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
Darci Delgado, PsyD. (Interim Chair)
Larry Dickey, MD, MPH, Vice Chair
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Catherine Hess, PhD
Carrie Kurtural, JD
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Allen Azizian, PhD
Maria Ventura, PhD
Jonni Johnson, PhD

Remote Attendees
Allen Azizian, PhD
Maria Dinis, PhD, MSW
Philip Palacio, EdD, MS
Larry Dickey, MD, MPH
Juan Ruiz, MD, DrPh, MPH

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

CPHS Administrator
Agnieszka Rykaczewska

Friday, February 2, 2024
8:30 a.m.

Zoom:
CPHS February 2, 2024, Full Committee Meeting

Meeting ID: 160 440 8440
Passcode: 940456

Location:
1215 O Street,
Allenby Building,
11th Floor,
Meeting Room 1181,
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Meeting ID: 160 440 8440

MINUTES

CDII
John Ohanian, Director
Nick Picinich, Deputy Director
Agnieszka Rykaczewska, Deputy Director

Committee Members Present In Person:
Darci Delgado, PsyD.
Catherine Hess, PhD
Carrie Kurtural, JD
Laura Lund, MA
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD

Committee Members Present Remotely:
Allen Azizian, PhD
Maria Dinis, PhD, MSW
Philip Palacio, EdD, MS
Larry Dickey, MD, MPH
Juan Ruiz, MD, DrPh, MPH

CPHS Staff Present:
Agnieszka Rykaczewska
Lucila Martinez
Sussan Atifeh

CPHS Staff Present Remotely:
Nicholas Zadrozna

Center for Data Insights and Innovation
Ruben Mejia
Bernard Gross

Also, Present (All via ZoomGov) Principal Investigators and Associate Investigators
Ninez Ponce, University of California, Los Angeles
Todd Hughes, University of California, Los Angeles
Royce Park, University of California, Los Angeles
Andrew Juhnke, University of California, Los Angeles
Adana Llanos Wilson, Columbia University
Jennifer Tsui, Keck School of Medicine of USC
Lihua Liu, Keck School of Medicine of USC
Toben Mintz, University of Southern California
Cynthia Burnson, Evident Change
Maria Lopez Gurrola, Evident Change
Joe Zickafoose, Mathematica Inc.
Holly Matulewicz, Mathmatic Inc.
Elisa Gonzalez, Mathmatic Inc.
Shannon Whaley, Public Health Foundation Enterprise WIC
Lia Fernald, University of California, Berkley
Rita Hamad, Harvard University
Wendi Gosliner, UCANR
Nicole Fernandez-Vina, University of California, Berkley
Zoe Varner, University of California, Berkley
Susan Sabatier, California Department of Public Health, WIC

A. Welcome and Chair Updates

a) The collaborative Institutional training Initiative (CITI) training for the Committee Members.

I) Dr. Delgado informs the committee members that CPHS administrative is in the process of arranging CITI training for all members. Members who have recently completed the CITI training are encouraged to forward their certificates to the CPHS administrative staff.

b) Common Rule/ IPA (Information Practices Act) Update.

I) A meeting has been scheduled for March 1st, 2024, at 8:30 am to discuss the Common Rule/ IPA update. Committee members willing to provide background information should submit it to the CPHS administrative staff by February 16, 2024.

c) CPHS Administrative update

I) Agnieszka Rykaczewska is transitioning into the role of the new CPHS administrator. Lucila Martinez will mentor Agnieszka Rykaczewska during this transition period over the next couple of months. Dr. Delgado recommended that any communication to the CPHS administrator be directed to both Agnieszka Rykaczewska and Lucila Martinez during this transition phase.

B. Administrator Updates

a) Update on Research Data Request Form (Common App)

Agnieszka Rykaczewska presented updates on the researcher data request form. The objective of this form is to include: 1) streamlining the application process for California Health and Human Services (CalHHS) data requests, 2) ensuring uniformity by developing specific criterion to reviewers, and 3) providing a guide for researchers. This guide will also help navigate the researchers through the process to request CalHHS data, while ensuring we are still having all the appropriate reviews and approvals in place.
The two members that have volunteered their time to provide expertise guidance to the research request team are Dr. Schaeuble and Dr. Bazzano.

The six (6) core components for the form include:

- Common Questions: These questions combined with required IRB inquiries with commonly asked questions across CPHS and departments. An example question is: "Data storage location: where is the primary location where research is being conducted?"
- Security & Safeguards: This section is being updated by the CalHHS Chief Information Security Officer to modernize security measures. An example question could be: "How will your project ensure the confidentiality and security of sensitive research data?"
- CPHS Section: A dedicated section for CPHS administrative staff to fill out administrative questions. For instance, determining whether a research project need expedited or full board committee review.
- Human Subjects: This section focuses on questions related to research involving human subjects. An example question is: "Offer a detailed account of the plans and measures in place to protect the rights and welfare of the subjects."
- Department Addendums: These add department-specific questions necessary for departments to provide letters of support. For example: "Specify below how the proposed research project will directly benefit the DHCS administration of the Medi-Cal program."
- Data Use Agreements (DUAs): The legal team is consolidating duplicative portions of each department DUA into a single DUA, with appendices added based on data requested.

Implementation Phases:

- Phase 1: Completing the initial iteration of the form for integration into IRBManager by April 2024.
- Phase 2: Piloting the form with five (5) departments in a development environment by Summer 2024.
- Phase 3: Adding additional departments and reassessing common questions and department addendums.
- Phase 4: Implementing selected platforms and automated workflows across CalHHS and CPHS, targeted for completion by the end of 2025.

The Research Data Request Team plans to present the final version of the form at the April 5th committee meeting, marking the end of Phase 1.

C. Review and Approval of Meeting Minutes

December 1, 2023, meeting minutes.

Motion: Dr. Schaeuble moved, and Dr. Hess seconded the motion to approve the Dec 1, 2023, meeting minutes.

Approve: Dr. Ruiz, Dr. Dickey, Dr. Dinis, Ms. Kurtural, Ms. Lund, Dr. Dinis, Dr. Azizian, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: Mr. Palacio.
Absent: Dr. Bazzano.

D. Projects with Reported Adverse Events and/or Deviations

1. Project # 16-11-2767 (Dickey)
   Title: Sample Collection for Biomonitoring Method Development and Refinement
   PI: Nerissa Wu, PhD
   Co-PI: Jianwen She, PhD
   Board Decision: Approved

Discussion:

Dr. Dickey presented a report classifying an incident as an "unanticipated problem," emphasizing that it did not result in harm to the study participants. According to the report, in August 2023, researchers provided data on levels of benzylalkyldimethyl ammonium compounds (BACs) to 18 participants, erroneously stating the measurements were in micrograms instead of nanograms. To rectify this error, researchers intend to issue a correction letter along with revised results. The letter was attached with tracked changes. .

Dr. Dickey proposed a protocol for future incidents, suggesting that the primary project reviewer, possessing the deepest understanding of the project among team members, collaborate with CPHS Chairs to determine whether the report warrants discussion at full board meetings. He also committed to drafting language for inclusion in the CPHS Policy and Procedures, clarifying the handling of adverse events and unanticipated problems. Dr. Dickey will work with Lucila Martinez and Agnieszka Rykaczewska to present the proposed language at the April full board meeting for voting by members.

Ms. Lund stressed the importance of distinguishing between an "adverse event," potentially harming participants, and an "unanticipated problem," which poses no risk. She asserted that if an incident is deemed an adverse event, it must be addressed in the full board meeting.

Motion: It was moved by Dr. Dickey and seconded by Ms. Lund to accept researchers' report of this event, along with the corrective actions that researchers have implemented.

Approve: Dr. Dickey, Ms. Lund, Dr. Ruiz, Dr. Dinis, Ms. Kurtural, Dr. Palacio, Dr. Schaeuble, Dr. Azizian, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano.

Total=11 In Favor-11, Opposed-0, Abstained-0

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

Discussion:
Researchers initially submitted an adverse event report for the project on 1/27/2023 to inform the Committee for the Protection of Human Subjects (CPHS) that the California Health Interview Survey (CHIS) study staff discovered non-compliance issues with the laptops used by the California Department of Public Health (CDPH) to access confidential CHIS data files. Despite the CDPH Virtual Desktop Infrastructure (VDI) system meeting the 2018 agreements with CHIS, CDPH, and CPHS, the laptops lacked critical protections such as restrictions on connecting to other applications or websites and measures to prevent screen sharing or recording during access to CHIS data. However, no evidence of data breach or inappropriate data access through the non-compliant aspects of the CDPH setup was found. The current adverse event report serves as a follow-up to provide final resolutions to the issues identified in the original report. Upon discovery of the issues, CDPH suspended access to the CHIS data while exploring alternative solutions. They shut down all the VDIs and collaborated closely with CHIS staff to resolve the issue. The corrective actions taken are outlined below:
CHIS conducted two webinars in the spring of 2023 for all funders, including CDPH, to provide an overview of CHIS compliance requirements, demonstrate examples of the main technical options that comply with CHIS requirements, and provide a list of standards that need to be met.
After the webinars, CHIS requested all funders to submit documentation about their current configurations. A checklist was provided for each funder to confirm compliance along with their technical documentation. CHIS staff reviewed the documentation provided by each funder and confirmed that all funders met storage and access requirements.
CHIS updated the funder Data Custodian Agreement (DCA) and Data User Agreement (DUA) that CHIS funders must sign, starting with CHIS 2022 data files in the fall of 2023, to include more detailed and specific compliance agreement items.
CHIS collaborated with CDPH staff to explore potential options for a compliant setup that would allow CDPH access to confidential CHIS data files. They decided to provide CHIS-controlled remote access laptops to CDPH staff for accessing CHIS data files. These laptops meet all CHIS data security requirements and guidelines and only allow connection to the CHIS data server remotely by authorized CDPH staff. No other functionality is possible via the laptops. Any data analysis results or output can only be removed from the server following the same procedures as internal CHIS operations, involving data disclosure review and approval by approved CHIS staff.

Motion: It was moved by Dr. Dickey and seconded by Ms. Lund to accept researchers' report of this adverse event, along with the corrective actions that researchers have implemented to prevent such occurrences in the future.

Approve: Dr. Dickey, Ms. Lund, Dr. Ruiz, Dr. Dinis, Ms. Kurtural, Dr. Palacio, Dr. Schaeuble, Dr. Azizian, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano.

Total=11 In Favor-11, Opposed-0, Abstained-0

E. New Projects – Full Committee Review Required

1. Project # 2024-011 (Kurtural)
   Title: The Structured Decision Making® (SDM) Reunification Assessment Tool: Perceptions of Case Planning and Family Engagement Practices
   PI: Cynthia Burnson, PhD
   Co-PI:
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:
This project focuses on evaluating the use of the Structural Decision Making (SDM) reunification assessment in making reunification decisions for children who have been removed from their home and what strategies they use to engage children and families who are receiving Family Reunification (FR) services within San Diego County's Child and Family Well-Being Department (CFWB).
Researchers plan to explore the use of the reunification assessment and its impact on permanency and placement stability for children and families in FR services in San Diego County. They also aim to evaluate the use of the reunification assessment in case planning and family engagement practices for Protective Social Workers (PSWs) working with children and families receiving FR services in San Diego County.
The goal of the study is to conduct interviews, focus groups, surveys, and case reviews to get a deeper understanding of the implementation of the reunification assessment as well as family engagement strategies that are taking place in San Diego County.
Summary by PI: Researchers are looking to understand the use of the Structural Decision Making (SDM) reunification assessment in San Diego County and getting the information from the staff who are managing the cases of children in home care, who are going towards reunification to help identify what the barriers are to using that tool as well as exploring strategies for family engagement.
Researchers have already addressed some of the reviewer's comments. They clarified in the application that the study would involve Protective Social Workers (PSWs) who are child welfare staff, and their role involves case management for families with a child in foster care and facilitating reunification. They also clarified in the application and recruitment materials that the subjects' participation would take place withing their regular working hours with no expectation for involvement outside of their work schedule.
The expectation during the focus groups would be talking about strategies and engagement at an aggregate level and patterns, and not about specific families and researchers will clarify about it in the recruitment materials and in the application to inform the subjects not to bring up identifiable information about families that they are speaking about.
Researchers will be looking at an aggregate thematic analysis, particularly because the focus of the study is much more about staff implementation and their reasons for using or not using a particular assessment. Researchers clarify in the application that they will not be publishing specific family circumstances.
The committee clarified that a request for HIPAA waiver is not required because the California Department of Social Services (CDSS) is not a covered entity and also researchers are not requesting direct information from the Social workers and the direct information will be acquired from the files.
The application is missing the actual focus group and interview questions. The PI is requesting flexibility for the focus group questions. The committee requested more structured questions around the focus groups with the caveat of deviating to some degree and it was clarified that the instruments of data collection is needed in addition to the domains that will be used. The committee mentioned, developing survey and interview questions after completing the focus

group is common and researchers should provide the actual interview and survey questions via submitting an amendment that should be discussed in a full board meeting after completing the focus group and gathering the information needed through focus group. The protocol is designed in a way that the committee can approve the focus group activity at first and then an amendment can be submitted to request approval for the interview questions.
Data protection will be adequate for both participants and also the families whose data will be used. Researchers plan to upload the information on a secure, HIPAA-compliant system, even though the data they're collecting isn't covered by HIPAA and recordings will be deleted after interviews are transcribed and quality checked, and researchers will maintain contact and consent data in electronic form in the Evident Change server for up to five years. then after five years those surveys will be deleted.
Researchers have clarified for the participants that they would not be sharing any information back to the agency and their work performance will not be reflected in this study.
Researchers will ensure that the used software will not retain data and they clarified that they would not use computerized programs and commercialized programs that retain the data for doing the analysis and they plan to upload the data in-house and process the data within their own organization using their own system.

Motion: It was moved by Ms. Kurtural 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. Kurtural.
1. Specify in the application, in the brochure, in the informed consent that social workers are not to disclose any identifiable information about the families.
2. PI is to confirm in the project application that they will submit an amendment for this project to request approval for the final interview and survey questions by including copies of the final interview and survey questions in the amendment application that will be reviewed by the CPHS full board for approval.
3. PI to confirm in the project application that they will add language to the amendment application that it should be reviewed by the CPHS full board.

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

2. 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:
This project was heard and approved by the committee in October, with stipulations, changes were made to the study by the research team, and the research team has asked to come back to the full committee, because they believe the revisions they've made no longer require those stipulations, particularly in regard to consent prior to the survey.
Researchers said they addressed all specified revisions except the requirements for written informed consent for the baseline survey and that's why they requested to come back to the full committee to discuss it again. They believe that the reviewers had asked the researchers to provide full written consent form for the baseline survey was due to some of the sensitive questions and the survey is now edited to reduce that level of sensitivity.
Ms. Lund, committee member, clarified that researchers are still collecting sensitive personally identifiable information in the survey, to link the survey with the medical records data and with the CCR data and she spoke about the five criteria when an informed consent can be waived explained in the OHRP (Office for Human Research Protections) website. One of the criteria for waiving an informed consent form is when the research could not practicably be carried out without the requested waiver or alteration while during a lengthy discussion in the CPHS October 2023, full board meeting all committee members unanimously agreed that it was feasible to contact participants for an informed consent because researchers planned to send materials to each subject and to talk to them on the phone. An informed consent requires that subjects be informed about the details of the baseline survey and that their data will be linked to the medical records and CCR data and all possible associated risks. That's why the subcommittee declined to set aside the stipulations that were made by this committee back in October.
Researchers said, they already have access to patient information to reach out to them and in the baseline survey they do not ask for any additional PII and that s why they are asking for a waiver of the documentation of the informed consent. Ms. Lund clarified that the documentation of the informed consent is a requirement of the Common Rule.
Dr. Schaeuble, committee member, mentioned, since researchers are contacting people and asking them to return the baseline survey there should not be any reason why they cannot sign and return the consent form of the same time, and this seems to be very important, because there should be acknowledgment that the subjects are fully aware that they are not just answering to the questions of the baseline survey but also their responses will be linked in the future to other pieces of information about them that could be collected in the future.
Dr. Hess, committee member, mentioned, the questions listed in the baseline survey are very invasive and the baseline survey asks about extensive information that makes a written informed consent a necessity.
Ms. Kurtural, committee member, mentioned, Personally Identifiable Information (PII) does not only include a direct identifier, like an account number, name, or an address, it also includes another point which is characteristic information for example a survey that dices into specific personal experiences especially when we live in a different world of Artificial Intelligence (AI).
Researchers said, written consent in the paper and online versions of survey is absolutely feasible but the problem is with only the telephone survey.
Researchers are asking questions around health care experiences, structural barriers, etc.,

because they plan to understand why for the cervical cancer that can be eliminated, it is still disproportionately affecting marginalized, non-English speaking, low-income women. in order to reach those populations and understand the factors that contribute to these disparities they have been trying to keep the telephone version as a mode since there are groups of the target patient population who may prefer to answer to the baseline survey over the phone and the request for a waiver of the written consent form is only for the phone survey and not for paper and online surveys.
Researchers mentioned, the problems associated with a written consent form for the telephone survey's participants are firstly how to make it accessible to the subjects who prefer to answer to the questions over the phone and secondly how they can stay consistent over this issue with other reviewing entities that have already approved a waiver of the written consent form for the baseline survey.
Ms. Lund, mentioned, this project is very specifically surveying vulnerable and marginalized populations and the Committee for the Protection of Human Subjects (CPHS) is instructed in Federal law to provide the highest protection for these populations. The committee had unanimously clarified that in this study the participants who take the survey over the phone needed to go through the same informed consent process as the participants in both the written questionnaire and the online version of the questionnaire because the consent form is five-page long and it is not possible for the phone survey participants to verbally consent over the telephone in a way that ensures they have a complete understanding of the study and what they are engaging in when they provide the researchers with the baseline survey information.
Researchers said, they planned to send an invitation packet in the very beginning of the study and participants would receive the packet at first with enough information about the study and then they could choose how to take the baseline survey. Ms. Lund clarified, just because the participants receive the consent form does not mean they saw, read and understood it.
Ms. Lund mentioned, in the October 2023, CPHS full board meeting, the committee members unanimously recommended researchers 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.
Researchers said, in the University of Southern California Institutional Review Board, the committee would approve a waiver of written consent form, because they do not want to have another piece of documents with the name of participant for better protection of patient's confidentiality and returning the survey has been approved as informed consent over many years.
Dr. Dickey mentioned, the federal Common Rule has specified that a subcommittee cannot reject a project, and so any rejection of a project has to occur by the full committee and researchers have the right to request their project to be discussed again in the next full board meeting. Also, Dr. Dickey recommended that CPHS committee members inform the researchers that if they disagree with the decisions made by the subcommittee, they can ask for a hearing with the full committee.

Motion: It was moved by Ms. Lund and seconded by Ms. Kurtural 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. Schaeuble.

— The waiver of the written informed consent is denied, and a written informed consent is required for all three modalities of the study.
— All of the stipulations were made in the CPHS October 2023, full board meeting regarding the study remain in effect as listed below:

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 (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, Ms. Kurtural, Dr. Schaeuble, Dr. Ruiz, Dr. Hess, Dr. Dinis, Dr. Palacio, Dr. Azizian, Dr. Ventura, Dr. Johnson,
Oppose: None.
Abstain: Dr. Dickey
Absent: Dr. Bazzano

Total=11 In Favor-10, Opposed-0, Abstained-1

3. Project # 2024-004 (Ventura)
   Title: CHIS Hate Incident Follow-On Study
   PI: Ninez Ponce, PhD
   Co-PI:
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:
The University of California, Los Angeles (UCLA) Center for Health Policy Research has received funding from the California Civil Rights Division (CRD) to conduct a follow-on study to the 2024 California Health Interview Survey (CHIS) to evaluate the realities faced by Californians who have experienced hate incidents, supports accessed, and needed after such incidents. The qualitative data from this study will not be linked to the CHIS study data, the study involves vulnerable population, and participants will receive the study information before they complete the interview on Zoom.

The informed consent and study materials will be sent via text, email, or mail to the participants prior to the interview, and then researchers during the Zoom session interview verbally repeat it and participants will be asked if they have any questions about this study, and if they verbally consent to participate. Interviews will be audio-recorded to ensure researchers accurately capture the respondent's thoughts and opinions.

Dr. Dickey mentioned, "As long as the process of the interview does not change, since the main CHIS study has been already approved, the follow-on questions do not need to come back to the full board, however regarding the questions about hate incidents in this current follow-on questionnaire, it should be clear to the respondents that they should not identify the offender.

Dr. Dickey requested researchers to clarify at the starting section of the questionnaire, consent form, and recontact form that respondents should not identify the offenders who have perpetrated the hate incident. Researchers will clarify in the application and recruitment materials that "SSRS" is the name of the study's contractor, and it is not an acronym.

A document named as "consent form" is attached in the "consent forms" section of the application. This document is a summary of the information sheet that researchers provide at the beginning of the interview, and they should change the name of this document to "information sheet."

Researchers will de-identify any results of this research project by not including a name during the Zoom call, referencing to the respondents' IDs throughout the study report, ensuring there will not be any citation of any specific quotes that could be identifiable like geographic location or specific place where something occurred, etc., and removing geographical and other identifiable information.

Motion: It was moved by Dr. Ventura and seconded by Ms. Lund 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 Drs. Ventura and Schaeuble.

1. PI must clarify at the starting section of the questionnaire, consent form, and recontact form that respondents should not identify the offenders who have perpetrated the hate incident.

2. PI must confirm in the application that this is only a request for the approval of English version of the study and
3. PIs to submit an amendment will be submitted for the approval of translated documents in other languages.

Approve: Dr. Ventura, Ms. Lund, Dr. Ruiz, Dr. Dickey, Dr. Hess, Ms. Kurtural, Dr. Schaeuble, Dr. Azizian, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Palacio, Dr. Dinis.

Total=9 In Favor-9, Opposed-0, Abstained-0

4. Project # 2024-003 (Azizian)
   Title: American Indian/Alaska Native (AIAN) CHIS Follow-On Study
   PI: Ninez Ponce, PhD
   Co-PI:
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:
The study will be an approximately 15-minute follow-on survey to the 2023-2024 California Health Interview Survey (CHIS).
The purpose of the study is to understand cultural experiences for American Indians and Alaska Natives (AIAN), and their health conditions, health behaviors, mental health, and alcohol or drug use. In addition, the survey will help to increase accurate data collection and data quality on the AIAN population's health needs, challenges, and barriers.
Researchers plan to conduct this study with a partnership with the California Tribal Epidemiology Center (CTEC), which is housed in the California Rural Indian Health Board (CRIHB).

Researchers noted that original CHIS participants are not required to give their names since researchers need to know about a combination of the subject's gender and age, and to confirm their identities for follow-up interviews researchers will ask if someone from their household has previously participated.

Researchers confirmed that the current request is only for the English version of the study and after the approval of the English version, they would submit an amendment to request approval for the translated documents in Spanish.

There are two components to the quality assurance that is done. The primary being done by the research team at the University of California Los Angeles (UCLA), who randomly select a series of the recorded interviews to provide that quality assurance, And then there is a standard quality assurance that's conducted by the supervisory staff at the telephone centers to ensure that their interviewing team are following the protocols as they are trained to do and they all are required to take the same training for ensuring the confidentiality of CHIS data.

Dr. Schaeuble mentioned, some of the populations that researchers described could likely be considered vulnerable population and the vulnerable population box in the application should be checked.

Dr. Schaeuble requested to remove mother's maiden name as a security question for logging in and consider other alternatives, since it can be linked to the financial information about people.

The survey's responses will be linked to an extensive list of variables which has been explained in the "Linkage" section of the application and it should be explained in the "Script" and "Information Sheet" to ensure they are representative of the topics that have been explained in the "Linkage" section of the application.
The SSRS organization is the study's subcontractor for data collection for the CHIS program and they conduct the main CHIS interviews as well as these follow-on studies. SSRS has the linked identifiers but does not provide the detailed identifiers like address or name information to UCLA. SSRS only provides a secure identification number to UCLA. SSRS is instructed in the contract with the study team to retain the linked identifiers for five years after collection of the original survey data, at which point SSRS is required by contract to delete that information as well.

Participants should know how long the survey response will be kept and that there is an indirect connection to another company who has contact information for all of the survey responses. The contact information is from publicly available sources which is a list of addresses that are sampled for the study. SSRS works to sample a set of selected addresses and mails invitations to respondents and then a third-party company will link telephone numbers to those addresses in the case that subjects don't respond, and researchers want to contact them by telephone. Researchers have clarified in the information sheet that the participants' de-identified data will be kept for use in future research without considering a timeline.
Researchers ask the SSRS to retain the information for five years in case there are other future follow-on studies and UCLA never obtains names, addresses, and telephone numbers for respondents.
SSRS collects the data directly from the respondents, retain any of the contact information, identifiable addresses, telephone numbers, names and they deliver to UCLA only the survey data information.
SSRS as the study subcontractor has the contact information and the survey data and researchers should clarify in the consent form and information sheet that even though UCLA does not have contact information, but SSRS does have contact information as well as the survey data." Researchers will add statement about how long that data will be retained by SSRS as well.

Motion: It was moved by Dr. Azizian and seconded by Dr. Dickey to grant the protocol 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. Azizian.

1. PI to check the vulnerable population box in the application.
2. PI to remove or change the mother's maiden name as a security question.
3. PI to include language in the script and information sheet to inform the subjects that the survey data will be linked to list(s) of variables and to ensure the language is parallel to what has been explained in the application about the topic of the survey questions.
4. PI to include language in the consent form and information sheet to inform participants that SSRS will retain the survey data for five years.
5. PI to clarify in the consent form and the information sheet that the SSRS does have contact information as well as the survey data and survey responses will be linked to contact information.
6.PI to confirm in the application that this request for CPHS approval is only for the English version and an amendment will be submitted for the approval of the translated documents in Spanish later.

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

Oppose: None.

Abstain: None.

Absent: Dr. Bazzano, Dr. Dinis.

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

5. Project # 2024-008 (Hess)
   Title: Language Development In Infants
   PI: Toben Mintz, PhD
   Co-PI:
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:
This project has been previously approved by CPHS(as project # 12-06-0313) but was not renewed before the pandemic. The goal of this research is to investigate the nature of the cognitive mechanisms that underlie language learning in infants. Researchers have requested birth and death record data from the California Department of Public Health/Vital Statistics Advisory Committee (CDPH/VSAC) to recruit participants in Los Angeles County.

The recruitment flyers will be made available in areas such as doctors' offices, day care centers, and through mailings to parents of children at or below the ages required for the studies. Potential candidates for mailings will be identified through birth records. Parents indicate their interest in participating in the study by returning an information card to provide their phone number, email address, and give permission to contact them. The death data is requested only to screen the birth data, so that the researchers do not contact parents of infants who are deceased.

In the brochure, parents are requested to provide child's name, date of birth, address, phone and email address, and they return the information card with this Personal Identifiable Information (PII). When researchers receive these information cards, they will store them in the locked lab and cabinets before destroying them.
Researchers clarified they can ask for less PII in the brochure. Researchers have implemented a QR code system for participation, and if parents choose to scan the QR code or to go online to register, then they can provide all that information through secure website.

The option to return the information card by mail was initially considered due to recognizing that some families may not have access to a computer, however, given the rarity of this scenario, the decision was made to remove the mail-back option and streamline the process, focusing on submissions through the QR code.

The reading level of the consent form has been adjusted to address the reviewer's comment.

The application should be revised to include the name of all the person who have access to the VSAC data.

Researchers will modify the attached document named "MacArthur Short Form", to ensure not requesting any name and Personal Identifiable Information (PII).
All DHS references in the application should be updated to CDPH.
Researchers will modify the application to clarify that the video recordings will be destroyed after five-year window instead of 'indefinitely.'

The committee requested that participants be made aware their data may be used in future studies without further consent. Additionally, participants should be provided with an option to opt out of their data being utilized in these studies.
Researchers clarified that they are not retaining any of the birth data as part of the study data and they are using the birth data only for recruitment purposes and then they will destroy the birth data and will not be saved in the analysis file.

It was clarified by the committee that California law places restrictions on the use and distribution of birth and death data and researchers cannot share the VSAC data with other researchers even if the data is de-identified. The committee suggested researchers to review the document named as “CPHS Statement for Birth and Death Data” posted on the CPHS website. With other data request not involving VSAC data, sharing the de-identified data may be permissible, provided that the committee approves the de-identification methodology.

Researchers will clarify in the consent form that the personal information about participants and video recordings will be kept “up to” five years.

Researchers will add language in the beginning of the related section in the consent form to clarify that the study data will be shared with other researchers without any further consent from to the parents unless they choose to destroy their data.

Motion: It was moved by Dr. Hess 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. Hess.

1. PI to include all persons who have access to data as research staff to the application in IRBManager.
2. PI to modify the McArthur Short form to remove Personal Identifiable Information (PII).
3. PI to clarify in the consent form and the protocol that the personal information about participants and video recordings will be kept “up to” five years.
4. PI to remove the option of returning the brochure by mail.
5. PI to clarify that birth data will not be retained or used in any analytical files and VSAC data will be used only for the recruitment purposes.
6. PI to clarify in the consent form that the de-identified data will be used for subsequent studies without further consent.
7. PI to provide an “opt out” box for the participants who do not consent to their data being shared with subsequent research projects.

Approve: Dr. Hess, Ms. Lund, Dr. Ruiz, Dr. Dickey, Ms. Kurtural, Dr. Schaeuble, Dr. Azizian, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Dr. Palacio

Total=9 In Favor-9, Opposed-0, Abstained-0

F. Full Board Continuing Review.

None.

G. Amendments – Full Committee Review Required

1. Project # 2023-108 (Schaeuble)
   Title: Evaluation of the Children and Youth Behavioral Health Initiative (CYBHI): Qualitative Data Collection and Analyses of Publicly Available, Deidentified Secondary Data
   PI: Joseph Zickafoose, MD, MS
   Co-PI: Dana M Petersen, MA, MPH, PhD
   Matthew Niedzwiecki, PhD
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:
This amendment is scheduled for the full board because it requested approval for new human subjects' contacts that were not previously approved in the initial submission of the project. This amendment is to include a primary survey as part of the evaluation of the Children and Youth Behavioral Health Initiative (CYBHI). This amendment focuses on collection and analyses of survey data from caregivers, youth, and young adults in California to understand their behavioral health knowledge, experiences, perceptions, and receipt of supports. The survey will serve as a complementary data source to the administrative data and qualitative data that researchers are gathering after the approval of the initial submission of this project. The survey will provide more timely data representing the perspectives of caregivers, youth, and young adults perspectives than are available in other existing data sources. The survey Instrument includes three modules: one for caregivers, one for youth, and one for young adults. Each modules includes respondent specific questions about behavioral health challenges, stigmatizing attitudes towards behavioral health, strengths and skills for dealing with behavioral health challenges, experiences with accessing behavioral health services, knowledge of available supports, and confidence in accessing behavioral health services.

Researchers are working with Ipsos, the vendor of KnowledgePanel which is an existing large-scale, online panel that is representative of the U.S. population.
For the existing panel members, Ipsos has contact information that they keep separate from the survey data and they only deliver the survey data which is anonymized for the researchers.

For opt-in participants, the contact information will be kept separately from the survey data.

For the youth respondents, researchers will only draw from youth whose caregivers are part of the existing KnowledgePanel sample. They will use a dyadic design in which the caregiver completes their own survey module including questions about themselves and a youth in the household who is randomly selected. When the caregiver completes their survey, they then hand the device to the randomly selected youth in the household to complete their own survey with a youth-specific module of the survey instrument. The youth respondent will not be able to go back to their caregiver's responses. The survey will ask the caregiver to allow the youth to complete and submit the survey on their own, but there is no mechanism to prevent the caregiver from overseeing the youth as they complete the survey or reviewing the youth's responses if the youth does not hit submit when finished.
For the existing panel, which is referred to as "KnowledgePanel", people receive an email notification that a survey is available for them. Once they access the survey platform there's

initial questions about their age and their location where they live to see whether they're eligible. Then they will be provided the consent form.

For the youth group, they would not receive any direct contact until their caregiver has consented to participate and completed the survey. A person receiving this email message will have indicated to Ipsos at some point that there were one or more children in the household.

Researchers should include a copy of the recruitment message that will be sent to the existing panel or to the other sources for the opt-in participants.

Researchers will send a primary recruitment message, and then two follow up messages that are spaced one week apart. Researchers were recommended to clarify in the protocol that they would not send more than three messages.

Researchers asked Ipsos's team about the privacy settings and the tools that they were using on their devices, and the global privacy settings. Researchers are still waiting that Ipsos clarifies whether participants are automatically ineligible if they are using those settings or if they receive a notification about how those settings affect their ability to participate.

Researchers provide participants with a link to the Ipsos website for explanations about Ipsos' privacy policy. However, the privacy policy in the Ipsos document does not provide any information about meeting the requirements of the California Privacy Act and there is not enough information about Ipsos' privacy policy in the materials that researchers provide to the participants.

Dr. Schaeuble, committee member, mentioned, "The ideal outcome would be that researchers could say in their consent forms that responses to the survey would never be linked to any other data, and that participants would not need to change any privacy settings or accept any cookies to do the survey. If Ipsos does honor Global Privacy Control settings, researchers wouldn't need to bring that up. But if it does not, researchers would need to explain this as an additional risk for participants, who could otherwise expect such protection under California's Privacy Act."

Parents are receiving compensation for minor's involvement and the caregiver could push the child to participate but the incentives are modest, $5 for the caregiver to participate and $10 for the youth. Since it is an online survey, there is very limited means to verify whether it is the child that is completing the survey or not.

Researchers were requested to revise the consent form and provide information about the incentives to youth in terms of dollars not bonus points to ensure transparency with the youth.

Researchers were requested to clarify in the application that there is no way to be certain that responses are coming from youth and not from the caregivers.
Receiving incentives is contingent to completing the survey not starting it. There is a 'stop gap' in place such that the youth cannot go back into the parents' answers and once the parents proceed to the youth case, it cannot go backwards, to protect the privacy of the parents and the information they provided.

Motion: It was moved by Dr. Schaeuble and seconded by Ms. Lund to grant the amendment a deferred approval with minimal risk pending the following specified

revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Schaeuble.

1. PI must provide the recruitment message that will be sent to potential participants and clarify the recruitment procedures in the protocol as discussed in the CPHS February 2nd, 2024, full board meeting.
2. PI must clarify the privacy aspects in the consent forms about the impact of various settings people have on their computer and smart phones with information that has been requested from Ipsos.
3. PI must indicate a dollar value of the reward for participation instead of just points for the youth in the study.
4. PI must clarify in the protocol that there is no way in these processes to be certain that it is the youth who is completing the survey.
5. PI to respond as appropriate to other comments added by the primary reviewer to the amendment.

Approve: Dr. Schaeuble, Ms. Lund, Dr. Dickey, Dr. Ruiz, Dr. Palacio, Dr. Hess, Ms. Kurtural, Dr. Azizian, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Dinis, Dr. Bazzano

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

2. 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: Tabled

Discussion:
Dr. Hess mentioned, “we were waiting for some information and guidance that we were seeking from Office of Human Rights Protections (OHRP) and United States Drug Admnistration (USDA) on the using Women’s, Infant and Children (WIC) participants for research and in particular recruiting by text. We need to seek further guidance from USDA on this and formally as a board, we won’t be able to make decision on this today. We do have concerns about texting WIC participants to participate in this study and use of WIC data by outside researchers for that purpose which we were seeking further guidance on. Dr. Hess will stay in contact with researchers about further information. Dr. Hess mentioned, they received new information 25 minutes ago which they need further clarification on, and she emailed researchers 20 minutes ago to let them know that she would provide more information to the researchers offline about the reviewers’ exact concerns and who they tried to reach out and why, but they are not at the point today to make a decision on this amendment.

Researchers mentioned, “This study is very time-sensitive, and we have to launch it during this stack season, ideally in the next few weeks and we might need to submit a slightly different amendment to receive approval faster.”

Dr. Delgado mentioned, “if we can get responses soon enough, this amendment can be heard in the CPHS special meeting which will be held before the regular April full board meeting, or a contingency plan might be planned.”

Dr. Hess provided a brief background and mentioned, “in the original study, researchers wanted to reach out to participants to encourage take up of the Earned Income Tax Credit (EITC) and the original protocol was approved to contact the participants via email. The subjects’ response rate was not enough through email, and researchers submitted this amendment to increase this response rate by recruiting participants via text messaging since text messaging is the primary mean by which WIC communicates by its participants.”
Dr. Hess also mentioned, “Texting can incur a cost prior to informed consent and CPHS cannot guarantee it does not, and the contingency plan for researchers would be to move forward to recruit via email even though it is not ideal.”

Researchers requested to increase the number of people that they send email to increase the recruitment rate if the approval of this amendment to recruit via text messaging needs more clarification. They stated that they have done various research during the past month and there were no longer plans to charge people for texting and in fact, email is more likely to cost people. These disadvantaged populations are least likely to have a computer at home, and their only means of Internet access is their smartphones, and many affordable cell-phone plans actually charge for data and to prevent any charges for the participants, researchers’ preferred way of communication with participants would be texting rather than emailing them.

Ms. Lund mentioned, “In the past CPHS had received request from researchers involved in the EITC research to contact people via text prior to informed consent and the committee did not

approve the request because it can cause costs for the participants, and they should be told about this cost before researchers incur this const for them.

For more clarifications Ms. Lund reached out OHRP who review this from a Common Rule perspective, and they advised that CPHS to reach out to USDA because OHRP had some privacy and confidentiality concerns regarding a federal program providing personal information that was provided to a federal program for the purposes of program administration, then being given to a third party of researchers, they wanted to ensure that we were in contact with USDA.

USDA has preliminary concerns whether the study will protect the PII of these disadvantage recipients, whether the recipients would incur texting costs, and about the link between the research and the WIC program. They are concerned about the potential perception by the WIC participants if they perceived the text message to be official correspondence about their WIC, and sent to them by WIC, not by researchers on behalf of the WIC.
Researchers were suggested to submit an amendment to increase the number of emails they send out to recruit participants to increase the response rate. This amendment can be approved through expedited review.

Dr. Hess clarified that the cost of the text was only one component of the concerns mentioned by USDA, and their other concern is that this text quickly perceived to be official communication to recipients about the WIC program when in fact they are not and whether or not WIC participants have opted to in or agree to receive texts that are not about their WIC benefits and the WIC program.

The researchers questioned the suitability of the email exchange conducted though Ms. Lund's personal email address with the USDA. Dr. Delgado acknowledged that CPHS is made up of members who are retired from State government after having a very lengthy career in the State Government, and appreciated their service in this voluntary position, despite the fact that they are no longer receiving benefits, like emails from the State, and encouraged current State employees to apply for this volunteer position.

Researchers requested a copy of the email correspondence between Ms. Lund and USDA after redacting Ms. Lund's personal email address. They requested this to understand what the communication was about and how it impacts the work that they do.

Motion: It was moved by Dr. Hess and seconded by Ms. Lund to table the amendment to the CPHS Special March 2024 full board meeting contingent upon receiving timely clarifications from the USDA and in the case of not receiving these clarifications in time, the amendment will instead be tabled to the April 2024 CPHS full board meeting.

Approve: Dr. Hess, Ms. Lund, Dr. Ruiz, Dr. Dickey, Dr. Schaeuble, Ms. Kurtural, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Dr. Palacio, Dr. Azizian.

Total=8 In Favor-8, Opposed-0, Abstained-0

3. 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

Discussion:
This amendment was decided to be discussed in the February 2, 2024, CPHS full board meeting because it has new human subjects' contacts that were not previously approved in the original project.

Researchers plan to complete a follow-up study with up to 614 participants who completed the 2023 California Los Angeles County Women Infants Child (WIC) survey whose caregivers agreed to be contacted again. The primary focus of this amendment is on the fruit and vegetable benefit which is now most under threat of discontinuation due to lack of congressional action.

The participants will be asked to complete a survey. The last question in the survey asks participants if they are willing to participate in a conversation with other participants in a focus group. The participants who agree would be invited to participate in one of two focus groups in English and Spanish. Researchers have already addressed all the reviewer's comments and provided the appropriate language in the informed consent form.

The survey will be a text survey. This request is only for the approval of the English documents.

The approval of the translated documents in Spanish, researchers will submit another amendment after the approval of this amendment.

Research study will involve minors; researchers have checked the "vulnerable population" box in the application.

Motion: It was moved by Ms. Lund and seconded by Dr. Hess to approve this amendment, with minimal risk.
Approve: Ms. Lund, Dr. Hess, Dr. Ruiz, Dr. Dickey, Dr. Schaeuble, Dr. Palacio, Ms. Kurtural, Dr. Ventura, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Dr. Azizian.

Total=9 In Favor-9, Opposed-0, Abstained-0

H. Second Review Calendar

None.

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 (12)

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 (24)

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 (77)

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 (17)

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

None.

M Exemption/Not Research Approvals

Total Project Count (20)

N. Final Reports

Total Project Count (13)

O. Public Comments

None.

P. Next Meeting

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

Q. Adjournment

This meeting was adjourned at 1:56 PM on February 2, 2024.