol, but the study subject refused the hotline transfer and instead wanted to continue with the research follow up interview. The interviewer assessed that the patient had an alert and clear demeanor. The subject revealed that she/he was in the hospital prior to the interview which means the follow up interview was conducted at the time of the subject's hospitalization. The interviewer agreed to continue with the survey and asked the participant about the reason of hospitalization, and the participant declined to answer this question. There was no indication that the hospitalization was related to the subject's participation in the CLARO study. Since the subject was already hospitalized and was under medical care, the interviewer did not take further action after completing the survey. At the end of the interview, the interviewer reported the event to the RAND IRB. The interviewer later followed up with the study subject to check in on the subject and to get more information about the reason of hospitalization, and how the study team can best support the subject and at that time, the study subject revealed that the hospitalization had been due to the study subject experiencing hallucinations and heart problem caused by ingesting cannabis via vaping. Therefore, the study team determined that the hospitalization was unrelated to the study. The RAND IRB determined that the event was handled appropriately since the participants has been already in the hospital and was offered linkage to a suicide hotline and closed the event. The determination letter released by RAND IRB was provided to CPHS."

Motion: It was moved by Dr. Dickey and seconded by Ms. Lund to accept this event as resolved.

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis.

Total=7

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

E. New Projects – Full Committee Review Required

1. Project # 2023-171 (Palacio)
Title: Community Health Workers, Healthy Homes, and Healthy Families
PI: Alma Torres-Nguyen, MPH
Co-PI: Abigail Ramirez, MS
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This study aims to explore the feasibility and acceptability of a pilot weatherization program in Tulare County while also assessing the effects on housing quality, energy costs, and health. In addition to improving health outcomes for low-income households, weatherization and energy efficiency measures can help reduce healthcare utilization, emergency department visits, and hospitalizations. Patients will be selected from Kaweah's Enhanced Care Management (ECM) Program, a Medi-Cal benefit program addressing the highest-need enrollees through intensive coordination of health and health-related services. Kaweah Community Health Workers (CHWs) will administer a housing and health assessment survey to understand each patient's need and eligibility for weatherization and energy efficiency services. The two data sources that will be used to establish baseline health status among the study population include Kaweah electronic health records (EHR) and a study-specific intake survey. Eligible patients referred to weatherization will be provided weatherization services free of charge and receive a follow-up post-intervention survey after one year to assess the effect on energy costs, health, and quality of life.

CHWs have all been trained utilizing the weatherization pilot project training manual developed in conjunction with Kaweah Health, CDPH, AEA, Proteus, Inc., and University of California, Davis and weatherization providers utilize locally based and professionally trained weatherization crews to create a comprehensive analysis of the home. Patients will have access to the CHWs in case they have any questions, and there will be multiple opportunities that patients can ask their questions.

All participating Kaweah Staff have been extensively trained in the voluntary nature of pilot participation and the weatherization referral process. CDPH staff engaged in this project will not have access to PID. Weatherization providers, Proteus service staff, and installers will not have access to PID.

The focus for selecting subjects is low-income communities. All ECM patients will be eligible for the pilot and rolling enrollment will be used until at least 25 patients have completed a study-specific intake survey administered by Community Health Workers (CHWs) and agreed to be referred to weatherization services. The study is supported by the Center for Disease Control and Prevention (CDC), and CDC evaluation team recommended the small sample size for this study and that is why the researchers called this group as "comparison group." Ten ECM patients who were not part of the initial outreach and ultimately not able to participate in the weatherization program will be randomly selected to serve as the comparison group. Both pilot and comparison group members' EHRs will be used to assess changes in health. This will provide some additional qualitative understanding and will help to understand how people experience weatherization assistance. Community Health Workers (CHWs) were provided with an overview of weatherization policies that protect tenants and best practices for communicating with landlords on behalf of tenants. These resources will be provided to study participants and all CHWs and Care Coordinators participating in the study were provided an in-depth training on best practices for how to obtain landlord and tenant participation in a weatherization program. Kaweah Health, CDPH, and Proteus, Inc. developed an educational brochure to inform CHWs and patients about the program objectives and weatherization benefits for renters and landlords. The brochure will be provided in English and Spanish because most of the participants are

monolingual Spanish speakers. Participants are required to receive Health Insurance Portability and Accountability Act (HIPAA) waiver that specifies what and how data will be used. For research purposes, there must be HIPAA authorization form specific to the study that specifies for the potential participants what specific information they are authorizing the researchers to access from their medical records for conducting the study.

The only information included in the Cover Sheet is the participants' names, addresses, and other contact information and the Cover Sheet will not have any information regarding participants' medical records, health condition, etc. Committee members requested to include a copy of the Cover Sheet in the application in CPHS' on-line system, IRBManager.

In this research study, if the patient is not interested in being referred for weatherization services, the CHW will capture reasons for not participating in the intake survey form, and committee members clarified that in a research study no information can be collected from subjects outside of the informed consent process. The participants should have gone through an informed consent so the researchers can ask questions about the reasons for not participating in the weatherization program, otherwise researchers cannot collect information without informed consent form.

Researchers said, "All participants should sign the informed consent form, we can incorporate some additional language that we will be collecting some data from them and even before the intake survey, which is where this information will be stored, the patients must first sign the consent form before we can use any of their information including their reasons for not participating.

Researchers will clarify in the protocol application that only patients' contact information will be shared out and no medical record will be shared.

Committee members clarified that the researchers cannot receive permission from tenants for doing anything with the property without contacting the landlords and having their permission. Researchers will clarify in the application that the homeowners essentially should approve any services and all landlords will be provided with complete explanation about the project and all possible measures that might happen in their homes. Also, researchers will get confirmation first from the landlords and sign an agreement with the landlords, before they move with weatherization services.

Researchers should describe in the protocol how all agreements with landlords will be enforced and attach any related documents to the application.

Researchers are recommended to receive consent from each adult prior to obtaining information about the adults in household because the study is not an individual intervention, it is a household level intervention, and they cannot ask for medical information about other adults in the household who have not consented to have that information shared.

Script is recommended to develop when talking with adults/children.

The research will look at patient clinic and emergency department visits at baseline and comparing health outcomes post intervention. Medical records to be used needs to be specified in protocol and consent form.

In the protocol, it has been mentioned, "The cover sheet will contain birth date" which is beyond contact information and is a HIPAA identifier, and this should be addressed by researchers in the protocol.

There should be an explanation in the consent form about the kinds of questions on the survey because it sounds like all questions would be related to eligibility for participating in the weatherization program but actually there are some questions about income and health conditions, and it needs to be explained in the consent form.

The consent form talks about asking for release of medical history but does not say anything about what kind of medical data is requested.

Motion: It was moved by Dr. Palacio and seconded by Ms. Lund 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. Palacio and Ms. Lund.

- 1. Clarify in the protocol that HIPAA authorization specific for the study needs to be collected from main participants and medical consent form should be received from all adults in household and when talking to children, identification of legally responsible adult needs to be in place.**
- 2. Include a copy of the cover sheet in the protocol.**
- 3. Make clear that no medical information will be shared with Proteus.**
- 4. Include in the protocol, the process of contacting landlords for consent to alter property.**
- 5. Describe in the protocol how all agreements with landlords will be enforced.**
- 6. Specify what kind of medical records will be used in protocol and consent form.**
- 7. Revise the consent form to reflect the changes requested in the meeting.**

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis, and Dr. Bazzano.

Total=6

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

2. Project # 2023-059 (Dickey)
Title: Ending Girls Incarceration Action Network
PI: Deinya Phenix
Co-PI: Rebecca DiBennardo, PhD, MA, MPA
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This is a data-only project but will be conducted by using very sensitive data.

Researchers explained about the project and said, "Vera Institute and California's Office of Youth and Community Restoration (OYCR) are partnering to reduce and eliminate girls' incarceration in California. The End Girls' Incarceration in California (EGI-CA) Action Network aims to support California counties in implementing court-based policy changes and community-based programming that will help keep young people out of court and incarceration, address race and gender disparities in the youth legal system and promote well-being of girls and gender expansive youth in the community. Through the EGI-CA Action Network, four selected counties will receive technical assistance, connections to national and local experts, resources on national best practices and research, and opportunities to learn from and support their peers in California and nationally. OYCR is partially funding this project and is not the source of the requested data. Vera Institute will collect and analyze data on referrals to probation, juvenile court petitions, detention admissions, and supervision. The counties selected to participate in the project include Imperial, Los Angeles (LA), Sacramento, and San Diego County. The data is and will continue to be collected by these counties and this project is a secondary data analysis. Because it is an administrative data set, a waiver of the written consent form is also requested. Individual data Memorandum of Understanding (MOUs) are being executed with each participating county, and these will be signed before any data is transferred to Vera. Project's data request as well as data MOUs highlight that all data must be deidentified before transferred to Vera and that county should assign random identifiers that are unique within and across entities, independent of any information related to those entities, and have no basic logic that could be encrypted. No data will be shared except as bound by the requirements imposed by the counties for the secure handling the criminal justice data and those imposed by Vera Secure data sharing protocols. The data will be used to provide suggestions for targeted court-based policy reforms that each county can reduce racial and gender disparities in youth incarceration to identify areas where there is an unequal distribution of incarceration. Vera staff will manage data on the secure server, clean the data, conduct analyses, and produce reports which will be shared and discussed with the leadership of the 4 participating counties. Additional data analysis will be performed on the request as determined over the course of 4 routine meetings, and a final report will be produced for evaluation of policy/practice in the 4 participating counties individually and as a whole."

Researchers plan to put together some data bases after the initial pilot for this project, but at this point they don't have any plan to share the data sets with OYCR and it is just between Vera and the counties.

Researchers were recommended to introduce language into their instruction for the counties about how to create unique identifiers that cannot be de-coded.

In the protocol, the explanation on how to protect against small cell sizes is inadequate, especially with minors who have the right to seal records. Researchers should ensure the de-identification method that they are utilizing is solid. A statistical de-identification method can be shared with Vera.

Researchers will update the application to include the CalHHS Data De-identification Guidelines (DDG).

Researchers should clearly explain in the application what identifiers will be removed, and what method will be used for the de-identification of the data. Also, the actual years of the requested

data should be included in the application.

Under the "HIPAA IDENTIFIERS" section of the application, researchers indicated "No Identifiable material" would be requested which is contradictory with other sections of the application and should be deleted.

Motion: It was moved by Dr. Dickey and seconded by Ms. Lund 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. Dickey.

1. Designate in the protocol that you will be in compliance with CalHHS Data De-Identification Guidelines (DDG).

2. Delete the section under HIPAA identifiers that says, "no identifiable data will be retained."

3. Include actual years of requested data in the protocol.

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis, and Dr. Bazzano.

Total=6

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

3. Project # 2023-117 (Lund)
Title: Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study
PI: Jennifer Tsui, PhD, MPH
Co-PI: Chanita Hughes Halbert, PhD
Lihua Liu, PhD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

Researchers explained about the study and said, “The goal of this study which is funded by the National Institute of Minority Health and Health Disparities, is to leverage two population-based Surveillance, Epidemiology, and End Results (SEER) Program registries including New Jersey State Cancer Registry and Los Angeles Cancer Surveillance Program (LACSP), to prospectively examine the impact of micro-, mezzo-, and macro-level factors on receipt of guideline concordant treatment for and survival from cervical cancer. Staff from LACSP will initiate patient contact by sending eligible cases an introductory letter requesting their participation in the study, Informed Consent Form, baseline survey, and some other recruitment materials as well as instructions for completing the survey via other modes (i.e., online via REDCap link or by phone with the study staff). Registry staff will send a follow up survey to all enrolled participants approximately 12 months after completion of the baseline survey. The follow up survey is not ready yet, and researchers will submit an amendment for this project to request approval for the follow up survey when it is ready.”

CPHS members requested some changes to the procedures of the study because in the original study the risk of collecting data from participant in the absence of an informed consent form was high for the participants who were to be surveyed via phone.

It was clarified by the CPHS members that for the phone survey, researchers should have received the completed mailed consent form or online consent form from the participants prior to any phone surveys and no telephone survey should be initiated prior to receiving the consent form.

Researchers were recommended to provide the revised materials to inform the study subjects that they need to mail back the completed written consent form or submit the completed online consent form before being contacted for the phone survey.

The first sentence in the section six of the consent form indicates “There are no known major risks associated with the proposed research.” Dr. Schaeuble suggested to remove the first sentence in the section six of the consent form. In the HIPAA form, paragraphs that are not relevant to study should be identified as non-applicable.

Motion: It was moved by Ms. Lund and seconded by Dr. Hess 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. John Schaeuble.

1. **Revise the protocol to remove descriptions of the follow up survey to add to the consent form permission to recontact in twelve months for the follow up survey.**
2. **Provide the final versions of the English questionnaires as the participants would see them.**
3. **Provide the revised materials to let people who are going to participate by telephone know that they need to return the consent form or return the online version of the consent form to allow the researchers to call them for obtaining the baseline questionnaire over the phone.**
4. **Modify the recruitment scripts so that no personally identifying information (PII) or protected private information will be disclosed.**
5. **Modify the recruitment scripts so that no telephone survey will be initiated through the recruitment scripts.**
6. **Remove the first sentence in the section six of the consent form.**
7. **Provide an option as “N/A” in the HIPAA form for paragraphs that are not relevant to the study so they could be identified as non-applicable.**

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis.

Total=7

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

4. Project # 2023-161 (Hess)
Title: TAKE UP III: Targeting Access and Knowledge of the Earned Income Tax Credit (EITC) Utilization and Policies
PI: Lia Fernald, PhD
Co-PI: Rita Hamad, MD, PhD
Wendi Gosliner, DrPH, RD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

Researchers explained about this project and said, “The Earned Income Tax Credit (EITC) is the largest US poverty alleviation program, providing up to \$6,600 for working families. California’s supplemental EITC (CalEITC) can additionally provide over \$3,000. Yet 20-33% of eligible individuals do not receive federal or state EITC benefits. The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) reaches families when women are pregnant, and their children’s brains are undergoing rapid development –a time during which poverty is particularly detrimental, and the EITC is especially impactful. Our recent study found that about 25% of California WIC families that were eligible for EITC benefits did not get them in 2020. In recent years the State of California and CDPH, in particular, have been encouraging its residents to file taxes and claim tax credits. WIC plans to test several interventions to encourage people to file taxes and claim the EITC. For this project, researchers from the University of California and Harvard University are partnering with California WIC to help them evaluate these interventions to determine their impact on EITC uptake.”

Dr. Hess mentioned, “This project has the potential to be greater than minimal risk because the EITC tax returns have significant higher rate of audit than standard tax returns and although relatively rare for any EITC participants to be audited, the financial and psychological consequences of an EITC audit can be a significant burden to the tax filer. If a woman who participates in this program, who has not previously filed any EITC return, is encouraged to do so, and then incurs an audit, the consequences could be significant burden of documentation that goes along the EITC audit, and that can also incur the individual having to repay tax refunds with penalties. Researchers were asked to include all of this information, information about additional support, and information about the EITC in the consent form. There are still some concerns about communicating risk to the participants and the importance of having a tax preparer involved and not attempting to do it on their own. Tax preparers have legal due diligence requirements for preparing tax returns for EITC returns and they have financial liability if there is an audit or a rejection of an EITC return. Tax preparers have to ensure that these individuals have the right documentation that greatly minimizes the risk of an audit and a bad outcome of an audit. Researchers have included some risk language in the informed consent about providing women with a tax preparer. With Arm three, researchers are providing \$100 incentive, which could potentially be too high. Another concern with Arm three is that it does not come with any information about the importance of working with the tax preparer, a list of local tax preparers, and the risks of filing an EITC return without a tax preparer, which could encourage women to file the EITC return without the proper support or documentation, thereby increasing their risk of an audit. Arm one should also have been provided with information about both, the tax preparers and the importance of using the free tax preparer if they’re going to file an EITC return.”

Committee members proposed, “Every participant in the study, regardless of which Arm they are in, should be connected personally to a free licensed tax preparer. In Arm three, the incentive will now be linked to providing evidence that the tax return has been prepared by a licensed tax preparer (instead of getting \$100 simply by showing evidence they filed taxes). Researchers should add some additional changes to the consent form around the implications of an audit and to inform participants that there is a mitigation plan in place and that they will

have support. The risks should be adequately described in the consent form so the participants will be aware of the importance of using a tax preparer and that using a tax preparer mitigates a lot of these risks and provides them support to make sure that they complete the EITC correctly, thereby reducing their risk, and then if they do have an audit, they will be provided real support. The participants should be aware that their tax preparer has to answer to the IRS if there is an audit. Also, the protocol should be revised to clarify that the participants only can consent at the time of interview.”

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

- 1. All participants in each protocol’s arm will be provided with a list of names of free licensed tax preparers in their local area based on their zip code.**
- 2. In arm three the incentive will be given to the participants when they show evidence of a tax return that has been prepared by a licensed tax preparer.**
- 3. The consent will take place at the time of interview and not in advance.**
- 4. The language in consent form should better communicate what an audit would entail and its associated risks.**

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis.

Total=7

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

5. Project # 2023-131 (Bazzano)
Title: Evaluating California's Reading Instruction and Intervention Initiative
PI: Shannon Coulter, PhD
Co-PI:
Board Decision: Approved

Discussion:

This project was discussed in the August 4, 2023, meeting and was voted to be tabled for an additional dialogue to the CPHS' October 6, 2023, meeting. The project is a professional learning intervention and aims to evaluate the California's Reading Instruction and Intervention (RII) grant program which is funded by the California Department of Education (CDE). The focus of the program is building capacity of teachers to teach reading with the goal of having all children read by the end of third grade and to determine methods to increase student literacy. The program administrators of the RII grant program will capture additional data from the participants, by surveying and interviewing them. The administrative data from CDE will be linked to educators' responses to the survey items. Results from the surveys will allow evaluators to determine changes in levels of capacity to provide literacy instruction, These changes will be linked to teachers and to student achievement records from the administrative data. To link the data, researchers must identify which teachers participated in the service and who those teachers' students are. Once researchers link teachers and students to the service, they remove all the personally identifiable information and report out at the service level. Other data including student level data will be aggregated and reported at this level. No individual results will be reported. No teachers will be compared to other teachers, or schools to other schools. Students' and teachers' names will not be collected and instead researchers collect unique identifiers for both students and teachers. All Personal Identifiable Data (PID) will be "hashed" and encrypted once it is loaded into a database. Any teacher opting out of the evaluation can participate in the professional development workshops. Survey responses is a separate set of data which will not be linked to student data. Teachers are aware that student achievement data is used. The data collected will not be used to evaluate teacher performance or school performance.

Motion: It was moved by Dr. Bazzano and seconded by Dr. Hess to approve the project, minimal risk, with a continuing review in one year.

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

Oppose: None.

Abstain: None.

Absent: Dr. Dinis.

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

F. Full Board Continuing Review.

None.

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 (1)

- 1. Project # 2023-131 (Bazzano)
 Title: Evaluating California’s Reading Instruction and Intervention Initiative
 PI: Shannon Coulter, PhD
 Co-PI:
 Board Decision: Approved

Total=7 In Favor-7, Opposed-0, Abstained- 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 (21)

J. 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 (27)

J1. 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 (114)

K. 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 (40)

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

None.

M Exemption/Not Research Approvals

Total Project Count (18)

N. Final Reports

Total Project Count (12)

O. Public Comments

None.

P. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, December 1, 2023.

Q. Adjournment

This meeting was adjourned at 1:36 PM.